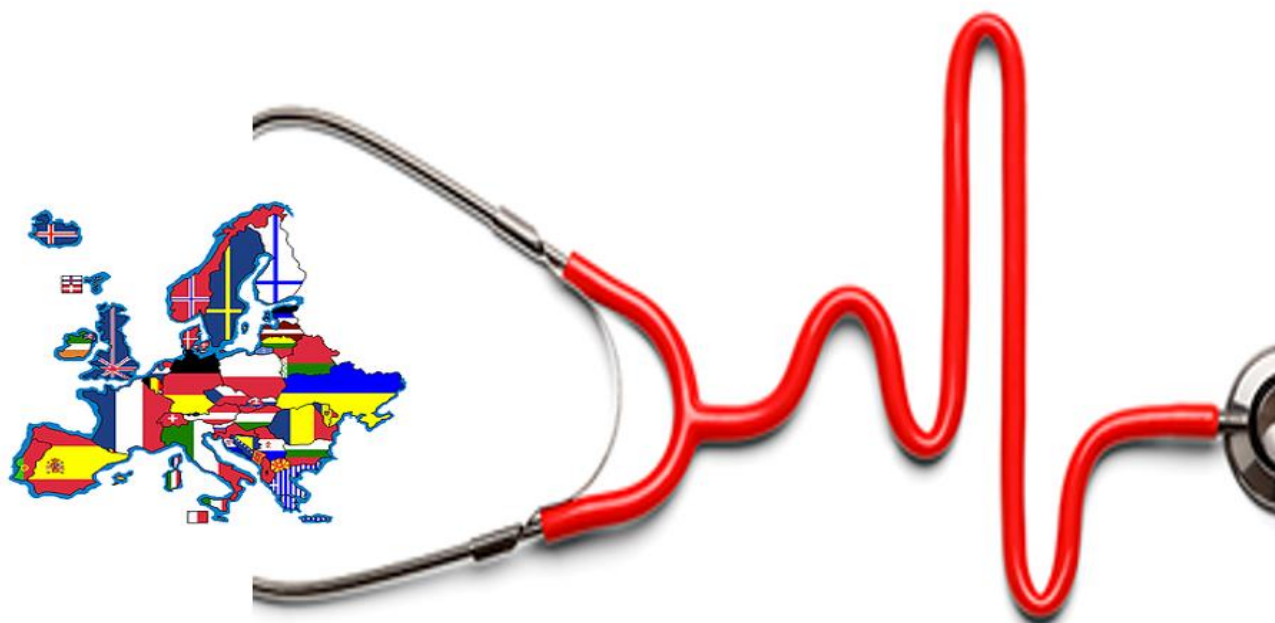


# Cross-border health care and European Union law



Edited by André den Exter



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André den Exter (ed.)

Illustration: European Parliament Research Service

Erasmus University Press

Published 2017

ISBN 978-90-9030461-8



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# List of Abbreviations

Art.	Article
ART	Artificial Reproductive Treatment
CBC	Cross-border care
CFREU	Charter of Fundamental Rights of the European Union
CJEU	Court of Justice of the European Union
COMP	Committee for Orphan Medicinal Products
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DG	Directorate(s) General
DG SANCO/SANTE	Directorate General for Food and Health Safety
Dir.	Directive
EC	European Commission
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
ECJ	European Court of Justice
EFTA	European Free Trade Agreement
EGE	European Group on Ethics in Science and New Technologies
EHR	electronic health record
EMA	European Medicines Agency
EP	European Parliament
eP	electronic Prescription
ERN	European Reference Network
EU	European Union
EUnetHTA	European Union network for Health Technology Assessment
GP	General practitioner
GDPR	General Data Protection Regulation
HMO	Health Maintenance Organisation

HTA	Health Technology Assessment
IVF	in-vitro fertilisation
LGBT	lesbian, gay, bisexual and transgender
MSA	Member State of affiliation
MST	Member State of treatment
NCP	National Contact Point
NGO	non-governmental organisation
NHS	National Health Service
OJ	Official Journal of the EU
OMC	Open Method of Coordination
OMP	Orphan medicinal products
PA	Prior authorisation
PGD	Preimplantation Genetic Diagnosis
PGS	Preimplantation Genetic Screening
PPO	Preferred provider organisation
RD	rare disease
REA	Relative Effectiveness Assessment
Reg.	regulation
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization

## List of Contributors

*Joaquín Cayón-De Las Cuevas* is director of the Research Group on Health Law and Bioethics at IDIVAL and associate professor of health law at the University of Cantabria (Spain). He holds a PhD in Law. He combines his academic activities with legal advice as Head of the Legal Advisory Service at the Health Ministry of the Government of Cantabria. He is a member of the Advisory Board of the European Association of Health Law and Coordinator of the Executive Board of the Ibero-American Health Law Network. His research activities are focused on the patient-consumer approach, patients' rights, healthcare mediation, healthcare systems, medical/pharmaceutical product liability, reproductive technologies, and end-of-life decisions.

*Timo Clemens* (1977) is a lecturer in health policy at the Department of International Health, Care and Public Health Research School (CAPHRI) at Maastricht University. Timo holds a Master in Public Health and a PhD in health policy (Maastricht University). His research interests include hospitals, EU policy impact analyses, governance in healthcare systems and regional cooperation in Europe and beyond. He has been involved as project officer in several EU funded projects including a tender 'Mapping Patients' Rights in 30 European Countries' (DG SANTE). Currently, research activities include a network on European Integration, Small States and Health (ERASMUS+) and an INTERREG project for cooperation on rare diseases in the Euregio Maas-Rhine.

*I. Glenn Cohen* is a Professor at Harvard Law School and Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics. He has authored, co-authored, edited, or co-edited 10 books and more than 100 articles and book chapters. He has spoken at legal, medical, and industry conferences around the world, to heads of state, and his work has been covered by or appeared on PBS, NPR, ABC, CNN, Mother Jones, the New York Times, the Washington Post, the Atlantic, the Boston Globe, and several other media venues.

*André den Exter* (1966) is a lecturer in health law at the Erasmus School of Health Policy and Management, Erasmus University Rotterdam, the Netherlands. André holds a Ph.D. in law. He is the holder of a Jean Monnet Chair of Global Health Law and has held several visiting professorships in international and European health law, including one at Danylo Medical University Lviv (Ukraine), and another at the National School of Public Health, Universidade Nova de Lisboa (Portugal). He has recently edited a handbook entitled *European Health Law*, published by Maklu Press Antwerp (2017) and covering the main aspects of health law from a European perspective.

*Markus Frischhut*, LL.M. is Jean Monnet Professor of "European integration & ethics" (<https://jeanmonnet.mci.edu>) and Study Coordinator European Union Law at MCI Management Center Innsbruck. His research and teaching focus on EU law in general, EU health law, as well as EU law and ethics. In this context, he has published several books and articles and has given numerous speeches, both at international conferences, as well as

invited guest speaker of EU institutions (e.g. in 2015 TAIEX event in Ankara on patient mobility, and in 2016 on EU law and ethics in the European Parliament, Strasbourg).

*Jean Herveg* received his Master in Law from the University of Louvain (UCL, Belgium) in 1993. He is a member of the Bar of Brussels. Since 2000, he has been with the Research Centre Information, Law & Society (CRIDS, University of Namur, Belgium) and is now Head of Research. He teaches Data Protection. His research activity deals with data protection (especially data concerning health) and ehealth products and services. He is the author of numerous communications on ehealth and data protection, as well as of several journal papers and book chapters in these domains. He is involved in European and national projects in the fields of ehealth and data protection.

*Tamara K Hervey*, LLB, PhD, FAcSS, PFHEA is Jean Monnet Professor of EU Law at the University of Sheffield, UK. She researches, teaches, and writes on EU social and constitutional law, in particular its application in health fields; on comparative health law and policy; on equality law; on interfaces between biosciences and (European) law; on social rights; and on legal pedagogy. Tamara has been writing on EU health law since the 1990s. Recent publications include the Research Handbook in European Union Health Law and Policy (Edward Elgar, 2017). Tamara is Special Advisor to the House of Commons Health Committee, on the health implications of Brexit, 2016.

*Miek Peeters* (1979) is currently working as Internal Market Affairs Officer at the EFTA Surveillance Authority. She started her career at the Catholic University of Leuven, where she carried out research on the impact of EU law on health care systems. She has been an adviser of several Flemish ministers of Public Health and was a legal adviser at Zorgnet-Icuro, the biggest Belgian association of hospitals, mental healthcare and elderly care institutions. She regularly publishes and gives guest lectures on EU health care related topics.

*Petra Schnell-Inderst*, MPH, is Senior Scientist and the Coordinator of the Program on Health Technology Assessment at the Department of Public Health, Health Services Research and Health Technology Assessment at UMIT - University for Health Sciences, Medical Informatics and Technology in Hall i. T., Austria. Her main research interests are in health technology assessment (HTA) methodology with a focus on medical devices, public health interventions such as screening programs and on personalised cancer medicine. Since 2010 she is also engaged in the European network for Health Technology Assessment (EUnetHTA).

*Dorte Sindbjerg Martinsen* is Professor at University of Copenhagen, Department of Political Science. Her research focuses on EU welfare policies, investigating integration, national implementation of and compliance with EU social policies, including health care. Her recent work has examined the interaction between legal integration and legislative politics in the European Union, published in the book "An Ever More Powerful Court? The Political Constraints of Legal Integration in the European Union" (2015) with Oxford University Press and in the article in Comparative Political Studies "Judicial Influence on Policy Outputs? The Political Constraints of Legal Integration in the European Union" (2015) vol. 48:12, 1622-1660.

*Pilar Nicolás* PhD, is Permanent Senior research fellow at the Chair in Law and the Human Genome (Public Law Department) of the University of the Basque Country. She teaches Criminal Law in Graduate Level, and Biolaw in Postgraduate level. She has participated in several national and international research projects related to data protection, patient's rights or biobanks. She is the author of about 50 publications. She is member of the Ethical Ethics Committee of the Instituto de Salud Carlos III and of the Ethics Committee of the Institute for Rare Diseases (both at the Spanish Ministry of Science and Innovation) and of the EuroBloodNet (ERN) Independent Advisory Board. Pilar Nicolás is Vice-Dean Coordinator of the Faculty of Law in the Vizcaya Campus

*Alceste Santuari* (Ph.D. Law-Cantab) is a senior lecturer of International law & health and of Non Profit Law at the University of Bologna (Italy). He has edited many books, articles and papers concerning social rights, patient mobility, health tourism and cross-border health care, with special reference to health SPAs. Since December 2015, he has been serving as Secretary-General of the European Association of Patients and Users of Thermal Centres. He has acted as legal advisor to several national, regional and local governments on the organisation and provision of health and social care services.

*Uwe Siebert*, MD, MPH, MSc, ScD, Professor of Public Health and Health Technology Assessment (HTA), is Chair of the Dept. of Public Health, Health Services Research and HTA at UMIT - University for Health Sciences, Medical Informatics and Technology, and Adjunct Professor at the Harvard Chan School of Public Health. His research interests include applying interdisciplinary evidence-based and translational methods from public health in the framework of HTA. He is President of the Society for Medical Decision Making (SMDM) and collaborates with many HTA agencies. He has authored more than 300 publications and is a member of several Journal Editorial Boards.

*Tomislav Sokol* obtained his initial degree in law at the University of Zagreb, Faculty of Law in 2006, magna cum laude. He obtained an LL.M. degree at the Katholieke Universiteit Leuven (KUL) in 2009, magna cum laude. He defended his Ph.D. at KUL, dealing with patient mobility in the EU and its impact on national health insurance systems in the EU, in 2014. He has published several articles in European journals, including *European Law Review* and *European Law Journal*. He has taught Introduction to European Union and Principles of Law courses since the academic year 2010/2011 at Zagreb School of Economics and Management and Health Law at Catholic University of Croatia since the academic year 2016/2017. He has presented papers in several international conferences dealing with EU health law.

*Karl Harald Sjøvig*, Dr. juris (1969) is professor of law at the faculty of law, University of Bergen. Dean at the faculty (2017-) and vice president of the European Association of Health Law (2015-). He has previously worked as a temporary judge at the district and court of appeal. His research has focused on different forms of coercive measures within the welfare state, as well as the rights of children. His most recent project was PROVIR (Provision of welfare to irregular migrants) funded by the Norwegian research council.

*Verena Stühlinger* is senior scientist at the Department of Public Health, Health Services Research and Health Technology Assessment (UMIT, Austria). She holds a doctoral degree in public health (UMIT), a master in law (University of Innsbruck, Austria) as well as in international law (GGU, San Francisco, USA). She teaches health law and ethics at several national universities. Her main research focus is on cross-border health care, frameworks for (bio)medical research and in clinical ethics committees. She chairs the Research Committee for Scientific and Ethical Questions of UMIT and fhg (RCSEQ) and is board member of the European Association of Health Law (EAHL).

*Ariel Teshuva* is a law student at Harvard Law School. Ariel is interested in the intersection of public policy and private life, and in the way the law must (and often does not) evolve to accommodate new developments in science and technology. At Harvard, Ariel represents indigent clients in a variety of criminal and immigration matters; she is also an editor of the Harvard Law Review, where she has written on issues of privacy and technology. Following graduation, she will clerk for a federal appellate judge.

# Introduction: patient mobility after the *Decker & Kohll* rulings

André den Exter

Since the landmark cases *Decker*<sup>1</sup> and *Kohll*,<sup>2</sup> the Court of Justice of the European Union (CJEU) has frequently been confronted with the phenomenon of cross-border health care, i.e. patients seeking medical care in another EU Member State.<sup>3</sup> The central issue in these rulings is that the so-called prior authorisation requirement, which is conditional for reimbursement of health care provided abroad, restricts free movement of patients and health services. The Court's rulings opened a fierce debate touching the heart of health care policy making, namely the organisation and financing of health care, which resulted in the Cross-Border Care (CBC) Directive, officially the Directive on the application of patients' rights in cross-border health care (Directive 2011/24/EU) that came into force on October 25, 2013.<sup>4</sup>

This book examines the Cross-Border Care Directive by exploring its rationale and its impact on solidarity and equal access in the Member States; explaining legal issues regulated by the directive, such as quality of care (what is quality of care?), reimbursement issues (diversity in national reimbursement rules, as well as legal uncertainties due to parallel reimbursement regimes), the use of internet and health care, as well as examining the broader context, i.e., the relationship with professional mobility and even the global setting of patient mobility. The outcomes show that patient mobility, and the CBC Directive in particular, raises important legal questions addressing both EU law and national health law, reflecting different concepts or interests (economic versus human rights law), which may result in different outcomes. Secondly, the directive covers a wide range of related topics facilitating patients seeking health care abroad (e.g. rare diseases, eHealth, health technology assessment).

Despite its laudable motive, the directive has its limitations. These can largely be explained by Member States' unwillingness (legitimate or not) to regulate key issues of cross-border health care at European level. Such limitations require alternative action in order to realise an internal market for patient care, and simultaneously, respecting national values and traditions in how to organise and finance health care systems. At best, aiming at (indirect)

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<sup>1</sup> Case C-120/95, *Decker v. Caisse de maladie des employés privés*, ECLI:EU:C:1998:167.

<sup>2</sup> Case C-158/96, *Kohll v. Union des caisses de maladie*, ECLI:EU:C:1998:171.

<sup>3</sup> E.g., Case C-368/98 *Vanbraekel* [2001] ECR I-5363; Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4509; Case C-372/04 *Yvonne Watts* [2006] ECR I-4325; Case C-444/05 *Stamatelaki* [2007] ECR I-3185; Case C-512/08 *European Commission v French Republic* [2011] ECR I-8833; Case C-173/09 *Elchinov* [2010] ECR I-8889, and Case C268/13 *Petru* ECLI:EU:C:2014:2271.

<sup>4</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88/45, 4.4.2011.

convergence of national health systems by means of “soft-law” mechanisms, seems the highest attainable objective so far.

Hereafter, several contributions explain the relevance of such initiatives, not necessarily regulatory, in terms of safety and quality of care, interoperability electronic health systems, rare diseases reference networks, joint performance of HTA studies, etc. In addition, bilateral agreements may further contribute to remove barriers hampering cross-border care initiatives. In that respect, the directive initiated various initiatives relevant to health lawyers interested in the intersection of patients’ rights and internal market law.

The book’s structure is as follows. In order to understand the outcomes of the Directive, it starts with explaining the political process of drafting the Directive. *Dorte Martinsen* painfully shows the clashes between several institutions, including the European Commission, the European Parliament, the European Council, as well as the Member States, in their search for an inter-institutional compromise.

Following the political debate, *Tamara Hervey* considers the bigger picture on the subject, i.e. the relationships between EU patient mobility law, solidarity and equal access to health care. Starting with no relationship, this assumption became increasingly difficult to sustain. Nowadays, and despite the fact that EU internal market law applies to health care services, *Hervey* argues that *in practice* patient mobility will *not* have an effect on solidarity or equal access as the CJEU takes into account the public interest argument on the financial sustainability of health care systems. Instead, national austerity measures and decreasing solidarity initiatives threaten the concept of equal access! Still, one cannot ignore that certain strata, i.e. those who are healthy, wealthy, have access to information and speak their languages, and are able to travel, may access EU-based health rights, whereas others are left behind.

In the following chapters, each of the authors focuses more on separate subtopics covered by the directive. For instance, *Karl Harald Søvig* explores the rights of citizens who seek health care in other Member States. But the scope of the directive is not restricted to health care services requiring the *physical* presence of the health provider. Article 7(7) of the directive explicitly mentions the reimbursement of health care provided by electronic means, i.e. all kind of health care services provided over the internet, provided that eHealth services are covered by the health care entitlements in the Member State of affiliation. Facilitating cross-border access of electronic health records/patient summary records by both the treating physician and the patient, is therefore a key element in realising cross-border care (*André den Exter*). The mutual recognition of ePrescriptions is another aspect of eHealth giving a new dimension to cross-border eHealth (*Joaquin Cayón-De Las Cuevas*). In addition, national contact points (*Timo Clemens*), European reference centres and networks for rare diseases (*Pilar Nicolás*) also contribute to the directive’s rationale: setting rules for facilitating access to safe and high-quality cross-border care.

But then, what are the overarching values of safe and quality care as standards of good medical practice may differ by country? As the directive is largely silent on operating principles of safety and good quality care, “soft law” modalities will bring more clarity



(*Markus Frischhut*). Although the directive and “soft-law” mechanism facilitate the exchange of information and best practices, it respects fundamental ethical choices of Member States. Controversial medical interventions (e.g., abortion, stem cell therapy, new reproductive technologies) can therefore be excluded from the benefit package in one Member State, yet be accepted in another Member State. Health spa treatment is another example (*Alceste Santuari*), although not controversial from a medical-ethical perspective, but more in terms of medical “added value” (evidence-based). Member States make their own decision on (de-)listing specific health services, which varies by country. Here, the directive introduces a relatively new phenomenon: health technology assessment (HTA), an evaluation tool supporting the reimbursement and pricing decision-making processes by competent authorities. By using a more multi-disciplinary approach, HTA could make the decision-making process more transparent and rational (*Verena Stühlinger-Petra Schnell-Inderst-Uwe Siebert*).

Aimed at clarifying citizens’ rights to cross-border health care, there remain some open questions, such as what is the relationship between the directive and the Social Security Coordination Regulation? This is particularly relevant as reimbursement rules under the Regulation can be more flexible and favourable to EU citizens in search of health care abroad. As argued, diversity in outcome does not provide legal certainty, or clarity as had been hoped (*Tomislav Sokol*).

New questions will arise from the border crossing use of eHealth services, like new liability issues raised by international legal conflicts on jurisdiction and choice of law. Transatlantic teleconsultation disputes for instance are not covered by the directive, but should be ruled according to the “Brussels rules”. Furthermore, eHealth technologies have much to offer in the public health sphere, integrating eHealth technologies with population health. These ePublic health surveillance systems may also change users’ behaviour by monitoring and promoting health behaviour (sexual health promotion, immunisation uptake, etc.). Automated sharing of population-based health information reveals major legal challenges, such as data protection and confidentiality concerns (*André den Exter*).

Not necessarily new, but due to increased mobility of both patients and health professionals, the exchange of information (the alert mechanism) on health professionals’ right to practice will become more eminent (*Miek Peeters*). In addition, as the directive confirmed the patient’s so-called “classical rights”, these rights are applicable to all patients, whether they have moved to another country for treatment or not.

Ensuring continuity of cross-border health care depends on the transfer of health data. The directive acknowledges the importance of data portability, while recognising the fundamental right to protection of personal data under the EU Charter of Fundamental Rights (Article 8). Directive 95/46/EC and the new General Data Protection Regulation (GDPR, 2016/679/EU) therefore grant patients several substantive rights in the context of cross-border care, such as the right to information, right of access, right to rectify, erase, object to data processing, etc. Of particular relevance is the right to data portability, allowing the patient to forward processed data to other health professions (*Jean Herveg*).

Finally, are there any lessons to be learned from other regulatory systems? Ariel Teshuva and Glenn Cohen's contribution on medical tourism in the US and Europe compares the motives and some regulatory hurdles of patients seeking medical treatment abroad (fertility treatment). Unlike the European medical tourist, US patients cannot use public or private health insurance raising a number of legal questions. What they have in common is the need to regulate the risks involved in access to medical services in a globalised world. That shared interest and the way nations have addressed them offer valuable lessons for policymakers on both sides of the Atlantic.

At the end of a three-year Jean Monnet period (2017), an ebook was scheduled covering the entire range of topics regulated under the directive, as well as some related topics. This book explores the relevance of EU law to patient mobility, addressing shortcomings and legal challenges regarding cross-border care, from a European and national perspective. As such, this book is aimed at lawyers and law-students interested in EU health law issues.

I am very grateful for the support from the European Commission's Jean Monnet programme.

# Chapter I      The Politics of the Cross Border Care Directive\*

Dorte Sindbjerg Martinsen

## 1. Introduction

The content of cross border care directive results from a difficult political process through which the directive was adopted. The legislative actors and institutions of that process disagreed strongly on the scope and limits of EU cross border care and the final text became a compromise between actors wanting to maintain national control and those advocating a strengthening of patient mobility and free choice. When studying the policy process from when the directive was proposed through its negotiation within and between the EU legislative institutions, it becomes clear that it was a process ripe with political conflicts. Although this book mainly looks at the directive from a legal perspective, it is important to have the political context and background in mind when examining the directive's current state and implications. The compromises put in place during negotiations condition subsequent implementation and de facto patient mobility. As the analysis below will demonstrate the key issue in negotiations concerned prior authorization. The negotiations hereof mirrors a conflict on how to balance EU and national competences, and demonstrate the disagreements within and between the EU legislative institutions, i.e. the Commission, member states in the Council and the European Parliament (EP) but also towards the judicial reasoning laid down by the Court of Justice of the European Union (CJEU).

## 2. Agenda-setting cross-border healthcare

Migrant workers' right to access healthcare in another member state was adopted between the original member states as one of the first Community Regulation no. 3/58, later reformed into Regulation 1408/71 and now being Regulation 883/2004. This regulation entitles its personal scope to have planned healthcare treatment in another member state if treatment has been authorized beforehand by the competent healthcare authority. If authorized beforehand, the competent institution holds the costs of the treatment in full. However, in fact member states seldom authorized planned healthcare treatment in another member state and have for long retained considerable control with this form of

patient mobility.<sup>1</sup> In a series of judgements from the CJEU,<sup>2</sup> prior authorization came up for legal challenge, accused to be in breach with EU law and the free movement principles of the internal market. It is against this judicial background, the policy-making process of the cross border care directive kicks off.

Political responses did not approve the Court's intervention into the political domains and reactions were harsh at first. The early jurisprudence sent chock-waves through the health political landscape across the Union<sup>3</sup> and a Treaty amendment was called for.<sup>4</sup> Such Treaty amendment should clarify once and for all that healthcare is a national competence and that internal market rules do not apply hereto. However, as we now know the Treaty amendment concerning healthcare was taken off the table. In the end member states did not prioritize the matter sufficiently. When negotiating the Treaty of Nice, other issues overshadowed the political concern of the Court's jurisprudence. A Treaty clarification exempting healthcare from the internal market was not inserted.

A period of 'deafening silence' followed the strong initial political reactions:

“..even though the Member States consulted each other, formally and informally, on the measures or stance to be taken following the rulings, in terms of public opinion the strategy taken was very much a conspiracy of silence and rejection”.<sup>5</sup>

The Commission's General Directorate for the Internal Market and Services, DG MARKT, was first assigned responsibility. In March 2004, DG MARKT proposed the case-law of the Court concerning cross border health codified into the Services Directive, also known as the Bolkestein Directive.<sup>6</sup> Member states responded most strongly against the proposal,

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\* The chapter draws on the empirics from DS Martinsen *An Ever More Powerful Court? The Political Constraints of Legal Integration in the European Union* (Oxford University Press 2015). The empirical material consist of official and official documents concerning the negotiations of a patient rights' Directive as well as a large set of interviews with key respondents, involved in the decision-making process of the Directive.

<sup>1</sup> E Mossialos, M McKee and W Palm, *EU Law and the Social Character of Health Care* (Peter Lang 2002) 85; DS Martinsen, 'EU for the patients: Developments, impacts, challenges' (Swedish Institute for European Policy Studies 2007) <http://www.sieps.se/sites/default/files/54-20076.pdf> accessed 1 March 2017, 14.

<sup>2</sup> See in particular: Case C-120/95 *Decker v Caisse de maladie des employés privés* [1998] ECR I-1831; Case C-158/96 *Kohll v Union des caisses de maladie* [1998] ECR I-01931; Case C-368/98 *Vanbraekel* [2001] ECR I-5363; Case C-157/99 *Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473; Case C-326/00 *IKA v Ioannidis* [2003] ECR I-1703; Case C-385/99 *Müller-Faurè and van Riet* [2003] ECR I-4509; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-372/04 *Watts* [2006] ECR I-4325; Case C-466/04 *Acereda Herrera* [2006] ECR I-5431; Case C-444/05 *Stamatelaki* [2007] ECR I-3185; Case C-211/08 *Commission v Spain* [2010] ECR I-5267; Case C-512/08 *Commission v France* [2010] ECR I-8833; Case C-490/09 *Commission v Luxembourg* [2011] ECR I-249; Case C-255/09 *Commission v Portuguese Republic* [2011] ECR I-10547; Case C-173/09 *Elchinov* [2010] ECR I-8889.

<sup>3</sup> W Lamping, W. (2005) 'European integration and health policy: a peculiar relationship' in M. Steffen (ed.), *Health Governance in Europe. Issues, Challenges and Theories*, (Routledge 2005), 39.

<sup>4</sup> DS Martinsen and G Falkner, 'Social Policy: Problem-Solving Gaps, Partial Exits, and Court-Decision Traps' in G Falkner (ed), *The EU's Decision Traps. Comparing Policies* (OUP 2011): 134; A Obermaier *The End of Territoriality? The Impact of ECJ Rulings on British, German and French Social Policy* (Ashgate 2009): 77.

<sup>5</sup> W Palm, J Nickless, H Lewalle and A Coheur, *Implications of recent jurisprudence on the co-ordination of health care protection systems* (AIM 2000) 78.

<sup>6</sup> Commission, 'Proposal for a Directive of the European Parliament and of the Council on services in the

refusing to have the health area made part of the de-regulation purpose of the Bolkestein directive.<sup>7</sup> But also the European Parliament was against and established majority to veto this part of the Services Directive. The healthcare part was taken out of the proposal and the Commission could start reworking on how to regulate cross border care as initiated by CJEU jurisprudence.

The college of Commissioners decide to shift responsible from DG MARKT to the General Directorate for Health and Food Safety, DG SANCO. In September 2016, SANCO called for stakeholder consultation and received no less than 266 responses from member states and EEA states, regional authorities, national parliaments, patient organizations and so forth. More than a year later, the Commission was apparently ready to present its proposal. However, on the 19 December 2007, the day set for presenting the proposal, the Commission decided to withdraw it. Internal disagreement in the Commission frustrated the presentation and demonstrates that from the very start regulating cross border care was high politics. The College of Commissioners disagreed strongly on the proposal and its principles.<sup>8</sup> Also MEPs from the Socialist and Democrats (S&D) intervened in the process and contacted their fellow Commissioners, urging them to withdraw the proposal and so it happened.

It took SANCO another 6 months to finally present its proposal but on 2 July 2008, the proposal came out and negotiations could start.<sup>9</sup> The Commission proposed non-hospital care to circulate freely, but for hospital care, and those non-hospital treatments defined as 'highly specialized' and 'cost-intensive', prior authorization would be justifiable. However, what constituted 'hospital care', 'highly specialized' and 'cost-intensive' care should rely on a EU-level definition.<sup>10</sup> Furthermore, if member states could not provide treatment without 'undue delay', they would be obliged to authorize cross-border healthcare. Also important to note is that what defined as 'highly specialized' and 'cost-intensive' care should be included on a specific list, under the control of the Commission and regulated by the comitology procedure. In addition, member states should prove that prior authorization was necessary by providing evidence that outflow of patients would 'seriously undermine or [was] likely to seriously undermine' the financial balance, planning, or rationalization of the hospital sector.<sup>11</sup> The member states' burden of proof when using the prior authorization

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internal market' COM (2004) 2 final, art 23 Commission, 'Proposal for a Directive of the European Parliament and of the Council on services in the internal market' COM (2004) 2 final, art 23.

<sup>7</sup> AD Ruijter, *A Silent Revolution: The Expansion of EU Power in the Field of EU Power in the Field of Human Health. A rights-based analysis of EU Health law & policy* (University of Amsterdam 2015): 234-235; E Szyszczak 'Patients' Rights: A Lost Cause or Missed Opportunity?' in J.W.v.d. Gronden, E. Szyszczak, U. Neergaard and M. Krajewski (eds.) *Health Care and EU Law* (T.M.C. Asser Press 2011): 116-117.

<sup>8</sup> SL Greer and Martín de Almagro Iñiesta 'How Bureaucracies Listen to Courts: Bureaucratized Calculations and European Law'. *Law & social inquiry* (2014) 39(2): 369.

<sup>9</sup> Commission, 'Proposal for a Directive of the European Parliament and of the Council on the application of patient rights in cross-border healthcare' COM (2008) 414 final.

<sup>10</sup> *ibid* art 8.2.

<sup>11</sup> *ibid* 14, recital 31, and art 8.3.b.

procedure was thus considerable.<sup>12</sup> Table I sets out the key provisions of the Directive as proposed by the Commission back in July 2008.

Table I: Key provisions in the Cross Border Care Proposal – COM (2004) 414, 2 July 2008

<b>Legal basis</b>	Proposed as <i>Article 95</i> of the Treaty (now Article 114 TFEU).
<b>Prior authorization</b>	<p><i>Article 7:</i> Non-hospital care shall not be subject to prior authorization</p> <p><i>Article 8:</i></p> <p>Prior authorization (PA) justifiable for hospital care, highly specialized and cost-intensive care included on a specific list</p> <p>What qualifies as highly specialized and cost-intensive shall be controlled by the Commission</p> <p>PA is justifiable provided that MS prove the outflow of patients is ‘seriously undermining’ or likely to ‘seriously undermine’ the financial balance of the social security system, its planning, or rationalization</p> <p>Authorization shall be granted when treatment cannot be provided without undue delay</p>
<b>Incoming patients</b>	Patients from other MS shall enjoy equal treatment
<b>Scope</b>	Only applies to healthcare which is part of the healthcare package in the MS of affiliation
<b>Providers</b>	Also non-contracted providers are within the scope of the Directive
<b>Reimbursement level</b>	Up to the level of costs in the MS of affiliation
<b>Payment</b>	Up front payment by the patient
<b>Rare diseases</b>	No recitals or articles deal herewith

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<sup>12</sup> L Hancher and W Sauter, *EU Competition and Internal Market Law in the Healthcare Sector* (OUP 2012) 206-207; Martinsen (n 6) 153.

### 3. Political negotiations in the European Parliament

In the political negotiations two clear conflict lines emerged. Political actors were split on an ideological left vs. right dimension concerning equal access to cross border care. Political actors disagreed on the extent to which means should be ensured to allow equality in patients' ability to benefit from the directive. The other conflict dimension concerned EU versus national competences. Here the disagreement concerned the primacy of internal market principles versus the justifiability of national control with cross border healthcare. Thus here the conflict line concerned more integration versus subsidiarity.

The directive was negotiated as part of the ordinary legislative procedure. The ordinary legislative procedure means that the EP is co-legislator together with the Council. The Council has to reach a qualified majority between the member states whereas a majority of MEPs has to vote in favour for the proposal. To establish the necessary majority in the EP, a compromise between the three largest political groups will suffice; the conservative European People's Party (EPP), the liberals (ALDE) and the Socialists and Democrats (S&D). To deliberate and negotiate a proposal, the EP has its own internal procedures. When the Commission comes forward with its proposal, the EP will assign one of its committees as responsible. In the healthcare area, the responsible committee is the Committee on Environment, Public Health, and Food Safety (ENVI). The committee will then nominate a rapporteur. The rapporteur's task is to prepare discussions on the dossier in the committee, to present a draft report and to amend it on the basis of the positions of committee members. The committee will then vote on the final report of the rapporteur. Subsequently the report will be presented to the EP plenary and a vote will be cast. EP Rapporteurship is highly important. Not only does the rapporteur have the task to try to get a common position in the EP, but s/he is also the primary negotiator with the Council presidency, when a compromise has to be adopted between the EP and the Council.

ENVI became the responsible EP committee on the proposal. The EPP held the rapporteurship on the dossier, which was granted to the British MEP, John Bowis. Bowis already had experience on the topic, having held rapporteurship on an earlier EP motion from 2005. EPP and ALDE supported the Commission's proposal from the outset. However, for ALDE it was important to work for the greatest possible equality in patients' ability to exercise their cross-border rights. ALDE therefore proposed a European patient ombudsman to which patients could complain. Furthermore, ALDE had preferred less national control with patient mobility than the Commission proposed. On the other hand, the S&D political group was much more critical towards the dossier. The group disagreed internally on the proposal. The German MEP Dagmar Roth-Behrendt became the S&D shadow rapporteur on the file, and her individual position was more in favour of the proposal than the S&D 'back-benchers'. The S&D members most supportive of the Commission's proposal viewed it as a European initiative strengthening patients' rights, whereas the more sceptical S&D members were concerned about the Directive's impact on the national healthcare systems and subsidiarity, seeing it mainly as an internal market initiative.<sup>13</sup> The common position of the group became that the Treaty basis of the proposal had to be changed into also

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<sup>13</sup> Martinsen (n 1) 158-159.

including Article 168 TFEU, emphasizing subsidiarity in healthcare policies, and not only be based on the internal market provision Article 114 TFEU. Furthermore, S&D worked for more national autonomy on when to grant prior authorization.

The first reading of the proposal took place six months before the 2009 EP election. Positions were thus rather firm, formed in the heat of elections. MEPs appeared less willing to compromise. 1600 amendments were submitted to the proposal. The rapporteur's task was then to merge these into a smaller number. A total of 115 amendments to the Commission's proposal were adopted during the first reading. The adopted EP amendments would imply more national control by extending the scope of when the prior authorisation procedure could be used for which type of care. Furthermore, the EP majority position aimed to strengthen patients' rights and ensure equality. A new article had been proposed which would allow patients with rare diseases to go for cross-border care without prior authorization (Article 8.9). Concerning equality, the EP added a voucher system according to which a patient could receive a voucher from their competent state authorizing cross-border care and certifying that the treatment would be paid by them (Article 10). Finally, the EP inserted a new Article 11, which would establish a European patient ombudsman, whose tasks would be to deal with patients' complaints on prior authorization, reimbursement, or harm.

One of the central discussions in the EP was how to respond politically to the case-law of the Court, which had found prior authorization for non-hospital care in breach with EU law. Up for EP discussion was thus the extent to which prior authorization was justifiable in the internal market and the ability to politically decide the scope of healthcare integration. As rapporteur John Bowis initiated his report:

*“Jamais poete n’a interpreté la nature aussi librement qu’un juriste la réalité’ Jean Giraudoux. (No poet ever interpreted nature as freely as a lawyer interprets the truth.)* Lawyers and politicians: For the past ten years, since the 1998 *Kohll* and *Decker* judgement at the European Court of Justice (ECJ), the lawyers of Europe have been deciding policy on patient mobility, because the politicians of Europe have failed to do so. If we do nothing, the Court will continue to interpret the Treaties, where patient mobility rights are concerned. They will provide the clarity that we politicians have failed to provide. If we are content to leave policymaking to lawyers, then we need do nothing – except of course pay the resulting unpredictable bills.”<sup>14</sup>

However, Bowis also made clear that judicial decisions precluded certain policy options, particularly regarding authorisation rules.

“..tighter authorisation rules would be inconsistent with the rulings of the European Court of Justice (ECJ) which originally put the question on the agenda” (European Voice; 31st March 2009).

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<sup>14</sup> Report A6-0233/2009, rapporteur Bowis, p. 77.



The Bowis report was debated in Strasbourg on 23rd April 2009, upon which the first reading vote was held. The debate was fierce and reflected the fact that the three largest political groups had not yet fully reached a compromise. During the debate, the jurisprudence of the Court was recurrently debated. Health Commissioner Androulla Vassiliou opened the debate by emphasising the Court of Justice as the '*origin of the proposal*':

“Allow me to recall briefly the rationale behind this proposed directive, as well as its main objectives and principles. The origin of the proposal lies in a decade of jurisprudence of the European Court of Justice, which ruled that patients have the right to be reimbursed for health care received abroad, even if they could have received that health care at home. This is important. This is a right that the Treaty directly grants to EU citizens. However, if the rulings were clear for the individuals concerned, the question of how they apply to all other cases was obscure” (Vassiliou, EP debate, 23rd April 2009).

Despite many disagreements the EP managed to reach a common position. However, the proposal was only approved by a narrow simple majority; 297 MEPs voted in favour, 120 voted against and 152 abstained from voting. Most S&D members abstained from voting and some voted against.

Although the EP had established a narrow majority, it had not done so in time to reach a first reading agreement with the Council. In June 2009, following the EP elections, the new EP was cast into a second reading of the proposal. As the former rapporteur John Bowis had not run for the new parliament, rapporteurship was taken over by EPP member Françoise Grossetête, whereas Dagmar Roth-Behrendt continued as S&D shadow rapporteur. During the EP second reading, the scope of prior authorization continued to be the main issue. ALDE and EPP members were critical of extending prior authorization, but S&D members wanted more national control with cross-border care and therefore supported the Council's position on extended national control. Against this background, the EP rapporteur, together with the shadow rapporteurs from S&D and ALDE, was ready to start triologue negotiations with the Council presidency and the Commission.

#### 4. Political Negotiations in the Council

The Council working group kicked off negotiations by much internal disagreement, and with only two or three member states, supporting the Commission's proposal from the outset. For the first year, the positions were largely divided into three groups. Sweden and Belgium were the supporters of the proposal. A second group of more reluctant member states, which were, however, willing to negotiate, included the UK, the Netherlands, France, Germany and Denmark among others. Finally a large third group of Southern and Eastern European Council members opposed the dossier and found it an unlawful intervention in national competences. The different positions were in part formed by the degree to which CJEU case-law had been implemented in the respective member states.<sup>15</sup>

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<sup>15</sup> Martinsen (n 1) 164-166.

The list of member states' concerns was long.<sup>16</sup> The majority of member states opposed the Commission's proposal of Community definitions of 'hospital care' and 'highly specialised' and 'cost-intensive care' and instead called for national definitions thereof. Additionally, most member states opposed the proposed article 8.2, according to which a Community list of 'highly specialised' and 'cost-intensive care' would be assembled and regularly updated by the Commission. The member states argued that the formulation of articles 8.1 and 8.2 would not allow them sufficient control, thus endangering the sustainability and steering capacities of national healthcare systems. A large number of member states also raised concerns about inflow of foreign patients and how to maintain sufficient healthcare capacity for national patients. However, the negative implications of patient inflow were not addressed in the Commission's proposal, where article 5.1.g of the proposal simply stated that 'patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment'.

During negotiations in the Council, the rotating presidencies formulated various compromise texts. SANCO took part in working group negotiations as well as in bilateral meetings with the presidencies and individual member states. However, the Commission found that negotiations had taken a wrong turn, in particular when it came to the national focus on extending the use of the prior authorization procedure. As noted by the Czech presidency, the Commission found that such extension would be against the case-law of the CJEU:

"The Commission has a general reserve on the entire Presidency compromise text. In particular it has major concerns with regard to the approach on quality and safety as provided for in Article 5; the approach on prior authorisation which in the Commission's view does not reflect the case law, including the definition of care that can be subject to prior authorisation, which has been significantly broadened"<sup>17</sup>

In December 2009, the Swedish presidency presented a compromise text for a Council common position. Among other changes to the Commission's proposal, it contained a dual legal basis, broadened the use of the PA procedure and abolished the Article 8.2 of the proposal. However, Spain led a blocking minority, which also included Poland, Romania, Portugal, Greece, Ireland, Hungary, Slovakia, Slovenia, and Lithuania. This alliance vetoed the Swedish compromise text. Spain wanted a special arrangement for EU citizens, having changed residence to another Member State. In more concrete terms, the controversy concerned pensioners from the Northern member states and the UK residing at the Southern coasts. According to Regulation 883/2004, an EU citizen who changes residence to another Member State also changes Member State of affiliation in healthcare terms. For residing pensioners, the new Member State of affiliation takes over responsibility, but is reimbursed a fixed amount from the member state of origin. The political concern was that the Directive would give residing pensioners from the UK, Germany and elsewhere in northern Europe a better opportunity to go back to their Member State of origin to have healthcare treatment there and the new member state of affiliation would have to bear the

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<sup>16</sup> Martinsen (n 1) 165-166.

<sup>17</sup> Czech presidency progress report, 3 June 2009, 2008/0142(COD), 5.

costs. The fear was that mobility on basis of the Directive would increase costs which the fixed amount granted by means of the Regulation would not cover. Furthermore, Spain and Poland also expressed strong views against access to non-contracted providers in other member states, arguing that this would be reverse discrimination for those patients not going for cross border healthcare.<sup>18</sup> In general, the blocking minority raised concerns about the (lack of) cost-containment implied by the proposal.

The veto put the Council in a peculiar position as the lead of the blocking minority, Spain, took over presidency in January 2010. The leader of the blocking minority was now to chair negotiations, and the member states that had supported the Swedish compromise proposal were sceptical, expecting Spain to halt negotiations. Until March 2010, the Spanish presidency was silent; however, it then presented a specific amendment to the Swedish text intended to address the Southern issue of residing pensioners from other member states. The Spanish text introduced a compromising article by which costs for pensioners were shared to a greater extent between the member state of origin and the new member state of residence. If a treatment required prior authorisation, the new member state of residence would pay the costs. This process would be less costly – and less risky – because the new member state of residence would maintain control by means of authorisation. If treatment did not require prior authorisation and was carried out in the member state of origin, the member state of origin would resume the costs of care.<sup>19</sup> A similar amendment had already been proposed by the Commission during the Swedish presidency but was rejected by the majority of sending member states. What seemed a minor amendment to the Swedish compromise text made it possible for the Council to reach a common position in June 2010. Spain left the blocking minority and the Council had reached the necessary qualified majority.

The Council did not, however, act in consensus. Poland, Portugal and Romania voted no to the compromise text, maintaining their opposition to the inclusion of non-contracted providers in the directive. Austria also voted no to the common position due to considerable opposition from its Länder. The Austrian Länder were very critical of the Directive, fearing that it could lead to a significant inflow of foreign patients.<sup>20</sup> Finally, Slovakia abstained from voting. However, a common council position had been reached.

## 5. Reaching an inter-institutional compromise

Inter-institutional negotiations on the dossier did not start in earnest before autumn 2010, as both the Council and the European Parliament had had their considerable difficulties in establishing an own institutional position. From October to December 2010, the Belgian

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<sup>18</sup> H. Nys, 'The Transposition of the Directive on Patients' Rights in Cross-Care Healthcare in National Law by the Member States: Still a Lot of Effort to Be Made and Questions to Be Answered' (2014) 21(1) *European Journal of Health Law* 1, 12.

<sup>19</sup> For this special rule, see European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45, art 7.2.b.

<sup>20</sup> Martinsen (n 1) 169-170; T Kostera, 'When Europa meets Bismarck. Cross-border Healthcare and Usages of Europe in the Austrian Healthcare System' (Doctoral Thesis, Université Libre de Bruxelles 2014), 243-269.

Council presidency held four formal dialogues and a set of informal ones with the EP rapporteur, shadow rapporteurs and the European Commission.<sup>21</sup> The major issue was still the scope of prior authorization. Whereas the Council and the EP were now in agreement, the Commission positioned against the compromise established, which it found to go against the case-law of the CJEU.

To make its position clear, the Commission first issued a declaration after the Council meeting in June 2010 and later a communication to the European Parliament in September 2010.<sup>22</sup> The Commission's declaration took the Council by surprise because issuing a declaration was not common practice.<sup>23</sup> Inter-institutional conflicts were thus considerable. In the declaration, the Commission declared that it would not oppose the presidency text but found that it was not sufficiently clear. Thus the Commission reserved the right to support the European Parliament on the issue of prior authorisation because the Parliament's position was more in line with the Commission's proposal, especially concerning the Commission's reading of the case-law of the Court:

"As the position of the European Parliament on prior authorisation and eHealth is more favourable to the patients, closer to the Commission's proposal and to its reading of the existing case-law, the Commission reserves the right to support the European Parliament's amendments on these issues during the second reading and will continue to collaborate closely with both institutions with the aim of further improving the text".<sup>24</sup>

In the communication, the Commission further detailed why it found the Council's common position problematic. The Commission could not support the extended, non-exhaustive and nationally controlled possibility of using prior authorisation, which it found to conflict with the case-law of the Court:

"The position of the Council at first reading introduces the possibility for the Member State of affiliation to make the reimbursement of costs of certain types of cross-border healthcare (hospital, specialised care and healthcare which could raise serious and concrete concerns related to the quality or safety of the care) subject to prior authorisation without any explicit request to demonstrate an outflow of patients resulting from the freedom of mobility or any risk to the system. The text simply foresees that the system of prior authorisation shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination. The introduction of a system of prior authorisation as proposed by the Presidency text is based on a very restrictive interpretation of the jurisprudence".<sup>25</sup>

However, the European legislators gained momentum in this late stage of negotiations when the CJEU on 5 October issued its ruling on the infringement procedure against France.<sup>26</sup> As a surprise to the Commission, the CJEU took a much more 'tempered

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<sup>21</sup> Martinsen (n 1) 173.

<sup>22</sup> COM (2010) 503 as of 20th September 2010.

<sup>23</sup> Martinsen (n 1) 171.

<sup>24</sup> Commission declaration, June 2010.

<sup>25</sup> COM (2010) 503, 7.

<sup>26</sup> Case C-512/08 *European Commission v France* [2010] ECR I-8833.

approach',<sup>27</sup> ruling that prior authorization was justified for non-hospital care when major medical equipment was used. The Commission was thus in a weaker position to argue against the extension of the prior authorization.

The EP also had to give in on some of its top priorities, which aimed to ensure equality in cross-border healthcare. It had already abandoned the idea of an European patient ombudsman in its second reading. Confronted with the Council common position, it now had to give up on the voucher system as well as a binding provision on cross-border treatments without prior authorization for patients with rare diseases. Instead rare diseases were written into the recitals and Article 13, but without binding measures.

Considering the final inter-institutional compromise, the Council stand out as the winner, with most of its concerns accommodated in the final text, especially concerning cost-containment and a rather extensive application of prior authorization. As proposed by the Commission, member states would only have to reimburse up to what a similar treatment cost in the member state of affiliation and only for treatments provided by the healthcare package of the Member State of affiliation. Furthermore, as evidenced in Articles 4-8, the adopted version of the Directive had enhanced the steering capacity of the national health authorities much when compared to the Commission's proposal.<sup>28</sup> The prior authorization procedure was enhanced and member states would set out what counts as 'hospital care', 'highly specialized' and 'cost-intensive' care. They would still have to grant authorization when treatment could not be provided without undue delay. However, the Directive did not contain any Community definition of 'undue delay' which remains a very open concept left to member state clarification. Also the burden of proof that member states would have to carry when using prior authorization had been relaxed.<sup>29</sup> Thus, concerning the outflow of patients, Member States had re-established considerable national control. Moreover, the inflow of patients was now also considered in a binding provision of the Directive. The Council had insisted that member states of treatment could derogate from the principle of equal treatment if need be, and a new safeguard measure had been adopted by means of Article 4.3, allowing member states the possibility 'to fence off their healthcare markets'.<sup>30</sup>

Comparing the proposal with the finally adopted text, it is clear how legislative politics downscaled key provisions of the original proposal and significantly modified the implications of what the CJEU had initiated.<sup>31</sup> The output of legislative politics became a much paled version of an internal healthcare market, with considerably more national

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<sup>27</sup> VG Hatzopoulos and TK Hervey, 'Coming into Line: the EU's Court Softens on Cross-Border Health Care' (2013) 8 *Health Economics, Policy and Law* 1.

<sup>28</sup> R. Baeten and W. Palm (2013) 'The Compatibility of Health Care Capacity Planning Policies with EU Internal Market Rules', in J.W. van de Gronden, E. Szyszczak, U. Neergaard and M. Krajewski (eds.), *Health Care and EU Law*. The Hague: T.M.C. Asser Press, pp. 389-413, 410.

<sup>29</sup> Hancher and Sauter (n 14) 207.

<sup>30</sup> Hancher and Sauter (n 14) 208.

<sup>31</sup> Martinsen (n 1).

control and territoriality reinserted. As a result of legislative politics, the adopted text demonstrate ‘Member State control of cross-border healthcare Directive’.<sup>32</sup>

Table II: Key provisions in the Cross Border Care Directive – as adopted in Directive 2011/24/EU

<b>Legal basis</b>	<p><i>Article 114</i> TFEU and <i>168</i> TFEU of the Treaty</p> <p><i>Article 7</i>: Non-hospital care shall not be subject to prior authorization</p> <p><i>Article 8</i>: Prior authorization is justified for ‘highly specialized and cost-intensive’ healthcare as well as for hospital care</p> <p>Member states defines what constitutes ‘highly specialized and cost-intensive care’</p> <p>PA has to be limited to what is necessary and proportionate</p> <p>Authorization shall be granted when treatment cannot be provided without undue delay</p>
<b>Incoming patients</b>	<p><i>Article 4.3</i>: MS of treatment may depart from the principle of non-discrimination and adopt measures for foreign patients access to treatment in order to ‘ensure sufficient and permanent access to healthcare within its territory’</p>
<b>Scope</b>	<p>Only applies to healthcare which is part of the healthcare package in the MS of affiliation.</p> <p>Sets out that the Directive does not apply to long-term care or to access to organs</p>
<b>Providers</b>	<p>Also non-contracted providers are within the scope of the Directive.</p>
<b>Reimbursement level</b>	<p>Up to the level of costs in the MS of affiliation</p>
<b>Payment</b>	<p>Up front payment of the patient.</p>
<b>Rare diseases</b>	<p>Recital and <i>Article 13</i>, but no binding measures</p>

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<sup>32</sup> T. Hervey and J. McHale (2015) *European Union Health Law: Themes and Implications*, Cambridge: Cambridge University Press, 197-8.

## 6. Conclusion

The policy process negotiating the cross-border care directive illustrates the high political salience of healthcare and that EU legislative politics do not simply codify what the Court of Justice initiated. In order to understand the textual complexity of the directive, legislative politics should be brought in as the various compromises within and between institutions set scope and limits of EU cross-border care.

The cross-border care directive constitutes the output of EU legislative politics analysed above. The output matters to who benefits from the directive and to what extent. As to the conflict dimensions entailed in the political process, it is clear that the directive does not ensure equality as voiced by political actors to the left. Furthermore, extensive national control was achieved, meaning less integration than envisioned by the Court, the Commission, few member states, the EPP and ALDE. Majoritarian politics adopted a set of key provisions, which in essence disincentivize patients from seeking healthcare in another member state:

- The patient can access only treatment to which s/he is already entitled at home.
- The patient will be reimbursed only up to what a similar treatment is tariffed to at home. In particular, patients from member states with low reimbursement levels will be disincentivised to go abroad.
- The patient will have to pay up front. Member states are not obliged to adopt a prior notification or voucher system. Patients with little means will be prevented from using the directive.
- The system of prior authorisation is maintained for hospital care and highly specialised and cost-intensive care. National control has been extended for the most important public treatments.
- Treatment of foreign patients can be refused for capacity, planning and financial reasons. The principle of non-discrimination does not apply in full.

The derogations from internal market principles created by legislative politics matter in the subsequent implementation of the Directive. Studies examining the implementation of the Directive and its outcome so far demonstrate limited use of the Directive.<sup>33</sup> The future impact of the Directive depends on the extent to which member states will loosen up on their rather extensive use of prior authorization policies and generally restrictive application

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<sup>33</sup> N Vasev and K Vrangbæk, 'Transposition and National-level Resources: Introducing the Cross-Border Healthcare Directive in Eastern Europe' (2014) 37(4) *West European Politics* 693; N Vasev, K Vrangbæk and F Křepelka, 'The End of Eastern Territoriality? CJEU Compliance in the New Member States' (2016) *Comparative European Politics*; H Vollaard and DS Martinsen, 'Bounded Rationality in Transposition Processes: The Case of the European Patients' Rights Directive' (2014) 37(4) *West European Politics* 711; DS Martinsen and J Mayoral Diaz-Asensio 'A Judicialisation of Healthcare Policies in Denmark and Spain? The Universalist Healthcare Model Meets the European Union' (2016) *Comparative European Politics*; S Olsena, 'Implementation of the Patients' Rights in Cross-border Healthcare Directive in Latvia' (2014) 21(1) *European Journal of Health Law* 46; N Azzopardi-Muscat, C Aluttis, K Sorensen, R Pace and H Brand, 'The impact of the EU Directive on patients' rights and cross border health care in Malta' (2015) 119 *Health Policy* 1285; H Vollaard, 'Patient mobility, changing territoriality and scale in the EU's internal market' (2016) *Comparative European Politics*.

of the directive. It also depends on the future steps of EU law and politics. The Commission may initiate a round of infringement procedure for misapplication of the directive and EU patients and national courts may refer preliminary questions to the CJEU. However, as long as EU legislative politics is preoccupied with cost-containment, capacity planning and control, national healthcare boundaries are likely to be too high for cross border care to overcome to any greater extent.



## Chapter II Patient Mobility, Solidarity, and Equal access

Tamara Hervey

### 1. Introduction

Patient mobility, solidarity, and equal access to health (care/services) in the EU. Imagine, if you will, a diagram involving the relationships between those three concepts. How do you see it? If you see a Venn diagram, do they overlap at all? If not, why not? If so, what is in the intersections? If you see a flow diagram, in which directions do the concepts flow? Are they positive, mutually reinforcing; or negative, destructive, causal relationships? Or do you see another kind of diagram altogether?

To some extent, of course, it depends on how each of the concepts is defined. I say a little more about 'solidarity' and 'equal access' below. 'Patient mobility' can mean either a situation where a patient receives health care in another country because they are there (e.g., as a tourist, temporarily for work, or even as a long-term resident) when they fall ill; or a situation where a patient chooses to seek out health services in another country.<sup>1</sup> The latter might be because the patient lives in a border-region, and it makes more sense, geographically or practically speaking, to cross a border for health care. Or it might be because of something about their home health care system that motivates them to seek treatment elsewhere: the cost, the waiting time, the choice of services available. In this chapter, as in the majority of the literature on the subject, the focus is on the latter motivation. This is not to imply that health care in EU border regions is unimportant: the question of what will happen to health services across the border between Northern Ireland and the Republic of Ireland on Brexit is a key contemporary example of the contrary.<sup>2</sup>

This chapter takes a step back from the legal technicalities of EU law on patient mobility,<sup>3</sup> and the literature on the subject, to consider the bigger picture. It does so through considering a series of possible relationships between EU patient mobility law, the solidarity inherent in European health systems, and the corresponding idea of equal access to health care on the basis of medical need, regardless of ability to pay.

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<sup>1</sup> See I Glinos and R Baeten, A Literature Review of Cross Border Patient Mobility in the EU (OSE, 2006) [http://www.ose.be/files/publication/health/WP12\\_lit\\_review\\_final.pdf](http://www.ose.be/files/publication/health/WP12_lit_review_final.pdf) (accessed 22 December 2016).

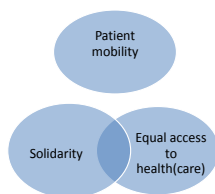
<sup>2</sup> See, e.g., <http://www.bbc.co.uk/news/uk-northern-ireland-36678588> (accessed 22 December 2016).

<sup>3</sup> These are described in detail in T Hervey and J McHale, *European Union Health Law: Themes and Implications* (CUP 2015).

## 2. No relationship

In the beginning, EU law, and the patient mobility within its scope, was generally understood as having no relationship with national health systems (Figure 1).

Figure 1



EU competence, especially in the context of the internal market, was understood as extending only to the 'economic'. Privately financed health care is covered by this notion.<sup>4</sup> But privately financed health care is very much the exception in the context of the national health systems of the EC, and now EU, Member States. Those systems are associated with public or collective sources of finance – through social insurance and taxation.

The history of European health systems – though resulting in different approaches at the level of detail<sup>5</sup> – is based on an underpinning principle of solidarity. Solidarity, with roots in several aspects of European social, cultural, and religious heritage, implies a transfer of resources: between wealthy and less-wealthy, young and old, more and less affluent.<sup>6</sup> These progressive policies are instrumentalised through practical, state-led mechanisms aimed at securing equal access on the basis of medical need. The concept of ethical medical professionalism – and the position of doctors in particular – is part of these arrangements. Doctors, rather than administrative or legal bodies, or private wealth, determine access to

<sup>4</sup> Cases C-286/82 and C-26/83 *Luisi and Carbone* EU:C:1984:35; Case C-159/90, *Grogan* EU:C:1991:378.

<sup>5</sup> See, e.g., Hervey and McHale, above n 3, p213-225; M McKee, E Mossialos and R Baeten (eds), *The Impact of EU Law on Health Care Systems* (PIE Peter Lang 2003); V Hatzopoulos, 'Health Law and Policy: The Impact of the EU' in G De Búrca (ed.), *EU Law and the Welfare State: In Search of Solidarity* (OUP 2005); M Steffen (ed.), *Health Governance in Europe: Issues, Challenges and Theories* (Routledge 2005); C Wendt, 'Mapping European Healthcare systems: a comparative analysis of financing, service provision and access to healthcare' (2009) 19(5) *Journal of European Social Policy* 432.

<sup>6</sup> P Baldwin, *The Politics of Social Solidarity: Class Bases of the European Welfare State 1875-1975* (CUP 1992); S Stjernø, *Solidarity in Europe: The History of an Idea* (CUP 2009); S Guibboni, 'Free Movement of Persons and European Solidarity' (2007) 13 *European Law Journal* 360; T Hervey, 'Health Equality, Solidarity and Human Rights in European Union Law' in A Silveira, M Canotilho, and P Madeira Froufe (eds), *Citizenship and Solidarity in the EU: From the Charter of Fundamental Rights to the Crisis, The State of the Art* (Peter Lang 2013); M Krajewski, U Neergaard, and J van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe: Between Competition and Solidarity* (TMC Asser Press 2009); B Prainsack and A Buys, *Solidarity, Reflections on an Emerging Concept in Bioethics* (Nuffield Council on Bioethics 2012); T Prosser, 'Regulation and Social Solidarity' (2006) 33 *Journal of Law and Society* 364; M Ross, 'The Value of Solidarity in European Public Services Law' in M Krajewski, U Neergaard, and J van de Gronden (eds), *The Changing Legal Framework for Services of General Interest in Europe: Between Competition and Solidarity* (TMC Asser Press 2009); European Commission, 'Solidarity in health: reducing health inequalities in the EU' COM (2009) 567 final.

health care, through their professional assessments of a particular patient's needs, within the context of a specific health system.

All of these arrangements are based on an assumption that healthcare systems are both *national* and *closed*. Solidarity obligations are owed *within a state*. With only some exceptions around the edges (for instance, pertaining to obligations in international law to refugees<sup>7</sup>), the health system is arranged so as to secure health care for the national population, and the national population alone. The EU regulations on social security coordination<sup>8</sup> were structured so that patients could access health care services in another Member State only where they contributed to that system through its social insurance or taxation arrangements, or where they had permission from their home state to access health services with their home health system meeting the cost. Significant 'planification' decisions – number and location of hospitals, laboratories, clinics and other health infrastructure, investment in medical education and training, coverage of services, 'basket of care' available, and so on – are based on those assumptions. There is also an associated assumption that public health arrangements (vaccination programmes, containment of contagious disease, health education, air, water and food quality, waste disposal) operate within a closed system.

As the European project unfolded, these assumptions became increasingly difficult to sustain. The EU's environmental law is based on the obvious observation that national borders are not respected by environmental threats such as air or water pollution.<sup>9</sup> Health threats from free movement of food within the EU,<sup>10</sup> as one of the most significant consumer products circulating within the EU's internal market, led to significant legal and administrative arrangements for food safety being made at EU level. EU food legislation seeks to secure the food chain 'from farm to fork'.<sup>11</sup> The European Food Safety Authority oversees the legislative framework, interacting with national regulatory and administrative agencies.<sup>12</sup>

EU law also sought to secure free movement of health professionals, as part of its freedom of movement of workers and freedom of establishment rules. The legal technique used to

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<sup>7</sup> UN Convention relating to the status of refugees, 1951; UNHCR Executive Committee Conclusion No 28(c), 1982).

<sup>8</sup> Now Regulation 883/2004/EC on the coordination of social security systems [2004] OJ L166/1.

<sup>9</sup> Articles 4 and 191 TFEU.

<sup>10</sup> Notably associated with 'mad cow disease', see A Alemanno and S Gabbi (eds), *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority* (Ashgate 2014); P Krapohl, 'Risk Regulation in the EU between Interests and Expertise: The Case of BSE' (2003) 10(2) *Journal of European Public Policy* 189; E Vos, 'EU food safety legislation in the aftermath of the BSE crisis' (2000) 23(3) *Journal of Consumer Policy* 227; M Westlake, "'Mad Cows and Englishmen": The Institutional Consequences of the BSE Crisis' in N Nugent (ed.), *European Union 1996: the annual review* (published in association with *Journal of Common Market Studies* 1997).

<sup>11</sup> Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, as amended; Regulation 1151/2012/EU on quality schemes for agricultural products and foodstuffs [2012] OJ L343/1; Regulation 652/2014/EU [2014] OJ L189/1.

<sup>12</sup> A Alemanno, and S Gabbi (eds), *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority* (Ashgate 2014); E Vos, and F Wendler, *Food Safety Regulation in Europe* (Intersentia 2006).

do so is mutual recognition of qualifications. To begin with, detailed legislation set out the education requirements of each profession.<sup>13</sup> A professional (doctor, dentist, midwife, nurse) qualified in one Member State was to be recognised as equally qualified in other Member States. Member States could therefore no longer ensure closure of their systems from health professionals educated and practising in other Member States.

As these arrangements of EU law gradually played out and bit deeper into national social structures, the control of Member States over the ‘social’, implied by the notion of constrained EU competence, came increasingly under strain. The phenomenon has been described as the ‘semi-sovereignty’ of the EU Member States.<sup>14</sup> The effects of EU law on health law are part of this broader pattern, consequent on the integration process. Although the EU’s internal market is based on the movement of ‘economic’ actors, the EU’s health systems were not entirely isolated from the ‘economic’, in terms of their structures. This meant that mobile factors of production (initially products, workers, professionals) could rely on EU law and de facto challenge the closed and national nature of European health systems.

By the time the *Decker*<sup>15</sup> and *Kohll*<sup>16</sup> cases came along, all the relevant principles of EU law were already well established and no longer contentious. Patients receiving services could rely on EU internal market law to secure access the health services in other Member States. These principles were originally established in cases involving privately remunerated health care.<sup>17</sup> The innovation of *Decker* and *Kohll* was to extend the concept of ‘remuneration’ in the context of freedom to provide and receive cross-border health services, to services

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<sup>13</sup> Directive 75/362/EEC concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in medicine, [1975] OJ L167/1; Directive 75/363/EEC concerning activities of doctors [1975] OJ L167/14; Directive 77/452/EEC of 27 June 1977 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of nurses responsible for general care [1977] OJ L176/1; Directive 77/453/EEC concerning activities of nurses responsible for general care [1977] OJ L176/8; Directive 78/686/EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry [1978] OJ L233/1; Directive 78/687/EEC concerning the activities of dental practitioners [1978] OJ L233/10; Directive 80/154/EEC concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in midwifery [1980] OJ L33/1; Directive 80/155/EEC concerning the activities of midwives [1980] OJ L33/8; Directive 85/432/EEC concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of certain activities in the field of pharmacy [1985] OJ L253/34; Directive 85/433/EEC concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy [1985] OJ L253/37. Now see Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22, as amended.

<sup>14</sup> S Leibfried and P Pierson (eds), *European Social Policy: Between Fragmentation and Integration* (The Brookings Institution 1995); see also M Ferrera, *The Boundaries of Welfare: European Integration and the New Social Politics of Social Welfare* (OUP 2005); M. Ferrera, ‘Beyond National Social Rights?’, in N. McEwen and L. Moreno (eds), *The Territorial Politics of Welfare* (Routledge 2005), at 225–243.

<sup>15</sup> Case C-120/95, *Decker v. Caisse de maladie des employés privés*, EU:C:1998:167.

<sup>16</sup> Case C-158/96, *Kohll v. Union des caisses de maladie*, EU:C:1998:171.

<sup>17</sup> All EU Member States’ health systems include some services remunerated by privately generated finance. But in the vast majority, most health care is remunerated by publicly generated finance. See, e.g., E Thompson, P Foubister, E Mossialos, *Financing Health Care in the European Union: Challenges and Policy Responses* (European Observatory on Health Systems and Policies 2009).

remunerated through social insurance systems. In those cases, the CJEU approaches the matter thus:

First, the CJEU deals with the scope question. Several of the intervening Member States, as well as the Union des Caisses de Maladies, argued that the matter fell entirely outside of the scope of EU law, as it concerned social security, a matter of national competence. The CJEU adopted a broader approach. It conceded that '[EU] law does not detract from the powers of the Member States to organise their social security systems',<sup>18</sup> and so Member States may determine personal scope and entitlement to benefits under such schemes.<sup>19</sup> But Member States are not free from compliance with EU law when making those determinations. There is nothing special about 'certain services' (here health care services) that removes them from the ambit of internal market law.<sup>20</sup>

Second, the CJEU frames the Luxembourg health system arrangements as an instance of protectionist trade discrimination. Authorisation is needed only to secure health care services from another Member State; if the patient receives the same service within Luxembourg, authorisation is automatic. That creates a deterrent, and hence a barrier to free movement of services:

While the national rules at issue in the main proceedings do not deprive insured persons of the possibility of approaching a provider of services established in another Member State, they do nevertheless make reimbursement of the costs incurred in that Member State subject to prior authorisation, and deny such reimbursement to insured persons who have not obtained that authorisation. Costs incurred in the State of insurance are not, however, subject to that authorisation.

Consequently, such rules deter insured persons from approaching providers of medical services established in another Member State and constitute, for them and their patients, a barrier to freedom to provide services.<sup>21</sup>

In just over 100 words, the CJEU thus demolishes the idea that health systems in EU Member States are closed, with everything that implies in term of the connections between patient mobility, solidarity and equal access. Member States could not simply exclude the entire public health sector from the scope of application of EU law.<sup>22</sup>

The legal principle, once established, is then extended by *Van Braekel*<sup>23</sup> and *Geraets-Smits/Peerbooms*<sup>24</sup> to benefits in kind social insurance systems. That accounts for about one half of all Member States.

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<sup>18</sup> Kohll, para 17, citing *Case 238/82 Duphar* [1984] ECR 523, para 16, and case C-70/95 *Sodemare* [1997] ECR I-3395, para 27.

<sup>19</sup> Kohll, para 18, citing case 110/79 *Coonan* [1980] ECR 1445, para 12, and case C-349/87 *Paraschi* [1991] ECR I-4501, para 15, cases C-4&5/95 *Stöber and Pereira* [1997] ECR I-511, para 36.

<sup>20</sup> Kohll, paras 19 and 20.

<sup>21</sup> Kohll, paras 34 and 35.

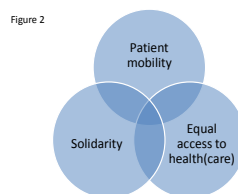
<sup>22</sup> Kohll, para 46.

<sup>23</sup> Case C-368/98, EU:C:2001:400.

<sup>24</sup> Case C-157/99, EU:C:2001:404.

Those remaining Member States, operating a national health system based on taxation, continued to argue, however, that the legal rules established in this line of case law did not apply to them. In effect, they argued that the model they had chosen for their health system, in terms of the allocation of competences between the EU and its Member States, kept patient mobility separate from solidarity and equal access to health care. This position was finally blown out of the water by *Watts*<sup>25</sup> and *Stamatelaki*,<sup>26</sup> in which the CJEU reasoned that the principles of *Kohll* apply irrespective of the type of health care system at issue, so long as there is ‘remuneration’ of some sort for the services being given to the patient concerned. It follows that none of the Member States by that time had a health care system outside of the scope of EU law.<sup>27</sup> In principle, therefore, the scope of EU law on patient mobility extends to cover arrangements concerned with every aspect of health systems in EU Member States: including, of course, solidarity and equal access provisions.

### 3. Patient mobility affects solidarity and equal access



Merely establishing that, in terms of scope rules, *in principle* EU internal market law applies to health care services does not necessarily mean that *in practice* patient mobility will have an effect on solidarity or equal access. On the contrary, many measures of public policy (broadly defined), which technically fall within the scope of internal market law, are nonetheless justified by reason of an objective public interest, and remain lawful under EU law. Indeed, solidarity-based arrangements, and measures that seek to secure equal access according to medical need, are precisely the kind of policies that constitute such objective public interests.

To begin with, however, the CJEU rejected all such interests. One such argument was that the restrictions in *Kohll* were necessary to secure public health, by ensuring quality of care

<sup>25</sup> Case C-372/04, EU:C:2006:325.

<sup>26</sup> Case C-372/04, EU:C:2006:325.

<sup>27</sup> The new CEE states, which previously had versions of the ‘Semashko’ system, changed to ‘Bismarckian’ systems. See, e.g., J Marreé and P Groenewegen, *Back to Bismarck: Eastern European Health Care Systems in Transition* (Ashgate 1997); Z Ferge, ‘Welfare and ‘Ill-fare’ Systems in Central and Eastern Europe’ in R Sykes, B Palier, and P Prior (eds), *Globalization and European Welfare States: Challenges and Change* (Palgrave Macmillan 2001); WHO and European Commission, ‘Health Status Overview for Countries of Central and Eastern Europe that are Candidates for Accession to the European Union’ (European Communities and WHO 2002).

through regulation of health professionals. The CJEU pointed out that medical professional qualifications are the subject of coordinating and harmonising EU Directives.<sup>28</sup> These mutual recognition rules require that ‘doctors and dentists established in other Member States must be afforded all guarantees equivalent to those accorded to doctors and dentists established on national territory, for the purposes of freedom to provide services’.<sup>29</sup> Member States may not use rules or practices distinguishing between national medical qualifications and medical qualifications in other Member States to restrict patient mobility, even if part of the reason for doing so is to secure equal access to health services in accordance with medical need.

A second argument concerns the financial security of health systems. In *Kohll*, the Luxembourg government and European Commission argued that its rules were ‘the only effective and least restrictive means of controlling expenditure on health and balancing the budget of the social security system’, which sought to ‘ensure a balanced medical and hospital service open to all’.<sup>30</sup> The Commission added that there was a ‘genuine and actual risk’<sup>31</sup> of upsetting the financial balance of Luxembourg’s social security scheme. The CJEU accepted that financial balance could be an objective public interest, but pointed out that it was not in this case,<sup>32</sup> given that ‘the reimbursement of the costs of dental treatment provided in other Member States in accordance with the tariff of the State of insurance has no significant effect on the financing of the social security system’.<sup>33</sup> A single patient seeking to receive cross-border dental services did not jeopardise the financial arrangements of Luxembourg’s system sufficiently to constitute a reason to restrict free movement.

Over time, though, the CJEU has accepted that some rules, including, in particular, planification rules concerning hospitals and other major elements of medical institutional infrastructure, and measures concerning the financial arrangements of health systems, can be objectively justified in internal market law. A ‘medical necessity’ test, for instance, which is designed inter alia to secure equal access to health services on the basis of medical need, can be lawful in EU law.<sup>34</sup> Rules designed to protect the financial balance of social security systems, such as reimbursement rules that limit the amount to be reimbursed to mobile patients to the level of reimbursement that would be received if the patient had received the service in the home Member State, are permissible.<sup>35</sup> Rules determining the ‘basket of care’ covered by a national health system are permissible.<sup>36</sup> Arrangements for expensive medical equipment are also permissible.<sup>37</sup>

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<sup>28</sup> Above n 13.

<sup>29</sup> *Kohll*, para 48.

<sup>30</sup> *Kohll*, paras 37 and 38.

<sup>31</sup> *Kohll*, para 39.

<sup>32</sup> *Kohll*, paras 40-42.

<sup>33</sup> *Kohll*, para 42.

<sup>34</sup> *Geraets-Smits*, above n 24, para 103.

<sup>35</sup> Case C-211/08 *Commission v Spain (Hospital Care)* EU:C:2010:340.

<sup>36</sup> Case C-173/09 *Elchinov* EU:C:2010:581; Case C-187/80 *Petru* EU:C:1981:180.

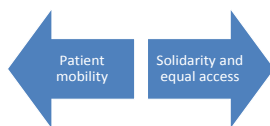
<sup>37</sup> Case C-255/09 *Commission v Portugal (Non-hospital medical care)* EU:C:2011:695.

Many of these aspects of the CJEU's jurisprudence are now enshrined in the Directive on Patients' Rights in Cross-Border Health Care.<sup>38</sup> Member States may provide a system of prior authorisation of reimbursement of costs of cross-border health care where planification, cost control, and the need to avoid waste of 'financial, technical and human resources' to secure 'sufficient and permanent access to a balanced range of high quality treatment' necessitate it, if the health care concerns either over-night hospital treatment, or use of cost-intensive medical infrastructure.<sup>39</sup> These ways of protecting equal access to health services on the basis of medical need are now secured within EU law.

To summarise: It became accepted that patient mobility affects and interacts with the bases of health systems in Europe, including by definition those aspects concerned with solidarity and equal access (Figure 2). But *how* does patient mobility do so? What is the nature of the relationship between the three concepts?

#### 4. A destructive relationship

Figure 3a



As EU law on patient mobility emerged, health policy communities (both in practice and in the academy, noting that these two often overlap significantly) began to articulate significant concerns about the relationship between patient mobility (on the one hand) and solidarity and equal access to health care (on the other). Commentators such as Rita Baeten<sup>40</sup> and Yves Jorens<sup>41</sup> were among the first to express fears that the impact of *Kohll* and the case law that followed it would have a negative impact on the stability and internal

<sup>38</sup> Directive 2011/24/EU on the application of patients' rights in cross-border healthcare [2011] OJ L88/45.

<sup>39</sup> Directive 2011/24/EU, Article 8.

<sup>40</sup> R Baeten, 'European Integration and National Healthcare Systems: a challenge for social policy' 8 infose November 2001, p 1-2.

<sup>41</sup> Y Jorens, 'The Right to Health Care across Borders' in R Baeten, M McKee and E Mossialos (eds), *The Impact of EU Law on Health Care Systems* (PIE Peter Lang, 2003), p 87-88 and 99-100.



balance of national health systems, and the viability of their social goals.<sup>42</sup> The ‘end of territoriality’<sup>43</sup> associated with patient mobility in EU law was a focus for particular concern.

First, health care planning and capacity maintenance would be negatively affected, with consequences for sustaining quality standards and values of social equity associated with equal access to health care according to medical need. There were worries about unplanned

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<sup>42</sup> See, non-exhaustively, A P van der Mei, ‘Cross-Border Access to Medical Care within the European Union – Some Reflections on the Judgments in *Decker and Kohll*’ (1998) 5 *Maastricht Journal of European and Comparative Law* 277; A Bayens, ‘Free movement of goods and services in health care: a comment on the Court cases *Decker* and *Kohll* from a Belgian point of view’ (1999) 6 *European Journal of Health Law* 373; P Cabral, ‘Cross-Border Medical Care in the European Union: Bringing Down a First Wall’, (1999) 24 *European Law Review* 387; K Sieveking, ‘The Significance of the Transborder Utilisation of Health Care Benefits for Migrants’ (2000) 2 *European Journal of Migration and Law* 143; J Nickless, ‘Were the ECJ decisions in *Kohll* and *Decker* right?’ 7 (1) *Eurohealth* (2001) 16; J Nickless, ‘The Internal Market and the Social Nature of Health Care’ in M McKee, E Mossialos and R Baeten (eds), *The Impact of EU Law on Health Care Systems* (PIE Peter Lang 2003); P Cabral, ‘The Internal Market and the Right to Cross Border Medical Care’, (2004) 29 *European Law Review* 673; M Flear, ‘Case C-385/99 *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij O.Z. Zorgverzekeringen .UA and E.E.M van Riet v. Onderlinge Waarborgmaatschappij Z.A.O. Zorgverzekeringen*, Judgement of the Court of 13 May 2003’, (2004) 42 *Common Market Law Review* 209; S L Greer, ‘Migration of Patients and Migration of Power: Politics and Policy consequences of Patient Mobility in Europe’, (2009) 26 *Wisconsin International Law Journal* 908; V Hatzopolous, ‘A (More) Social Europe: A Political Crossroads or a Legal One-Way? Dialogues between Luxembourg and Lisbon’, (2005) 42 *Common Market Law Review* 1599; V Hatzopoulos, ‘Killing National Health and Insurance Systems but Healing Patients? The European Market for Health Care Services after the Judgements of the ECJ in *Vanbraekel* and *Peerbooms*’, (2002) 39 *Common Market Law Review* 683; Y Jorens, M Coucheir and F Van Overmeiren, ‘Access to Health Care in an Internal Market: Impact for Statutory and Complementary Systems’, (2005) 18 *Bulletin Luxembourgeois des Questions Sociales* 1; A Kaczorowska, ‘A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and Its Outcomes’, (2006) 12 *European Law Journal* 345; C Newdick, ‘Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity’, (2006) 43 *Common Market Law Review* 1645; K Sieveking, ‘ECJ rulings on health care services and their effects on the freedom of crossborder patient mobility in the EU’ (2007) 9(1) *European Journal of Migration and Law* 25; Newdick (2009) *op cit* n 20 *supra*; J. van de Gronden, ‘Cross-Border Health Care in the EU and the Organization of the National Health Care Systems of the Member States: the Dynamics Resulting from the European Court of Justice’s Decisions on Free Movement and Competition Law’, (2009) 26 *Wisconsin International Law Journal* 705; S L Greer, ‘Ever Closer Union: Devolution, the EU and Social Citizenship Rights’ in S L Greer (ed), *Devolution and Social Citizenship in the United Kingdom* (Policy Press 2009); W Gekiere, R Baeten, and W Palm, ‘Free Movement of Health Services in the EU and Health Care’ in E Mossialos, G Permanand, R Baeten and T Hervey (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010); T Sokol, ‘Rindal and Elchinov: A(n) (Impending) Revolution in EU Law on Patient Mobility’ (2010) 6(6) *Croatian Yearbook for European Law and Policy* 167; J W van de Gronden, E Szyzszak, U Neergaard and M Krajewski, *Health Care and EU Law* (Springer-Verlag New York Inc, 2011); F Pennings, ‘The Cross-Border Health Care Directive: More Free Movement for Citizens and More Coherent Law’, (2011) 13 *European Journal of Social Security* 424; E Zanon, ‘Healthcare across borders: Implications of the Directive on crossborder health care for the English NHS’ (2011) 17(2-3) *Eurohealth* 34; S de la Rosa, ‘The Directive on Cross-Border Healthcare or the Art of Codifying Complex Case Law’, (2011) 49 *Common Market Law Review* 15; L Hancher and W Sauter, *EU Competition and Internal Market Law in the Health Care Sector* (OUP 2012); D Sindbjerg Martinsen and H Vollaard, ‘Implementing Social Europe in Times of Crises: Re-established Boundaries of Welfare’ (2014) 37(4) *West European Politics* 677; D Sindbjerg Martinsen and H Vollaard, ‘Bounded Rationality in Transition Processes: The Case of the European Patients’ Rights Directive’ (2014) 37(4) *West European Politics* 711; A de Ruijter, *A Silent Revolution: the expansion of EU power in the field of health* (OUP 2016); A de Ruijter, ‘The impediment of health laws’ values in the constitutional setting of the EU’ in T Hervey, et al, (eds), *Research Handbook in European Union Health Law and Policy* (Edward Elgar, 2017).

<sup>43</sup> A Obermeier, *The End of Territoriality? The Impact of ECJ rulings on British, German and French social policy* (Ashgate 2009).

influxes, and effluxes, of patients. For instance, Member States with higher standards of service, better value for money, and greater patient choice, especially for novel and untested treatments,<sup>44</sup> were expected to experience unpredictable patient in-flows, with consequent implications for domestic patients, for instance, in the form of longer waiting times.<sup>45</sup>

A case study from Greece in the early 1990s, reported by Baeten and Irene Glinos in 2006,<sup>46</sup> typifies these concerns about the systemic social, institutional and fiscal impacts of EU-law-led patient mobility. The Greek government had taken the decision to enable patient mobility in order to deal with domestic capacity deficits – a decision that seems appropriately driven by a need to secure equal access to health care in accordance with medical need. However, because of the way that the relevant social insurance funds operated, in fact, what happened was an increase in social inequalities. For instance, rural workers had significantly lower rates of mobility than those who worked in the banking sector. The patients' real needs, in a medical sense, were not the primary driving factor behind patient mobility. Instead, the type of sickness fund coverage and the individual's income were the key bases for access to cross-border health care. In short, wealthier patients accessed health services outside of Greece more quickly than less wealthy patients. Further, the study found that institutional inefficiencies arose, due to bilateral agreements between the sickness funds and hospitals in specific Member States (UK, France, Germany). Patient mobility was therefore detrimental to the Greek health system as a whole, because the increased and uneven spending on particular types of patients had a highly adverse impact on Greece's social security budgets.

Second, the CJEU's reasoning that medical qualifications were to be regarded as equivalent across the whole EU comes in for particular criticism in both the literature and in legal argument. While *initial training* may be harmonised at EU level for some health professionals, continuing professional development is not included within EU law. Yet the implication of the CJEU's position is that differences in quality standards could not be used to justify a refusal to reimburse cross-border health care.<sup>47</sup> This concern is to some extent rectified by the Patients' Rights Directive, which allows Member States to require prior authorisation if a treatment involves 'a particular risk for the patient or the population' or 'is provided by a healthcare provider that ... could give rise to serious and specific concerns relating to the quality or safety of the care'.<sup>48</sup> But note that the Patients' Rights Directive imposes no obligations on Member States to *improve* quality of health care, or access to health services, for instance through cooperative efforts.<sup>49</sup> A worst-case scenario, floated but rejected by Tamara Hervey and Jean McHale,<sup>50</sup> would be a national response that

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<sup>44</sup> See *Geraets-Smits/Peerbooms*, above n 24.

<sup>45</sup> See Case C-385/99 *Müller-Fauré/ Van Riet* EU:C:2003:270.

<sup>46</sup> J E Kyriopoulos and others, *Cross-border Flow of Health Care: the Greek Experience - Facts and Figures*. Athens, Athens School of Public Health - Dept of Health Economics, cited in Glinos and Baeten, above n 1.

<sup>47</sup> See Jorens, above n 41; Nickless, (2001), above n 42.

<sup>48</sup> Directive 2011/24/EU, Article 8 (b) and (c).

<sup>49</sup> De la Rosa, above n 42.

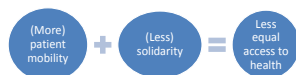
<sup>50</sup> T Hervey and J McHale, *Health Law and the European Union* (CUP, 2004) p 138-144.

*reduced* quality of services, to discourage medical tourism – in short, a ‘regulatory race to the bottom’.

Third, there are significant concerns about the reframing of relationships within national health systems, in ways which undermine the solidarity bases of these systems. Christopher Newdick writes of the ‘accidental death’ of social citizenship, through the CJEU’s decisions.<sup>51</sup> ‘Killing’ national health systems is Vassilis Hatzopoulos’ assessment too.<sup>52</sup> Tomislav Sokol writes of ‘decomposition’.<sup>53</sup> EU law puts patients into a new relationship with their health systems: they become individual rights holders, rather than members of a community based on solidarity. The ‘salient concern’<sup>54</sup> of EU law is for individual patients and their market-based rights, not for the whole community served by a national health system. Indeed, the rights concerned are sometimes even conceptualised as ‘human rights’, as in the case, for instance, of the Advocate General’s Opinion in *Stamatelaki*:

However, although the case-law takes as the main point of reference the fundamental freedoms established in the Treaty, there is another aspect which is becoming more and more important in the Community sphere, namely the right of citizens to health care, proclaimed in Article 35 of the Charter of Fundamental Rights of the European Union, since, ‘being a fundamental asset, health cannot be considered solely in terms of social expenditure and latent economic difficulties’. This right is perceived as a personal entitlement, unconnected to a person’s relationship with social security, and the Court of Justice cannot overlook that aspect.<sup>55</sup>

Figure 3b



There are consequences, too, for equality of access to health care. Statistics on healthcare spending show very wide disparities between EU Member States.<sup>56</sup> Health outcomes are

<sup>51</sup> C Newdick, ‘The European Court of Justice, Transnational Health Care, and Social Citizenship - Accidental Death of a Concept?’ (2009) 26 *Wisconsin International Law Journal* 845.

<sup>52</sup> V Hatzopoulos, ‘Killing National Health and Insurance Systems but Healing Patients? The European Market for Health Care Services after the Judgements of the ECJ in *Vanbraekel* and *Peerbooms*’, (2002) 39 *Common Market Law Review* 683.

<sup>53</sup> T Sokol, ‘Entitlement to Socially Covered Healthcare versus Priority Setting: ECJ’s Decomposition of the NHS?’ (2011) 13 *European Journal of Social Security* 317.

<sup>54</sup> Newdick, above n 51; see also C Newdick, ‘Disrupting the Community – Saving Public Health Ethics from the EU Internal Market’ in J van de Gronden, et al, (eds) supra n 42; C Newdick, ‘Citizenship, free movement and health care: Cementing individual rights by corroding social solidarity’ (2006) 43(6) *Common Market Law Review* 1645; C Newdick, ‘Preserving Social Citizenship in Health Care Markets - There May be Trouble Ahead’, (2008) 2 *McGill Journal of Law and Health* 93.

<sup>55</sup> AG Opinion, in *Stamatelaki*, above n 26, at para 40.

<sup>56</sup> Source: World Development Indicators 2014 <http://data.worldbank.org/data-catalog/world-development-indicators>.

also very different: average life expectancy at birth varies by 8 years, and infant mortality ranges from 9 (Bulgaria) and 10 (Romania) per 1000, to only 2 per 1000 (Estonia, Luxembourg), although these gaps are slowly narrowing.<sup>57</sup> These stark facts show profound inequality in health across the EU. Within those bare figures, a very different range of entitlements to access different types of health care is found across different EU Member States.

Neither the CJEU case law nor the Patients' Rights Directive<sup>58</sup> deals with the question of disparities in patients' rights to access health care in practice, levels of health care spending and so on. Nothing in the Patients' Rights Directive will smooth out the major discrepancies in access to health care when one compares patients' rights across different Member States. And nothing at all in that legislation deals with the very different and unequal health outcomes for individuals across the EU. As Scott Greer and Tomislav Sokol put it:<sup>59</sup>

The European Court of Justice strengthened the right to health care in other Member States, but this cannot create an equal right to health care when Member States are so different.

These concerns about equality of access to health care were raised, for instance, by the English Court of Appeal in *Watts*. That court was concerned that an unfettered right to obtain medical treatment elsewhere in the EU would disrupt and undermine the NHS's planning, especially its use of waiting lists to secure access to health care according to medical need, within budgetary constraints.<sup>60</sup> Patients with less urgent medical needs could use EU law to access treatment before those with more urgent medical needs. In short, as Newdick puts it:

This framework of analysis appears blind to community interests and suggests that concerns for social justice cannot stand in the way of individual, market-based rights.<sup>61</sup>

There is much to be said for this interpretation of the relationship between patient mobility, and solidarity and equal access. In particular, the scope rules suggest a negative and devastating effect on solidarity. However, it is important not to overstate the case here. It is not that EU law replaces national rules on 'social citizenship'. EU law provides only that those rights must comply with minimum (mainly procedural) rules: 'rules for rights'.<sup>62</sup> Following a detailed analysis of scores of CJEU decisions and EU legislation, Hervey and McHale<sup>63</sup> found that EU health law does treat health services (and health products) as commodities, to be traded within the EU's internal market. Correspondingly, EU health law (including its law on patient mobility) treats patients as consumers. It follows that the very application of EU law (its scope rules) requires that relationships are conceptualised within a consumerist frame. But Hervey and McHale also showed that a strong version of the claim

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<sup>57</sup> *ibid.*

<sup>58</sup> Directive 2011/24/EU OJ 2011 L 88/45.

<sup>59</sup> S L Greer and T Sokol, 'Rules for Rights: European Law, Health Care and Social Citizenship' (2014) 20 *European Law Journal* 66.

<sup>60</sup> *R (Watts) v Bedfordshire PCT* [2004] 77 BMLR 26, para 105, cited in Newdick, above n 51.

<sup>61</sup> Newdick, above n 51.

<sup>62</sup> Greer and Sokol, above n 59.

<sup>63</sup> Above n 3.

that EU health law replaces relationships of solidarity with those of consumer relations cannot be supported. For instance, the EU legislature and the CJEU recognise the need to secure financial sustainability of national health (insurance) systems, the practical arrangements for solidarity and equality of access to health care based on medical need.

Figure 5



Rather than patient mobility being the most important driver in break-down in solidarity and equal access to health, since the Eurozone crisis, authors such as Scott Greer point to the EU's attempts to constrain Member States' macroeconomic policies as much more important.<sup>64</sup> In 2012, for instance, a study from Greece suggested that fiscal austerity measures, imposed by the International Monetary Fund and the EU, led the Ministry of Health to call for a 40% cut to hospital budgets in 2011.<sup>65</sup> By 2014, some twenty Member States were subject to 'country specific recommendations' concerning their health systems under the European Semester.<sup>66</sup> The key issue for solidarity and equal access to health is not so much access to medical treatments per se. It is the question of payment: who bears the costs of health care? How much is borne by the social insurance or taxation system? How much is borne by the patient him or herself, through co-payment (or private insurance)? Many Member States (including Bulgaria, Croatia, Estonia, Hungary, Ireland, Italy, Greece, Latvia, Romania, Portugal and Spain) have reduced the amount (and proportion) of public health spending since 2007, in some cases drastically.<sup>67</sup> Many countries did so by introducing or increasing flat rate co-payments for medical consultations or for prescriptions. These obviously affect patients of lower incomes more significantly than more wealthy patients.

<sup>64</sup> See, for detail, S L Greer, 'The Three Faces of European Union Health Policy: Policy, markets, austerity' (2014) 33(1) *Policy and Society* 13; T Sokol and N Mijatović, 'EU Health Law and Policy and the Eurozone crisis' in T Hervey, C Young and L Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar, 2017).

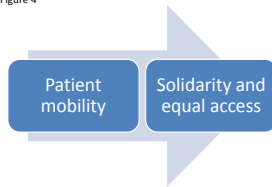
<sup>65</sup> A Kentikelenis and I Papanicolas, 'Economic crisis, austerity and the Greek Public health system' (2012) 22 *European Journal of Public Health* 4-5.

<sup>66</sup> The European Semester is a framework of 'soft governance' for coordination of Member States' employment and social policies. It complements the coordination of economic and fiscal policies through the Stability and Growth Pact.

<sup>67</sup> P Mladovsky and others, 'Health policy responses to the financial crisis in Europe' (Policy Summary WHO 2012).

## 5. Is there anything constructive or positive about the relationship?

Figure 4



Could it be that the relationship between patient mobility, solidarity and equal access is a positive one? There are a few proponents of what must be admitted is very much a minority view. Chief among these is the European Commission. A good example is its 2009 Communication on *Solidarity in Health: Reducing Health Inequalities in the EU*.<sup>68</sup> This seeks to encourage the EU to support Member States to reduce health inequalities in the EU. Support comes in the form of coordination of national policies,<sup>69</sup> essentially data collection and dissemination of good practice, with the aim of moving towards ever greater efficiency in health care systems. Nonetheless, the Commission does not explain in detail how its proposed work will ensure that greater *efficiency* translates into greater equality within Member States' health systems, still less greater equality in access to health care (and the bigger picture of equality in health) across the EU as a whole. But there is some attention to inequalities, as the Commission calls on the EU's Fundamental Rights Agency to 'collect information on the extent to which vulnerable groups may suffer from health inequalities in the EU, particularly in terms of access to adequate health care, social and housing assistance'.<sup>70</sup> The EU's Fundamental Rights Agency has done so, for instance, commissioning research and reports on health of vulnerable minorities.<sup>71</sup>

One of the hoped-for outcomes from the Patients' Rights Directive and the CJEU's case law relates to its obligations to provide procedural entitlements and information to patients. Article 9 of the PRD entitles patients to individual, timely, transparent, and judicially reviewable decision on whether they may receive cross-border health services that are paid for by their home health system. Through its transparency rules, the PRD may contribute

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<sup>68</sup> COM(2009) 567 final.

<sup>69</sup> Given the constrained legislative competence in general, and the lack of harmonising competence in particular, that the EU has in the area of health, see Article 5 TEU; Articles 4 and 6 TFEU; Article 168 TFEU, especially Article 168 (7) TFEU.

<sup>70</sup> COM(2009) 567 final, p 8.

<sup>71</sup> See, e.g., European Union Agency for Fundamental Rights (FRA), 'The Situation of Roma in 11 Member States' (FRA 2012); see Hervey and McHale, above n 3, p 166-169.

*indirectly* to increased awareness of poor quality health services, or unsafe health care practices.<sup>72</sup> However, there is little evidence of this in practice.<sup>73</sup>

Stephane de la Rosa sees these provisions of the PRD as a positive – an expression of the values of ‘universality, access to good quality care, equity and solidarity’.<sup>74</sup> But as noted above,<sup>75</sup> EU patient mobility law moves national health systems away from collective welfare-based approaches, towards an individual rights approach. The associated rebalancing – or perhaps unbalancing – of the relationship between autonomy and individual choice, and equal access according to professionally determined medical need is unlikely to secure the latter. Those who are healthy enough, and wealthy enough, to travel, may access EU-based rights. Those who are not, are left behind.

Further, too strong a ‘health rights’ basis of EU law entitlements to patient mobility would result in political and administrative chaos, as individual legal claims to particular health services were pursued. Member States would struggle to provide equivalent entitlements to all, including (as would be politically necessary, though not of course mandated by EU patient mobility law) those who do not move to another Member State to receive health services. The political pressures from such chaos might well also exert a downward pressure on the more generous Member States, resulting in a lowering of standards overall – the ‘regulatory race to the bottom’ noted above.

## 6. Conclusions: A de jure, but not de facto, relationship (in some states – but not in others)

Some of the most recent empirical studies concerning the effects of EU patient mobility law on solidarity and equal access show that, if there are effects, they are very slow to materialise, and do not fundamentally challenge the bases of national health systems in EU Member States.<sup>76</sup> Medical professionals (especially GPs) remain gatekeepers of health

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<sup>72</sup> M Schwebag, ‘Implementation of the Cross-border Care Directive in EU Member States: Luxembourg’ (2014) 21(1) *European Journal of Health Law* 56.

<sup>73</sup> L Prudil, ‘Implementation of the Directive 2011/24/EU in the Czech Republic’ (2014) 21(1) *European Journal of Health Law* 15.

<sup>74</sup> De la Rosa, *supra* n 42, at 34-35.

<sup>75</sup> B van Leeuwen, ‘The doctor, the patient, and EU law: the impact of free movement law on quality standards in the healthcare sector’ (2016) 41 *European Law Review* 638.

<sup>76</sup> I Glinos, R Baeten, and H Maarse, ‘Purchasing Health Services Abroad: Practices of Cross-Border Contracting and Patient Mobility in Six European Countries’, (2010) 95 *Health Policy* 103; S Greer and S Rauscher, ‘Destabilization Rights and Restabilization Politics: Policy and Political Reactions to European Union Health Care Services Law’, (2011) 18 *Journal of European Public Policy* 220; Obermeier, *supra* n 43; S Greer and H Jarman, ‘Managing risks in EU health services policy: Spot markets, legal certainty and bureaucratic resistance’, (2012) 22(3) *Journal of European Social Policy* 259–272; Greer and Sokol, *above* n 59; Prudil, *above* n 73; Schwebag, *above* n 72.

services. Dorte Sjinbjerg Martinsen and Juan Mayoral Díaz-Asensio's 2016 study of Denmark and Spain is a case in point:<sup>77</sup>

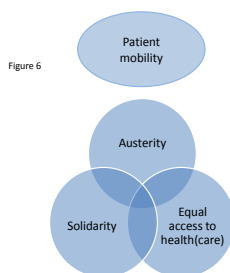
'The transposition of the [Patients' Rights] directive implies yet other gradual steps of change to allow for EU cross-border healthcare but does so without bringing Denmark outside its comfort zone of a nationally controlled healthcare system.'

'... similar to Denmark, Spain has been reluctant to adapt to the sequences of EU-induced change. Although national courts managed to extend crossborder healthcare rights of Spanish patients in 15 cases by means of the CJEU jurisprudence, these court cases did not change the administrative practices or national law. CJEU case law was not devoted political or administrative attention, and national courts did not have the power or the sword to instigate broader national change.'

Fewer than 50 patients across the two countries had been reimbursed for crossborder health services under the Patients' Rights Directive. With a combined population of over 50 million, this is hardly grounds for describing any significant impact on equality of access to health services, or the solidarity principle on which those systems are based.

By contrast, the effects of EU law on access to health care services in other countries, particularly Eurozone countries subject to fiscal governance through 'Memorandums of Understanding' with the EU and IMF, are, as noted above, significant.

Perhaps after all, the best way to understand the relationships between patient mobility, equal access to health care, and solidarity is that they are not directly related in as significant a way as some commentators expected, or as the formal, legal position suggests. The much more important relationship is that between EU-led austerity policies, and the solidarity and equality aspects of European health systems.



But let us give the last words to Rita Baeten and Irene Glinos. The conclusions of their study, now over 10 years old, hold true today:

'One of the lessons of the study appears to be that it is very difficult to draw general, sweeping conclusions about patient mobility, its direction and purposes'.<sup>78</sup>

<sup>77</sup> D Sjinbjerg Martinsen and J A Mayoral Díaz-Asensio, 'A judicialisation of healthcare policies in Denmark and Spain? The universalist healthcare model meets the European Union' (2016) 14 *Comparative European Politics* doi:10.1057/cep.2016.7, at 11 and 15.

<sup>78</sup> Glinos and Baeten, above n 1.



# Chapter III      Convergence and divergence in patients' rights

Karl Harald Søvig

## 1. Introduction

The directive on the application of patients' rights in cross-border healthcare is presented in other parts of the book, and different elements are analysed in the various chapters. The aim of this contribution is to reflect upon the directive in respect of convergence and divergence in patients' rights. For that purpose, some general features of the directive should be emphasised. The phrase "patients' rights" is used in the title of the directive, but the directive itself does not contain a definition or elaboration of this notion.<sup>1</sup> In the literature it is not established a general consensus on which entitlements that should be regarded as patients' right, although that there are several mutual characteristics. Various legal instruments also identify core elements of patients' rights, like the Convention on Human Rights and Biomedicine<sup>2</sup> and the European Charter of Patients' Rights.<sup>3</sup> Some patients' rights will also fall within the scope of the European Convention on Human Rights as developed by the European Court of Human Rights and will as such be ensured at a European level. It falls outside the scope of this contribution to analyse which entitlements that are to be considered as patients' rights. Some core elements are identified in part 2, namely *access to health care* (2.1), *standard of care* (2.2), *information and consent* (2.3), *protection of medical data* (2.4), *fair and proper procedure* (2.5) and *redress* (2.6). To which extent the directive contains these patients' rights and the major elements in these entitlements will be a major topic of this contribution.

According to Article 35 CFREU everyone has the "right of access to preventive health care and the right to benefit from medical treatment" under the conditions "established by national laws and practices". This division of competence between the Union and the member states leaves healthcare under the domain of the member states. Some issues may still belong to the Union level affecting more than one member state, like the directive addressing "cross-border healthcare". Consequently, the counterpart is national health care, which is falling outside the scope of the directive, cf. Article 1(4). This division between cross

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<sup>1</sup> See sect. 2.3 regarding the use of "patients' rights" in Article 6(3).

<sup>2</sup> Convention (Council of Europe) for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (4 April 1997).

<sup>3</sup> The document is of the work of a Cittadinanzattiva-Active Citizenship Network group (Rome, November 2002).

border and national health care will be addressed later in the contribution.<sup>4</sup> Which kind of services to be included under the term “health care” is not self-evident, but the directive contains a definition in Article 3. Some services are excluded in Article 3(3), either being in the outskirts of the definition (borderline to social services, cf. *litra a*) or being excluded due to ideological motivations (organ transplants, cf. *litra b*).

The history of the directive (cf. Martinsen’s contribution, Chapter 1) shows that different solutions were at the table, but the outcome was a directive giving significant leeway to the member states. The national flexibility concerns foremost the internal healthcare, but also regarding cross-border healthcare the directive gives rooms for varieties in the national implementation.<sup>5</sup> Still, as to “cross-border healthcare” the directive establishes in several ways a European standard. This is indeed a challenging task since the organization of health care varies between the different member states. The directive contains several provisions referring to different national levels (cf. Article 1(4), Article 7(3), Article 7(6) Article 7(7)), while the directive is also cross cutting by laying obligations on the member states which they are obliged to fulfil regardless of internal structure. The variety concerning organisation of health services concern not only the different levels, but also the providers (public, private, non-profit, etc.) and the bearer of the cost (state, private or public insurance scheme, etc.).

While health *law* is to a large extent national, the health *care* services are globally or European oriented. Which treatment to be given in cases of a heart stroke is basically universal, although with local variations. Even though the directive is a legal instrument, it partly refers to medical standards, cf. Article 8(6)(d) and what to be considered “medical justifiable”. Such references to medical standards and the impact on convergence and divergence in patients’ rights will be addressed later in the contribution.

## 2. A selection of patients’ rights

### 2.1 Access to health care

Access to health care is a main element of patients’ rights. As emphasised earlier, the directive is directly providing access to cross-border healthcare, while access to internal health care is under the domain of the member states. Subsequently, the starting points are reverse. For cross-border healthcare access is the general principle and the directive addresses the exceptions, while access to internal care is outside the scope of the directive, although with some modifications laid down in the directive. The theme for the forthcoming

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<sup>4</sup> See H. Nys, *The Transposition of the Directive on Patients’ Rights in Cross-Care Healthcare in National Law by the Member States: Still a Lot of Effort to Be Made and Questions to Be Answered* (editorial), (2011), 21(3) *Eur J Health Law* 1, 5 regarding this distinction.

<sup>5</sup> See several contributions on the implementation of the directive in a selection of member states in (2014) *Eur J Health Law* 21(1) 15.

analysis is the legal mechanisms in the directive and to which extent they level the different starting point for cross border and internal health care.

The scope of the directive is to “facilitate” to cross border health care, cf. Article 1(1). The main obligation of the member state of affiliation is to cover the costs of cross-border healthcare in forms of reimbursement (the limits of the costs will not be dealt with here), cf. Article 7(1). The member state of treatment is as a starting point obligated to accept patients from other states. However, neither the responsibility of the sending or receiving member state is not unfettered. The exceptions may be divided into two main groups. The first group consists of general EU law principles, like equal treatment, proportionality, etc. The second group consists of more specific health related requirements, like cost control, patient safety, etc.

The health related requirements could in turn be divided into two main sub-groups. The first concerns societal needs. Illustrations of such an approach could be found in Article 4(3) and Article 7(9). The latter states that member states may limit the application of the rules of reimbursement based on “overriding reasons of general interest”. Examples given in the text of the directive are “planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment” or “to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources”. The system of prior authorisation established in Article 8 is itself based on societal needs, giving the member state of affiliation a remedy to limit the use of cross border health care, within the boundaries of the directive. Article 8(2)(a) uses the same phrases concerning “planning requirements” as in Article 7(9), before adding two alternative conditions. Overnight hospital accommodation (i) may be seen as an indicator of “use of highly specialised or cost-intensive medical infrastructure or medical equipment” (ii). According to Article 8(5)(d) a patient is not entitled to cross border health care if the state of affiliation can provide health care on its territory within a time limit which is “medically justifiable”, based on an “objective assessment”. The societal need to control the number of outgoing patients is here given priority, but the decision is based on medical assessments.

The second-sub group concerns patient’s needs. This could either be on an individual basis, or on a group basis. Illustration of both these concerns could be found in the provisions stipulating grounds for refusal of prior authorisation, cf. Article 8(6). According to litra a) prior authorisation could be denied if the patient, “according to a clinical evaluation”, would with reasonable certainty be exposed to a “patient safety-risk that cannot be regarded as acceptable”. Even though patient oriented, the provision is based on paternalistic reasoning since the patients’ request for healthcare provider is overruled by societal concerns. According to litra b) prior authorisation could be denied if the general public would be exposed with “reasonable certainty to a substantial safety hazard” as a result of the cross-border healthcare in question. Both the cited provisions relies on medical assessments, although foremost litra a).

Article 8(2)(c) is an example of the limitation of patient’s needs and concerns. A member state can introduce prior authorisation if the health services are offered by a healthcare provider could that give “rise to serious and specific concerns” relating to “the quality or

safety of the care”. Such an assessment must be taken on a “case-by-case” basis. However, prior authorisation could not be introduced if the healthcare is subject to “Union legislation ensuring a minimum level of safety and quality throughout the Union”. The provision is based on the notion that in some fields other legal instruments are establishing a European minimum standard which is sufficient to rule out that there is a feasible risk for the patient.

The other main group of access mechanisms are mirroring general principles in EU law. The member state of treatment is obliged to apply the principle of non-discrimination with regard to nationality, cf. Article 4(3). If the member state of affiliation limit the application of the rules on reimbursement, this shall be restricted to what is “necessary and proportionate”, cf. Article 7(11). Furthermore, such limitations may not constitute “means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services”. While the limitations of the limitations in Article 7(11) are inserted at the end of the provision, they are introduced at the beginning of Article 8. Norms that are to be considered as general principles of EU law, will normally apply also without being mentioned in the text of a directive. Some of the provision referring to general principles will therefore be of a pedagogic character, although function as a useful reminder. Additionally, as general principles they will also apply when not mentioned in the text of the directive. If a member state reimburses costs beyond the minimum standards of the directive according to Article 7(3) third paragraph, they cannot differentiate bases on nationality.

Article 7(7) enables the member state of affiliation the option to impose on an insured person certain procedures when seeking reimbursement of the costs of cross border healthcare. The member state of affiliation may require that a patient have to meet the same “conditions, criteria of eligibility and regulatory and administrative formalities” as it would have impose as “if the healthcare were provided at its territory”. This provision enables the member states to maintain the same administrative system, both regarding content and procedure, as with internal patients. Article 7(7) states that this may include an “assessment by a health professional or health care provider”, such as “the general practitioner or primary care practitioner” with whom the patient is registered. However, formalities imposed by this provision may not be discriminatory or the free movement of patients, services and goods, and the text of the directive is then using the same wording as in Article 7(9), cited above. Article 7(7) is based on an acknowledgment of the variety of the different entrance system to health care in the member states and does intervene in this. Patients seeking cross-border health care should be treated on equal footing with internal patients.

Article 5(c) may be regarded as a genuine right to access to healthcare established by the directive. If a patient has received cross-border healthcare and where medical follow proves necessary, member states are obliged to ensure that “the same follow-up is available” as would has been if that healthcare had been provided on its territory. In this respect the directive is intervening in national health care regulations, although the provision could be regarded as a specification of the prohibition against discrimination, cf. Article 4(3). The directive does not oblige the member state to provide follow-up treatment that is not

already provided within the member state, but grants access to follow-up treatment on equal footing with other patients.

Turning to the provisions regarding prescriptions in Article 11 the directive is establishing requirements which in effect will ease the access to medicines in cross-border situations. The provisions in Article 11(1) apply also to medical devices. Reimbursement on costs of medical products and devices are governed by the ordinary scheme stipulated in the directive in Chapter III. If a medical product is authorised to be marketed on a territory of a member state according to the Directive 2001/83/EC or Regulation (EC) No 726/2004 member states shall ensure that that prescriptions for such a product in another member state can be dispensed on their territory "in compliance" with "their national legislation in force". The referral to national legislation is here not meant as a possibility to restrict the use of prescriptions stemming from other member states, but is stating that the ordinary procedures laid down by the legislation must be followed also in such situations. Furthermore, the member states are obliged to prohibit "any restrictions on recognition of individual prescriptions". In this respect the directive is establishing a right to access to medicines on a European level. However, some exceptions are stipulated in litra a and b. Litra a is in line with similar exceptions concerning cross-border healthcare, and is combining a societal purpose with general EU principles. Limitation must be "necessary and proportionate" to safeguard "human health", and "not discriminatory". Litra b addresses a rather special situation for prescriptions and is related to patients' safety. The provision allows limitation based on "legitimate and justifies doubts" about the authenticity, content or comprehensibility of an individual prescription. Moreover, Article 11(1) states that national rules can contain provisions regarding generic exchange or other forms of substitution, as long as they are "compatible with Union law". A rather distinctive limitation is accepted by Article 11(1). A pharmacist may refuse to dispense a product that was prescribed in another member state for "ethical reasons". The condition is that the pharmacist would have the right to refuse to dispense the product if the prescription had been issued in the member state of affiliation. It is noteworthy that a similar limitation is not stipulated for medical personnel that experience similar reasons of conscience in situations of medical treatment.

A rather corresponding provision as in Article 5(c) (follow-up treatment initiated in another member state) is also found in Article 11(1) concerning prescriptions. The member state of affiliation shall take all "necessary measures", in addition to the recognition of prescription in order to ensure continuity of treatment in cases where a prescription is issued in another member state. Like its sibling in Article 5(c), this part of Article 11(1) may be regarded as a genuine right to access to healthcare established by the directive.

This presentation of the different mechanisms of access gives reason to emphasise that the directive is living up to the limitation indicated in the title, the scope is "cross-border healthcare". However, some of the provision has an impact also on internal healthcare, like follow-up treatment and prescription. In these situations the patient is given access to internal health care, for treatment initiated in another member state, which is granted by the directive and thus establishing a European access. The rules governing access to

reimbursements of costs and prior authorisations are many, and complex. The directive gives in many situations a margin of appreciation to the member states, which means that access to cross-border healthcare could differ between various countries. Still, the leeway is not unfettered and the directive is refining the principles developed in the case law of ECJ. The directive is setting a European standard “for facilitating the access to ... cross-border healthcare”, cf. Article 1. Article 8(2)(c) is explicitly referring to a “minimum level of safety” established by Union legislation and the resting on a European standard. A phenomenon of special interest is the referral to medical assessments as an operational part of the directive, which in turn makes the rule “transborderal”. It is not an assessment based on national criteria, but it is rooted on standards set by the international medical community. The medical assessments are crossing borders in a different way than traditional legal norms.

## 2.2 Standard of care

A core element in patients’ rights are the quality of the treatment offered (standard of care). According to Article 1 the aim of the directive is to “facilitating the access to safe and high-quality cross-border healthcare”. Article 4(1) starts with taking into account the “principles of universality, access to good quality care, equity and solidarity”. Cross border healthcare shall be provided in accordance with: a) “the legislation of the Member State of treatment”, b) “standards and guidelines on quality and safety laid down by the Member State of treatment” and c) “Union legislation on safety standards”. Even though the starting words of the provision indicates a kind of European standard by referring to “universality” and principles that can be regarded as common, the operable part of the directive in litra a) and b) is referring to the legislation and standards in the member state of treatment. In this respect the directive cements the existing differences in the member states and does not aim to develop European standards of care. Litra c) is referring to already existing Union legislation on safety standards. The provision should also be read in conjunction with Article 2 that is referring to several directives and regulations already in force in the field of health law.

Even though the directive is not itself contributing to the development of standard of care in Europe, the development of common standards in the medical professions are on-going, which indirectly has an impact on the standard of care in the member states. As stated earlier, what is considered to be “state of the art” treatment for a common disease goes beyond what could be decided by a national level. National legislation will often refer to such standards. One could therefore claim that there is a kind of Europeanization of the standard of care, but this is not driven by legislative tools but by the professionals providing health care. It should also be emphasised that in some fields of health law there is already a European standard, developed by the instruments in Article 2. Since these already are developed by the Union by other legal mechanisms the directive is not itself contributing to the development.

### 2.3 Information and consent

The right to informed consent is a classical patient's right. The consensual part of this notion is not regulated by the directive. It is still up to the member state of treatment to regulate the form of consent (written, oral, tacit, etc.), which can be of a surprise for patients crossing borders used to another consent form in home state than in the state of treatment. It is also under the domain of the member states to regulate which kind of treatment that can be legally consented to, e.g. end of life decisions. However, a patient going abroad for an intervention not recognised in the state of affiliation (e.g. abortion), can do so, although the costs will not be reimbursed, cf. Article 7(7). Counter wise, a patient coming from a member state allowing certain forms of treatment, cannot claim such interventions in a state of treatment not offering such kinds of healthcare. Turning to information as part of a prospective or on going treatment, the directive does not affect the national legislation concerning the use of languages, cf. Article 4(5). In practice language barriers is a hurdle for many patients, although the directive explicitly states that the member states may choose to deliver information in other languages than those which are the official languages. Regarding informed consent the directive may be considered to preserve the existing variations in national health law.

When it comes to information about cross border healthcare the directive contains several provisions. In this respect the provisions are innovative, and is not merely consolidating and developing case law from the ECJ prior to the directive, but is introducing new legal tools. The national contacts points play a core role, cf. Article 6 (see Chapter VI of this book for an in depth analysis of the national contact points). The member states are obliged to designate national contact points. Upon request, a national contact point shall also provide patients with contact information about national contact points in other member states, cf. Article 6(2). The national contact points “shall facilitate” the exchange of information as stipulated in Article 6(3). Such information is of a general nature, like health care providers in the member state of treatment. The national contact points shall also, “on request” provide more detailed information regarding specific health care providers, cf. Article 6(3), including information on “patient's rights” (referring to national regulations) and various administrative procedures. Similar obligations rest upon the member state of treatment, cf. Article 4(2)(a). The health care providers in the member state of treatment are also obliged to provide “relevant information” to “help individual patients to make an informed choice”, including treatment options, quality of the healthcare and clear information on prices, etc., cf. Article 4(2)(b). However, as long as the member state of treatment already provide the relevant information as part of their ordinary health care system, the directive does not oblige health care providers to “provide more extensive information”, cf. Article 4(2)(b) last sentence. It should be reminded that the member state of treatment is not obliged to provide information in a foreign language, cf. Article 4(5).<sup>6</sup> However, by setting some

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<sup>6</sup> L M H Bongers and D M R Townend, ‘The Implementation of the Directive on the Application of Patients' Rights in Cross-Border Healthcare in the Netherlands’, (2011) 21(1) Eur J Health Law 65, 72.

minimum standard on the information it will indirectly also have an impact on information to internal patients.<sup>7</sup>

The member state of affiliation shall ensure that there are mechanisms in place to provide patients “on request” with information on their rights and entitlements relating to receiving cross border health care, cf. Article 5(b). The provisions states explicitly the terms and conditions for reimbursement. This obligation is also vested to the national contact points in the member state of affiliation, cf. Article 6(4). For patients seeking cross border health care by reimbursement cost is of vital interest. The member states should therefore have a “transparent mechanism for calculation of costs”, cf. Article 7(6). In order for patients to foresee the possibilities for cross-border healthcare by prior authorisation, the member state of affiliation shall make “publicly available which healthcare that is subject to prior authorisation” for the purposes of the directive, as well as “all relevant information” on the system of prior authorisation, cf. Article 8(7). The member state of affiliation is also obliged to have “publicly available” information regarding administrative procedures concerning prior authorisation, cf. Article 9(2). The directive is also setting a standard for the information. It shall be “easily accessible”, cf. Article 6(5) and 9(2). Article 6(5) also states that information shall be made “available by electronic means” and “in formats accessible to people with disabilities”, as appropriate, cf. Article 6(5). This provision applies directly only to national contact points, but it should have bearing also on information given by the member states or health care providers and health personnel.

This short review shows that the directive has a comprehensive regulation on information concerning cross-border healthcare. The obligations are laid both on the national contact points, as well as on the member states and the health care providers, although the content of the obligations may vary between the different actors. Partly, the information obligations are on a general level, where the target group is all potential patients. Partly, the information obligations are on an individual level, but then limited “on request” by specific patients.<sup>8</sup> This may be considered as a limitation, but it would be difficult with tailored information to potential cross-border patients. It should also be emphasised that some of the provisions concerning general information are fairly broad, cf. Article 4(2)(b). The information provisions of the directive are quite uniform. Patients in different member state can expect to find the same information in various member states, and in this respect the directive is setting a European standard for the member states. On the other hand, the directive is rather general when stipulating the obligations. Health care provider shall provide “relevant” information regarding treatment options, quality and prices, etc., cf. Article 4(2)b and it can be difficult for patients to compare options from different countries as long as there is no uniform standards in these matters.<sup>9</sup>

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<sup>7</sup> D Delnoij and W Sauter, ‘Patient information under the EU patients' rights Directive’, (2011) 21(3) Eur J Public Health 271, 272.

<sup>8</sup> Note the difference in wording between Article 4(2)b) and recital 20.

<sup>9</sup> See Delnoij and Sauter (n 7) 271, 272.



## 2.4 Protection of medical data

Protection of medical data and medical confidentiality is a widely accepted patients' right.<sup>10</sup> The driving forces within this field are not the directive, but other instruments of the Union. The member state of treatment shall ensure that the fundamental right to privacy with respect to the processing of personal data is protected in conformity with the national measures implementing Union provisions on the protection of personal data, in particular directives 95/46/EC and 2002/58/EC, cf. Article 4(2) *litra* e. Patients who have received cross border treatment are entitled to a written or electronic medical records of such treatment, cf. Article 4(2) *litra* f. The latter provision is a responsibility of the member state of treatment and is mirrored by Article 5 *litra* d addressing the member state of affiliation. Patients who seek to receive or do receive a cross border health care should have remote access to or have at least a copy of their medical records. Most member states will by national regulation have introduced a right for the patient to medical records, but if not so, patients have an entitlement established by the directive.

## 2.5 Fair and proper procedure

An effective access to cross-border healthcare implies also remedies for patients who have been unsuccessful in their attempts to achieve their rights.<sup>11</sup> A major component of the directive is different procedural elements. When it comes to the distribution of tasks, the directive is emphasising that it is up to the member states to decide at which level (local, regional or national level) decisions concerning cross-border healthcare should be taken, cf. Article 7(3), Article 7(7) and Article 10(2). At an institutional level, the directive introduces national contact points which have a kind of procedural element, but foremost are facilitating cross-border healthcare by distributing information (see section 2.3 above). The directive also contains specific administrative procedures regarding cross-border healthcare, cf. Article 9. The provision is partly requiring some procedures to exist, and is partly setting quality standard for the procedures. Article 9(1) states that the member state of affiliation shall ensure that the administrative procedures regarding the use of cross border healthcare and reimbursement are based on "objective, non-discriminatory criteria" which are "necessary and proportionate" to the objective to be achieved. Implied in this provision is the existence of an administrative procedure in cases concerning cross border healthcare. The wording of the provision is expressing well accepted principles of administrative law. Article 9(3) is in this respect more specific. Member states shall "set up reasonable periods of time" within request for cross border health may be dealt with and make them public in advance. Such fixed limits for speediness of administrative procedures may be a stranger in some jurisdictions used to have an approach based on overall assessments. In individual cases concerning cross border healthcare the decisions shall be "properly reasoned" and subject to "review" and a being capable of "being challenges in judicial proceeding", cf. Article 9(4). Patients should also have a remedy for "interim measures". The demands are

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<sup>10</sup> See also Herveg's contribution in Chapter 13 of this book.

<sup>11</sup> See also D Shaw, D Townend, H Nys, 'Mapping enforcement systems for patients' rights in 30 European countries' (2016), 26(suppl. 1) *Eur J Public Health* 210.

rather modest and will unlikely require alterations of national legislation, especially since the provision does not address whether the administrative and judicial review should be full or limited.

The directive also stipulates procedural requirements in cases of complaints over given cross-border healthcare. The member state of treatment shall have “transparent complaint procedures and mechanisms” in place for patients, in order for them to seek remedies “in accordance with the legislation of the member state of treatment” if they suffer harm from the healthcare that they provide, cf. Article 4(2)(c). The directive is here setting a uniform standard when requiring that the complaint procedures and transparent mechanisms should be “transparent” while at the same time accepting regional differences by merely referring to national legislation concerning the conditions for compensation.

The member state of affiliation shall ensure that there are “mechanisms in place” to provide patients on request with information about their rights (see also above concerning information), cf. Article 5(b). Furthermore, these mechanisms should particularly include “procedures” for accessing and determining those entitlements and for appeal and redress, “in accordance” with Article 9. As with Article 9(4) these demands are rather modest.

In some specific situations the directive requires certain procedures. In cases where patients with rare diseases apply for prior authorisation, a “clinical evaluation” may be carried out by experts in the field, cf. Article 8(4). If no experts can be found or if the expert’s conclusions are inconclusive, the member state of affiliation may request scientific advice. Also Article 8(5) has a procedural element, by calling for an “objective medical assessment” in cases of healthcare that may be subject to prior authorisation. While the procedural elements required by Article 8(4) are eligible, they are compulsory as stipulated in Article 8(5).

This short presentation of the procedural elements indicates a variety. Partly the directive refers to “national legislation” and thus fortifies the existing legal differences between the member states. Other provisions are setting rather modest requirements, which in turn does not contribute to level the differences between the member states. However, some provisions are more demanding, e.g. the requirement of fixed time limits. When it comes to procedural elements it should also be born in mind that the administrative system of the member states varies. Within the legal system of the member states, health law may be part of different legal disciplines (administrative law, civil law, etc.), as well as in some country being a separate topic. A full harmonisation of the procedural system would be a breach of the distribution of competence between the Union and the member states.

## 2.6 Redress

A major component of patients' rights are the possibility to seek redress in cases of medical wrongdoings. According to Article 4(2)(d) the member state of treatment is obliged to have “systems of professional liability insurance” or “a guarantee or similar arrangement” that is “equivalent or essentially comparable” as regards its purpose and which is “appropriate to the nature and extent of the risk”. The duty is here to have a system, which already will be

in place in most, if not all member state. The provision does not stipulate rules regarding the content of the liability system, whether concerning the foundation for responsibility (culpability or strict liability) nor concerning the quantification of damages. It should also be added that the directive is restricted to address civil liability and does not require a system of criminal liability. In sum the requirements in the directive concerning redress must be said to be rather modest, and it does not intent to level the differences between national legislation in this field.

### 3. Facilitating convergence

One of the aims of the directive is to promote “cooperation on healthcare” between the member states. The directive contains several provisions that could be said to facilitate convergence by various mechanisms in order to require or encourage the member state to cooperate. According to Article 10(1) member states shall render such “mutual assistance” as is “necessary” for the implementation of the directive. The wording of the directive mentions “standards and guidelines on quality and safety” and the “exchange of information”, especially between the national contact points.

According to Article 10(3) the Commission shall encourage neighbouring countries to conclude agreements by themselves concerning cross-border healthcare. Furthermore, the Commission shall encourage member states to “cooperate ... in border regions”.

Article 7(5) may also be regarded as an encouraging provision, although not as explicit as Article 9(3). Member states may adopt provisions in accordance with the TFEU aimed at ensuring that patients enjoy “the same rights” when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the member state of affiliation. The provision is clearly built on the view that the member states are not obliged to introduce such a system of legal equality treatment, but is a form of indirect encouragement to provide the same internal patients’ rights to cross-border patients as domestic patients.

Article 12 states that the Commission shall support the member states in the development of European reference networks between healthcare providers and centres of expertise in the member state, in particular in the “area of rare diseases”. The networks shall “be based on voluntary participation”. The provision is clearly encouraging, although setting up minimum requirements in order to become a European reference network, cf. Article 12(2). Article 12 is also emphasising the autonomy of the member states in this field, and Article 12(6) states that measures pursuant to Article 12 shall not “harmonise laws or regulations” of the member states and shall “fully respect” the responsibilities of the member state for the organisation and delivery of health services and medical care.

When it comes to rare diseases the Commission shall “support” the member states in cooperating the development of diagnosis and treatment, cf. Article 13. The tasks of the Commission is partly to make health care professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases (litra a), as well as to

make patients and other performers aware of the possibilities offered by Regulation 883/2004 in this respect (litra b).

Regarding eHealth “the Union” shall “support and facilitate cooperation” and “the exchange of information” among the member states working within a voluntary network connecting national authorities responsible for eHealth, cf. Article 14(1). The Commission is responsible to adopt the necessary measures for the establishment, management and transparent functioning of the network, cf. Article 14(3).

As with eHealth the “the Union” shall “support and facilitate cooperation” and “the exchange of scientific information” in the field of health technology assessment, cf. Article 15(1). The Commission is responsible to adopt the necessary measures for the establishment, management and transparent functioning of the network, cf. Article 15(4). The members of the network shall contribute and participate “in accordance with the legislation” of the member state where they were established, cf. Article 15(1).

Also regarding prescriptions a system of cooperation is institutionalised by the directive. In order to facilitate the implementation of Article 11(1) the Commission shall adopt several measures according to Article 11(2) litra a–d (including guidelines according to litra b).

The different mechanisms according to Article 10–15 are primarily addressing the Commission and the member states, and for the latter most of the mechanisms are of a voluntary character. The patients are not addressed with the exception of Article 11(1) on prescriptions (see section 2.1 regarding access) and Article 13(b) (information concerning rare diseases and the possibilities of Regulation 883/2004). The various mechanisms are generally not affecting the internal legislation of the member states. One could therefore not claim that Articles 10–15 are aiming to level the differences of the patients’ rights in these fields. However, the encouraging approach may in the long run have an effect on patients’ rights in these fields. If the cooperation leads to development of common standards between the member states this could pave the way for future EU legislation. Especially when it comes to prescriptions such a development may not be unlikely.

#### 4. Reflections

The directive may be diagnosed with a kind of identity disorder when it comes to patients’ rights. On the one hand the directive shall respect the division of competence stipulated by Article 35 CFREU between the Union and the member state in the field of healthcare. This leaves patients’ rights under national jurisdiction. On the other hand the directive shall live up to its aims and facilitate cross-border health care. The patients are the main target group of the directive (although many of the provisions are addressing the member states and the healthcare providers, etc). Even though the directive aims to regulate the patients who are crossing the borders, the actual treatment will not take place at the border but in a member state. These cross-border patients will have rights and entitlements secured by the directive and in most member state it would be both political impossible and legal undesirable to

grant better entitlements to incoming patients than to domestic patients. The directive will therefore inevitably have an impact on the national regulation on patients' rights.

The main approach by the directive may be considered to play along with national regulation concerning patients' rights. The member states can still decide which kind of treatment to be legally offered (e.g. end of life decisions) within their jurisdiction, in which form a consent shall be given (written or oral) and the condition for redress after damages (culpability or strict liability) and which language to use in health services and when giving information about it. Nevertheless, when it comes to cross-border healthcare the patients' have a right to access stipulated by the directive. As discussed in section 2.1 this access is not unconditional, but within the frame of the directive it creates a European standard. An access to health services without any further patients' rights would in practice leave cross-border healthcare to persons already present in the member state of treatment and would not encourage patients to cross borders in order to have treatment. A major part of the directive is the pre-treatment information, where the obligations on the states and the partly corresponding rights of the patients, either as a group or individual are intended to fertilise increased use of cross-border healthcare. Another intentional part of the directive is to secure the legal position of patients during and after treatment. In general the directive is limited to give cross-border patients the same entitlements as other patients in the country of treatment, although it implicitly requires some elements already to be in place, cf. discussions above concerning complaint procedures and systems of liability. In some areas the EU legislation is so developed that it sets a common European standard that has an impact also on patients' rights, e.g. concerning data protection. One may say that the directive is facilitating convergence in the outskirts of patients' rights, while accepting divergence on core patients' rights. This may be criticised, but the target should then be CFREU Article 35 and not the directive.

Apart from the intentional effect on national legislation concerning patients' right, the directive could also have possible side effects. Even though member states are entitled to have national rules which applies to others than cross-border patients, it will be complicated for the legislator and confusing for the users of the legislation to have to two separate sets of rules. As an illustration the member state can have a national definition of health care that deviates from Article 3(a) of the directive, but in the long time it is not unlikely that the wording of the directive may have an impact as pattern for national legislation.

A recurring topic in the literature of the directive is the language issue.<sup>12</sup> Information in an understandable language is crucial for patients before, during and after healthcare. In practise language barriers, together with cultural barriers as well as hesitation to choose a provider far away from home, is a more important obstacle to trans border healthcare than diversity in patients' rights. It should also be noted that the practitioners to some extent still have a common language by Latin.

While patients' rights are to a large extent still under the domain of the national legislator, quality standards within the field of medicine are not decided within the national states. The

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<sup>12</sup> See Nys (n 4) 9 and Bongers and Townend (n 6) 72.

same goes to other aspects, e.g.. what that would be regarded as diligent conduct for a patient for a given condition. Both national legislation, as well as various provisions of the directive, is referring to assessments made by health personnel. In some fields a European standard may already have been developed, although not by the legislator, although adopted by the legislator.

The directive is not a corpus, where the legal commentators can take the role of coroners. Even if the wording is fixed until amended, the directive is a living instrument that shall be interpreted. The ECJ will likely have several cases, although few disputes have reached the court so far. The ECJ will interpret the directive according to its legal method and it is not unlikely that various aspects of patients' rights will be developed by case law. Some commentators will probably call for a more dynamic approach while other will urge the court to respect the competences of the member states. In this respect it should be noted that healthcare encompasses rather different activities, from healing a small wound to complex surgeries or long-term psychiatric treatment, and where cultural elements plays a vital role. To uniform rules concerning healthcare maybe not even a desirable aim, but if so, it is long-term project and patience with patients' right is needed.

# Chapter IV

## issues

# Reimbursement and authorisation

Tomislav Sokol

## 1. Introduction

Social security reimbursement and authorisation in cases of persons socially insured in one EU Member State receiving health care in another represent core issues of patient mobility in the EU. These topics have been regulated since the very beginning of the European integration through the regulations on social security coordination facilitating free movement of persons across Member State borders.<sup>1</sup> In the recent years, however, case-law predominantly dealing with free movement of health care services<sup>2</sup> has provided

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<sup>1</sup> See Regulation (EEC) 3 of the Council of 25 September 1958 on social security for migrant workers [1958] OJ 30/561 (originally: Règlement 3 concernant la sécurité sociale des travailleurs migrants, last amended by Règlement (CEE) n 419/68 du Conseil, du 5 avril 1968, modifiant et complétant certaines dispositions des règlements n 3 et 4 concernant la sécurité sociale des travailleurs migrants OJ L87/1); Regulation (EEC) 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1971] OJ L149/2, as amended; Regulation (EEC) 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to their families moving within the community [1972] OJ L74/1, as amended; Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004] OJ L166/1, as amended and Regulation (EC) 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) 883/2004 on the coordination of social security systems [2009] OJ L284/1, as amended. See also, on the coordination of sickness benefits, for example Yves Jorens and Filip Van Overmeiren, 'General Principles of Coordination in Regulation 883/2004' (2009) 11 European Journal of Social Security 47, 59-61, 69; Franz Marhold, 'Modernisation of European Coordination of Sickness Benefits' (2009) 11 European Journal of Social Security 119, 121; Vicki Paskalia, 'Co-ordination of social security in the European Union: An overview of recent case law' (2009) 46 CML Rev 1177, 1201-1204 and Paul Schoukens and Lieven Monserez, 'Introduction to social security co-ordination in the EU' in Paul Schoukens (ed), Course materials Master programme Social Security in Europe (RUESS, Leuven 2010), 58-67.

<sup>2</sup> See, for example, on the case-law concerning free movement of services and coordination regulations Case C-158/96 *Raymond Kohl v Union des caisses de maladie* [1998] ECR I-1931; *Zorgverzekeringen* [2001] ECR I-5473; Case C-368/98 *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC)* [2001] ECR I-5363; Case C-385/99 *VG Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and EEM van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; Case C-56/01 *Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine* [2003] ECR I-12403; Case C-496/01 *Commission of the European Communities v French Republic* [2004] ECR I-2351; Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit* [2004] ECR I-2641; Case C-372/04 *The Queen on the application of Yvonne Watts v Bedford Primary Care Trust Secretary of State for Health* [2006] ECR I-4325; Case C-466/04 *Manuel Acereda Herrera v Servicio Cántabro de Salud* [2006] ECR I-5341; Case C-444/05 *Aikaterini Stamatelaki v NPDD Organismos Asfaliseos Eleftheron Epangelmaton (OAE)* [2007] ECR I-3185; Case C-211/08 *European Commission v Kingdom of Spain* [2010] ECR I-5267; Case C-512/08 *European Commission v French Republic* [2011] ECR I-8833; Case C-173/09 *Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa* [2010] ECR I-8889; Case C-255/09 *European Commission v Portuguese Republic* [2011] ECR I-10547; Case C-157/99 *BSM Geraets-Smits v Stichting Ziekenfonds VGZ and HTM Peerbooms v Stichting CZ Groep* Case C-490/09 *European Commission v Grand Duchy of Luxembourg* [2011] ECR I-247. For the latest case-law, concerning EU coordination regulations and cross-border health care, see Case C-255/13 *I v Health Service Executive* (ECJ, 5

alternative rules on reimbursement and authorisation, resulting in a codification via the Patients' Rights Directive.<sup>3</sup> The current situation is, thus, very complex, so it is necessary to present its core issues in this book.

The aim of this chapter is to present the current EU legal framework on reimbursement and authorisation in cases of persons socially insured in one EU Member State receiving health care in another.

To achieve this aim, EU rules on social security coordination will be described, to be followed by an analysis of the case-law on free movement of health care services in the EU. Finally, the rules of the Patients' Rights Directive concerning authorisation and social security coverage of cross-border health care will be analysed and compared with the other existing legal routes of obtaining cross-border health care (covered by social security) in the EU.

## 2. Social security coordination

According to the rules on social security coordination, when persons who are socially insured in one Member State (competent state) go to another Member State in order to receive health treatment (planned), they have to ask for authorisation from their social health insurer, if they want the first Member State to pay for the treatment. This rule is also applicable to family members. If family members have residence in a third Member State which receives reimbursement from the first Member State (for those persons' health care in that state of residence) through fixed amounts, the third Member State is considered to be the state competent for covering the treatment. The authorisation has to be given when the health care treatment is provided as part of the social health benefits package of the patient's state of residence and when that person cannot be given such a treatment within a medically justifiable time-limit, taking into account his/her state of health and the probable course of the illness. Corresponding rules also apply to pensioners. The social security institution of the competent state pays the cost on basis the rules and tariffs which are applicable in the Member State where the treatment in question is provided, and the patient is treated as if he/she is socially insured in the latter state. Payment of the expenses is generally settled between the social health insurers of the two states in question. Due to the fact that the whole procedure is governed by the institutions of social health insurance, patients are only allowed to access providers who affiliated with the social security system of the Member State of treatment.<sup>4</sup> In case the legislation of the competent state prescribes

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May 2014) and Case C-268/13 *Elena Petru v Casa Judeţeană de Asigurări de Sănătate Sibiu and Casa Naţională de Asigurări de Sănătate* (ECJ, 9 October 2014).

<sup>3</sup> Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare [2011] OJ L88/45 (Patients' Rights Directive).

<sup>4</sup> See Regulation 883/2004 (n 1) art 20, 27(3), 36(2a); see also Regulation 1408/71 (n 1) article 22(2) which contained an equivalent provision, but stated that the authorisation may not be refused when the patient cannot be given the health treatment within the time which is normally necessary for obtaining the treatment in question in the state of residence, taking into account the current state of health and probable course of the disease. It should be added that the authorisation must not be refused where it is because of a lack of



reimbursement of the costs of travel and stay which are inseparable from the treatment itself, these costs must also be paid for concerning treatment obtained abroad.<sup>5</sup>

Certain issues in this area require special emphasis. First, it should be noted that in cases when national legislation of the competent state does not provide detailed and precise lists of covered health care treatments (but broader definitions, for example mentioning types of diseases), the competent state's social health insurer must pay for the most effective health treatment which is available anywhere within the EU (which may fall within the broad legislative definitions), even if the said treatment is not provided in the territory of the competent state. The competent state is not allowed to presume that a treatment not provided on its territory is excluded from its social health insurance package.<sup>6</sup>

Next, there are certain exceptions with respect to mandatory prior authorisation, resulting from the case-law of the Court of Justice. Notably, competent state's rules which completely exclude payment for hospital treatment, provided in another Member State without prior authorisation, are not allowed by the EU law when a patient, because of his/her state of health or the need to receive urgent health treatment, is not able to apply, or to wait for the authorisation.<sup>7</sup> Additionally, patients who are unlawfully refused prior authorisation are entitled to the reimbursement in the same amount as if the authorisation had been properly granted in the first place.<sup>8</sup>

Finally, there is also an entitlement to additional reimbursement on basis of the more favourable (for the patient) rules of the competent state in certain cases. This entitlement exists when a patient receives health treatment in another EU Member State. In such cases, according to the case-law, the competent social health insurer must calculate the amount of coverage on basis of both coverage systems (the coordination system which is based on the tariffs prescribed by the state of treatment, and the system based on the competent state's tariffs, which is analysed in more detail in the next section), and apply the system more favourable for the patient.<sup>9</sup> According to the implementing coordination Regulation 987/2009, when an insured person has paid for a treatment abroad him/herself, and the costs which must be paid by the competent social health insurer (to the insured person or the institution of the state of treatment) are lower than the costs of the same treatment in

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medication and basic medical infrastructure that the hospital care in question cannot be provided in good time in the insured person's Member State of residence. The determination whether that is impossible, or not must be made by reference to all the hospital establishments in that Member State that are capable of providing the treatment in question and by reference to the period within which the treatment could be obtained in good time. See *Petru* (n 2) para 36.

<sup>5</sup> See Regulation 883/2004 (n 1 Arts 4-5 and Regulation 987/2009 (n 1) Arts 26(8), 33.

<sup>6</sup> See *Elchinov* (n 2) paras 67, 72-73. It should also be mentioned that, when a patient has residence outside the competent state, the state of residence's package of covered health care is relevant for giving the authorisation for a health treatment paid for by the competent state. See Regulation 987/2009 (n 1) Arts 26 (1-5), 33.

<sup>7</sup> See *Elchinov* (n 2) paras 43-51; see also *Commission v France* C-512/08 (n 2) para 27.

<sup>8</sup> See *Vanbraekel* (n 2) para 34 and *Elchinov* (n 2)) para 48.

<sup>9</sup> See *Vanbraekel* (n 2) para 53.

the competent state, the competent social health insurer must cover the difference, up to the cost which the insured person actually paid, at his/her request.<sup>10</sup>

### 3. Free movement of services

EU Treaty rules on free movement of goods and services are also applicable to situations of social health insurance cover of persons travelling abroad to receive health care. This fact was first proclaimed by the European Court of Justice in *Decker* (goods) and *Kohll* (services).<sup>11</sup> The logic of the Court is that, in these cases, patients pay the health care provider in another Member State directly, thus giving market character to the whole transaction, which makes internal market rules applicable.<sup>12</sup>

The route based on free movement of services has some differences and similarities when compared to the coordination route. As far as similarities go, only treatments included within the social health insurance package of the competent state must be covered when provided abroad. It should be added that, when national legislation of the competent state defines its coverage as including “normal treatments”, the said Member must pay for all the treatments which are considered normal by international medical science. In this way, discrimination against foreign providers, through prioritising competent state’s domestic treatments, is avoided.<sup>13</sup> Another rule corresponding to the coordination system applies when the legislation of the competent state prescribes reimbursement of the costs of travel and accommodation for treatments available on its territory. In such a case, costs of travel and accommodation must also be paid for concerning treatments obtained abroad.<sup>14</sup>

There are also some important differences between the free movement of services and coordination regulations rules on cross-border health care. First, prior authorisation requirement by the competent state (prescribed by the coordination regulations) is considered an obstacle to free movement of services. Still, the existence of mandatory prior authorisation procedure may be justified by the competent state’s: need to maintain treatment facilities or a health service on its national territory which are essential for public health or survival of the population; need to maintain balanced medical services open to all;

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<sup>10</sup> See Regulation 987/2009 (n 1) arts 26(7) 33.

<sup>11</sup> See *Kohll* (n 2) and *Decker* (n 2); For a judgement summary, see Pedro Cabral ‘Cross-border medical care in the European Union - bringing down a first wall’ (1999) 24 EL Rev 387.

<sup>12</sup> See *Watts* (n 2) paras 88-90; For a more detailed description of the judgement, see Mel Cousins, ‘Patient Mobility and National Health Systems’ (2007) 34 Legal Issues of Economic Integration 183; see also Christopher Newdick, ‘Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity’ (2006) 43 CML Rev 1645 and Christopher Newdick ‘The European Court of Justice, Trans-National Health Care, and Social Citizenship: Accidental Death of a Concept?’ (2008) 26 Wisconsin International Law Journal 844.

<sup>13</sup> See *Geraets-Smits* (n 2) para 94; on this topic, see Herman Nys, ‘Comparative health law and the harmonization of patients’ rights in Europe’ (2001) 8 European Journal of Health Law 317, 318; on the issue of the Court of Justice’s motivation, see Scott L Greer, ‘Migration of Patients and Migration of Power: Politics and Policy Consequences of Patient Mobility in Europe’ (2008) 26 Wisconsin International Law Journal 908, 911. See also *Elchinov* (n 2) paras 67, 72-73.

<sup>14</sup> See *Watts* (n 2) paras 139-140; also confirmed by the Court of Justice in *Acereda Herrera* (n 2) para 38.

and need to preserve the financial balance of the competent state's social security system.<sup>15</sup> In practice, mandatory prior authorisation requirement by the competent state is justified in cases of hospital treatments,<sup>16</sup> and treatments involving "major medical equipment", unless urgency of a situation requires subsequent approval of the coverage.<sup>17</sup> In cases of non-hospital treatment, mandatory prior authorisation is not justified since it is not probable that many patients would travel to receive non-hospital health care in another Member State, because of various existing barriers like distance, language, lack of information and cost.<sup>18</sup> Prior authorisation is to be granted according to essentially the same requirements as in the case of coordination regulations, since there is no particular reason to distinguish between the two in this sense.<sup>19</sup>

An important issue in this area concerns waiting lists. Their existence in the competent state, on basis of administrative approach, without taking into account medical condition of an individual patient, is not enough reason to refuse prior authorisation.<sup>20</sup> In this context, the Court of Justice stated that waiting lists must be set in a way which allows the medical treatment to be provided within the time "which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned". The patient's history, medical condition, probable course of the illness, nature of the disability influencing, for example, his/her ability to work and the degree of pain are to be taken into account when deciding whether to grant authorisation or not.<sup>21</sup> If, in the individual case, the waiting time exceeds the waiting time which is medically acceptable, authorisation must be given.<sup>22</sup>

Second, there is the question of applicable tariffs. As stated in the previous section, coordination rules primarily provide for the coverage on basis of state of treatment's rules and tariffs. Under the free movement of services rules, however, rules of the state of social health insurance are applicable to cross-border health care.<sup>23</sup> Even though protection of the competent state social security system's financial stability represents justification for limiting access to foreign health care, covering foreign treatment according to competent

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<sup>15</sup> The first two justifications stem from the Treaty while the last one stems from the rules of reason recognised by the Court of Justice. See *Kohll* (n 2) paras 41, 50-51 and Treaty Establishing the European Community (EC Treaty) Art 56 (after amendment EC Treaty Art 46 and the current Treaty on the Functioning of the European Union - TFEU Art 52) and EC Treaty Art 66 (after amendment EC Treaty Article 55 and the current TFEU Art 62) for services; see also for instance, *Geraets-Smits* (n 2) paras 72-74; see also Koen Lenaerts and Tinne Heremans 'Contours of a European Social Union in the Case-Law of the European Court of Justice' (2006) 2 European Constitutional Law Review 111; see, on the rule of reason, Koen Lenaerts and Piet Van Nuffel, *European Union Law* (3rd ed. Sweet and Maxwell, London 2011) 280-284.

<sup>16</sup> See *Müller-Fauré* (n 2) paras 72-92; See also, for more details, Anne Pieter Van der Mei, 'Cross-Border Access to Health Care within the European Union: Recent Developments in Law and Policy' (2003) 10 European Journal of Health Law 369, 372-375; see also Pedro Cabral, 'The internal market and the right to cross border medical care' (2004) 29 EL Rev 673, 685-686.

<sup>17</sup> See *Elchinov* (n 2) paras 45-51 and *Commission v France C-512/08* (n 2) paras 27, 42.

<sup>18</sup> See *Müller-Fauré* (n 2) paras 75, 95.

<sup>19</sup> See *Watts* (n 2) paras, 60-61, 65.

<sup>20</sup> *ibid*, para 63.

<sup>21</sup> *ibid*, paras 62, 68.

<sup>22</sup> *ibid*, para 72.

<sup>23</sup> See *Kohll* (n 2) para 27. These rules generally do not influence the coordination rules regulating unplanned health care, meaning they do not provide the entitlement to higher reimbursement of hospital treatment costs on basis of the competent state's rules and tariffs. See *Commission v Spain C-211/08* (n 2).

state' tariffs is not likely to have significant financial consequences for that system.<sup>24</sup> As noted when describing coordination rules, between the coverage provided by the coordination system and the one prescribed by the free movement of services system, the patient is entitled to the more beneficial one. In this way, patients are not made worse off because of the application of free movement of services rules to cross-border health care.

Next, it must be noted that, under free movement of services, patients can access all providers who are lawfully providing medical care in the Member State of treatment. The said interpretation also includes providers who are not attached to the social security of the latter state, or any state for that matter.<sup>25</sup> The approach by the Court of Justice is logical from the point of view of the internal market, since all providers who legally offer health care services on the territory of the Member State of treatment are in fact service providers. This is so even concerning providers who are not contracted by social health insurance of the state of treatment, and are not affiliated with the social security system of that state. The reasoning of the Court of Justice stems from the fact that the requirements regarding the providers in the medical professions in question have been to a large extent harmonised at the EU level,<sup>26</sup> meaning that the quality and safety of health care provision do not vary significantly between different EU Member States.<sup>27</sup> Also, since the free movement of services route is not organised within the framework of social security institutions of the competent state and the state of treatment, the patient has to pay for all the costs by him/herself and subsequently ask for reimbursement from his/her social health insurer, after returning to the competent state, unless that state pays the foreign provider directly.<sup>28</sup>

#### 4. Patients' Rights Directive

The Patients' Rights Directive has been enacted mainly to codify the case-law on the free movement of services described in the previous section. Still, apart from many similarities, there are some important differences between the Directive and the case-law concerning reimbursement and authorisation issues which are the focus of this chapter. First, it must be mentioned that the Directive applies to cross-border health care, which includes any health care prescribed or provided in a Member State other than the state of affiliation (competent state, the state where the person in question is socially insured). This means that unplanned health care obtained by a person while temporarily staying outside the latter state seems to be covered by the Patients' Rights Directive. This is in partial contrast to the case-law on free movement of services which generally does not influence the coordination rules

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<sup>24</sup> See *Kohll* (n 2) para 42.

<sup>25</sup> See *Stamatelaki* (n 2) paras 24-38.

<sup>26</sup> See, for example, *Kohll* (n 2) para 47 and *Stamatelaki* (n 2) para 37.

<sup>27</sup> Currently regulated by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22, as amended.

<sup>28</sup> See *Kohll* (n 2) para 42.

regulating this area, meaning it does not provide the entitlement to higher reimbursement of hospital treatment costs on basis of the competent state's rules and tariffs.<sup>29</sup>

Of course, in those cases in which prior authorisation may be imposed by the state of affiliation, it makes sense to speak primarily about planned care. In practice, the only time Patients' Rights Directive's provisions on prior authorisation would be relevant for unplanned health care would be if a person temporarily staying in another Member State developed a medical condition, or if an existing medical condition worsened, but the need for treatment was not urgent and there was enough time to ask for prior authorisation from the Member State of affiliation. Conversely, what would happen in case there was no time to wait? Could the Patients' Rights Directive be applied in these cases? This topic remains legally unclear, since the Preamble to the Patients' Rights Directive primarily refers to patients "seeking" health treatment abroad, which implies planned health care. Also, according to the same Preamble, patients' rights to unplanned health care prescribed by the coordination regulations are not affected by the Patients' Rights Directive. However, the Directive seems to be currently applied to unplanned health care.<sup>30</sup> Therefore, all the rules that might be applied to unplanned health care will be analysed.

A second important difference between the case-law on free movement of services and the Patients' Rights Directive concerns possibilities to impose prior authorisation by the state of affiliation. According to the Patients' Rights Directive, mandatory prior authorisation may be imposed as a requirement for obtaining health care abroad when the health care in question:

"(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

(i) involves overnight hospital accommodation of the patient in question for at least one night; or

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<sup>29</sup> See Patients' Rights Directive (n 3) Art 1, 3, 7. See also *Commission v Spain C-211/08*. Concerning the definition of the state of affiliation, it must be added that, if a Member State is mentioned in Annex IV to Regulation 883/2004 and has, thus, recognised the rights to health care for pensioners and their family members residing in another Member State, it must provide them health care under the Patients' Directive at its own expense when those person stay on its territory, according to its own legislation, as though they resided there. In this way, if a German pensioner living in France obtains health care treatment in Germany (listed in Annex IV), Germany will have to pay for that treatment. A similar logic is applied in cases of non-hospital treatments, where Member States which are responsible for bearing health care costs on basis of the coordination regulations, are also responsible for costs of health care provided on basis of the Patient's Rights Directive. See Patients' Rights Directive (n **Error! Bookmark not defined.**) Art 7(2).

<sup>30</sup> See, for example, Preamble to the Patients' Rights Directive (n 3) paras 11, 20; see also *Commission v Spain C-211/08* (n 29) and Preamble to the Patients' Rights Directive (n 3) para 28, on the relationship with coordination. See also Commission, 'Report from the Commission to the Council and the European Parliament compliant with the obligations foreseen under Article 20(3) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare' COM (2014) 044 final, 9.

(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;

(b) involves treatments presenting a particular risk for the patient or the population, or

(c) is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.<sup>31</sup>

As can be seen, the Directive prescribes possibilities to impose prior authorisation which are not provided by the free movement of services case-law described in the previous section, namely those under b) and c). It should be added that the list of treatments under a) must be notified by each individual Member State to the European Commission. Also, the prior authorisation and reimbursement systems must be limited to what is necessary and proportionate to the sought objective and may not result in an unjustified obstacle to the free movement of patients or arbitrary discrimination.<sup>32</sup>

Possibilities to refuse prior authorisation are also wider under the Patients' Rights Directive than under the case-law on free movement of services, prescribed through a closed list. Thus, the authorisation can be refused if:

- It is reasonably certain, according to a clinical evaluation, that the patient will be subject to an unacceptable safety risk if authorisation is granted,
- It is reasonably certain that the general public will be subject to a significant safety hazard if authorisation is granted,
- The foreign health care provider raises concrete and serious concerns about safety and quality of care,
- The treatment in question can be provided in the Member State of affiliation within a medically justifiable time-limit, taking into account the patient's state of health and the probable course of the illness.<sup>33</sup>

Prior authorisation may not be refused when the treatment cannot be provided on the territory of the state of affiliation within the medically justifiable time, taking into account the patient's history, medical condition, probable course of the illness, nature of the disability and the degree of pain.<sup>34</sup> The said provisions do not overrule the other reasons for refusal. It can be seen that the rule regulating situations in which prior authorisation may not be refused, and the one regulating situations in which prior authorisation may be refused, are not completely the same. One of these rules has been taken over from the free movement of services case-law and the other from the coordination regulations. Since the

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<sup>31</sup> See Patients' Rights Directive (n 3) Art 8(2).

<sup>32</sup> See Patients' Rights Directive (n 3) Art 8(1), 9. The same proportionality test as is the case concerning the Directive is applied within the context of the free movement of services case-law. See, for example, *Watts* (n 2) para 106.

<sup>33</sup> See Patients' Rights Directive (n 3) Art 8(6).

<sup>34</sup> See Patients' Rights Directive (n 3) art 8(5).

two sets of rules are to be interpreted in the same way, a similar logic should also apply to the Directive. Unlike the free movement case-law, the Directive does not refer to one's (in)ability to work when assessing need to grant prior authorisation.<sup>35</sup>

As is the case with the previously described free movement case-law, the sole existence of health care waiting lists is not enough reason to refuse prior authorisation.<sup>36</sup> Member States may also establish different criteria for refusal of prior authorisation for different administrative levels and regions, or concerning different health treatments, provided that the system in question is easily accessible and transparent.<sup>37</sup> Additionally, in the case of treatments abroad, Member States may apply the same conditions and eligibility which are already applicable to domestic treatments, like mandatory GP referrals for secondary care. Of course, the said conditions may not represent an unjustified obstacle to the free movement of goods, services and persons, or discriminate against patients obtaining health care abroad.<sup>38</sup>

Another important difference between the Patients' Rights Directive and the free movement case-law concerns travel and accommodation costs. It seems the normative part of the Patients' Rights Directive gives autonomy to Member States in deciding whether they should pay for travel and accommodation costs outside the hospital itself.<sup>39</sup> Contrary to this, the Directive's Preamble implies that the said autonomy only exists when there is no coverage of domestic travel and accommodation costs, so as to avoid discrimination against patients who receive health care abroad, when compared to the patients who receive health care domestically, within the state of affiliation.<sup>40</sup>

Other provisions of the Patients' Rights Directive dealing with reimbursement and authorisation generally correspond to the rules provided by the free movement case-law. So, the state of affiliation covers health care treatments which are provided by its own national legislation, the rules and tariffs of the state of affiliation are applicable to cross-border health care, patients can access all providers who are lawfully providing medical care in the Member State of treatment and the patient has to pay for all the costs by him/herself and subsequently ask for reimbursement from his/her social health insurer, after returning to the state of affiliation, unless that state pays the foreign provider directly. As noted at the beginning of this section, the only difference here relates to unplanned hospital care, in case of which the case-law does not provide for the more beneficial coverage of the state of affiliation, while the Directive does.<sup>41</sup>

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<sup>35</sup> See Patients' Rights Directive (n 3) Art 8(5); see also Frans Pennings, 'The Cross-border Health Care Directive: More Free Movement for Citizens and more Coherent EU Law?' (2011) 13 *European Journal of Social Security* 424, 442 and *Watts* (n 2) paras 60-62, 65.

<sup>36</sup> See Preamble to the Patients' Rights Directive (n 3) para 43.

<sup>37</sup> See Preamble to the Patients' Rights Directive (n 3) para 44.

<sup>38</sup> See Patients' Rights Directive (n 3) Art 7(7); see, on these issues also Kyriaki M. Raptopoulou, 'The Directive on cross-border health care: signalling the coordination or the harmonisation of public health systems?' [2012] *European Journal of Social Law* 193, 210-211.

<sup>39</sup> See Patients' Rights Directive (n 3) art 7(4).

<sup>40</sup> See Preamble to the Patients' Rights Directive (n 3) para 34.

<sup>41</sup> See Patients' Rights Directive (n 3) art 3, 7, 9, 11. See also Preamble to the Patients' Rights Directive (n 3) paras 5, 31, 34, 36.

## 5. Concluding remarks

The developments of the EU legal framework on cross-border health care in the last couple of decades have distinguished between different sets of rules on reimbursement and authorisation. In addition to the well-established coordination regulations, free movement of services case-law and its codification through the Patients' Rights Directive have created additional possibilities to obtain health care outside the state of one's social health insurance. Also, the case-law has influenced the coordination regulations themselves, leading to the establishment of, for example, the right to additional coverage on basis of the competent state's rules and tariffs.

Still, there are important differences between the free movement and Patients' Rights Directive on one side and coordination regulations on the other side. Additionally, there are even differences between the free movement case-law and the Patient's Rights Directive. One of those differences relates to wider possibilities for imposing and refusing prior authorisation prescribed by the Patients' Rights Directive. How the said discrepancy will be resolved, remains to be observed. It should be mentioned here that EU secondary legislation can be set aside by the European Court of Justice if contrary to EU primary law. However, it should be mentioned that the jurisprudence of the Court of Justice has dealt with specific cases and justifications at hand during individual judicial proceedings. So, other grounds for justification might still be relevant in future situations which come before the Court. Finally, one should emphasise that the state of affiliation must establish whether the conditions for granting authorisation prescribed by the coordination regulations have been met. If that is the case, the authorisation must be given in accordance with the regulations, unless the patient him/herself requests otherwise. The patient should also be told if the application of the coordination regulations is more advantageous for him/her than the application of the Patient' Rights Directive.

Another important discrepancy between the case-law and the Patients' Rights Directive relates to unplanned health care. Although the Directive is primarily meant to regulate planned health care abroad, it is also applicable to unplanned health care. This means that it provides for higher coverage on basis of state of affiliation's rules and tariffs, while this is not the case with the free movement case-law concerning unplanned hospital health care abroad. Finally, there is also the legal framework on travel and accommodation costs, where the normative part of the Directive seems to give more autonomy to the Member States than the free movement case-law or the coordination regulations. These issues should also be resolved by the Court of Justice.

All in all, it can be concluded that the current legal framework on reimbursement and authorisation of cross-border health care in the EU is very complex. The existence of, essentially, three distinct legal routes of obtaining cross-border health care does not help legal certainty or clarity of patients' rights to health care abroad. It remains to be seen how the described situation will be resolved.



# Chapter V Standards on quality and safety in cross-border healthcare\*

Markus Frischhut

## 1. Introduction - setting the agenda

A recent report on the right to health has addressed the principles of availability, accessibility, acceptability and quality as being “essential elements of the right to health”.<sup>1</sup> When it comes to quality and safety of healthcare, not only patients’ rights and quality of care are “highly interdependent”,<sup>2</sup> also information on quality is crucial. However, such information is often asymmetric,<sup>3</sup> which can give rise not only to legal,<sup>4</sup> ethical,<sup>5</sup> but also very practical<sup>6</sup> challenges for patients. Apart from the patients’ perspective, unsafe care can also result in an economic burden for the public health sector.<sup>7</sup>

Obviously, these challenges can further increase in case of EU cross-border healthcare,<sup>8</sup> which also holds true for the more global<sup>9</sup> perspective. In cross-border healthcare, quality of care can both be a motivation to go abroad, as well as a barrier.

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\* This research has been realized in the context of this Jean Monnet Chair on "European integration & ethics", generously supported by the European Commission’s Erasmus+ programme. This contribution has been inspired by the Conference “healthcare in Europe – a safe haven? ‘standard of care’ from a multidisciplinary perspective” (<http://standardofcare2016innsbruck.mci.edu/>) and has been finished in February 2017. The author wants to thank Lena Wahlberg (Lund University) for valuable comments; the usual disclaimer applies.

<sup>1</sup> Gian L Burci and others, *Advancing the right to health: The vital role of law* (2017) 6.

<sup>2</sup> Aart Hendriks, ‘High-quality of Care throughout Europe — But Do We Speak the Same Language?’ (2016) 23(1) *European Journal of Health Law* 14.

<sup>3</sup> Asymmetric in the sense that one group of stakeholders (e.g. medical doctors) has more or better information than others (e.g. patients), which makes it difficult for the latter to properly assess the quality of the good or service received; for this notion of economics see Robert S Pindyck and Daniel L Rubinfeld, *Microeconomics* (8th ed, Pearson 2013) 631–659.

<sup>4</sup> Gabriella Berki, ‘Lightning or Lightning Bug: The Role of the Language Gap and the Access to Proper Information on Entitlements in Cross-border Patient Mobility’ (2017) *European Journal of Health Law* 1, 12–21.

<sup>5</sup> Harvey S Jr James, ‘Asymmetric Information’ in Robert W Kolb (ed), *Encyclopedia of Business Ethics and Society* (Sage Publications 2008) 125

<sup>6</sup> Hendriks (n 2), 2 addressing the discussion within the Standing Committee of European Doctors (CPME).

<sup>7</sup> According to European Commission, ‘Costs of unsafe care and cost-effectiveness of patient safety programmes: Final report’ (2016) 18, the “economic burden for the public health care sector was about EUR 21 billion of direct costs or 1.5 percent of health expenditure for EU member-states in 2014”.

<sup>8</sup> Neil Lunt and others, ‘Medical Tourism: Treatments, Markets and Health System Implications: A scoping review’ (2011) 24; Helena Legido-Quigley and others, ‘Chapter 5: Quality and safety’ in Matthias Wismar and others (eds), *Cross-border Health Care in the European Union: Mapping and analysing practices and policies* (Observatory studies. WHO Regional Office for Europe 2011) 139–148.

<sup>9</sup> I. G Cohen, *Patients with passports: Medical tourism, law and ethics* (Oxford University Press 2015) 41–77; Neil Lunt and others, ‘Quality, safety and risk in medical tourism’ in Colin M Hall (ed), *Medical tourism: The ethics, regulation, and marketing of health mobility* (Routledge 2013).

According to a recent Eurobarometer survey of 2015, better quality remains<sup>10</sup> the second most important motivation for patients to seek healthcare abroad (see Figure 1).

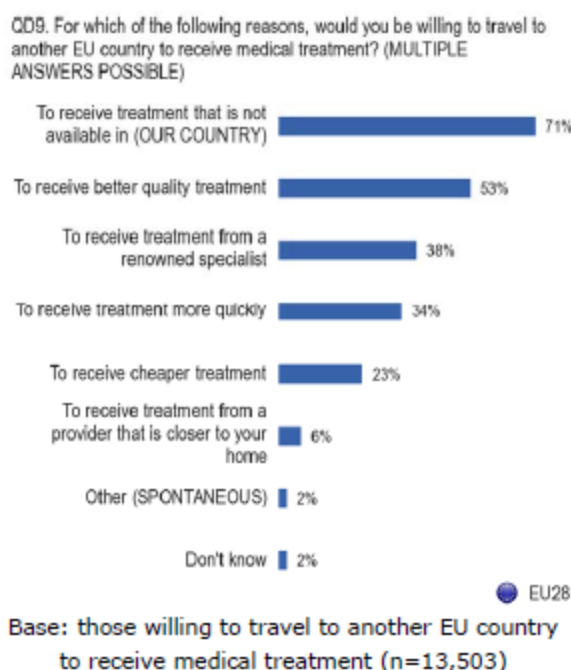


Figure 1: Reasons to seek cross-border healthcare<sup>11</sup>

On the other hand, quality of care can also be a barrier, for instance if a patient does not get reimbursement of costs of treatment in another Member State of the European Union (EU), based on the argument that the Member State of affiliation (MSA) considers the therapy used in the Member State of treatment (MST) as being experimental, and thus “not regarded as normal within the professional circles concerned”,<sup>12</sup> this was the standard used in the Netherlands (the MSA), which obviously may differ from standards in other Member States.<sup>13</sup>

The impact of EU law on national law and policy is often described by the two notions of positive and negative integration.<sup>14</sup> When it comes to harmonization of national law via EU law (i.e. positive integration), Member States are still responsible “for the definition of their

<sup>10</sup> In 2007 also ranked second (after “treatment that is not available” in home country) with 78%, according to European Commission, ‘Cross-border health services in the EU - Analytical report: Flash Eurobarometer 210’ (The Gallup Organization May 2007) 11.

<sup>11</sup> European Commission, ‘Patients’ rights in cross-border healthcare in the European Union: Report: Special Eurobarometer 425’ (available at [http://ec.europa.eu/public\\_opinion/index\\_en.htm](http://ec.europa.eu/public_opinion/index_en.htm) May 2015) 14.

<sup>12</sup> Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, paras 31-39.

<sup>13</sup> On this case see *infra* section 3.4.

<sup>14</sup> According to Carl Baudenbacher and Frank Bremer, ‘European State Aid and Merger Control in the Financial Crisis: From negative to positive integration’ (2010) 1(4) *Journal of European Competition Law & Practice* 267 267, this “distinction was first made by the Dutch economist Jan Tinbergen”.

health policy and for the organisation and delivery of health services and medical care”, which includes “the management of health services and medical care and the allocation of the resources assigned to them”.<sup>15</sup> Therefore, we don’t find a uniform and cross-sectoral definition of quality in healthcare. We rather find both soft-law and related activities in the context of the Open Method of Coordination (OMC),<sup>16</sup> as well as some sectoral approaches of legislating on quality of care.

In the context of negative integration (the application of the fundamental freedoms of the internal market), public health is one of the reason of justification,<sup>17</sup> i.e. reasons why Member States can restrict patients from receiving health related services abroad (also called: patient mobility<sup>18</sup>). As public health basically falls within the Member States’ competence, this reason of justification has been strengthened by the CJEU insofar as “health and life of humans rank foremost [!] among the assets and interests protected by the Treaty and [therefore] it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved”.<sup>19</sup>

Content-wise, “public health” has been defined by the CJEU<sup>20</sup> as follows:

The Court has held that it cannot be excluded that [1.] the possible risk of seriously undermining the *financial balance of a social security system* may constitute an overriding reason in the public interest capable of justifying an obstacle to the freedom to provide services. The Court has likewise acknowledged that [2.] the objective of *maintaining a balanced medical and hospital service open to all* may also fall within the derogations on grounds of public health under Article [52 TFEU] in so far as it contributes to the attainment of a *high level* of health protection. It has also held that Article [52 TFEU] permits Member States to restrict the freedom [3.] to provide medical and hospital services in so far as the *maintenance of treatment capacity or medical competence* on national territory is *essential for public health, and even the survival of the population* [...].<sup>21</sup>

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<sup>15</sup> Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/47, as corrected by [2016] OJ C400/1 and [2017] C 59/1 (TFEU) Art 168(7).

<sup>16</sup> Vassilis Hatzopoulos, *Regulating services in the European Union* (1st ed, Oxford University Press 2012) 311–316; see also European Commission, ‘Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the “open method of coordination”’: COM(2004) 304 final’ (20 April 2004); and the recent report Expert Group on Health Systems Performance Assessment, *So What? Strategies across Europe to assess quality of care* (2016).

<sup>17</sup> TFEU, Articles 36, 45(3) and 52(1) (in connection with Article 62).

<sup>18</sup> The notion of ‘patient mobility’ relates to the so-called passive freedom of services (if the receiver crosses the border). The notion of “cross-border healthcare” also comprises active freedom of services (if the provider crosses the border), eHealth (if only the service crosses the border), as well as different forms of cooperation between MS or private stakeholders (i.e. irrespective of patients; see *infra* section 4.2). For an overview of the notions of ‘health tourism’, ‘medical tourism’ etc. see Colin M Hall, ‘Medical and health tourism: The development and implications of medical mobility’ in Colin M Hall (ed), *Medical tourism: The ethics, regulation, and marketing of health mobility* (Routledge 2013) 12.

<sup>19</sup> Case C-171/07 *Apothekerkammer des Saarlandes and Others* ECLI:EU:C:2009:316, para 19.

<sup>20</sup> This abbreviation refers to the Court of Justice of the EU in the sense of TEU (Consolidated version of the Treaty on European Union [2016] OJ C202/13, as corrected by [2016] OJ C400/1 and [2017] C 59/1) Article 19(1), which comprises not only the Court of Justice, but also the General Court.

<sup>21</sup> Case C-173/09 *Elchinov* ECLI:EU:C:2010:581, para 42 (emphases added).

The link between public health, as a reason of justification, and quality of care<sup>22</sup> has been emphasized by the CJEU in the context of national prior authorisation requirements for hospital treatment, where planning requirements can be legitimate, as they seek “to achieve the aim of ensuring that there is sufficient and permanent access to a balanced range of *high-quality* hospital treatment in the State concerned”.<sup>23</sup> This approach has to be seen against the background of TFEU Article 168(1), according to which a “high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”.

The objective of this contribution is to illustrate the role of quality of care and patient safety in EU law<sup>24</sup> from the both perspectives of positive and negative integration.<sup>25</sup> While the European Group on Ethics (EGE)<sup>26</sup> has addressed quality issues in several of its opinions, this ethical perspective has to be excluded from this contribution.

Also in patient mobility, we have seen the transition from negative integration (i.e. patients paving the way by relying on their rights to receive cross-border health services) to positive integration, i.e. the harmonization of these rights in Directive 2011/24/EU (Directive patient mobility).<sup>27, 28</sup> Therefore, this contribution will be structured as follows: first it will shed some light on the notion of “quality of care” (section 2), before it will high-lighten the general setting, comprising the relevant provisions of EU primary law (TFEU Articles 9, 114, 168, and CFREU<sup>29</sup> Article 35), EU soft-law as well as the relevant CJEU case-law (section 3). It will then focus on how quality of care and patient safety are reflected in Directive patient mobility (section 4), before taking a broader view on quality issues in related healthcare fields (section 5).

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<sup>22</sup> As it can be seen as the broader term, in the following when referring to quality of care, this shall be read as also comprising patient safety.

<sup>23</sup> Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, para 78 (emphasis added); Case C-173/09 *Elchinov* ECLI:EU:C:2010:581, para 43.

<sup>24</sup> For a policy perspective see e.g. Expert Group on Health Systems Performance Assessment (n 16); for a detailed analysis see also Legido-Quigley and others (n 8).

<sup>25</sup> There is still another perspective, which cannot be covered in this contribution, i.e. the impact of Country-specific Recommendations (CSR) and the European Semester on health systems and quality of care. Rita Baeten and Bart Vanhercke, ‘Inside the black box: the EU’s economic surveillance of national healthcare systems’ (2016) *Comparative European Politics* 1, 9, 16 mention that while the CSR focus on improving access to and quality of care (at 9), the European Semester “primarily deals with the fiscal issues, without taking into account the consequences of the fiscal policies on quality and accessibility of care” (at 16); see also Natasha Azzopardi-Muscat and others, ‘EU Country Specific Recommendations for health systems in the European Semester process: Trends, discourse and predictors’ (2015) 119(3) *Health Policy* 375. European Commission, ‘Annual Growth Survey 2017: COM(2016) 725 final’ (16 November 2016) 10 addresses the “need to ensure access to quality services and in-kind benefits, such as [...] healthcare and long-term care” (merely) in the context of creating jobs.

<sup>26</sup> Commission Decision (EU) 2016/835 of 25 May 2016 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies [2016] OJ L140/21.

<sup>27</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45, as amended by [2013] OJ L353/8.

<sup>28</sup> Markus Frischhut and Hans Stein, *Patientenmobilität: Aktuelle Richtlinie und EuGH-Rechtsprechung* (Facultas.wuv 2011) 25–39.

<sup>29</sup> Consolidated version of the Charter of Fundamental Rights of the European Union [2016] OJ C202/389.

## 2. Defining quality of care

As can be seen from Figure 2, there are different definitions of quality of care:

**Table 1.1** *Definitions of quality of care*

<i>Author/Organization</i>	<i>Definition</i>
<i>Donabedian (1980)</i>	Quality of care is the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts.
<i>IOM (1990)</i>	Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
<i>Department of Health (UK) (1997)</i>	Quality of care is: <ul style="list-style-type: none"> <li>• doing the right things (what)</li> <li>• to the right people (to whom)</li> <li>• at the right time (when)</li> <li>• and doing things right first time.</li> </ul>
<i>Council of Europe (1998)</i>	Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge.
<i>WHO (2000)</i>	Quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population.

*Notes: IOM: Institute of Medicine; WHO: World Health Organization.*

Figure 2: Definitions of quality of care<sup>30</sup>

In an US context, the following definition<sup>31</sup> has “probably the widest currency in both the policy and academic literature”:<sup>32</sup> “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”<sup>33</sup>

In an EU context, quality of care in literature has been defined by describing the concept according to different dimensions. “The most frequently quoted dimensions include (in descending order of frequency) effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, satisfaction, patient responsiveness or patient-centeredness, and continuity of care. These dimensions are, however, neither comprehensive nor mutually exclusive.”<sup>34</sup> All these different definitions can be clustered, amongst other reasons, as either more focussing on individual patients or on the health system as such, putting an emphasis on resources or outcome.

<sup>30</sup> Helena Legido-Quigley and others, *Assuring the Quality of Health Care in the European Union: A case for action* (World Health Organization 2008) 2.

<sup>31</sup> Also mentioned in Figure 1.

<sup>32</sup> Legido-Quigley and others (n 8) 123.

<sup>33</sup> Kathleen N Lohr (ed), *Medicare: A Strategy for Quality Assurance, Volume I* (National Academies Press 1900) 4, 23-24. On issues related to the professional state-of-the-art see *infra* section 3.4.

<sup>34</sup> Legido-Quigley and others (n 9) 124.

Patient safety has been defined by the Council of Ministers as “freedom, for a patient, from unnecessary harm or potential harm associated with healthcare”.<sup>35</sup>

### 3. The general setting

As mentioned above, this section will depict the general setting, i.e. the relevant provisions of EU primary law (TFEU Articles 9, 114, 168, and CFREU Article 35), soft-law as well as the relevant CJEU case-law.

#### 3.1 High level of protection of human health

There are several provisions of EU primary law requiring a high level of protection of human health.

This is true for TFEU Article 9, one of the co-called horizontal clauses, which also covers other social issues.<sup>36</sup> However, this horizontal clause creates no rights, neither for the Member States, nor for individuals.<sup>37</sup> It is addressed to the EU and its institutions and can only have an indirect impact for the interpretation of EU secondary law, which has to be interpreted in the light of the objectives of EU primary law.<sup>38</sup>

Whilst the wording is similar, the impact of TFEU Article 114 is definitely higher, as it is the legal basis for harmonization in the internal market. According to its para 3, the “Commission, in its proposals [...] concerning *health*, safety, environmental protection and consumer protection, will take as a base a *high level of protection*, taking account in particular of any *new development based on scientific facts*. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.”<sup>39</sup> This provision is clearly addressed to the three main institutions in EU decision-making and, since the Amsterdam Treaty, requires not only scientific facts to be taken into account,<sup>40</sup> but also that on an EU wide level the level of protection has to be increased.<sup>41</sup> The substantive requirements of this provision are subject to the legal control of the CJEU.<sup>42</sup>

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<sup>35</sup> Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, [2009] OJ C151/1 (Recommendation 2009 patient safety).

<sup>36</sup> “In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health”.

<sup>37</sup> Eberhard Eichenhofer, ‘Art. 9 AEUV’ in Rudolf Streinz (ed), *EUV/AEUV: Vertrag über die Europäische Union und über die Arbeitsweise der Europäischen Union* (Beck'sche Kurz-Kommentare vol 57, 2. Auflage. Beck 2012) 354.

<sup>38</sup> Markus Kotzur, ‘Article 9 TFEU’ in Rudolf Geiger, Daniel-Erasmus Khan and Markus Kotzur (eds), *European Union Treaties: A Commentary* (Beck; Hart Publishing 2015) 219.

<sup>39</sup> Emphases added.

<sup>40</sup> On how the European Commission seeks scientific advice, see European Commission, ‘Commission decision on establishing Scientific Committees in the field of public health, consumer safety and the environment: C(2015) 5383 final’ (7 August 2015).

<sup>41</sup> Stefan Leible and Meinhard Schröder, ‘Art. 114 AEUV’ in Rudolf Streinz (ed), *EUV/AEUV: Vertrag über die Europäische Union und über die Arbeitsweise der Europäischen Union* (Beck'sche Kurz-Kommentare vol 57, 2. Auflage. Beck 2012) 1472.

<sup>42</sup> *ibid.*

TFEU Article 114 was the legal basis for Directive patient mobility, besides the next provision in this context, i.e. TFEU Article 168 (sectoral policy of “public health”). Also para 1 of this provision requires a “high level of human health protection”, which “shall be ensured in the definition and implementation of all Union policies and activities”.

The essential wording of TFEU Article 168(1) can also be found in CFREU Article 35, where the second sentence of this Article has been qualified as only entailing a principle, and not a right.<sup>43</sup> Besides this, also this provision is only addressed to the EU, not to the Member States.<sup>44</sup>

### 3.2 High vs highest level of health

While it might be unclear what exactly this high level in health protection means for the quality of care, it has to be emphasized that a high level does not mean “highest level”. This is not only true for TFEU Article 114(3)<sup>45</sup> and CFREU Article 35,<sup>46</sup> but also for TFEU Article 168(1), as recently confirmed by the General Court.<sup>47</sup>

This situation under EU law is in contrast to international law, where the International Convention on Economic, Social, and Cultural Rights in Article 12(1) recognizes “the right of everyone to the enjoyment of the highest [!] attainable standard of physical and mental health.”<sup>48</sup> Also the G7 Summit recently referred to the “enjoyment of the highest [!] attainable standard of health [as being] one of the fundamental rights of every human being”.<sup>49</sup> Only the Council of Europe’s Oviedo Convention merely stipulates “appropriate quality”,<sup>50</sup> and recently the OECD Health Ministers also “only” referred to “high-quality care”.<sup>51</sup>

Against this background, the European Commission in its proposal for Directive patient mobility referred to “highly specialised services of the highest [!] quality” as one of the

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<sup>43</sup> Beate Rudolf, ‘Artikel 35 Gesundheitsschutz’ in Jürgen Meyer (ed), *Charta der Grundrechte der Europäischen Union* (4. Aufl. Nomos 2014) 551.

<sup>44</sup> Gregor Ribarov, ‘Art 35 Gesundheitsschutz’ in Georg Lienbacher and Michael Holoubek (eds), *Grundrechtecharta der Europäischen Union* (MANZ’sche Wien 2014) 473.

<sup>45</sup> Leible and Schröder (n 41) 1471–1472.

<sup>46</sup> Rudolf (n 43) 551.

<sup>47</sup> Case T-177/13 *TestBioTech and Others v Commission* ECLI:EU:T:2016:736, para 106 (“That high level does not necessarily, in order to be compatible with that provision [i.e. TFEU Article 168(1)], have to be the highest that is technically possible [...]”).

<sup>48</sup> International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR); see also United Nations Committee on Economic, Social and Cultural Rights, ‘General Comment No. 14: The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)’ (11 August 2000).

<sup>49</sup> G7 Summit, ‘Leaders’ Declaration’ (7 and 8 June 2015) 10.

<sup>50</sup> Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted 4 April 1997, entered into force 1 December 1999) CETS 164 (Oviedo Convention) Article 3 (“Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality”).

<sup>51</sup> OECD Health Ministers, ‘The Next Generation of Health Reforms: OECD Health Ministerial Meeting’ (17 January 2017) 2.

objectives of European reference networks (ERN);<sup>52</sup> however, this reference to a highest level did not make it into the final directive; likewise in the drafting of the provision prior to TFEU Article 114,<sup>53</sup> a reference to a “highest level” has also been rejected.<sup>54</sup>

### 3.3 Soft-law clarification on quality and safety

Due to the aforementioned vertical distribution of competences in the field of public health, EU hard-law does not provide a lot of clarification with regard to quality of care and patient safety. Let us therefore turn to EU soft-law.

The Lisbon Treaty has defined the EU’s values as hard-law in EU primary law (TEU Article 2<sup>55</sup>) in 2007,<sup>56</sup> while in June 2006 the Council has defined the EU’s health values<sup>57</sup> as soft-law. This statement by the EU Health Ministers has to be seen against the background of the drafting of the contested<sup>58</sup> services directive (Commission’s proposal from March 2004,<sup>59</sup> amended proposal from April 2006<sup>60</sup>, final Directive adopted in December 2006<sup>61</sup>), which finally has excluded healthcare services<sup>62</sup> and therefore paved the way for a distinct Directive on patient mobility (Commission’s proposal from 2008, final Directive adopted in March 2011).<sup>63</sup> By stating these values and principles, the Health Ministers wanted to them to be “respected” in the entire upcoming decision making process, from proposal to final Directive.

These Conclusions define both the overarching values of universality, access to good quality care, equity, and solidarity, as well as operating principles of quality, safety, care that is based on evidence and ethics, patient involvement, redress, and finally privacy and confidentiality.

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<sup>52</sup> European Commission, ‘Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare: COM(2008) 414 final’ (2 July 2008) Article 15(2) (f).

<sup>53</sup> Treaty establishing the European Community (TEC) Article 95(3).

<sup>54</sup> Werner Schroeder, ‘Die Sicherung eines hohen Schutzniveaus für Gesundheits-, Umwelt- und Verbraucherschutz im europäischen Binnenmarkt’ (2002) 117 Deutsches Verwaltungsblatt 213 215; Leible and Schröder (n 41) 1472.

<sup>55</sup> “The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail.”

<sup>56</sup> [2007] OJ C306/1; signed 13 December 2007, entered into force on 1 December 2009.

<sup>57</sup> Council Conclusions on Common values and principles in European Union Health Systems, [2006] OJ C146/1.

<sup>58</sup> Joanna Flower, ‘Negotiating European Legislation: The Services Directive’ (2007) 9 Cambridge Yearbook of European Legal Studies 217.

<sup>59</sup> European Commission, ‘Proposal for a Directive of the European Parliament and of the Council on services in the internal market: COM(2004) 2 final/3’ (5 March 2004).

<sup>60</sup> European Commission, ‘Amended proposal for a Directive of the European Parliament and of the Council on services in the internal market: COM(2006) 160 final’ (4 April 2006).

<sup>61</sup> Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, [2006] OJ L376/36.

<sup>62</sup> Article 2(2) (f) leg. cit.

<sup>63</sup> For more details see Frischhut and Stein (n 28) 25–39.



Therefore, quality is both part of one of the overarching values,<sup>64</sup> as well as a distinct operating principle, where the latter is defined as follows:

All EU health systems strive to provide *good quality care*. This is achieved in particular through the obligation to *continuous training* of healthcare staff based on *clearly defined national standards* and ensuring that staff have access to *advice about best practice in quality*, stimulating *innovation* and spreading *good practice*, developing systems to ensure *good clinical governance*, and through *monitoring* quality in the health system. An important part of this agenda also relates to the principle of safety.<sup>65</sup>

The operating principle of safety is defined as follows:

Patients can expect each EU health system to secure a *systematic approach* to ensuring patient safety, including the *monitoring of risk factors* and adequate, *training* for health professionals, and protection against misleading advertising of health products and treatments.<sup>66</sup>

Patient safety has also been further clarified in two soft-law documents, i.e. a Council recommendation of June 2009<sup>67</sup> and Council conclusions of December 2014,<sup>68</sup> as mentioned above,<sup>69</sup> the 2009 recommendation defined patient safety as “freedom, for a patient, from unnecessary harm or potential harm associated with healthcare”; this 2009 recommendation has been followed by two reports about its implementation in Member States in November 2012<sup>70</sup> and June 2014,<sup>71</sup> as well as by a Eurobarometer survey (also June 2014).<sup>72</sup>

These two soft-law documents (i.e. the Council recommendation of June 2009 and the Council conclusions of December 2014), emphasize the need, first, for the Member States to work on:

- efficient and transparent patient safety programmes (including their cost-effective evaluation),
- policymaking and decision-making processes which should be evidence-based,
- classification and measurement of patient safety at EU level,
- dissemination of best practices,

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<sup>64</sup> Two years before, in 2004 (European Commission (n 16) 5, 8), although slightly different in wording, these values have merely been referred to as ‘principles’ (“of universal access, fairness and solidarity”).

<sup>65</sup> Emphases added.

<sup>66</sup> Emphases added.

<sup>67</sup> Recommendation 2009 patient safety.

<sup>68</sup> Council conclusions on patient safety and quality of care, including the prevention and control of healthcare-associated infections and antimicrobial resistance, [2014] OJ C438/7.

<sup>69</sup> *Supra* at note 35.

<sup>70</sup> European Commission, ‘Report on the basis of Member States’ reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections: COM(2012) 658 final’ (13 November 2012).

<sup>71</sup> European Commission, ‘The Commission’s Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections: COM(2014) 371 final’ (19 June 2014).

<sup>72</sup> European Commission, ‘Patient Safety and Quality of Care: Special Eurobarometer 411’ (Conducted by TNS Opinion & Social June 2014) European Commission, ‘Patient Safety and Quality of Care: Special Eurobarometer 411’ (Conducted by TNS Opinion & Social June 2014).

- just and blame-free reporting by health professionals or patients and support blame-free handling of errors and adverse events,
- prevention and control of healthcare associated infections<sup>73</sup> as well as antimicrobial resistance,<sup>74</sup> and
- electronic health records or e-prescriptions, which can contribute to improve patient safety.

Second, also healthcare workers play a key role for patient safety, which is addressed in terms of

- education and training on patient safety and infection prevention, as well as
- recruitment of health professionals specialising in infection control.

Third, both aforementioned soft-law documents also take into account the patient's perspective by addressing the importance of patient empowerment and involvement.

These two soft-law documents on patient safety address similar issues as the aforementioned operating principle of quality on care in the 2006 Council Conclusions, namely training of staff, national standards, best practice and monitoring.

The link between quality of training of future health professionals and quality of care has also been acknowledged by the CJEU in a Belgian case on discrimination in the access to higher education, where the Court has held as follows:

In that regard, it cannot be ruled out a priori that a reduction in the *quality of training of future health professionals* may ultimately *impair the quality of care* provided in the territory concerned, since the quality of the medical or paramedical service within a given area depends on the *competence of the health professionals* who carry out their activity there.<sup>75</sup>

It is also worth to mention that in this case the Court has made indirect reference to the precautionary principle<sup>76</sup> by stating that “where there is uncertainty as to the existence or extent of the risks to the protection of public health in its territory, the Member State may take protective measures *without having to wait* for the shortage of health professionals to materialise”.<sup>77</sup>

Besides the Council recommendation of June 2009, the Council conclusions of December 2014 also emphasize the need to work towards a better understanding of the cost-effectiveness<sup>78</sup> of patient safety policies under the principles of efficacy, efficiency,

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<sup>73</sup> On communicable diseases, see Markus Frischhut and Scott L Greer, ‘EU public health law and policy – communicable diseases’ in Tamara Hervey, Calum Young and Louise E Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017).

<sup>74</sup> See Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance, [2016] OJ C269/26.

<sup>75</sup> Case C-73/08 *Bressol* ECLI:EU:C:2010:181, para 67 (emphases added).

<sup>76</sup> On this principle see: Frischhut and Greer (note 73) 331-333; Olivier Ganry and others, ‘The Precautionary Principle: Is it Safe’ (2013) 20(3) *European Journal of Health Law* 261; Soren Holm and Elen Stokes, ‘Precautionary Principle’ in Ruth F Chadwick (ed), *Encyclopedia of Applied Ethics* (2nd ed. Academic Press 2012).

<sup>77</sup> Case C-73/08 *Bressol* ECLI:EU:C:2010:181, para 70 (emphases added).

<sup>78</sup> See European Commission (n 7).

appropriateness, safety and quality of care, and that policymaking and decision-making processes should be evidence-based.

These clarifications overlap with the wider context of the Council of Europe, where the Committee of Ministers has adopted respective Recommendations in 1997.<sup>79</sup>

### 3.4 Case-law clarification on quality of care

This notion of evidence-based decisions brings us back to the example mentioned in the introduction, the *Smits* and *Peerbooms* case, where quality of care was a barrier to patient mobility, as the MST considered certain treatment as being experimental, and thus “not regarded as normal within the professional circles concerned”.<sup>80</sup> For solving this case, the Court would have had the possibility either to refer to the standards of the MSA (a kind of country-of-origin principle,<sup>81</sup> so to say), or to the MST, as well as the Court could have referred to a European notion of what should be the state-of-the-art.<sup>82</sup>

However, the Court opted for a different approach by referring to “what is considered normal according to the state of international medical science and medical standards generally accepted at international level”.<sup>83</sup> When referring to international<sup>84</sup> medical science, the Court emphasized the need that treatment has to be “sufficiently tried and tested”;<sup>85</sup> in this context, account has to be taken of “existing scientific literature and studies, the authorised opinions of specialists [etc.]”.<sup>86</sup>

This case-law does not only apply to the 28 EU Member States, also the EFTA Court has adopted a similar case-law for the countries of the European Economic Area (EEA) in 2008.<sup>87</sup>

In a French case on the exclusion of men who had sexual relations with other men from blood donation, the Court had referred to the need to check if “in the light of current *medical, scientific and epidemiological knowledge*”<sup>88</sup> the relevant data put forward in this

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<sup>79</sup> See Council of Europe - Committee of Ministers, ‘Recommendation No. R (97) 17 on the Development and Implementation of Quality Improvement Systems (QIS) in Health Care’ (30 September 1997).

<sup>80</sup> Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, paras 31-39.

<sup>81</sup> On this topic see: Matthias Wismar, ‘Möglichkeiten und Grenzen europäischer Qualitätsverbesserung in der Gesundheitsversorgung’ in Thomas Gerlinger, Kai Mosebach and Rolf Schmucker (eds), *Gesundheitsdienstleistungen im europäischen Binnenmarkt* (Peter Lang 2010) 124-126.

<sup>82</sup> The European approach would of course have faced legal challenges against the background of the aforementioned vertical distribution of health competences between the EU and the Member States. Hendriks (n 2), 3 calls it “naïve to assume that there is as yet an autonomous European meaning of ‘high-quality healthcare’ and that this concept could be applied in a uniform way”.

<sup>83</sup> Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, para 92 (emphases added). This notion of ‘international medical science’ developed in the context of patient mobility has also been transferred to the field of biotechnological inventions; Case C-364/13 *International Stem Cell Corporation* ECLI:EU:C:2014:2451, para 36 (not mentioning “and medical standards”).

<sup>84</sup> For the need to take into account the international perspective in the field of risk assessment (and communicable diseases) see Frischhut and Greer (n 73) 329-330.

<sup>85</sup> Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, para 94.

<sup>86</sup> *ibid.*, para 98.

<sup>87</sup> Joined Cases E-11/07 and E-1/08 *Rindal and Slinning* [2008] EFTA Ct. Rep. 320.

<sup>88</sup> Emphases added.

case “is reliable and, if that is the case, whether it is still relevant”;<sup>89</sup> thus, although different in wording we can identify a similar underlying approach.

While, at first sight, it sounds logic to refer to the international level and to scientific facts, some questions still remain open:

- First of all, it can be questioned from a medical perspective, if such an international standard always exists for certain medical treatment.<sup>90</sup> Irrespective of whether in the end we have such a consensus or not, the question is how to reach such a consensus.
- This approach in case-law (negative integration) of referring to science goes hand in hand with what we have seen in TFEU Article 114(3) (i.e. positive integration), where since the Amsterdam Treaty there is a need of “taking account in particular of any new development based on scientific facts”. However, as we know from science and society literature, the concept of scientific facts in general is also politically determined;<sup>91</sup> this is especially true for the legislative power, hopefully less for the judiciary (i.e. case-law).
- The need to take into account science leads us to the issue of evidence-based decisions. Evidence-based medicine (EBM) has been described as “a procedure, or approach, that ensures, or perhaps maximises, justifiable decisions”.<sup>92</sup> EBM has been criticized in situations, where evidence does not lead to decisions, but rather first decisions are taken, “followed by the opportunistic choice of supporting evidence”.<sup>93</sup>
- EBM is also critically seen in terms of being too much driven by clinical trials and data, and not taking into account the individual situation of the patient, also requiring important exchange between patient and physician;<sup>94</sup> it has been argued elsewhere that there is a need to “individualise evidence and share decisions through meaningful conversations in the context of a humanistic and professional clinician-patient relationship”, by having “many stakeholders—patients, clinicians, educators, producers and publishers of evidence, policy makers, research funders, and researchers from a range of academic disciplines—[...] work together”.<sup>95</sup>
- As it is crucial for determining good quality healthcare,<sup>96</sup> the relationship of what could be called ‘science in terms of clinical trials and data’ on the one side, and ‘doctors’ experience’ on the other, has also been addressed in an intriguing project called

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<sup>89</sup> Case C-528/13 *Léger* ECLI:EU:C:2015:288, para 44.

<sup>90</sup> Elias Mossialos and Martin McKee, ‘Is a European healthcare policy emerging?’ (2001) 323(7307) *British Medical Journal* 248; Markus Frischhut and Nick Fahy, ‘Patient Mobility in Times of Austerity: A Legal and Policy Analysis of the Petru Case’ (2016) 23(1) *European Journal of Health Law* 36-46.

<sup>91</sup> Sheila Jasanoff, *Designs on nature: Science and democracy in Europe and the United States* (Princeton University Press 2007).

<sup>92</sup> Johannes Persson and others, ‘Science and proven experience - a Swedish variety of evidence-based medicine?: Paper presented at PSA 2016: The 25th Biennial Meeting of the Philosophy of Science Association, Atlanta, United States.’ (3 November 2016) 13.

<sup>93</sup> Marica Ferri, ‘What can we learn from the evidence based medicine manifesto?: BMJ Blogs’ (24 January 2017) <<http://blogs.bmj.com/bmj/2017/01/24/marica-ferri-what-can-we-learn-from-the-evidence-based-medicine-manifesto/>> accessed 3 February 2017.

<sup>94</sup> Joseph J Fins, ‘What’s Wrong with Evidence-Based Medicine?’ (2016) 46(1) *Hastings Center Report*.

<sup>95</sup> Trisha Greenhalgh, Jeremy Howick and Neal Maskrey, ‘Evidence based medicine: a movement in crisis?’ (2014) 348 *BMJ (Clinical research ed)* g3725 5.

<sup>96</sup> Lena Wahlberg and Johannes Persson, ‘Importing Notions in Health Law: Science and Proven Experience’ (2017) *European Journal of Health Law*, 6–7.

“science and proven experience”, contrasting general issues of EBM with this 100 years old tradition in Sweden.<sup>97 98</sup>

- Within this project, Wahlberg and Persson argue not only that research on the one side and clinical expertise on the other can be combined, but furthermore that this view is not at odds with the concept of EBM.<sup>99</sup> While this Swedish notion of ‘science and proven experience’ resonates with EBM in terms on its focus on evidence, science and the need for integration, it also differs from EBM as it “it treats two sources of evidence as special: Science and proven experience”.<sup>100</sup> While this Swedish concept refers to both components, it has also been stated that one could be sufficient, if the other is lacking.<sup>101</sup>
- There are six dimensions of ‘proven experience’ in the Swedish medical literature, which included the seriousness of test, practice as origin of the experience, practice as a mechanism for testing the experience, practice as evidence, the amount of an individual’s experience, as well as experience of a defined group.<sup>102</sup> Irrespective of this detailed analysis of the substance of this notion of ‘science and proven experience’, the authors nevertheless admit that it is a “very vague legal notion”.<sup>103</sup>
- What can we learn from this Swedish tradition for the clarification of the Court of Justice’s approach in *Smits* and *Peerbooms*? Obviously, referring to such standards is important in terms of safeguarding healthcare of good quality, which also has to be up-to-date.<sup>104</sup> Besides this, this project also addresses the fact that notions such as the Court of Justice’s ‘international medical science and medical standards’, or the Swedish ‘science and proven experience’ are used as “a vehicle of communication between the courts and medical experts”.<sup>105</sup> Similarly as we can observe a tendency in EU law to refer to ethics and morality,<sup>106</sup> importing such notions from a non-legal environment into a legal context does not mean that these concepts should only be determined in a non-legal way, or in other words: “it should be recognized that the content of the notion is *relative* [!] to

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<sup>97</sup> Lund University, ‘VBE - Science and Proven Experience’ <[www.vbe.lu.se](http://www.vbe.lu.se)> accessed 3 February 2017. For further details see Persson and others (n 92).

<sup>98</sup> For a similar discussion on EBM vs. customary standards of care in the US see Sandra H Johnson, ‘Structure of Governmental Oversight of Quality in Healthcare’ in I. G Cohen, Allison Hoffman and William M Sage (eds), *The Oxford handbook of U.S. health law* (Oxford University Press 2017) 511.

<sup>99</sup> Wahlberg and Persson (n 96), 13 (“EBM highlights the need to integrate research findings with individual clinical expertise”).

<sup>100</sup> *ibid.*

<sup>101</sup> *ibid* 7.

<sup>102</sup> *ibid* 14.

<sup>103</sup> *ibid* 23; as Wahlberg clarifies, the vagueness of proven experience in the medical context is in due to the many dimensions that the notion has there; the conceptual profile depends on the particular dimension(s) that a particular user relies on in a particular context. The vagueness of the legal context is moreover a result of the unclear connection between the medical and the legal meaning of proven experience.

<sup>104</sup> *ibid* 7.

<sup>105</sup> *ibid* 6.

<sup>106</sup> Markus Frischhut, “EU”: Short for “Ethical” Union?: The Role of Ethics in European Union Law’ (2015) 75(3) *Heidelberg Journal of International Law (HJIL)* 531.

legal purpose, and that it has *legal content*".<sup>107</sup> The same should be true for cross-border healthcare. Also here the reference to international science has to be "imported" in a relative way, i.e. taking into account the legal context of patients' rights in cross-border healthcare and the above mentioned values of universality, access to good quality care, equity, and solidarity.<sup>108</sup>

- The Court of Justice has not only referred to "medical science and medical standards",<sup>109</sup> "existing scientific literature and studies, the authorised opinions of specialists [etc.]",<sup>110</sup> but has also emphasized the need of "taking into consideration all the relevant medical factors and the available scientific data".<sup>111</sup> Therefore, it seems that there is place for both perspectives of science (clinical trials) on the one side, and 'proven experience' on the other.
- While the solution in *Smits* and *Peerbooms* was definitely convincing for this case, this shall not mean that this concept will not have to be further developed if the appropriate cases are referred to the Court of Justice. If this will be the case, the wheel will not have to be reinvented and we can learn from existing national experience, such as from this Swedish concept. However, a challenge can arise if the scientific factor has more of an international background, and the experience factor more of a national one, as then we would be stuck in the situation which was our starting point, the *Smits* and *Peerbooms* case.
- Last but not least, not only in this context,<sup>112</sup> new standards which are just about to emerge will initially be perceived as not being state-of-the-art and only then one day become state-of-the-art. Although there is a need to determine when they change their status, time does not change their content, but only their (medical and/or legal) acceptance.

Anyway, supposing that we can agree on how to get to such a common understanding of the international state-of-the-art and also supposing that in the end it finally exists for a certain treatment, it might be questionable if there can be exceptions to this state-of-the-art.

This issue of possible exceptions can arise in a situation where the accepted state-of-the-art cannot cure, but only treat a certain disease. This question, for instance, can occur in case of rare diseases, which at EU level have been defined as diseases that meet a prevalence threshold of not more than five affected persons per 10 000.<sup>113</sup> The German Constitutional

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<sup>107</sup> Wahlberg and Persson (n 96), 20 (emphases added).

<sup>108</sup> Taking into account these values is definitely different from what has been criticized above (at n 93). For EU documents referring to ethics and morality, I have argued in a similar way, i.e. filling those gaps etc. by referring to the EU's values (TEU Article 2), the CFREU, and the 'corner-stone' of human dignity; Frischhut (n 106), 565–569.

<sup>109</sup> Case C-157/99 *Smits and Peerbooms* ECLI:EU:C:2001:404, para 92.

<sup>110</sup> *ibid* para 98.

<sup>111</sup> Case C-173/09 *Elchinov* ECLI:EU:C:2010:581, para 62.

<sup>112</sup> When customary law is emerging, a similar challenge lies in determining when exactly, apart from the *opinion iuris*, this legal practice is established.

<sup>113</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, [2000] O J L18/1, as amended by [2009] O J L188/14, Recital 5; see also Directive patient mobility, Recital 55.

Court (BVerfG) in its famous “*Nikolausbeschluss*”<sup>114</sup> had to decide on the case of a person having mandatory public German health insurance and suffering from a certain life-threatening and often deadly rare disease.<sup>115</sup> As there have been no treatment methods<sup>116</sup> according to academic medicine (“*Schulmedizin*”), he has not been offered other treatment and would have had to pay on his own for bio resonance therapy etc. In this exceptional situation, the BVerfG has accepted a deviation from the state-of-the-art (as it could only treat but not heal<sup>117</sup>), under the condition that the chosen alternative treatment method is based on indications and has promise some kind of hope of healing, or at least a noticeable positive impact on the course of disease.<sup>118</sup> This solution was also backed by referring to the core area of the State’s obligation to provide treatment in such an extreme situation.<sup>119</sup>

Consequently, while there should be one single (international scientific and experience proven) understanding of (high but not necessarily highest) state-of-the art, there can be alternative approaches with less stringent requirements in exceptional life-threatening situations. Therefore, it remains challenging to grasp the notion of quality of care.

Another exceptional case had to be decided at EU level. This case was about a Romanian lady, Ms Elena Petru, suffering for some years from a serious cardiovascular disease. The medical examinations finally led to the decision to proceed with open heart surgery. The problem was that she perceived the hospital establishment in Romania to be inadequate for such a surgical procedure,<sup>120</sup> as she complained about a substantial shortage of material resources such as painkillers, antiseptic/disinfectant, absorbent cotton wool or sterile dressings.<sup>121</sup>

Assuming that the situation as presented by Ms Petru was actually the case,<sup>122</sup> the question is how a reduction in quality affects patients’ rights of receiving cross-border healthcare against the background of the EU legal principles in place. According to these, first, the treatment in question has to be among the benefits provided for by the MSA (i.e. be part of the national health basket<sup>123</sup>), and, second, there has to be a situation where the treatment “cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence, taking account of his current state of health and the probable course of his disease”.<sup>124</sup>

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<sup>114</sup> Decision from 6 December 2005, 1 BvR 347/98; for related issues see Ruhr-Universität Bochum, ‘Nikolaus Projekt’ <[www.nikolaus-beschluss.de/](http://www.nikolaus-beschluss.de/)> accessed 2 February 2017.

<sup>115</sup> Here, a prevalence of 1 out of 3.500; *Nikolausbeschluss* (n 114) para 20.

<sup>116</sup> See Case C-173/09 *Elchinov* ECLI:EU:C:2010:581, para 62 on health baskets only defining types of treatment, and the obligation under EU law, also to take into account different treatment methods.

<sup>117</sup> *Nikolausbeschluss* (n 114) para 20.

<sup>118</sup> *ibid.* para 64 (“Dabei muss allerdings die vom Versicherten gewählte andere Behandlungsmethode eine auf Indizien gestützte, nicht ganz fern liegende Aussicht auf Heilung oder wenigstens auf eine spürbare positive Einwirkung auf den Krankheitsverlauf versprechen”).

<sup>119</sup> *ibid.* para 65.

<sup>120</sup> Case C-268/13 *Petru* ECLI:EU:C:2014:2271, paras 10-11.

<sup>121</sup> Case C-268/13 *Petru* ECLI:EU:C:2014:2023, Opinion of Advocate General Cruz Villalón, para 6.

<sup>122</sup> Case C-268/13 *Petru* ECLI:EU:C:2014:2271, para 35.

<sup>123</sup> Case C-268/13 *Petru* ECLI:EU:C:2014:2271, para 35.

<sup>124</sup> Case C-173/09 *Elchinov* ECLI:EU:C:2010:581, para 54 (for further details see also para 66).

As the first precondition (being part of the health basket) was no issue, the Court, for the second precondition, simply equated inadequate treatment with unavailable treatment.<sup>125</sup> According to the Court, “such a lack of *medication* and of *medical supplies* and *infrastructure* can, in the same way as the lack of specific *equipment* or particular *expertise*, make it impossible for the same or equally effective treatment to be provided in good time in the Member State of residence”.<sup>126</sup>

This might be the compelling solution for a case about open heart surgery and a lack of very fundamental medical equipment, but does not answer the question which level of quality of care can be expected.<sup>127</sup> Theoretically, this would be the international state-of-the-art; however, this might be challenging for countries which cannot afford this high and expensive level.

Another question which relates to the aforementioned definition of quality of care<sup>128</sup> is whether quality of care should be measured more in relation to resources (here: allegedly-missing resources) or in relation to outcome, which is most important, but where data might not always be available for patients and in addition might be difficult for patients to interpret.<sup>129</sup>

After a first wave of cases of patients from rather wealthy countries seeking treatment in equally rich countries, *Petru* was part of a second wave of cases after the Eastern European enlargement,<sup>130</sup> where also the legal basis on which patients from the new Member States relied on was a different one.<sup>131</sup>

When during the first wave of cases countries were more comparable with regard to quality of care, the Court had to deal with possible barriers to cross-border healthcare motivated by alleged quality concerns. However, both due to a lack of evidence brought forward in the proceedings before the Court of Justice,<sup>132</sup> as well as due to harmonization in this field,<sup>133</sup> alleged cross-border quality concerns with regard to eyeglasses,<sup>134</sup> doctors or

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<sup>125</sup> For further details (also on the different approach of the Opinion of Advocate General Cruz Villalón) see Karl-Jürgen Bieback, ‘Öffnung des Krankenhausmarkts in Europa für Qualitätswettbewerb?’ (2015) *Zeitschrift für europäisches Sozial- und Arbeitsrecht* 55; Frischhut and Fahy (n 90).

<sup>126</sup> Case C-268/13 *Petru* ECLI:EU:C:2014:2271, para 33 (emphases added).

<sup>127</sup> The question of a different level of quality can be different from the above mentioned discussion of national vs. international and science vs. proven experience.

<sup>128</sup> *Supra* section 2.

<sup>129</sup> Frischhut and Fahy (note 90) 47.

<sup>130</sup> Markus Frischhut and Rosella Levaggi, ‘Patient mobility in the context of austerity and an enlarged EU: The European Court of Justice’s ruling in the *Petru* Case’ (2015) 119(10) *Health Policy* 1293.

<sup>131</sup> Frischhut and Fahy (n 90), 52–53.

<sup>132</sup> Case C-385/99 *Müller-Fauré and van Riet* ECLI:EU:C:2003:270, para 70.

<sup>133</sup> Now: Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, [2005] OJ L255/22, as amended by [2016] OJ L134/135 (Directive recognition qualifications).

<sup>134</sup> Case C-120/95 *Decker v Caisse de maladie des employés privés* ECLI:EU:C:1998:167, paras 42-45 (equivalent quality guarantees in case of spectacles bought abroad).



dentist,<sup>135</sup> or private hospitals<sup>136</sup> have not been accepted by the Court.<sup>137</sup> As the Court has stated, it is not the task of the MSA, but rather of the MST to conduct quality controls, e.g. in private hospitals.<sup>138</sup>

This case-law of the Court of Justice on patient mobility started in 1998<sup>139</sup> and finally led to Directive patient mobility. Before we now turn to quality of care and patient safety in this Directive, the following overview (Figure 3) depicts some of the aforementioned documents and cases in a timeline, also already including the three directives to be covered in section 5.

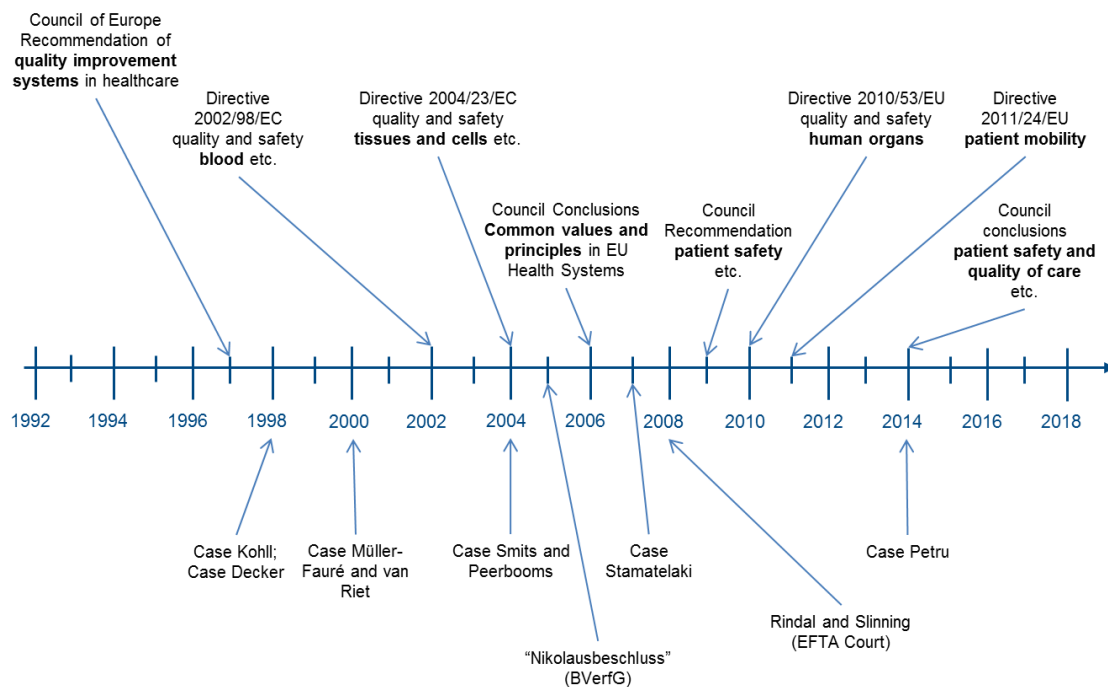


Figure 3: Historic development (excerpt)<sup>140</sup>

#### 4. Quality of care in Directive patient mobility

Although patient mobility developed mainly due to different cases, we shall not forget the bigger picture.<sup>141</sup> As can be seen from Figure 4, quality of care and patient safety are part of

<sup>135</sup> Case C-158/96 *Kohll v Union des caisses de maladie* ECLI:EU:C:1998:171, paras 47-49 (equivalent quality guarantees in case of doctors and dentists abroad); confirmed in Case C-255/09 *Commission v Portugal* ECLI:EU:C:2011:695, para 81.

<sup>136</sup> Case C-444/05 *Stamatelaki* ECLI:EU:C:2007:231, para 36 (equivalent quality guarantees in private hospitals abroad).

<sup>137</sup> See also Ferdinand Wollenschläger, 'Patientenmobilität in der Europäischen Union: Von der Rechtsprechung des EuGH zur neuen Richtlinie 2011/24/EU über die Ausübung der Patientenrechte in der grenzüberschreitenden Gesundheitsversorgung' (2012) *Europarecht* 149, 162.

<sup>138</sup> Case C-444/05 *Stamatelaki* ECLI:EU:C:2007:231, para 37.

<sup>139</sup> Case C-158/96 *Kohll v Union des caisses de maladie* ECLI:EU:C:1998:171.

<sup>140</sup> Source: author's own visualization.

<sup>141</sup> In this section, references without further specification refer to Directive patient mobility.

the EU’s agenda for effective, accessible and resilient health systems,<sup>142</sup> which also addresses Directive patient mobility, codifying the Court’s case-law.

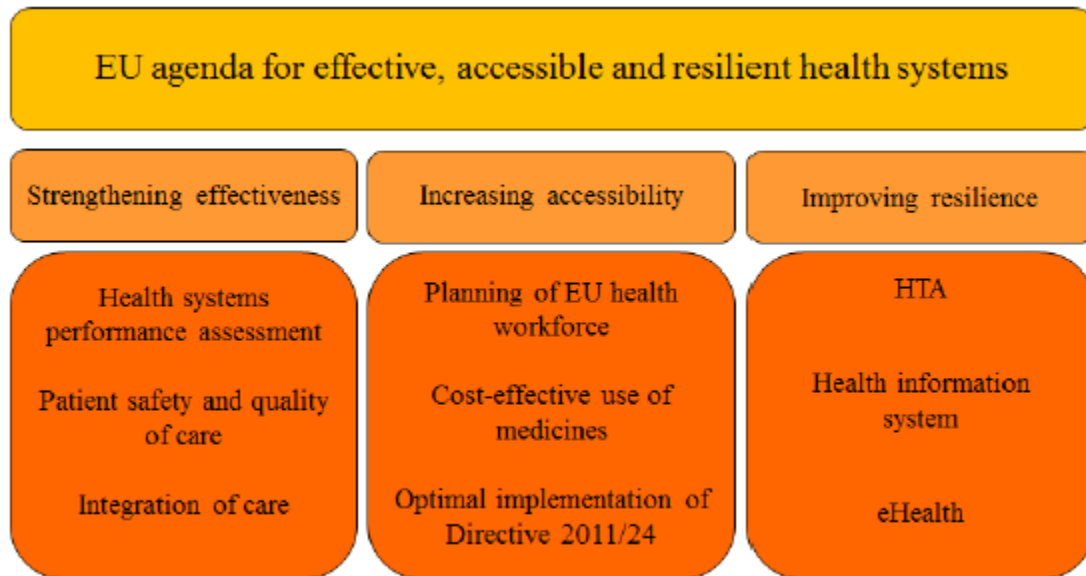


Figure 4: EU agenda for effective, accessible and resilient health systems<sup>143</sup>

#### 4.1 Patients’ rights

As mentioned above, also the Directive identifies the desire for better quality as one of the motivations for patients to seek healthcare abroad.<sup>144</sup> The aim of this Directive is “to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union”.<sup>145</sup>

In addressing the “overarching values of universality, access to good quality care, equity, and solidarity [which] have been widely acknowledged in the work of various Union institutions”,<sup>146</sup> the Directive establishes to link between soft- and hard-law. It also aligns negative and positive integration by picking up the wording of the Courts case-law when referring to “advances in international medical science and generally recognised good medical practices as well as taking into account new health technologies” in the systematic and continuous efforts of improving quality and safety standards.<sup>147</sup>

As we remember, the Court didn’t allocate the competence of defining what type of treatment should be considered as being ‘normal’ solely between either the MSA or the

<sup>142</sup> European Commission, ‘On effective, accessible and resilient health systems: COM(2014) 215 final’ (4 April 2014).

<sup>143</sup> *ibid* 17.

<sup>144</sup> Recital 39.

<sup>145</sup> Recital 10; see also Recital 64 and Art 1(1).

<sup>146</sup> Recitals 21 and 22.

<sup>147</sup> Recital 22.

MST, but opted for the international perspective; this is of course irrespective of the basic competence of the MSA to define its basket of care.

In terms of quality of care, the Directive first in a general way emphasizes the Member States' (and not the EU's) "responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare".<sup>148</sup> Second, like the Court, the Directive assigns one country, i.e. the MST, which is in charge of quality of care.<sup>149</sup>

Healthcare in the MST shall be provided in accordance with the MST's legislation, its "standards and guidelines on quality and safety", and EU legislation on safety standards; in doing so, the MST shall take into account "the principles of universality, access to good quality care, equity and solidarity"; it is worth mentioning, that in this Article 4(1) the values (as defined in the 2006 Council conclusions) are only referred to as 'principles'.<sup>150</sup>

When comparing this provision of the Directive with the Commission's proposal,<sup>151</sup> the proposal was stricter as in Article 5 it had foreseen an obligation to "define clear quality and safety standards for healthcare provided on their territory". As this was "considered by the Member States a bridge too far", we now find this softer wording in Article 4(1) lit b of the final Directive, and therefore this 'obligation to define' was amended to a mere 'obligation to inform', a fact which was criticized in literature.<sup>152</sup>

It is the obligation of the MST to make sure that this information is available, but it is healthcare providers<sup>153</sup> which have to provide "relevant information to help individual patients to make an informed choice, including [...] quality and safety of the healthcare they provide".<sup>154</sup> <sup>155</sup> This information only has to be provided on request, has not to be more extensive compared to the one for patients resident in the MST and it can also be provided by other actors.<sup>156</sup>

Quality of care in general has been acknowledged in the context of reasons of justification for the "aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment".<sup>157</sup> In case-law, it has always been the MSA trying to justify barriers for not having to reimburse costs of treatment received abroad (outbound perspective). The

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<sup>148</sup> Recital 4 (emphasis added); see also Recital 42.

<sup>149</sup> For further details on the competences of the MSA and the MST, see Frischhut and Stein (n 28) 43–48; see also *supra* at note 138.

<sup>150</sup> As Recital 21 addresses them (in the same context of the MST) as values, this reference to principles can be understood as meaning values.

<sup>151</sup> European Commission (n 52).

<sup>152</sup> Willy Palm and Rita Baeten, 'The quality and safety paradox in the patients' rights Directive' (2011) 21(3) *European Journal of Public Health* 272, 273.

<sup>153</sup> Defined in Article 3(g), in contrast to health professionals who are defined in Article 3(f).

<sup>154</sup> Article 4(2) (b).

<sup>155</sup> As Herman Nys, 'The Right to Informed Choice and the Patients' Rights Directive' (2012) 19(4) *European Journal of Health Law* 327, 329 points out, a right to 'informed choice' is different to a right to 'informed consent'. As Palm and Baeten (n 152), 273 and Nys (at 330) also point out, obliging healthcare providers to provide this information can potentially result in a conflict of interests.

<sup>156</sup> Recital 20. On the question who has to provide which information see also Vicki Paskalia, 'Cross-border Healthcare in the EU: And What if Something Goes Wrong?' (2016) *European Journal of Health Law*, 11–12

<sup>157</sup> Recital 12; see also Recitals 40 and 43, Article 7(7) and (9), Article 8(2) (a).

Directive now does not only codify the case-law, but also addresses the inbound perspective by allowing the MST “to adopt measures regarding access to treatment” aimed at “ensuring sufficient and permanent access to a balanced range of high-quality treatment”.<sup>158</sup> In a health related context we have seen such in-bound situations for incoming medicine students in the above mentioned Belgian<sup>159</sup> (or a similar Austrian<sup>160</sup>) case.

Coming back to the MSA, while in case-law barriers to the reimbursement of costs of treatment received abroad were mainly based on the idea not to endanger the financial balance of the social security system,<sup>161</sup> the Directive also allows the MSA to limit the reimbursement of cross-border healthcare “for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health”.<sup>162</sup> What is also new in comparison to case-law,<sup>163</sup> is the possibility to make cross-border healthcare subject to prior authorisation if this is provided “by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union”.<sup>164</sup> While this provision refers to a general setting, the MSA may also refuse to grant prior authorisation in an individual situation for the following reasons:

- “(a) the *patient* will, according to a clinical evaluation, be exposed with *reasonable certainty* to a *patient-safety risk* that cannot be regarded as *acceptable*, taking into account the potential benefit for the patient of the sought cross-border healthcare;
- (b) the *general public* will be exposed with *reasonable certainty* to a *substantial safety hazard* as a result of the cross-border healthcare in question;
- (c) this healthcare is to be provided by a *healthcare provider* that raises *serious and specific concerns* relating to the respect of standards and guidelines on *quality of care and patient safety*, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment”.<sup>165</sup>

This new clarification combines three different perspectives, of the individual patient (lit a), of the general public (lit b), as well as of the provider (lit c); the general public could for example be endangered in case of communicable diseases<sup>166</sup> imported into the MSA. For all three perspectives a certain threshold (risk not acceptable; substantial hazard; serious

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<sup>158</sup> Article 4(3).

<sup>159</sup> Case C-73/08 *Bressol* ECLI:EU:C:2010:181.

<sup>160</sup> Case C-147/03 *Commission v Austria* ECLI:EU:C:2005:427.

<sup>161</sup> Case C-173/09 *Elchinov* ECLI:EU:C:2010:581, para 42.

<sup>162</sup> Recital 11.

<sup>163</sup> New, in the sense that so far it has not been addressed as detailed and, as mentioned above, never been accepted by the Court of Justice; see *supra* at notes 130-138.

<sup>164</sup> Article 8(2) (c); this also has to be seen in conjunction with Article 10(4), according to which the MST shall provide information on the right to practise of health professionals to the other Member States.

<sup>165</sup> Article 8(6) (emphases added); lit d addressing undue delay is not mentioned here.

<sup>166</sup> Frischhut and Greer (n 73).

concerns) as well as an evidence-based decision (according to clinical evaluation; reasonably certainty; specific concerns) is required.

In terms of the aforementioned division of competences between the MSA and the MST, the following ones briefly have to be mentioned in terms of quality of care:

- Comparing healthcare to cross-border healthcare, important new features brought by the Directive in terms of the MSA are rules on follow-up treatment<sup>167</sup> as well as on medical records,<sup>168</sup> which play an important role<sup>169</sup> for the aforementioned continuity of care.<sup>170</sup>
- As the Directive itself acknowledges, information with regard to patient safety is crucial<sup>171</sup> “in a sector well known for information asymmetry”.<sup>172</sup> With regard to the MST, information for patients from providers etc. has already been mentioned.<sup>173</sup> Also the new national contact points (NCPs)<sup>174</sup> have to provide “upon request, relevant information on the standards and guidelines” on quality and safety laid down by MST.<sup>175</sup> Due to still existing differences,<sup>176</sup> equally important with regard to quality and safety in cross-border healthcare are transparent complaints procedures,<sup>177</sup> systems of professional liability insurance,<sup>178</sup> and, inversely to the MSA, medical records<sup>179</sup> for ensuring continuity of care.

## 4.2 Cooperation

Besides chapter II on Member States’ responsibilities and chapter III on reimbursement of costs, the Directive has added another chapter (IV) on mainly voluntary<sup>180</sup> cooperation between Member States, which can also contribute to strengthen patients’ rights.

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<sup>167</sup> Article 5 (c).

<sup>168</sup> Article 5 (d). The importance of “electronic health records” for patient safety has also been stressed (not only in a cross-border context) by Recommendation 2009 patient safety, Recital 12.

<sup>169</sup> Also stressing the importance of electronic health record systems in the US (as what “should be the primary policy focus”): Kristin Madison, ‘Legal and Policy Issues in Measuring and Improving Quality’ in I. G Cohen, Allison Hoffman and William M Sage (eds), *The Oxford handbook of U.S. health law* (Oxford University Press 2017) 700.

<sup>170</sup> See note 34.

<sup>171</sup> Therefore, it is quite astonishing that in the last Eurobarometer survey the reason of not having information on patient safety and quality of care abroad only ranked second last (20%) of reasons for which patients would be unwilling to receive treatment abroad; European Commission (n 11) 23. Already Recommendation 2009 patient safety has emphasized the importance of information for patient safety (point I.2.b).

<sup>172</sup> Recital 43.

<sup>173</sup> Article 4(2) (b).

<sup>174</sup> Article 6.

<sup>175</sup> Article 4(2) (a).

<sup>176</sup> Paskalia (n 156), 10 has pointed out that “national systems still differ as to their systems regarding medical liability in general, and of claiming compensation in cases of harm in particular”.

<sup>177</sup> Article 4(2) (c).

<sup>178</sup> Article 4(2) (d).

<sup>179</sup> Article 4(2) (f).

<sup>180</sup> Article 1(1) provides rules on patients’ rights, but only “promotes [sic] cooperation on healthcare between Member States”.

Besides other examples already mentioned, also the Commission's idea to develop guidelines for the purpose of defining these quality and safety standards (etc.) at EU level has not made it to the final directive and was replaced by the mainly non-binding articles on mutual assistance and cooperation between Member States.<sup>181</sup> According to Article 10 (1) this includes "cooperation on standards and guidelines on quality and safety", as well as necessary information exchange.<sup>182</sup>

All the Articles of this chapter IV either directly address quality and safety concerns, or are at least indirectly related to this issue:

- Within the context of the recognition of prescriptions issued in another Member State, the Commission has to adopt measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, "including measures to address patient safety concerns in relation to their substitution in cross border healthcare".<sup>183</sup>
- With regard to the voluntary European reference networks, which shall be established "in particular in the area of rare diseases",<sup>184</sup> the Directive addresses high quality and safety several times in terms of the objectives to be met by these networks.<sup>185</sup>
- Article 14 mainly addresses 'public' eHealth in terms of cooperation and exchange of information between Member States,<sup>186</sup> where one of the objectives of the eHealth network is also to enhance to aforementioned continuity of care and to ensure "access to safe and high-quality healthcare".<sup>187</sup>
- Also Article 15 on health technology assessment (HTA) addresses cooperation within a voluntary network, which can support Member States not only through economies of scale and the avoidance of duplication of effort, but at the same time can "provide a better evidence base for optimal use of new technologies to ensure safe, high-quality and efficient healthcare".<sup>188</sup>

Besides cooperation between Member States themselves, they shall also facilitate cooperation at different levels, i.e. between healthcare providers, purchasers and regulators of different Member States "in order to ensure safe, high-quality and efficient cross-border healthcare".<sup>189</sup>

Due to the wide notion of healthcare, the Directive applies to a broad range of services, with the exception of certain types of long-term care, vaccination programmes and the

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<sup>181</sup> Palm and Baeten (n 152), 273.

<sup>182</sup> See also the Recital 22: "Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technologies".

<sup>183</sup> Article 11(2) (c); see also Recital 53.

<sup>184</sup> Article 13, Recital 55.

<sup>185</sup> Article 12(2) (c), (g) and (h); see also para 4 (a) (iii) and Recital 54.

<sup>186</sup> On 'private' eHealth see Recital 57, Article 3 (d) and Article 7(7).

<sup>187</sup> Article 14(2) (a); see also (b) (i).

<sup>188</sup> Recital 58.

<sup>189</sup> Recital 50.

“allocation of and access to organs for the purpose of organ transplants”.<sup>190</sup> At the same time, the Directive is based on – and is subsidiary to – the existing health acquis enumerated in Article 2, which, amongst others, also refers to blood (lit i), tissues and cells (lit k), and the just mentioned organs intended for transplantation (lit r). These three explicitly address health and safety issues and therefore will be depicted in the next section.

## 5. Related healthcare fields (excerpt)

Apart from patient mobility and the aforementioned closely related topic of professional qualifications,<sup>191</sup> quality of care and patient safety plays an important role also in other fields of negative integration, such as for example in case of the freedom of establishment (e.g. pharmacies<sup>192</sup>), or in case of the free movement of goods.<sup>193</sup>

When it comes to positive integration, while TFEU Article 168 basically only tasks the EU with a competence to support, coordinate or supplement the actions of the Member States,<sup>194</sup> it also provides for a shared competence of the EU and the Member States for common safety concerns in public health matters.<sup>195</sup>

In this context, TFEU Article 168(4) is the legal basis for both

- measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives (lit a),
- as well as measures setting high standards of quality and safety for medicinal products and devices for medical use (lit c).

In the latter field of medical devices (lit c leg. cit.), in the past the three relevant directives (on active implantable medical devices,<sup>196</sup> medical devices<sup>197</sup> and in vitro diagnostic devices<sup>198</sup>) were less aiming at patient safety, but rather on internal market purposes (i.e.

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<sup>190</sup> Article 1(3) (a)-(c).

<sup>191</sup> For further details see: Tamara Hervey and Jean V McHale, *European Union health law: Themes and implications* (Law in context, Cambridge University Press 2015) 146–151.

<sup>192</sup> Case C-570/07 *Blanco Pérez and Chao Gómez* ECLI:EU:C:2010:300, para 64 (“objective of ensuring that the provision of medicinal products to the public is reliable and of good quality”).

<sup>193</sup> Case C-421/09 *Humanplasma* ECLI:EU:C:2010:760, para 33 (“that blood and blood components marketed in Austria satisfy the criteria of high quality and safety”).

<sup>194</sup> TFEU Article 2(5) and Article 6(a).

<sup>195</sup> TFEU Article 4(2) (k).

<sup>196</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, [1990] OJ L189/18, as amended by [2007] OJ L247/21.

<sup>197</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, [1993] OJ L169/1, as amended by [2007] OJ L247/21 (Directive Medical Devices), see note 201.

<sup>198</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, [1998] OJ L331/1, as amended by [2011] OJ L341/50, see note 201.

free circulation). However, due to the PIP<sup>199</sup>-scandal,<sup>200</sup> the ongoing reform of this framework is now more aiming at patient safety.<sup>201</sup>

As they are explicitly mentioned in Article 2 of Directive patient mobility, let us have a closer<sup>202</sup> look at the three directives on blood,<sup>203</sup> tissues and cells<sup>204</sup> and organs.<sup>205 206</sup>

As already foreseen in TFEU Art 168(4)(a), the Blood Directive allows Member States to maintain or introduce more stringent measures,<sup>207</sup> that is to say only requiring minimum harmonization; the same is true for the Tissues and cells Directive.<sup>208</sup>

Against the background of the aforementioned discussion of a high vs. a highest level of health,<sup>209</sup> it is worth mentioning that while basically all three Directives refer to high standards of quality and safety, the Tissues and Cells Directive tasks the EU to “promote the highest possible level of protection”.<sup>210</sup> Also the Organs Directive refers to the “highest possible protection of living donors” when requiring Member States to take all necessary measures in order to fully guarantee the quality and safety of organs for transplantation.<sup>211</sup>

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<sup>199</sup> Poly Implant Prothèse.

<sup>200</sup> In Case C-219/15 *Schmitt* ECLI:EU:C:2017:128, the Court had to deal with the question whether Directive Medical Devices requires the so-called ‘notified body’ to carry out unannounced inspections, to examine devices and/or to examine the manufacturer’s business records; such an obligation was rejected by the Court, unless there is evidence indicating that a medical device may not comply with the requirements of this Directive (para 48). The question of the liability of the notified body (and not of the manufacturer) for the harm caused to Mrs Schmitt by defective breast implants made of silicone had been raised, because the manufacturer of those implants had become insolvent.

<sup>201</sup> For further details see Hervey and McHale (n 191) 366–378. See now [2017] OJ L117/1 and 176.

<sup>202</sup> However, due to limited space, this contribution will not cover the Commission’s implementing measures in these three fields.

<sup>203</sup> Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, [2003] OJ L33/30, as amended by [2009] L188/14 (Blood Directive); the two above mentioned cases C-421/09 *Humanplasma* ECLI:EU:C:2010:760 and Case C-528/13 *Léger* ECLI:EU:C:2015:288 both concerned this directive (respectively the implementing directive).

<sup>204</sup> Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, [2004] OJ L102/48, as amended by [2009] OJ L188/14 (Tissues and Cells Directive).

<sup>205</sup> Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, [2010] OJ L207/14, as corrected by [2010] OJ L243/68; from “Directive 2010/45/EU” to “Directive 2010/53/EU” (Organs Directive).

<sup>206</sup> At the moment, the European Commission is evaluating the legal framework on blood, as well as tissues and cells; European Commission, ‘Evaluation of EU blood, tissues and cells legislation: Commission publishes Roadmap: Europe’s sante Newsroom’ (2017)

<[http://ec.europa.eu/newsroom/sante/itemdetail.cfm?item\\_id=52459&newsletter=327](http://ec.europa.eu/newsroom/sante/itemdetail.cfm?item_id=52459&newsletter=327)> accessed 28 February 2017.

<sup>207</sup> Article 4(2).

<sup>208</sup> Article 4(2), Recital 22 with reference to CFREU and ECHR.

<sup>209</sup> See sections 3.1 and 3.2.

<sup>210</sup> Recital 5.

<sup>211</sup> Article 15(1), see also Recital 27 in the context of traceability.



While they of course differ in details, as can be seen from Table 1, all three directives in general have a similar approach with regard to rules on quality and safety in their respective field.<sup>212</sup>

- All three Directives require a competent authority, responsible for the implementation of the requirements of the respective Directive. Both the Blood Directive as well as the Tissues and Cells Directive require the designation, authorisation, accreditation or licensing of an establishment in the respective field, while the Organs Directive stipulates requirements of organisations involved in organ procurement etc.
- As has been emphasized by several documents so far, also all three Directives set up requirements with regard to qualification and training of the responsible persons and personnel involved in the described tasks.<sup>213</sup>
- The Blood, as well as the Tissues and Cells Directive, require inspections and control measures. According to the Blood Directive, the competent authority has to organise inspections and appropriate control measures in blood establishments, while according to the Tissues and Cells Directive, the competent authority or authorities organise inspections, and the tissue establishments carry out appropriate control measures.<sup>214</sup>
- As the underlying philosophy of these three Directives is to guarantee quality and safety in their respective fields, we can find different rules on quality management, such as rules on documentation, record keeping, a framework for quality and safety, reporting systems, etc. (see Table 1).
- Similarly as in case of communicable diseases,<sup>215</sup> we can find rules on traceability in all three directives. The most recent directive, the Organs Directive from 2010, provides a definition of traceability, according to which traceability means “the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal”, which, in case of organs, includes identification of the donor and the procurement organisation, identification of the recipient and information on products and material coming into contact with that organ.

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<sup>212</sup> Anne-Maree Farrell, ‘Risk, Legitimacy, and EU Regulation of Health Technologies’ in Mark L Flear and others (eds), *European Law and New Health Technologies* (Oxford University Press 2013) 215 points out that the Organs Directive elaborates on the protections to be provided to organ donors and recipients in more detail than the Blood Directive; another difference relates to that fact that the Commission acknowledged that a different approach was needed in relation to managing risk- and ethics-based concerns due to the chronic organ shortage within the EU (at 217, 218, 220).

<sup>213</sup> The Organs Directive also refers to the above-mentioned Directive recognition qualifications (see *supra* notes 133 and at 191).

<sup>214</sup> As mentioned above with regard to Case C-219/15 *Schmitt* ECLI:EU:C:2017:128 (note 200), the question of such inspections can be linked to the question of liability for harm caused in the context of the respective Directive.

<sup>215</sup> Frischhut and Greer (n 73) 336-337.

Table 1: Quality and safety in Directives on Blood, Tissues and Cells, and Organs

	<b>Establishments and authorities</b>	<b>Staff requirements</b>	<b>Inspection and control</b>	<b>(other) Quality management</b>	<b>Traceability</b>
Blood Directive (2003)	<ul style="list-style-type: none"> <li>Art 4(1) [Designation of <b>competent authority</b>]</li> <li>Art 5 (Designation, authorisation, accreditation or licensing of blood <b>establishments</b>)</li> </ul>	<ul style="list-style-type: none"> <li>Art 9 (Responsible person)</li> <li>Art 10 (personnel)</li> </ul>	Art 8 (Inspection and control measures)	<p>Chapter IV (Quality management, Art 11-13):</p> <ul style="list-style-type: none"> <li>Art 11 (Quality system for blood establishments)</li> <li>Art 12 (Documentation)</li> <li>Art 13 (Record keeping)</li> </ul> <p>Chapter VI [Quality and safety with regard to donors]</p>	Art 14 (Traceability)
Tissues and cells Directive (2004)	<ul style="list-style-type: none"> <li>Art 4(1) [designation of <b>competent authority</b>]</li> <li>Art 6 (Accreditation, designation, authorisation, or licensing of tissue <b>establishments</b> and tissue and cell preparation processes)</li> </ul>	<ul style="list-style-type: none"> <li>Art 5 (Supervision of human tissues and cell procurement)</li> <li>Art 17 (Responsible person)</li> <li>Art 18 (Personnel)</li> </ul>	Art 7 (Inspections and control measures)	<ul style="list-style-type: none"> <li>Chapter III (Donor selection and evaluation)</li> <li>Chapter IV (Provisions on the quality and safety of tissues and cells), and especially ... <ul style="list-style-type: none"> <li>Art 16 (Quality management)</li> </ul> </li> </ul>	Art 8 (Traceability) and Art 25(1)
Organs Directive (2010)	<ul style="list-style-type: none"> <li>Art 17 (Designation and tasks of <b>competent authorities</b>), defined in Art 3(a) and (b)</li> <li>Art 5 (<b>Procurement organisation</b>)</li> </ul>	<ul style="list-style-type: none"> <li>Art 12 (Healthcare personnel)</li> <li>Art 4(3), Art 6(1), Art 7(4), Art 15(2)</li> </ul>		<p>Chapter II (Quality and safety of organs)</p> <ul style="list-style-type: none"> <li>Art 4 (Framework for quality and safety)</li> <li>Art 11 (Reporting system and management concerning serious adverse events and reactions)</li> </ul> <p>Chapter III (Donor and recipient protection and donor selection and evaluation)</p> <ul style="list-style-type: none"> <li>Art 15 (Quality and safety aspects of living donation)</li> <li>(Art 18 Records and reports concerning procurement organisations and transplantation centres)</li> </ul>	Art 10 (Traceability), defined in Art 3(s)

## 6. Conclusions

As we have seen, there is no uniform definition of quality of care in EU law which would apply across different sectors.<sup>216</sup> Also definitions in literature differ, putting an emphasis on individual patients or health systems, respectively focussing more on resources or outcome.

The CJEU had always concentrated on the patients' perspective, for instance when the Court had to determine the notion of 'undue delay' in the context of waiting lists.<sup>217</sup> However, as we have seen in Figure 4, also the broader perspective should not be disregarded. When it comes to definitions either focusing more on resources (e.g. missing infrastructure as in the *Petru* case) or on out-come, the patients' perspective also has to be a strong guiding principle which, however, can put an emphasis on either perspective.

Taking a more holistic approach in quality of care has not only been demanded in literature,<sup>218</sup> as we have seen in the soft-law clarification of patient safety, different stakeholders' perspectives (i.e. Member States, healthcare workers and patients) have been addressed. Also the 'new' rea-sons of justification in Directive patient mobility Article 8(6) addressed different perspectives, both of individual patients, but also comprising the general public.

The Directive also addressed the fact that decisions have to be evidence-based, which has also been identified as one of the operating principles in the context of the 2006 definition of EU health values.<sup>219</sup> Likewise, in the definition of this state-of-the-art and evidence-based decisions, there is a need to take into account both perspectives (scientific research and proven experience), which is true both for negative as well as for positive integration.

Patient centeredness also plays a role at the interface of the different disciplines of law and medicine, as references to international science etc. have to be 'imported' in a relative way, i.e. taking into account the legal context of patients' rights in cross-border healthcare and the above mentioned values of universality, access to good quality care, equity, and solidarity.

Not only do we lack a clear and precise definition of quality of care, challenges can further rise in case of a newly emerging state-of-the-art, as well as in situations where the state-of-the-art is in-sufficient, for instance if it can only treat but not heal (cf. the *Nikolausbeschluss*).

This difficulty of facing a lack of clear and precise definition was not only true for the Swedish concept of 'science and proven experience', but also for the just mentioned

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<sup>216</sup> With the exception of pharmaceuticals, basically there is more diversity than universal aspects when it comes to quality and safety; Legido-Quigley and others (n 8) 121.

<sup>217</sup> Case C-372/04 *Watts* ECLI:EU:C:2006:325, paras 68-79; para 68: "not exceed the period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned in the light of his medical condition and the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the authorisation is sought".

<sup>218</sup> Recently (for the US): Madison (n 169) 700.

<sup>219</sup> Care that is based on evidence and ethics.

situation of the *Nikolausbeschluss*, and the same criticism has been addressed in literature<sup>220</sup> with regard to quality as reason of justification in Directive patient mobility.

Apart from the hard-law clarification in some sectors (blood, tissues and cells, organs, etc.), we have rather found clarification in soft-law and related activities in the context of the OMC. The content of these soft-law documents (section 3.3) cannot only implicitly be found in a lot of hard-law documents, the EU health values defined as soft-law in 2006 have become hard-law by explicitly mentioning them in Directive patient mobility (section 4.1).

Against the background of this challenge of lacking a clear and precise definition, also the requirement of a high level of healthcare cannot determine a clear solution, but can, as a guiding principle, lead into the right direction. As we have seen, this requirement of a high level can be of relevance in the interpretation of EU Secondary law (i.e. positive integration), and the Court's emphasis on public health as a reason of justification which ranks "foremost", leads into the same direction in negative integration.

Therefore, the fact that the reference to a highest level did not make it into the final version of Directive patient mobility is maybe of less importance and we will see, if the identified references to a highest level in the Tissues and Cells Directive and the Organs Directive make that much of a difference.

Directive patient mobility has confirmed that the MSA is competent to define its basket of care, and the MST being competent for quality of care (having to take into account the international state-of-the-art), although the final Directive is softer in its wording as the Commission's proposal.

As addressed at the beginning of this paper, quality of care already is an issue in a purely domestic context, but additional challenges can arise in case of cross-border healthcare. Therefore, Directive patient mobility has addressed some issues which are of particular importance for quality in cross-border situations, such as medical records, follow-up treatment, and information.<sup>221</sup>

At least in theory, patients should now have more information available, thus hopefully reducing information asymmetries. However, this information on quality of care can affect not only, as intended, cross-border situations, but also purely domestic ones.<sup>222</sup>

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<sup>220</sup> Kyriaki-Korina Raptopoulou, *EU law and healthcare services: Normative approaches to public health systems* (Kluwer Law International 2015) 102.

<sup>221</sup> The importance of more transparency has also been addressed by Expert Group on Health Systems Performance Assessment (n 16) 10–11.

<sup>222</sup> Nys (n 155), 328; Miek Peeters, 'Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare' (2012) 19(1) *European Journal of Health Law* 29 55, 58.

# Chapter VI Information for patients and health system cooperation by means of the National Contact Points for cross-border healthcare\*

Timo Clemens

## 1. Introduction

The establishment of National Contact Points for cross-border healthcare (hereafter NCPs) is the most tangible outcome Directive 2011/24/EU (hereafter the Directive) has produced in Member States. The Directive requested Member States to designate an institution to fulfil the tasks assigned to the NCP in the Directive. They are basically twofold: NCPs need to provide patients with information on their rights and entitlements to receive cross-border healthcare (Article 6) and NCPs are deemed to be key for mutual assistance and collaboration among Member States (Article 10) in the areas described in Chapter IV of the Directive.<sup>1</sup> By setting up NCP offices and websites the Directive goes beyond requesting the transpositions of EU law into national legislation (“the law in books”) but includes an instance of practical policy formulation (“the law in action”).<sup>2</sup> The established or designated NCP offices are institutions that citizens can phone, email and sometimes even go to. On NCP websites people can look for information and get answers on their questions regarding cross-border care. Via the NCPs stakeholders and decision makers in Member States of treatment and Member States of affiliation, are supposed to exchange information and cooperate to facilitate cross-border care. In this regard, NCPs are institutions that require staffing, resources, intelligence systems and networks to fulfil their tasks. All this needs to be facilitated and budgeted by domestic policy makers. Because NCPs are very practical creations of the Directive and by its mission for information and collaboration they are a vehicle to put the Directive into practice and at the same time a gauge how well the legal provisions have been transposed into practice.

The two objectives of NCP for information and collaboration can be seen in a broader context of developments in European health systems. Firstly, providing information to patients as to make decisions about various aspects of their healthcare has gained attention since the 1990s. In many European countries comparative information on the features of

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\* Acknowledgements. This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors. However, would I like to thank Eveline Cox, Matt Commers, Brigitte van der Zanden and Helmut Brand for their input and comments on earlier versions of this analysis that has been published as activity report. I would like to thank the AZ Vesalius and especially Mr Hermans in Tongeren, Belgium for hosting the placement of Eveline Cox during her master at Maastricht University which provided the preparatory work for this research. Moreover, I am grateful to EPECS for dedicating human resources to this project.

<sup>1</sup> Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45.

<sup>2</sup> I have borrowed these terms from Esther Versluis, ‘Even rules, uneven practices: Opening the ‘black box’ of EU law in action’ (2007) 30 *West European Politics* 50.

care providers, the quality of services offered or patient experiences has been published increasingly.<sup>3</sup> In some European countries these developments towards “consumer” rights have even been codified into a patient right for information, second opinion or quality of care.<sup>4</sup> However, the quality of information and its usefulness for patients to base treatment decisions on is still discussed.<sup>5</sup> This is the context in which the Directive requires Member States to provide information to patients on the financial and non-financial aspects of cross-border care.<sup>6</sup> For this, NCPs tap into the available information resources and aligned expert networks in their domestic healthcare systems.

Secondly, EU cooperation among Member States on aspects of (cross-border) healthcare already existed before. The ECJ’s *Kohll*<sup>7</sup> and *Decker*<sup>8</sup> rulings and subsequent cases<sup>9</sup> made clear that under certain conditions patients can enjoy access to health services in other EU member states and that likewise services providers can deliver their services to patients across borders.<sup>10</sup> Initially, between 2002 and 2004 a High level Process of Reflection on Patient Mobility and Healthcare Developments in the European Union has been established. Its recommendations called for a more stable structure to EU level cooperation regarding health systems, the High Level Group in Health Services and Medical Care. The High Level Group has been a forum for discussion between 2004 and 2006 and shortly relaunched activities in 2008.<sup>11</sup> Although the plenary meetings of the High level group have ended, some of the working groups are still active today such as the Working group on Quality of Care and Patient Safety or on the European Workforce for Health. Likewise, the new Cross-border Healthcare Expert Group has been set up by referring to the High level group.<sup>12</sup>

Not only patient mobility has been covered by EU level cooperation but also professional mobility. The right to free movement and establishment of healthcare providers is codified

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<sup>3</sup> Karsten Vrangbaek and others, ‘Choice policies in Northern European health systems’ (2012) 7 Health Economics, Policy and Law 47; Bernd Rechel and others, ‘Public reporting on quality, waiting times and patient experience in 11 high-income countries’ (2016) 120 Health Policy 377.

<sup>4</sup> Pre-Max consortium, *Patients’ Rights in the European Union – Mapping eXercise – Final Report* (European Commission, forthcoming).

<sup>5</sup> Olga C Damman and others, ‘An International Comparison of Web-based Reporting About Health Care Quality: Content Analysis’ (2010) 12 Journal of Medical Internet Research e8.

<sup>6</sup> Willy Palm and others, ‘Towards a renewed community frame-work for safe, high quality and efficient cross-border healthcare within the European Union’ in Matthias Wismar and others (eds), *Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity* (World Health Organization on behalf of the European Observatory on Health Systems and Policies 2011).

<sup>7</sup> Case C- 158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931.

<sup>8</sup> Case C- 120/95b *Decker v Caisse maladie des employes privés* [1998] ECR I-1831.

<sup>9</sup> Including Joined Cases C-157/99. *Geraets-Smits v Stichting Ziekenfonds VGZ and Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473, Case C-372/05 *Watts* [2006] ECR I-4325, Joined Cases C-385/99 *Mueller-Faure v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* and *van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; Case C-368/98 *Vanbraekel v Alliance nationale des Mutalites Chretiennes (ANMC)* [2001] ECR I-5363; Case C-56/01 *Inizan v Caisse primaire d’assurance maladie des Hauts-de-Seine* [2006] ECR I-12403; Case C-173/09 *Elchinov v Natsionalna zdravnoosigurnitelna kasa* [2011] ECR I-8889; Case C-268/13 *Petru v Casa Judeteana de Asigurari de Sanatate Sibiu* [2015] PTSR 139.

<sup>10</sup> Tamara K Hervey and Jane V McHale, *Health Law and the European Union* (Cambridge University Press 2004).

<sup>11</sup> E Mossialos and others (eds), *Health Systems Governance in Europe - The Role of European Union Law and Policy* (Cambridge University Press 2010).

<sup>12</sup> European Commission, *Rules of procedure of the cross-border healthcare expert group. Ref.Ares (2017) 414436-26/01/2017* (European Commission 2017).

in the Professional Qualification Directive,<sup>13</sup> which has required cooperation inter alia on exchange of information on disciplinary measures for health professionals, recognition of qualifications and experiences or health workforce planning.

Next to the cooperation at EU level, multiple cooperation initiatives for steered cross-border care have occurred throughout the European Union. This involves in many cases arrangements in border regions where healthcare infrastructures across the border are made available to patients in another Member State, healthcare professionals practice at both sides of the border or joint infrastructures are set up.<sup>14</sup> In other cases, cross-border arrangements occur along historically routed ties with other, not geographically close Member States.<sup>15</sup> Cross-border care occurs where patients' needs are not met, since they are not available in a country or region, and covers collaboration on emergency care, general hospital care but as well highly specialised treatments such as reproductive medicine, cancer treatment or complex surgical interventions.<sup>16</sup>

It became clear in the preparation of the Directive in order to facilitate cross-border care for patients, not only reimbursement questions needed to be addressed but also the availability of information about other non-financial issues surrounding the enjoyment of care in another Member State needed to be improved. On these grounds, cooperation became integral to the design of the Directive to addressing "flanking measures" to create trust for patients and also among professionals engaging in cross-border care in the other Member States' healthcare systems. These additional conditions cover various aspects of relevant information, transparency about quality and safety standards, facilitation of continuity of care, and knowledge about mechanisms for redress and compensation in the case of harm.<sup>17</sup>

In the following, an analysis will be provided of what kind of information NCP websites provide and how cooperation of NCPs started. To study the information available to patients a content analysis of NCP websites was conducted in early 2014 and combined with an analysis of data derived from evaluative studies commissioned by the European Commission for which data was collected in 2014, 2015 and 2016.<sup>18</sup> Furthermore, the analysis on how NCPs collaborate is based on data of the same evaluative studies combined with the documents of the NCP coordinators meetings that have taken place so far. The analysis in

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<sup>13</sup> Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22.

<sup>14</sup> Magdalena Rosenmöller, Martin McKee and Rita Baeten (eds), *Patient Mobility in the European Union: learning from experience* (World Health Organization on behalf of the Europe 4 Patients project and the European Observatory on Health Systems and Policies 2006); Irene Glinos and Matthias Wismar (eds), *Hospitals and borders. Seven case studies on cross-border collaboration and health system interactions* (World Health Organization acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies 2013).

<sup>15</sup> Natasha Azzopardi-Muscat and others, *Health care systems in transition – Malta* (WHO Regional office for Europe 2015).

<sup>16</sup> Rosenmöller (n 14).

<sup>17</sup> Palm (n 6).

<sup>18</sup> Giulio Zucca and others, *Evaluative study on the cross-border healthcare Directive (2011/24/EU) -Final Report* (European Union 2015); European Commission, *Member State Data on cross-border healthcare following Directive 2011/24/EU – Year 2015* (European Commission 2015); Grega Strban (ed.) and others, *Access to healthcare in cross-border situations - Analytical Report 2016* (European Union 2017).

this chapter will evolve in four steps. Firstly, the legislative requirements set out by the Directive for NCPs regarding information provisions and collaboration are described. Secondly, an overview about how NCPs are configured in the national health systems is provided. Thirdly, an assessment of the information they provide is given. And fourthly, the ways NCPs collaborate and the current and future issues for collaboration are analysed. The chapter will end by way of a concluding section.

## 2. Responsibilities of Member States

The provisions in Directive 2011/24/EU on NCPs set out responsibilities for Member States in three domains: (1) on the setup and establishment of NCPs, (2) on information to be provided, specified for Member States of treatment and Member States of affiliation, and (3) for cooperation with relevant stakeholders and among NCPs themselves. Article 6 is the main reference in the Directive regarding the establishment of NCPs, its design and functions.

### 2.1 The structure and setup of the National Contact Points

First of all, Member States are supposed to “*designate one or more NCPs*” in their country according to Article 6(1) of the Directive, leaving open to whether set up a new one or mandate an existing “*information centre*” to take up the role of the NCP (Recital 49). Moreover, no specification of what kind of institution or legal format the NCPs should have is provided. Recital 49 reiterates that “*form and number*” of NCPs is up to Member States and they are free to establish other linked contact points at regional or local level. Moreover, NCPs should be established in “*an efficient and transparent way*” but “*should have the appropriate facilities*” for providing information.

The approach by the EU to obligate Member States to designate a NCP acknowledges the situation that very different national institutions across and within Member States are providing information to patients on features of treatment and patients’ rights in general and on cross-border care specifically. The designation of NCPs differs from the approach the EU has used under the coordination of social security scheme<sup>19</sup> where the involved authorities, institutions and persons were called to directly communicate, mutually inform and cooperate with each other.

### 2.2 Responsibilities for information provision

The Directive predominantly addresses *what kind of information* should be provided discerning the responsibilities of a Member State of treatment and of a Member State of

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<sup>19</sup> Regulation (EC) No 883/2004 of 29 April 2004 on the coordination of social security systems [2004] OJ L166/1, Article 76; Regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 of 16 September 2009 on the coordination of social security systems [2009] OJ L284/1, Article 22(1).



affiliation. In this regard, recital 48 indicates that a compulsory set of information “should be specified” and that NCPs “may provide more voluntarily”.

Providing information via NCPs includes for Member State of treatment the following aspects:

- on standards and guidelines on quality and safety laid down by Member State of treatment
- on the supervision and assessment of healthcare providers
- on which healthcare providers are subject to these standards and guidelines
- on accessibility of hospitals for persons with disability (Article 4(2)a).

Member State of affiliation’s responsibilities cover, according to Article 5(b), provision of information:

- on their rights and entitlements in that Member State relating to cross-border healthcare
- on the terms and conditions for reimbursement of costs
- on procedures for accessing and determining those entitlements
- and for appeal and redress in case patients consider that their rights have not been respected
- on the rights patients have by virtue of this Directive and rights from Regulation (EC) No 883/2004.

Furthermore, the Implementing Directive 2012/52/EU requires NCPs in Article 4 to “inform patients about the elements to be included [...] in prescriptions issued in a Member State other than the Member State where it is dispensed”.<sup>20</sup>

Hence, the Directive does not require Member States to ensure harmonized patients’ rights across the EU – something that has been described by Member States as a red line not to be crossed during the political discussion in establishing the Directive – but only to provide information on existing relevant rights, standards and guidelines in countries.<sup>21</sup>

Secondly, the way how information should be provided is addressed to a lesser extent by the Directive. NCP are obligated to provide information

easily accessible [...] by electronic means and in formats to people with disabilities,... [Article 6(5)] in any of the official languages [...]. Information may be provided in any other language (recital 48).

The Directive invites Member States to rely on existing information sources (recital 49) and is prescribing which information regarding patients’ rights to be provided to patients, but it does not – and most likely cannot so far – determine how information should be edited to be ‘*easily accessible*’ for patients.<sup>22</sup>

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<sup>20</sup> Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State [2012] OJ L356/68.

<sup>21</sup> Willy Palm and Rita Baeten, ‘The quality and safety paradox in the patients’ rights Directive’ (2011) 21 The European Journal of Public Health 272.

<sup>22</sup> *ibid*, Palm and Baeten.

### 2.3 Responsibilities for cooperation

As Article 6 sets out the main obligations of NCPs' cooperation tasks are specified to involve, to

- consult with patient organisations, healthcare providers and healthcare insurers
- cooperate closely with each other and with the Commission
- provide patients on request with contact details of NCPs in other Member States.

In addition, Article 10 on Mutual assistance and cooperation further highlights the NCP's role in "exchanging of information among each other including [exchange of information] on the supervision of providers and content of invoices".

Member States in general are obliged in recitals 49 "to work together [with the Commission] to facilitate cooperation among NCP". They are encouraged to "facilitate cooperation between healthcare providers, purchasers and regulators of different MS to ensure safe, high quality and efficient cross border care" (recital 50). Furthermore, recital 51 reiterates that the "Commission should facilitate cooperation in the areas set out in Chapter IV by identifying obstacles, recommendations and disseminating information and best practices". As such, Article 10 sets out a number of areas where Member States should cooperate, including

- cooperation on standards and guidelines on quality and safety and the exchange of information (Article 10(1))
- to facilitate cooperation in cross-border healthcare provision at regional and local level as well through ICT and other forms (Article 10(2))
- to cooperate in cross-border healthcare in border regions (Article 10(3))
- [to] ensure that information on the right to practice of health professionals [...] is made available to the authorities of other Member States [...] via the Internal Market Information System (IMI). (Article 10(4))

Beyond these areas for cooperation described above to achieve the immediate aims of the Directive, cooperation is foreseen on a number of "flanking measures" for cross-border care<sup>23</sup> including recognition of prescriptions (Article 11), European Reference Networks (Article 12), Rare Diseases (Article 13), eHealth (Article 14) and health technology assessment (Article 15) in chapter IV of the Directive. The totality of provisions on cooperation have been described as to establish "massive European cooperation structure".<sup>24</sup> Outside the cooperation in the framework of the Directive 2011/24/EU and the Regulation 883/2004, a number of cooperation agreements for cross-border healthcare exists on a bilateral basis involving neighbouring countries such as Belgium, The

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<sup>23</sup> Wolf Sauter, *Harmonisation in healthcare: the EU patients' rights Directive*. TILEC Discussion Paper No 2011-030. (Seminar on social Protection and Social Inclusion in the EU: interactions between law and policy 2011).

<sup>24</sup> Miek Peeters, 'Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare' (2012) 19 *European Journal of Health Law* 2.

Netherlands, Germany, Luxembourg and France, but as well non bordering countries such as the Malta–UK agreement.<sup>25</sup>

### 3. Structures of National Contact Points

On the basis of the provisions set out by the Directive, largely Member States have chosen for a unified approach how to set up their NCP within their healthcare systems. Some differences in the establishment can be attributed to the flexibility given to Member States in the Directive and the attempt for an efficient way of setting up the NCP given the domestic healthcare system structures. A vast majority of Member States have chosen to simply mandate existing general patient information centres for the general public or institutes with cross border care expertise, to take on the role of the NCP; only very few Member States have chosen for a more innovative way across existing institutions to set up the NCP. Largely, the NCP is linked to a governmental or public body such as the Ministry of Health or an agency (see Table 1).

The great majority of Member States chose to establish a single NCP. The UK and Denmark designated NCP tasks to multiple regional entities reflecting the decentralised character of their health systems. Hungary, Lithuania and Sweden kept the structures for information provision for own citizens wishing to seek care abroad and EU citizens interested to be treatment in their healthcare systems apart. An overview of the NCP's affiliations and setup is shown in Table 1.

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<sup>25</sup> J Pacolet and F De Wispelaere, Planned cross-border healthcare – PD S2 Questionnaire, Report prepared in the framework of Network Statistics FMSSFE, 2014, p 16; Strban (n 18).

Country	URL NCP webpage	Host institution	Number of NCPs offices & websites
Austria	<a href="http://www.gesundheit.gv.at">www.gesundheit.gv.at</a>	private/MoH	1/1
Belgium	<a href="http://www.crossborderhealthcare.be">www.crossborderhealthcare.be</a>	MoH	1/1
Bulgaria	<a href="http://www.nhif.bg">www.nhif.bg</a>	NHIF	1/1
Croatia	<a href="http://www.hzzo.hr">www.hzzo.hr</a>	NHIF	1/1
Cyprus	<a href="http://www.moh.gov.cy/cbh">www.moh.gov.cy/cbh</a>	MoH	1/1
Czech Rep.	<a href="http://www.cmu.cz">www.cmu.cz</a>	9 insurers	1/1
Denmark	<a href="http://www.patientombuddet.dk/">www.patientombuddet.dk/</a>	gov. agency	4/1
Estonia	<a href="http://www.kontaktpunkt.sm.ee">www.kontaktpunkt.sm.ee</a>	MoSocAff	1/1
Finland	<a href="http://www.kela.fi/yhteyspiste">www.kela.fi/yhteyspiste</a>	SHI institute	1/1
France	<a href="http://www.sante.gouv.fr/point-de-contact-national-pour-la-france.html">www.sante.gouv.fr/point-de-contact-national-pour-la-france.html</a>	MoH	1/1
Germany	<a href="http://www.eu-patienten.de">www.eu-patienten.de</a>	HI associations	1/1
Greece	<a href="http://www.eopyy.gov.gr">www.eopyy.gov.gr</a>	NHS	1/1
Hungary	<a href="http://www.eubetegiog.hu">www.eubetegiog.hu</a> <a href="http://www.patientrights.hu">www.patientrights.hu</a>	gov. agency	1/2
Ireland	<a href="http://www.hse.ie/eng/services/list/1/schemes/cbd/CBD.html">www.hse.ie/eng/services/list/1/schemes/cbd/CBD.html</a>	NHS	1/1
Italy	<a href="http://www.salute.gov.it/">www.salute.gov.it/</a>	MoH	1/1
Latvia	<a href="http://www.vmnvd.gov.lv/">www.vmnvd.gov.lv/</a>	MoH & gov. agency	1/1
Lithuania	<a href="http://www.lncp.lt/">www.lncp.lt/</a> <a href="http://www.vaspvt.gov.lt/en">www.vaspvt.gov.lt/en</a> <a href="http://www.vlk.lt/vlk/en/">www.vlk.lt/vlk/en/</a>	NHIF & gov. agency	2/1
Luxemb.	<a href="http://www.cns.lu">www.cns.lu</a>	MoH	1/1
Malta	<a href="http://www.gov.mt/en/Pages/gov.mt%20homepage.aspx">www.gov.mt/en/Pages/gov.mt%20homepage.aspx</a>	MoH	1/1
Netherlands	<a href="http://www.cbhc.nl">www.cbhc.nl</a>	gov. agency	1/1
Poland	<a href="http://www.nfz.gov.pl/new/index.php">www.nfz.gov.pl/new/index.php</a>	NHIF	1/1
Portugal	<a href="http://diretiva.min-saude.pt/home-2/">http://diretiva.min-saude.pt/home-2/</a>	NHS PT	1/1
Romania	<a href="http://www.cnas-pnc.ro">www.cnas-pnc.ro</a>	NHIF	1/1
Slovakia	<a href="http://www.udzs-sk.sk">www.udzs-sk.sk</a>	MoH & HI	1/1
Slovenia	<a href="http://www.nkt-z.si/wps/portal/nktz/home">www.nkt-z.si/wps/portal/nktz/home</a>	NHI institute	1/1
Spain	<a href="http://www.msssi.gob.es/">www.msssi.gob.es/</a>	MoH	1/1
Sweden	<a href="http://www.socialstyrelsen.se">www.socialstyrelsen.se</a> <a href="http://www.forsakringskassan.se">www.forsakringskassan.se</a>	gov. agency	2/2
UK <sup>3</sup>	<a href="http://www.nhs.uk/nationalcontactpoint">www.nhs.uk/nationalcontactpoint</a>	NHS UK	5/1

3 Information presented retrieved from NCP England. Characteristics and information can differ on the other regional webpages.

MoH	Ministry of Health
NHIF	National health Insurance Fund
MoSocAff	Ministry of Social Affairs
(S)HI	(Social) Health Insurance

## 4. Information provision

For the purposes of the analysis the information requirements defined in Article 4(2a) for Member States of affiliation and Article 5(b) regarding Member States of treatment have been grouped into five domains: information on (1) quality and patients safety standards; (2) provider rights; (3) patients' rights; (4) dispute procedures and (5) entitlements for cross-border care. The analysis of web content has checked for the extent to which MS complied with these information obligations. Domains were deemed satisfactory if respective information was presented either on the website of the NCP itself or by a referral to another page using a link.

Many NCP websites provided only short overviews containing incomplete information but frequently links were used to refer to existing additional web content. Some NCP websites would only give a web-link as the single source of information outside the NCP website. Linked web content often was deemed very technical and less accessible from the perspective of patients. These linked websites were often only available in the official language of the respective country as these were institutions, laws or pre-existing web content dealing with respective information. Moreover, web content of a certain information domain differed between national NCP websites and often provided only parts of the rights or regulation regime. In this regard, it reflects the strive of many Member States to organise the NCP in an efficient way – relying on what is already existing elsewhere rather than aiming at a well-established informative “single stop shop” for patients seeking cross-border care.<sup>26</sup> The object of an efficient organisation of NCPs should be seen as well in the light of the number of information requests NCPs receive. Estimations<sup>27</sup> of information requests from 2015 indicate that the majority of NCPs receives only a couple of hundreds requests per year.<sup>28</sup> Likewise, data from 2014 indicated that the most of the NCPs (7/9) on average received less than 100 requests per month.<sup>29</sup>

### 4.1 What kind of information is provided?

Information on quality and patient safety provision was available on three-quarter (18/24) of the NCP websites where frequently links to web content of institutions, laws and other sources dealing with quality and patient safety was given. Information on provider rights was present on approximately half (13/24) of the NCP websites referring predominantly to the web content of professional or medical associations. When it came to the domain of patients' rights, many NCP websites (20/24) varied what kind of patients' rights issues they addressed. These issues covered access to medical records, patients' right to information, informed consent or data protection regulations but a comprehensive overview was often lacking. Also, web content on dispute settlement procedures (18/24) appeared to be incomplete referring often only to a selection of complaint procedures such as an

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<sup>26</sup> Andre den Exter, Alceste Santuari and Tomislav Sokol, 'One Year after the EU Patient Mobility Directive: A Three-Country Analysis' (2015) 40 *European Law Review* 279.

<sup>27</sup> Quality of data is contested given different national registration systems for requests and overlaps with information requests for other tasks of institutions hosting the NCP.

<sup>28</sup> European Commission, Member State Data (n 18).

<sup>29</sup> European Commission, Evaluative study (n 18).

ombudsman, civil and criminal law procedures, the medical code of practice, or via medical associations. On many NCP websites (23/24) we found good, understandable information on the entitlements involving the rights and procedures for cross-border healthcare including an explanation of the differences between the Directive 2011/24/EU and Regulation 883/2004.<sup>30</sup> A few NCP websites contrasted the advantages and disadvantages of using the different regulations or provided the required forms to apply for authorisation directly on the websites.

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<sup>30</sup> Regulation (EC) No 883/2004 (n 19).

Country	quality and safety standards	provider rights	patients' rights	dispute procedures	entitlements for crossborder care
	18/24	13/24	20/24	18/24	23/24
Austria	✓	✓	✓	✓	✓
Belgium	✓	o	✓	✓	✓
Bulgaria	o	o	✓	✓	✓
Croatia	✓	o	✓	✓	✓
Cyprus	✓	o	✓	✓	✓
Czech Republic	o	✓	✓	✓	✓
Denmark	✓	✓	✓	✓	✓
Estonia	✓	o	✓	✓	✓
Finland	✓	✓	✓	o	✓
France	✓	✓	✓	✓	✓
Germany	✓	✓	✓	✓	✓
Greece <sup>1</sup>					
Hungary	✓	✓	✓	✓	✓
Ireland	✓	o	o	o	✓
Italy <sup>1</sup>					
Latvia	✓	✓	✓	o	✓
Lithuania	✓	✓	✓	✓	✓
Luxembourg	o	o	o	o	✓
Malta	✓	o	✓	✓	✓
Netherlands <sup>2</sup>	o	o	o	o	o
Poland	o	o	✓	✓	✓
Portugal <sup>1</sup>					
Romania <sup>1</sup>					
Slovakia	✓	✓	✓	✓	✓
Slovenia	✓	✓	✓	✓	✓
Spain	✓	✓	✓	✓	✓
Sweden	✓	✓	✓	✓	✓
UK (England) <sup>3</sup>	o	o	o	o	✓
1 website at initial data collection not operational					
2 website was operational, but content under construction					
3 Information presented retrieved from NCP England accessed at <a href="http://www.nhs.uk/NHSEngland/Healthcareabroad/Pages/Healthcareabroad.aspx">www.nhs.uk/NHSEngland/Healthcareabroad/Pages/Healthcareabroad.aspx</a> Characteristics and information can differ on the other regional webpages.					

An initial analysis of users of NCP websites indicates that patients considering the cross-border route are mostly interested to find answers to administrative questions rather than on the question which provider to choose.<sup>31</sup> Regarding administration of cross-border care, patients were looking for information on coverage, reimbursement and administrative

<sup>31</sup> European Commission, Evaluative study (n 18).

procedures such as prior authorisation.<sup>32</sup> A similar priority of information needs has been detected among German patients treated in other European countries.<sup>33</sup> Patients seeking information for determining the choice for a certain cross-border provider including quality and safety information rather rely on the advice of their domestic healthcare provider (e.g. GP or medical specialist) or the experiences of other patients, friends or family than on web-based information as provided by NCPs.<sup>34</sup> However, information on quality and patient safety aspects of care is only emerging in European countries<sup>35</sup> and the effectiveness of different formats to inform patients' choices is largely not understood yet.<sup>36</sup>

#### 4.2 How is information presented

Based on the provisions set out in Article 6(5) of the Directive web formats supporting people with disabilities were identified and grouped if available. Moreover, language versions and general communication channels with the NCP were covered as well. Only half of the NCPs' websites did provide any format to support the access of web-content for people with disabilities at the start of 2014. Formats included the change of letter size, a high contrast view, voice reader and easy content view.

The Italian, Irish and English NCP websites remained with the minimum requirement of one official language version (Recital 49). Although, the English NCP website offers a built-in Google translate function. Many NCP websites provided information in between one and three different language versions. English was the preferred second choice of a non-domestic language. Although the website analysis did not systematically compare web content between different language versions, a number of raters reported that non-domestic language versions, such as in many countries English, do not provide the same level of information. This difference in the level of information has been corroborated by the Analytic Report 2016.<sup>37</sup> Next to retrieving information from NCP websites, NCP offices in all Member States could be approached for individual questions or request for information by either via email or a contact form. In some countries, NCP offices offered to send written requests via the post. NCP offices in Austria, France, the Netherlands and Italy did not provide a telephone line, but relied on written routes of contacts only. Moreover, a number of NCP have arranged office hours to allow citizens to personally present a request.

Based on the website analysis and additional consulted analytic studies the picture emerges that the establishment of NCPs as a source of information to patients is very welcomed but that information provided by NCPs is often too general, sometimes incomplete and not well accessible due to technical language, being scattered or language barriers in order to make an informed decision about whether or not using the cross-border route. It has been called for a harmonization of web contents provided by the NCPs – although this goes certainly

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<sup>32</sup> *ibid.*

<sup>33</sup> Demitra Panteli and others, 'Know before you go: information-seeking behaviour of German patients receiving health services abroad in light of the provisions of Directive 2011/24/EU' (2015) 3 *Journal of Health Services Research & Policy* 154.

<sup>34</sup> *ibid.*; European Commission, *Evaluative study* (n 18).

<sup>35</sup> Vrangbaek (n 3).

<sup>36</sup> Vrangbaek (n 3); Damman (n 5); Mads S Nybo and Jane Skov, 'Patient knowledge of anticoagulant treatment does not correlate with treatment quality' (2016) 141 *Public Health* 17.

<sup>37</sup> Strban (n 18).



beyond the current provisions in the Directive. However, (1) continued exchange and cooperation along the lines described in the next section, (2) the development of a toolbox and training material<sup>38</sup> and (3) the idea of an umbrella EU contact point for cross-border healthcare complementing NCPs<sup>39</sup> may all serve towards such a harmonising effect.

## 5. Cooperation

### 5.1 Cooperation with relevant stakeholders

Cooperation between the NCP and relevant stakeholders such as health insurers, healthcare providers and patient organisations was encouraged by the Directive to ensure cross-border care (recital 50). In the majority of Member States health insurer, the national health insurance fund, the Ministry of Health or a related agency are involved as the (joint) host institution operating the NCPs which provide immediate and strong links for cooperation among those stakeholders and the NCP (see Table 1). Patient organisations seem to be rather a new stakeholder in many countries with whom cooperation is encouraged by the Directive; only half of NCPs sought cooperation with them initially. This pattern of cooperation along pre-existing links is confirmed by the EC's commissioned evaluation with a subset of eight NCPs at a later point in 2014. However, while it was held that cooperation with relevant stakeholders improved, cooperation was often sought on an ad-hoc basis to fix individual patient requests rather than to establish general procedures.<sup>40</sup>

Given the ties with patient organisations were not well established, NCPs organised seminars, consultations or questionnaires, to receive their feedback or input. In this regard cooperation with patient organisations served different goals. Some NCP sought cooperation with patient organisations during the actual transposition process into national law and the establishment of the NCP. Some NCPs cooperated with them for information provision and other NCPs for evaluating the website content because they represent patients' view.

### 5.2 Cooperation among National Contact Points

In 2014, only a few NCPs had established formal contacts with NCPs in other countries themselves initially – most often, when arrangements for cross-border cooperation existed, already previously. Many other NCPs reported some informal contacts or pointed to the first NCP coordinators meeting organised by the European Commission in February 2014 to use for cooperation and networking. Data from the EC's evaluative study suggested that cooperation among NCPs has intensified throughout 2014 since from the subsample all 8 NCPs indicated to have frequent contacts (>8 per year) with other NCPs.<sup>41</sup>

In order to support cooperation among NCPs the Commission itself organised a number of meetings for NCP coordinators from 2014 onwards. Overall, the meetings were used to

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<sup>38</sup> European Commission, *Cross-Border Healthcare Expert Group, Meeting of National Contact Points for Cross-Border Healthcare, Agenda 5 May 2017* (European Commission 2017).

<sup>39</sup> Strban (n 18).

<sup>40</sup> Zucca (n 18).

<sup>41</sup> Zucca (n 18).

exchange information (1) on the status of implementation of the Directive, (2) on linked data collection exercise using NCPs, (3) on project results in relevant areas such as patients' rights or payment of cross-border care and (4) discuss ways and areas for cooperation of NCPs. Regarding the latter, the first meeting in February 2014 focussed on an exchange of experiences regarding the design and content of NCP websites and exchange of invoices between providers and payers in different Member States.<sup>42</sup> The Internal Market Information System (IMI) was presented as a possible tool to collaborate and clarify the status of healthcare providers across border.<sup>43</sup> In addition, future areas of cooperation were discussed. While the EC stressed the obligation to cooperate on safety and quality standards and guidelines, the meeting concluded by intending to work further together on invoices and how to communicate best towards citizens.

A subsequent coordination meeting of NCP representatives in December 2015<sup>44</sup> followed up on the intention to collaborate regarding information provision towards patients. Participants wished to work together to establish a common Frequently Asked Questions for NCP websites while additional areas for cooperation on informational texts and documents were suggested. An extended use of the IMI system was proposed to cover exchanges regarding questions on patients' rights in different Member States as well.<sup>45</sup> The next meeting of the Cross-border Healthcare expert group<sup>46</sup> in March 2016 proposed, as a new measure, a feedback exercise on the NCP system towards provision of patient information which was welcomed by participants. During a conference on the Directive in October 2016, where 18 representatives of NCPs participated, it was emphasised (1) that the number of applications to NCP offices are comparatively few, (2) that NCPs are still occupied to update and improve information material and communication and (3) that the Commission was encouraged to facilitate the exchange between NCPs even further.<sup>47</sup> During the Cross-Border Healthcare Expert Group Meeting on the same day the results of the data collection exercise for 2015 were discussed in the context of the status of implementation of the Directive (see Section 4).<sup>48</sup> The meeting in May 2017 addressed the findings and work plans of a number of Commission financed studies regarding cross-border cooperation that are connected to the work of the NCPs. These studies focus on "enhancing information provision to patients" in cross border care inter alia by developing training material and a toolbox aimed at NCP staff; an analysis of "access to healthcare in cross-border situations" addressing flows, form, means and content of information<sup>49</sup> and mapping "existing initiatives for cooperation in cross-border regions". Moreover, the possibility to inform

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<sup>42</sup> European Commission, *Coordination Meeting of National Contact Points (NCPs) - Agenda* (European Commission 2014).

<sup>43</sup> European Commission, *Summary record of the 1st meeting of the National Contact Points Coordinators* (European Commission 2014).

<sup>44</sup> European Commission, *Coordination Meeting of Representatives of National Contact Points 2 December 2015 Agenda* (European Commission 2015).

<sup>45</sup> European Commission, *Minutes of Meeting - Coordination Meeting of Representatives of National Contact Points 2 December 2015* (European Commission 2015).

<sup>46</sup> The meeting of representatives of NCP is a sub-group to the Cross-border Healthcare expert group.

<sup>47</sup> European Commission, *Report of the Conference "Towards amplified awareness of EU rights to cross-border care"*, 24 October 2016 Brussels (European Commission 2016).

<sup>48</sup> European Commission, *Cross-Border Healthcare Expert Group Meeting, Draft Agenda (Version 2)* 24 October 2016 (European Commission 2016).

<sup>49</sup> Strban (n 18).

about treatment for rare diseases via NCP websites was discussed in the context of the launched European Reference Networks (ERNs).<sup>50</sup>

Beyond those immediate areas for cooperation, addressed in the meetings, new areas for cooperation among NCP are likely to emerge. The Directive has endorsed cooperation on the recognition of prescriptions (Article 11), European Reference Networks (ERNs, Article 12), Rare Diseases (Article 13), e-health (Article 14) and health technology assessment (EUnetHTA, Article 15) in chapter IV. In these areas NCPs offices and website will likely play a role in communicating to citizens and cooperating with professionals. For example, low recognition (56% overall) of foreign medical prescriptions in five Member States indicates that pharmacies are an important stakeholder in ensuring cross-border treatments<sup>51</sup> NCPs should reach out to. In addition, discharge summaries seem to be another important vehicle to ensure continuity of care.<sup>52</sup> NCPs can play a role in providing insides into practical obstacles and useful information that prescriptions and discharge summaries should contain. Likewise, in the course of establishing European Reference Networks on highly specialised treatments, NCPs will need to have an understanding how ERNs and national models and systems of highly specialised care are organised to be able to reach out to national centres for excellence and provide respective information on their websites and on individual request. This will include aligning information provision between NCPs and the Orphanet website<sup>53</sup> in the area of rare diseases. Thus, cooperation among NCPs is likely to intensify to contribute to the smooth operation of cross-border care - not without challenges - and the collaboration of domestic health systems in the EU.

## 6. Conclusions

At first sight, NCPs are designed to be the information portal for own citizens and patients from other Member States seeking care abroad – benefiting comparably few people. However, NCPs could potentially benefit domestic patients in general as well by pooling and presenting information in an understandable way about patients’ rights in the home country’s health system. This information is currently scattered and most often not presented in a patient friendly way. Moving beyond the function of an information portal to patients, NCPs could act as the communication hub for professionals and decision makers to provide detailed insights into national practices across the border. To facilitate a fruitful cooperation could benefit the smooth operation of cross-border care and domestic health systems in the EU in general. However, the current rather minimalistic implementation of the NCPs in many countries is not facilitating purposes beyond cross-border care.

Finally, law and new governance modes are linked in the implementation of the Directive to help enlarging the health system agenda of the EU, as well<sup>54</sup>. The contour of this agenda is

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<sup>50</sup> European Commission (n 38).

<sup>51</sup> Lorena San Miguel and others, ‘Obstacles to the recognition of medical prescriptions issued in one EU country and presented in another’ (2013) 23 *European Journal of Public Health* 972.

<sup>52</sup> Ketivan Glonti and others, ‘European health professionals’ experience of cross-border care through the lens of three common conditions’ (2015) 7 *European Journal of Integrative Medicine* 29.

<sup>53</sup> ORPHANET – The portal for rare diseases and orphan drugs [www.orpha.net](http://www.orpha.net).

<sup>54</sup> Tamara K Hervey and Bart Vanhercke, ‘Health care and the EU: the law and policy patchwork’ in Mossialos and others (eds), *Health Systems Governance in Europe - The Role of European Union Law and Policy* (Cambridge University Press 2010).

not legally prescribed, but the Directive instigates an array of objectives and principles in which these rules are to be developed between national and EU officials, experts and other stakeholders.<sup>55</sup> The Commission – invited by means of technical support and expertise – will keep alive and potentially advance cooperation as the examples of Commission actions in this analysis indicate. It may lead to a further “formalisation of [...] cooperation”<sup>56</sup> at EU level in areas relevant to cross-border care and health systems in general.

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<sup>55</sup> Charles F Sabel and Jonathan Zeitlin, ‘Learning from Difference: The New Architecture of Experimentalist Governance in the EU’ (2008) 14 *European Law Journal* 271.

<sup>56</sup> Sauter (n 23).

# Chapter VII e-Health challenges under EU law\*

André den Exter

## 1. Introduction

One of these latest innovations in healthcare concerns electronic health, also known as e-Health. It is expected that electronic communication and exchange of medical data will change the course of medicine in many ways. But in what direction and how does it relate to law, European Union (EU) law in particular?

Hereafter, the main legal challenges of e-Health, and various e-Health applications will be explored, answering the question of what is going to happen from a legal perspective. For obvious reasons, the focus has been on the human rights perspective, how the use of information and communications technologies in healthcare will impact human rights.<sup>1</sup> But given the border-crossing potential of exchanging electronic information, e-Health services fall under the scope of EU law, triggering internal market and competition rules, as well as EU Charter rights. Therefore, this chapter will explain the EU perspective, focusing on how EU internal market law affects national e-Health policies, by way of several e-Health applications, such as cross-border access to electronic patient records, and deployment of so-called medical and lifestyle 'apps'. Another application, the use of electronic prescriptions will be discussed more extensively one of the next chapters. In the following sections, the 'digital single health market' will be addressed, explaining the main legal consequences.<sup>2</sup> But first, how to define the e-Health concept?

## 2. Defining e-Health

Basically, eHealth reflects the use of Internet medicine, locally as well as at a distance, but it encompasses more than only the use of the Internet. Generally speaking, it covers any electronic exchange of health-related data collected or analysed through an electronic connectivity for improving efficiency and effectiveness of healthcare delivery.<sup>3</sup> According to

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\*A previous version was published as 'eHealth law: the final frontier?' in EU Health Law and Policy, TK Hervey, CA Young, LE Bishop (eds), Edward Elgar Publishing 2017, 242-263.

<sup>1</sup> For instance, NP Terry, 'Privacy and the Health Information Domain: Properties, Models and Unintended Results' (2003) 3 *European Journal of Health Law* 223; E Rynning, 'Public Trust and Privacy in Shared Electronic Health Records' (2007) 2 *European Journal of Health Law* 105; AL McGuire and others, 'Confidentiality, privacy, and security of genetic and genomic test information in electronic health records: points to consider' (2008) 10 *Genetics in Medicine* 495; P Kierkegaard, 'Electronic health record: Wiring Europe's healthcare' (2011) 5 *Computer Law & Security Review* 503.

<sup>2</sup> European Commission, 'Digital Single Market Strategy for Europe' (Communication) COM (2015) 192 final

<sup>3</sup> JP Harrison and others, 'The Role of E-Health in the Changing Health Care Environment' (2006) 6 *Nursing Economics* 283.

the World Health Organisation (WHO) eHealth is ‘the cost-effective and secure use of information and communications technologies in support of health and health-related field, including health care services, health surveillance, health literature, and health education, knowledge and research’,<sup>4</sup> meaning that eHealth applications are not restricted to individual healthcare only.<sup>5</sup> The European Commission defines eHealth very generally as: ‘the use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills’.<sup>6</sup> This definition is relatively detailed, emphasising the patient-healthcare professional interaction, or interactions between healthcare providers, or even patient-to-patients interactions (patients’ groups).

What these definitions have in common are their goals: to strengthen healthcare access, improving efficiency and quality of health services, and administrative cost-reduction in healthcare delivery.<sup>7</sup> More goals have been formulated, such as making healthcare access more equitable, enhancing empowerment of patients, educating patients and improving the quality of life.<sup>8</sup> Indeed, eHealth is a promising innovation. Also, the range of eHealth applications seems endless. Innovative eHealth examples include the picture archiving and communication systems (PACS) containing patient radiology reports and images such as hospital-based CT scans, ultrasounds, MRIs, mammograms and x-rays. Healthcare providers can share images and reports securely with other providers.

More common is the use of electronic decision support systems (DSS), an application to aid physicians in clinical decision-making (diagnosis, treatment options) based on the patient’s medical history. Another initiative is the electronic prescribing system (ePs), which enables general physicians to transfer prescriptions electronically to the pharmacy. The use of intelligent ePs can increase the safety (reduce improperly prescribed medications) and efficiency of the prescribing process. Ultimately, these applications will be integrated into the patient’s electronic health record (EHR), available for physicians at local, regional, and (inter)national level, although this remains complicated.<sup>9</sup>

But this is not the complete picture. The latest gadgets are mobile health (m-Health) applications. These health apps are software applications run on a tablet or smartphone designed to deliver health-related services, such as Apple’s ‘Health Kit’, collecting and sharing health and fitness data (heart rate, calories burned, blood sugar, cholesterol, etc.).

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<sup>4</sup> WHO, ‘eHealth’ Fifty-eighth World Health Assembly (May 2005), Resolution WHA58.28.

<sup>5</sup> E.g., the use of eHealth technologies in the surveillance of public health events, see section 3.6 on ePublic health.

<sup>6</sup> European Commission, ‘eHealth Action Plan 2012–2020 – Innovative healthcare for the 21st century’ COM (2012) 736 final, 3.

<sup>7</sup> In times of austerity, eHealth technologies may even help reducing the gap in health inequalities. T Clemens and others, ‘Supporting health systems in Europe: added value of EU actions?’ (2014) 1 *Health Economics, Policy and Law* 58.

<sup>8</sup> G Eysenbach, ‘What is eHealth?’ (2001) 3(2) *Journal of Medical Internet Research* 2; WHO, ‘eHealth Report by the Secretariat’ Executive Board 115th session (December 2004), EB115/39, 1.

<sup>9</sup> An overview of the national laws on EHRs in EU Member States and their interaction with the provision of cross-border e-health services is provided in: Milieu and Time.lex, ‘Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services: Final report and recommendations’ (July 2014) <[http://ec.europa.eu/health/ehealth/projects/nationallaws\\_electronichealthrecords\\_en.htm](http://ec.europa.eu/health/ehealth/projects/nationallaws_electronichealthrecords_en.htm)>.

Although the focus is more on pseudo-health than genuine healthcare, this is rapidly changing.<sup>10</sup> More serious apps are targeting patients (home and remote monitoring) and health professionals (clinician-driven bedside tools, diagnostics and decision support apps, etc.). As mobile health applications become more user-friendly and reliable, they will play a key role in the provision of healthcare, and not only in remote areas.

### 3. e-Health applications under the EU legal framework

But the complex legal environment in which e/m-Health takes place is also challenging. For instance, legal concerns address human rights aspects such as privacy, confidentiality, access to high-quality healthcare services, risk management and reimbursement issues, while the border-crossing dimension of eHealth applications further complicates the realisation of information and communications technologies in healthcare. Buying eHealth services (international outsourcing tele-radiology, tele-consultations and remote monitoring) and goods (Internet medicines) are no longer hypothetical occurrences, although the scale is unknown.<sup>11</sup> Particularly international offshoring and outsourcing – subcontracting foreign providers for providing health services – are raising controversial questions on legal and policy issues such as securing information privacy, contractual requirements and informed consent, since it happens ‘behind the scenes’, with patients unaware that certain services will be delivered by foreign providers.<sup>12</sup> Buying and selling medicines over the Internet raises several national and European legal issues.

Closely related is the phenomenon of patient mobility, when patients are in search of medical care in another EU Member State, or even outside the EU. This emanates a trend of cross-border access of electronic health records or patient summaries, the practice of teleconsults and surgery, and use of online pharmacies. In the EU, this has been facilitated by the Patients’ Rights Directive 2011/24/EU and the EU eHealth Action Plan 2012–2020.<sup>13</sup>

In addition, the use of mobile health apps brings forth important legal questions in the field of medical devices and liability issues covered by existing EU law. Hereafter, three case studies have been selected, exploring the main legal challenges from an EU perspective posed by several eHealth applications. The examples selected (cross-border access of the

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<sup>10</sup> So far health apps like Apple’s Health Kit were ‘of little use’ for medical professionals. ‘To date they have been focused on low-lying fruit such as fitness tracking and not focused on the big issues of management of disease which consumes the bulk of the cost of the healthcare system and resources. It is also the area that affects people most,’ interview G Margelis, ‘Health apps ‘useless’ says health app expert Sydney Morning Herald (Sydney, 9 October 2014), though this is rapidly changing. More serious apps are ‘HealthMap’, tracking the spread of diseases such as H1N1, Ebola; several diabetes apps, checking the patient’s blood glucose level, etc.

<sup>11</sup> N Burute and B Jankharia, ‘Teleradiology: The Indian perspective’, (2009) 1 Indian Journal of Radiology and Imaging 16; SN Singh and RM Wachter, ‘Perspectives on Medical Outsourcing and Telemedicine – Rough Edges in a Flat World?’ (2008) 358(15) The New England Journal of Medicine 1622.

<sup>12</sup> Sing and Wachter (n 11) 1625.

<sup>13</sup> European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45 (Patients’ Rights Directive), Article 14; COM (2012) 736 final (n 6).

patient's electronic health records, the rapidly growing use of mobile health apps, and ePublic health technologies) although far from complete, illustrate the complexity of the EU eHealth policy domain.

### 3.1 Cross-border Access to EHRs?

On 25 October 2013 a new era in the patient mobility debate began when the Patients' Rights Directive came into force.<sup>14</sup> This legal document allows EU citizens to seek healthcare in other Member States. The Directive is the result of a number of rulings by the Court of Justice of the EU on reimbursement claims for medical treatment abroad based on the principles of free movement.<sup>15</sup> The scope of the Directive is not restricted to healthcare services requiring the physical presence of the health provider. Article 7(7) explicitly mentions the reimbursement of healthcare provided by electronic means, i.e. all kind of healthcare services provided over the Internet. This applies provided that eHealth services are covered by the healthcare entitlements in the Member State of affiliation.

Besides the mutual recognition of prescriptions dispensed in another Member State (Article 11), the Directive also facilitates co-operation initiatives on eHealth. Reading the patient's history in his/her electronic health record or patient's summary record (country of origin) allows the physician in the Member State of treatment to continue medical treatment without duplicating all kinds of – expensive – diagnostic tests, treatment methods and thus to ensure continuity of care, increase efficiency and save costs. Facilitating cross-border access of electronic health records/patient summary records by both the treating physician and the patient, is therefore a key element in realising cross-border care.

Numerous obstacles, some of which are legal, to this exchange of information hamper the deployment of eHealth on a large scale.<sup>16</sup> To overcome these obstacles, Article 14(1) promotes and facilitates the cooperation and the exchange of information among Member States by establishing an eHealth network of national authorities.<sup>17</sup> Aimed at solving the missing interoperability of electronic health systems and limited data exchange,<sup>18</sup> the eHealth network of national authorities formulated guidelines on the standardisation of patient summary records to be exchanged across borders.<sup>19</sup> At the same time, this voluntary

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<sup>14</sup> Patients' Rights Directive.

<sup>15</sup> For an in-depth analysis on reimbursement issues see Chapter 5 in this book.

<sup>16</sup> E.g., lack of data exchange due to lacking interoperability of cross-border e-health services, lack of clarity in legal norms on data, protection, liability and reimbursement issues, etc.

<sup>17</sup> Commission Implementing Decision 2011/890/EU of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth [2011] OJ L344/48. This 'Article 14 network' elaborates on the European eHealth Governance Initiative (eHGI), supporting cooperation between Member States at political governance levels and eHealth stakeholders.

<sup>18</sup> Interoperability means the ability of two or more electronic health record systems to exchange both computer interpretable data and human interpretable information and knowledge. COM (2012) 736 final (n 6) 6.

<sup>19</sup> A Patient Summary dataset comprises patient administrative data and patient clinical data accessible for emergency or unplanned care situations abroad. See eHealth Network, 'Guidelines on minimum/non-



network will support Member States in developing common identification (who are you) and authentication (proof that you are who you claim to be) measures (eID) to facilitate transferability of data in cross-border healthcare (Article 14(2)(c)) to enhance the security on health information exchange. According to the European Commission, these measures should contribute 'to reap all the benefits from a fully mature and interoperable eHealth system in Europe'.<sup>20</sup>

But standardisation alone is insufficient to remove all barriers to cross-border data exchange. The legal requirement of cross-border interoperability of national EHR laws or systems is largely absent in most Member States but crucial for the cooperation and cross-border exchange of health data.<sup>21</sup>

New questions will arise from the border-crossing use of eHealth services, based on the diversity in national reimbursement rules, hampering the use of cross-border eHealth services. One example is when national law renders in-person examination conditional for reimbursement, therefore prohibiting remote 'first time encounters' with the patient.<sup>22</sup> The face-to-face requirement for the initial contact is based on the belief that the first doctor-patient contact requires a physical consultation and/or examination of the patient's condition, not conducted by phone or electronically. Moreover, it is intended to be a tool for reducing fraud, waste and abuse by assuring that physicians have actually met with potential patients to ascertain their specific care needs. Reading Article 7(7), 'member states of affiliation may impose patients seeking cross-border care ... the same conditions, criteria of eligibility and regulatory and administrative formalities ... as it would impose if this healthcare were provided in its territory', the face-to-face first encounter can be considered a regulatory or administrative measure, justified as long as it is not an unnecessarily stringent requirement impeding cross-border teleconsultations.

Facilitating cross-border eHealth services may also create novel inequalities due to poor digital literacy skills of vulnerable groups.<sup>23</sup> But disparities in health information by vulnerable groups is a phenomenon that cannot be solved by regulatory intervention, more acceptable solutions will focus on the role of health professionals and IT developers in educating 'not online' groups how to utilise the Internet.

Another issue concerns the licensing and registration of health professionals performing cross-border eHealth services, such as consultations or monitoring services. By national law, most health professions are considered regulated professions, therefore specific conditions are set for performing their profession, e.g., registration at the health professions' association or council, subject to disciplinary law, etc. The requirements differ by country.<sup>24</sup>

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exhaustive patient summary data set for electronic exchange in accordance with the Cross-Border Directive 2011/24' Release 1 (19 November 2013).

<sup>20</sup> COM (2012) 736 final (n 6) 3.

<sup>21</sup> Milieu and Time.lex (n 9) 55.

<sup>22</sup> This is the case in several countries, such as the Netherlands, Germany and Austria.

<sup>23</sup> Health literacy is the capacity of an individual to gain access to the Internet to find and understand the health information obtained.

<sup>24</sup> For more details, see AM Duguet and N De Grove-Valdeyron, 'Regulation of health professions in Europe' in A den Exter (ed), *European Health Law* (Maklu 2017) 649-668.

Performing their profession in another country means that the health professional should comply with the provisions set by the host Member State. In case of telemonitoring or consultations, however, the physician does not physically move to another EU Member State, meaning that the Directive regulating the recognition of diplomas is not applicable.<sup>25</sup> Instead, the eCommerce Directive is applicable, which means that the rules of the country where the health provider is established ('country of origin') are applicable.<sup>26</sup> In case of licensing and registration it is assumed, therefore, that the health professional already complies with the national requirements (state of establishment or country of origin). This also applies to the treatment, as the Patients' Rights Directive requires cross-border treatment to be provided according to the rules of the country of treatment, which, in the case of telemedicine, is defined as the country 'where the healthcare provider is established'.<sup>27</sup> Ultimately, this means that the legal framework of both Directives applies (eCommerce and Patients' Rights Directive).<sup>28</sup>

What remains are new liability issues raised by international legal conflicts on jurisdiction and choice of law. The Patients' Rights Directive itself does not provide a comprehensive set of rules dealing with eHealth liability issues. Instead, in case of defective products, the product liability regime is applicable. Alternatively, border-crossing liability issues on eHealth services are covered by the 'Brussels Regime' (e.g., the [Recast] Brussels I Regulation, Rome I and II Regulations), meaning that legal proceedings can, as a general principle, be initiated only in the Member State where the defendant has his domicile (Article 4(1) Recast Regulation).<sup>29</sup> The applicable law will be decided by Rome I (in case of contractual cases), meaning that eHealth service contracts 'shall be governed by the law of the country where the service provider has his habitual residence' (Article 4 (1)(b), when not explicitly expressed),<sup>30</sup> and as a fall-back option – the 'law of the country with which [the contract] is most closely connected' (Article 4(4) Rome I). But in matters of consumer contracts a contract 'shall be governed by the law of the country where the

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<sup>25</sup> European Parliament and Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications [2005] OJ L255/22, Article 5(2) expressly stated that: 'The provisions of this title shall only apply where the service provider *moves* to the territory of the host Member State to pursue, on a temporary and occasional basis, the profession referred to in paragraph 1.'

<sup>26</sup> E.g., the European Parliament and Council Directive 2001/31/EC of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market [2000] OJ L178/1 (eCommerce Directive), Article 2(a) defines the legal framework for providing remote e-services (in this case provided by health professionals) for remuneration, at the individual request. Nonetheless, Member States may restrict eCommerce services for reasons of public health, Article 3(4)(a)(i).

<sup>27</sup> Patients' Rights Directive, Article 4(2).

<sup>28</sup> Further details, see Commission, 'The applicability of the existing EU legal framework to telemedicine services' (Staff Working Document) SWD (2012) 414 final.

<sup>29</sup> Council Regulation (EC) 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters [2001] OJ L12/1 (Brussels I Regulation) as amended by the recast European Parliament and Council Regulation (EU) 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters [2012] OJ L351/1 (Brussels II Regulation); European Parliament and Council Regulation (EC) 593/2008 of 17 June 2008 on the law applicable to contractual obligations [2008] OJ L177/6 (Rome I); European Parliament and Council Regulation (EC) 864/2007 of 11 July 2007 on the law applicable to non-contractual obligations [2007] OJ L199/40 (Rome II).

<sup>30</sup> Similar as under the eCommerce Directive (n 26), where e-services providers are – in principle – subject to the law of the Member State in which the service provider is established.

consumer/patient has his domicile'. Meaning, that in case of cross-border teleconsultation disputes, legal proceedings will start in the country, and be governed by the law of that country where the patient normally lives.

Rome II deals with non-contractual obligations, i.e. primarily tort issues. In case of tort in an EU country, the law applicable 'shall be the law of the country in which the damage occurs irrespective of the country in which the event giving rise to the damage occurred and irrespective of the country or countries in which the indirect consequences of that event occur' (Article 4(1) Rome II). However, generally speaking, cross-border teleconsultation disputes have a contractual basis and, therefore, are regulated by Rome I.<sup>31</sup>

Questions arise when teleconsultation disputes have a non-EU dimension. For instance, in case of a transatlantic teleconsultation provided by a US physician to a patient living in an EU Member State. Prior to 15 January 2015, when the defendant would have his domicile outside the EU, the Brussels Regulation was generally not applicable. But the Recast Regulation brings consumer contract disputes under the Brussels rules of jurisdiction (Article 6(1)), i.e., ruling according to the law of the country where the patient lives (i.e., has his habitual residence).

### 3.2 Mobile health applications

Mobile health, or more commonly mHealth, is a component of eHealth and defined as 'the use of wireless devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices to support clinical practice or public health',<sup>32</sup> as well as health and lifestyle applications or 'apps' connected to phones.<sup>33</sup> mHealth applications have received increased attention due to the worldwide growth of mobile applications.

Roughly estimated, there are about 97,000 health apps available (2012), and the prediction is that in 2017, more than 1.7 billion people will have downloaded health apps on their smartphones or tablets.<sup>34</sup> Mobile medical applications focus on communications in the clinical context between the individual patient and health professionals, e.g., appointment reminders, access to EHRs, monitoring, treatment compliance, consultations, etc. But mobile platforms can also be used for educational purposes for health professionals, whereas public health applications can be used for disease and epidemic outbreak

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<sup>31</sup> The same counts for a so-called second opinion, when a patient requests another physician for his professional opinion concerning a diagnosis or suggested treatment option. Generally speaking, such a second opinion has a contractual basis. This might be different when the second opinion doctor is hired by the treating physician.

<sup>32</sup> WHO, *mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Vol 3* (WHO 2011) 6.

<sup>33</sup> European Commission, 'Green Paper on mobile Health (mHealth)' COM (2014) 219 final, 3.

<sup>34</sup> R-G Jahns and P Houck, 'The mobile health global market report 2013–2017: the commercialisation of mHealth apps (vol. 3)' (Research2Guidance 2013).

surveillance, thus facilitating a tracking method for infectious diseases.<sup>35</sup> The unprecedented circulation and use of mHealth applications seems endless but is not without risks. To cope with these risks, regulating mHealth applications is, therefore, crucial. Legal issues address a number of topics such as privacy and liability issues, whether or not regulated at EU level.

An emerging question is how to safeguard users from unnecessary risks; is it safe to use health apps in a clinical setting? Safety concerns trigger the question whether health apps can be classified as medical devices under the Medical Devices Directive (MDD).<sup>36</sup>

When confirmed, these apps should comply with the Directive's safety requirements, such as CE marking with the objective of protecting patients with regard to the use of medical devices, as well as the obligation of Member States to guarantee market access of such devices within the Internal Market. Article 1(2)(a) MDD defines a medical device as:

any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means..

From the above description it may be concluded that health apps meant as decision support tools for diagnosis or treatment (monitoring blood pressure, glucose level, etc.), or to calculate the dosage of medication (insulin), will meet the definition, therefore should comply with the Directive's safety and registration requirements. In case of wellness or fitness apps, where the medical purpose seems absent, they would, therefore, be beyond the scope of the medical devices directives. But the difference between wellness and medical apps becomes blurred when patient care becomes more integrated, i.e. when preventive and self-monitoring activities (fitness apps) are integrated in a treatment regime. In each case, the 'medical purpose' of new apps needs to be examined as ambiguity in the classification may expose patients to unsafe products.<sup>37</sup> In case of harm, the physician may face liability for using such an 'unregistered app'.

Another concern related to the use of health apps addresses the confidentiality of health data collected by health and lifestyle apps, and are often stored 'in the cloud'. Taking into account that combining several apps provides (commercially) valuable information about one's health status, there is a need to protect consumers from unauthorised use, and processing of such information by health providers as well as by third parties (health industry, insurance companies, employers, etc.). This is even more important when the

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<sup>35</sup> AJ Barton, 'The regulation of mobile health applications' (2012) 10 *BMC Medicine* 46 AJ Barton, 'The regulation of mobile health applications' (2012) 10 *BMC Medicine* 46.

<sup>36</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L169/1.

<sup>37</sup> Also the proposed Regulation on Medical Devices does not bring clarity on the 'intended medical use'.

processing of ‘big health data’ enables profiling, i.e. using data to predict personal (health) aspects, behaviour or interests of individuals, creating privacy risks for data subjects.

Under the previous Data Protection Directive (95/46/EC) the processing of health data was prohibited but it allowed for certain derogations, subject to strict requirements.<sup>38</sup> What is considered as health data seems evident, although a comprehensive definition seems to be missing. Instead, under the new Data Protection Regulation (GDPR), it includes ‘personal data which relates to the physical or mental health of an individual’,<sup>39</sup> while it remains unclear whether and to what extent lifestyle and well-being information collected by health apps constitutes health data.

Not depriving individuals from adequate protection, in its Opinion, the European Data Protection Supervisor, however, suggests a broad notion of health data.<sup>40</sup> In case of explicit consent by the data subject, as well as in the context of the doctor-patient treatment relationship, such processing is justified (Article 9(2)(a), (h) GDPR).<sup>41</sup> At the same time, the General Data Protection Regulation protects the patient by providing him the right to access of data including the right to rectify and erasure (‘right to be forgotten’).<sup>42</sup> Moreover, the controller (e.g., the physician or mHealth platform) must provide sufficient guarantees to secure that data cannot get lost or be hacked by cybercriminals (Article 32 GDPR).

Using wearables and health apps in the treatment setting, storage and exchange of medical information among health professionals are allowed as long as (mobile) health professionals abide by the rules of professional secrecy. After all, handing information to third parties could expose the treating physician to certain risks when these persons are not bound by national professional confidentiality rules. In such cases, the deployment of health information to third persons (e.g., technical staff) does not fall under the treatment exemption and, therefore, requires explicit consent. Whether this requirement will hinder the widespread use of mHealth applications among health professionals, thereby causing inefficiencies of care, is doubtful.<sup>43</sup>

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<sup>38</sup> European Parliament and Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L381/321 (Data Protection Directive). Data processed in the context of mHealth are considered personal data, therefore fall under the Directive’s scope. Health data processing by mHealth apps are generally considered sensitive data, falling under the special regime (Article 8). This might be different from lifestyle and well-being data, see also European Data Protection Supervisor, ‘Opinion 1/2015 Mobile Health: Reconciling technological innovation with data protection’ (May 2015) 5.

<sup>39</sup> European Parliament and Council Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1 (GDPR) Article 4(15).

<sup>40</sup> European Data Protection Supervisor (n 55) 6; similarly see Article 29 Working Party, ‘Opinion 8/2014 on the Recent Developments on the Internet of Things’ (September 2014) 17.

<sup>41</sup> Alternative exemptions are: processing information for public health interests, such as protecting against serious cross-border threats or epidemiological research purposes (Article 9(2)(i), (j) GDPR).

<sup>42</sup> Articles 15–17 GDPR.

<sup>43</sup> Different in: P Quin and others, ‘The Data Protection and Medical Device Frameworks – Obstacles to the Deployment of mHealth in Europe’ (2013) 2 *European Journal of Health Law* 185, 199–200, arguing that ‘express consent is requested each time before data is shared, which limit rapid and efficient consultation with

The mHealth data collected in the treatment context can be extremely valuable for other medical and non-medical purposes, and refers to the 'secondary use' of health data. Under the previous Directive the re-use of (mHealth) data for public health monitoring, and surveillance of health threats purposes is justified and excluded from explicit consent.<sup>44</sup> A similar exemption can be found in the new Regulation (Article 9(2)(h), (i)). But for purposes other than in the healthcare setting, such as for medical scientific research purposes, the European Parliament introduced the data subject's explicit informed consent for processing mHealth data (Article 89).<sup>45</sup> Such a strict consent clause would seriously hamper scientific research since health professionals cannot rely on the general consent provided by the patient in the treatment setting.<sup>46</sup> Therefore, the new Regulation covers a more researcher-friendly text, safeguarding the processing of mHealth data for scientific purposes, similar to under the previous Directive's regime (Article 89 GDPR).

In accordance with the Regulation's requirements, mHealth data can be transferred to health providers in other Member States.<sup>47</sup> In case of non-EU countries, such processed mHealth data may not, as a rule, be transferred outside the EU when there is 'no adequate level of protection guaranteed' (Article 45(1), (3)).<sup>48</sup> But what does an adequate level of protection mean? According to the European Data Protection Supervisor, it means that processors (or controllers) should perform an adequacy risk assessment, analysing the level of protection provided by the recipient of the data, taking into account 'all circumstances surrounding a data transfer operation'.<sup>49</sup> In practice, however, it is not always feasible for the controller to perform such a substantive test, meaning that the level of protection is assumed inadequate.<sup>50</sup> However, transfers without adequate safeguards can be justified in exceptional circumstances, provided that all data subjects have given 'unambiguous consent', given freely and informed.<sup>51</sup> In the global setting of mHealth, the patient's general consent when downloading certain apps is then considered insufficient for such

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specialist expertise found elsewhere in Europe'. However, interpreting 'treatment relationship' less strict, such express consent is not required.

<sup>44</sup> Data Protection Directive, Article 8(2)(a) and Recital 34 authorising Member States 'to derogate from the prohibition on processing sensitive categories of data where important reasons of public interest' so justify in areas such as public health...[and] scientific research...'

<sup>45</sup> Which is different from the Data Protection Directive, Article 11 (2). Controllers are not required to provide notices to individuals where the data is processed for scientific research and the provision of the notice would be impossible or would involve a disproportionate effort, provided that data are processed fairly and lawfully, Article 6(1)(a).

<sup>46</sup> See, for instance, the European Data in Health Research Alliance <[www.datasaveslives.eu/](http://www.datasaveslives.eu/)> See, for instance, the European Data in Health Research Alliance <[www.datasaveslives.eu/](http://www.datasaveslives.eu/)>.

<sup>47</sup> For a definition of what constitutes a 'transfer', see Case C-101/01 *Lindqvist* ECLI:EU:C:2003:596, [2003] ECR I-12971.

<sup>48</sup> GDPR, Article 45. The Commission's decision on the adequacy of third countries' data protection law (known as the Safe Harbour decision) can be challenged by the national Data Protection Authority/CJEU, see Case C-362/14 *Max Schrems v Data Protection Commissioner* ECLI:EU:C:2015:650.

<sup>49</sup> For example: the nature of the data, the purpose and duration of the proposed processing operation, European Data Protection Supervisor, 'The transfer of personal data to third countries and international organisations by EU institutions and bodies' (Position paper, July 2014) 10–11.

<sup>50</sup> *ibid* 13.

<sup>51</sup> GDPR, Article 49(1)(a).

international transfers. Sharing and transferring mHealth data with health providers outside the EU remains, therefore, not without risks.

Accuracy and reliability are a major concern when using medical apps in the healthcare setting, especially when physicians have to make critical decisions based on information from these apps. Despite the increasing number of apps available on the market, mostly downloaded from a website, there is little evidence that the accuracy of health apps is indeed addressed.<sup>52</sup> For example, certain apps designed for opioid dosage conversion or melanoma detection demonstrate dangerously poor accuracy, while a number of other medical apps do not follow evidence-based guidelines.<sup>53</sup> Strict compliance with product safety requirements (e.g., the medical devices framework and general product safety rules under Directive 2001/95/EC) is, therefore, required.<sup>54</sup>

Risks inherent to health apps may be reduced through appropriate regulation but cannot prevent inaccurate apps from entering the market which, consequently, might endanger patient safety. In the case of a defective product (software or device), this will trigger the Product Liability Directive, introducing a generic system of liability for defective products, covering most products. The Directive harmonises the issues it covers, such as 'defect', 'product', and 'producer'.<sup>55</sup> Relevant questions in the mHealth setting are: can mobile health applications be considered products under the Directive, who is the producer of medical apps, who is using the app: the patient or health professional?

In the case of a defective health app, for instance, calculating an incorrect dosage of insulin for the patient, the app producer remains liable for damages caused by the defective product (introducing a so-called 'no-fault' or 'strict liability' regime).<sup>56</sup> So far, it is assumed that the producer is the one who manufactured the device. In the mHealth setting, it is the

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<sup>52</sup> TL Lewis and JC Wyatt, 'mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use' (2014) 9 *Journal of Medical Internet Research* e210 DOI: 10.2196/jmir.3133 <[www.jmir.org/2014/9/e210/](http://www.jmir.org/2014/9/e210/)>; 'Lacking regulation, many medical apps questionable at best' New England Center for Investigative Reporting, Boston University (Boston, 18 November 2012) <http://necir.org/2012/11/18/medicap-apps>.

<sup>53</sup> F Haffey, RR Brady and S Maxwell, 'A comparison of the reliability of smartphone apps for opioid conversion' (2013) 2 *Drug Safety* 111; JA Wolf and others, 'Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection' (2014) 4 *JAMA Dermatology* 422, quoted by Lewis (n 52).

<sup>54</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L 210/29 (Product Liability Directive).

<sup>55</sup> For an extensive analysis, see M Tulibacka's chapter on 'Medical Product Liability' in A den Exter (n 24).

<sup>56</sup> Product Liability Directive, Article 6 provides that a product is defective if it does not provide the safety which the 'public at large' is entitled to expect, taking all the circumstances into account at the time the product was put into circulation, for instance the intended purpose, the objective characteristics and properties of the product in question and the specific requirements of the group of users for whom the product is intended. According to the MDF, Mobile health applications, both devices and – stand alone – software when.... 'intended to be used by the general public, ...' can be classified as medical devices.

manufacturer or app designer who introduced the product to the market, or (when the product was made outside the EU) the importer.<sup>57</sup>

Although the Directive does not differentiate between liabilities, in so-called manufacturing defects, the CJEU and national jurisprudential approach follows a strict liability, whereas applying the Directive to so-called ‘design’ and ‘failure to warn’ defects, courts fall back on fault-based liability.<sup>58</sup> But still, national courts assess the obligation to warn for unknown or unforeseeable defects differently, by which the concept of defect remains opaque.<sup>59</sup> The lack of consensus on interpreting the Directive’s defect is problematic as it directly affects the assessment of defectiveness for stand-alone software (apps) and mobile devices, causing divergence and legal uncertainty.

Novel challenges regarding mHealth liability arise as only a limited number of health apps bear a CE mark. CE review bodies, such as Health Inspectorates simply cannot cope with the large volume of marketed health apps, which increases the risk of unsafe products and, therefore, increases mHealth liabilities. This raises the question whether other review mechanisms should be considered (self-regulation, guidelines, etc.)

Apart from the wave of liabilities, we may expect new potential liabilities: intermediates when a physician gives incorrect advice in reliance on information from a device or app, or a health insurer promoting medical apps providing incorrect information. Second, when there are multiple potential defendants involved. The diversity of actors involved will complicate the mHealth liability debate even further. Finally, defective apps cause only one type of liability. One should not exclude the medical liability, liability for unauthorised disclosure information, fraud, etc. and mHealth applications.

### 3.3 ePublic Health Technologies

So far, the examples and relevant legal issues mentioned focus on the individual doctor-patient setting. But apart from the clinical focus, eHealth technologies have much to offer in the public health sphere, integrating eHealth technologies with population health. For instance, EHRs facilitate public health research since large EHR databases allow researchers to conduct observational studies for health purposes (study disease progress, health inequalities, spread of infectious diseases, chronic diseases, etc.).<sup>60</sup> Moreover, these ePublic

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<sup>57</sup> In reality it is even more complex as there are several parties involved in providing an application to the end user: the software developer, the owner of the platform on which health applications are available, the provider of the telecommunication network, the producer of the smartphone, and others.

<sup>58</sup> J Stapleton, ‘Liability for Drugs in the US and EU: Rhetoric and Reality’ (2007) 26 *Review of Litigation* 991, 1006, quoted by Tulibacka (n 55).

<sup>59</sup> *ibid.*

<sup>60</sup> More about the public health functionality of EHRs: R Kukafka and others, ‘Redesigning electronic health record systems to support public health’ (2007) 4 *Journal of Biomedical Informatics* 398. Although lacking interoperability and the inaccuracy of data deploying EHRs for public health purposes, threaten the reliability of public health research, see S Hoffman and A Podgurski, ‘Big Bad Data: Law, Public Health, and Biomedical Databases’ (2013) 41(suppl.1) *The Journal of Law, Medicine and Ethics* 56.



health surveillance systems may also change users' behaviour by monitoring and promoting health behaviour (sexual health promotion, immunisation uptake, general lifestyle issues).<sup>61</sup>

At EU level, an ePublic health surveillance system has been established by Decision 1082/2013/EU but restricted to categories of serious cross-border health threats, including contagious diseases (Article 2(1) scope). The European Centre for Disease Prevention and Control (ECDC) operates and coordinates such a network for epidemiologic surveillance. In addition, a 'rapid alert system' (Early Warning and Response System, EWRS) for notifying serious cross-border health threats was established, exchanging (health) information to protect public health.

Although the advantages of automated monitoring and sharing of population-based health information seem evident from the public health perspective, it also reveals major legal challenges, such as data protection (the 'secondary use' concept)<sup>62</sup> and confidentiality concerns. Under the Decision, the processing of personal data should comply with the Data Protection Directive (see also 2.3). In particular, the EWRS provides for the specific safeguards of exchange of personal data for tracing purposes (Article 16). With the new Regulation (GDPR), such processing and use of health data for public health, epidemiological purposes should comply with the principle of data minimisation and concepts of anonymisation techniques, legitimate interests, necessity and proportionality, and at the same time the rights granted to data subjects (transparency, rights of access, rectification erasure, and the right to be forgotten, Article 89 GDPR).

The recent Ebola outbreak emphasised the need for a global health surveillance network, collecting, disseminating and intervening in global surveillance, as stipulated under the International Health Regulations (WHO 2005).<sup>63</sup> The global exchange of web-based health information to respond and fight public health events and its impact on citizens' rights will then become even more complex when third countries are involved.

#### 4. Final remarks

Without doubt, the variety of e/mHealth applications may offer unprecedented possibilities for both clinical- and population-based purposes but raises major legal and regulatory issues (equal access, consent, privacy, confidentiality, reimbursement, safety, liability, jurisdiction, etc.) at national and EU level.

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<sup>61</sup> K Raychandhuri and P Ray, 'Privacy Challenges in the Use of eHealth Systems for Public Health Management' in J Rodrigues (ed), *Emerging Communication Technologies for E-health and Medicine* (Medical Information Science Reference 2012) 155-66; O Kulyk and others, 'Enhancing Wellbeing of Adolescents vis Persuasive eHealth Technology in ePublic Sexual Health' (Poster presented at DemAAL 2013 Conference), see <http://purl.utwente.nl/publications/89677>.

<sup>62</sup> I.e., sharing information to other persons that were not party to the original disclosure, for instance for scientific research purposes.

<sup>63</sup> J Gostin and others, 'The Ebola Epidemic. A Global Health Emergency' (2014) 11 *The Journal of the American Medical Association* 1095.

In the near future, it is foreseen that the emerging infiltration of new eHealth startups (call centres, remote and multidisciplinary consultations, telemonitoring options, etc.) with flexible contracted virtual doctors, allow patients to have instant access to healthcare, similar to the Uber app allowing instant access and online tracking for taxi services. Such a process, which is also called, the 'Uberisation' of healthcare, may further complicate the legal debate by initiating new eHealth disputes.

# Chapter VIII Mutual recognition of cross-border prescriptions at EU level: concerns and challenges

Joaquin Cayón-De Las Cuevas

## 1. General framework on mutual recognition of cross-border prescriptions

Policy makers have been traditionally more focused on cross-border medical services rather than on cross-border prescriptions. However, we must be aware that if the EU really wishes to ensure a successful cross-border healthcare environment, it is not only necessary to implement the possibility of receiving healthcare within another Member State but the reciprocal recognition of foreign prescriptions as well. Otherwise European patients' right to mobility will not be complete enough since they may also need to obtain their medicinal products abroad. This cross-border access to medicines is especially significant for vulnerable patients such as patients with chronic diseases travelling to another country, patients living in border regions or smaller Member States for whom filling out a cross-border prescription is a necessity, or patients with a rare disease, where the best expertise can be found across a border.<sup>1</sup> In this regard, one of the major challenges facing cross-border healthcare lies in ensuring that patients may obtain their legally prescribed medicines when the prescription has been issued in another Member State.

Mutual recognition of cross-border prescriptions aims to improve patients' access to medicines abroad.<sup>2</sup> For this reason, Article 11(1) of the 2011 Cross-Border Care Directive (hereinafter CBC Directive)<sup>3</sup> states as a general rule that, if a medicinal product is authorised to be marketed on their territory,<sup>4</sup> Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their

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<sup>1</sup> D van den Steen, 'Cross-Border Health Care: Common Rules on Medical Prescription when Travelling to another EU Country' (2013) 19(4) *Eurohealth* 28.

<sup>2</sup> MK Sheppard, 'The patient mobility directive and the mutual recognition of prescriptions in the EU: a cause for concern for patients and pharmacists alike?' (2016) 35 *Med Law* 37.

<sup>3</sup> Officially called Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45. Partially amended by Council Directive 2013/64/EU of 17 December 2013 amending Council Directives 91/271/EEC and 1999/74/EC, and Directives 2000/60/EC, 2006/7/EC, 2006/25/EC and 2011/24/EU of the European Parliament and of the Council, following the amendment of the status of Mayotte with regard to the European Union [2013] OJ L353/8.

<sup>4</sup> This authorization should be in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 (hereinafter 'Community code relating to medicinal products for human use directive') or Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1.

territory in compliance with their national legislation in force. In this way, restrictions on recognition of individual prescriptions are banned. There are only two exceptions to this prohibition: (i) where the restriction limited to what is necessary and proportionate to safeguard human health, and non-discriminatory; or (ii) where the restriction based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription. Furthermore, the cross-border recognition is not applicable to medicinal products subject to special medical prescription.<sup>5</sup> By contrast, the recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

This general principle of recognition established by the CBC Directive does not impact on any domestic framework that Member States have for prescribing and dispensing. In this way, the recognition of prescriptions shall not affect national rules if those rules are compatible with EU law, including generic or other substitution. Nor shall it affect the rules on reimbursement costs of medicinal products, which will be covered by Chapter III of the CBC Directive,<sup>6</sup> so that medical recognition shall also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products among the benefits covered by the social security system of affiliation.

Concerning national rules, there is also a special safeguard clause especially related to the conscientious objection of pharmacists. In this regard, the recognition of prescriptions shall not affect a pharmacist's right, by virtue of national rules, to refuse, for ethical reasons, to dispense a product that was prescribed in another Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

Finally the CBC Directive states the obligation for the Member State of affiliation to take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation.

## 2. Dispensing errors: critical points and implementing legal measures

### 2.1 Potential risks of dispensing errors

Having described the general framework on cross-border prescriptions, it is important to note that the CBC Directive content is not complete enough to eliminate all the practical barriers that mutual recognition poses, even though the number of cross-border prescriptions at EU level has not been very large to date. There is evidence that the real application of cross-border prescriptions is still suboptimal. In fact, cross-border

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<sup>5</sup> Article 11(6).

<sup>6</sup> Articles 9 to 11.

prescriptions were assumed to account for a small proportion of all prescriptions in the EU in the range of 0.02% to 0.04%.<sup>7</sup>

Despite this low average, potential risks from a public health perspective could perfectly arise. In particular, a prescribed product may not be dispensed to a patient who needs it; an inappropriate product could be dispensed or inappropriate instructions may be given at the time of dispensing, and finally a product may be dispensed and further consumed or sold based on a false prescription.<sup>8</sup>

Taken into consideration this risk perspective, three critical points regarding dispensing errors can be listed as follows: (a) the authenticity of the prescription; (b) the identification of medicinal products or medical devices prescribed; and (c) the comprehensibility of the information to patients. According to CBC Directive, the Commission was entitled to adopt measures in order to facilitate implementation of the mutual recognition.<sup>9</sup> In any case, in adopting measures the Commission had to take into account the proportionality of any costs of compliance with and the potential benefits of those measures.<sup>10</sup> This job was carried out through the 2012 Implementing Directive<sup>11</sup> which identifies critical points and lays down different legal measures to overcome possible barriers to the recognition of medical prescriptions issued in another Member State.

## 2.2 Authenticity of the prescription

Pursuant to the CBC Directive, the Commission had to adopt a non-exhaustive list of elements to be included in cross-border prescriptions which should be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection. That list should enable the dispensing health professional to verify the authenticity of the prescription and whether it was issued by a member of a regulated health profession who is legally entitled to do so.<sup>12</sup> In this regard, the Implementing Directive has established such a non-exhaustive list so that Member States shall ensure that prescriptions contain at least the elements set out in the Annex.<sup>13</sup> These elements are: (a) identification of the patient (surname-s, first name-s and

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<sup>7</sup> Commission (Health and Consumers Directorate-General), 'Impact Assessment accompanying Commission Implementing Directive 2012/52' (Staff Working Paper) SWD (2012) 451 final, 14. Based on Matrix Insight Ltd/Executive Agency for Health and Consumers, 'Health Reports for Mutual Recognition of Medical Prescriptions: State of Play', Final Report, (2012). The provided range is just an approximation since only six Member States were targeted by the Matrix study.

<sup>8</sup> L San Miguel and others, 'Recognition of pharmaceutical prescriptions across the European Union: a comparison of five Member States' policies and practices' (2014) 116(2-3) Health Policy 206.

<sup>9</sup> Article 11(2).

<sup>10</sup> Article 11(4).

<sup>11</sup> Commission Implementing Directive 2012/52/EU of 20 December 2012, laying down measures to facilitate the recognition of medical prescriptions issued in another Member State [2012] OJ L356/68). The deadline for the transposition of the Implementing Directive was the same as that for transposition of Directive 2011/24/EU (25 October 2013).

<sup>12</sup> Point (a) of Article 11(2) of the CBC Directive.

<sup>13</sup> Article 3 of the Implementing Directive.

date of birth); (b) authentication of the prescription (issue date); and (c) identification of the prescribing health professional (surname-s, first name-s, professional qualification, details for direct contact by email, telephone or fax and work address, including the name of the relevant Member State, and written or digital signature, depending on the medium chosen for issuing the prescription).

We must emphasize that the non-exhaustive list of elements should only affect to prescriptions intended to be used in another Member State.<sup>14</sup> As the principle of mutual recognition of prescriptions derives from Article 56 of the Treaty on the Functioning of the European Union (TFEU),<sup>15</sup> the Implementing Directive does not preclude the Member States from applying the principle of mutual recognition to prescriptions that do not contain the elements set out in the non-exhaustive list. At the same time, nothing in this Directive prevents the Member States from providing that prescriptions drafted on their territory, with a view to be used in another Member State, contain additional elements that are provided for under the rules applicable on their territory, as long as these rules are compatible with EU law.<sup>16</sup> In this way, the non-exhaustive list should simply apply as a minimum standard which allows countries to go further regarding mutual recognition of prescriptions.

### 2.3 Identification of the prescribed product

The CBC Directive entitles the Commission to adopt measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution.<sup>17</sup> This point is particularly critical since national prescribing and dispensing rules are very diverse. In many European countries, prescribing by brand is still common practice.<sup>18</sup> Furthermore, generic substitution is forbidden for private prescriptions in some countries which makes the dispensation of an equivalent product illegal.<sup>19</sup>

For this purpose, the Implementing Directive sets within the non-exhaustive list of elements some key points concerning the identification of the prescribed product, where applicable:<sup>20</sup>

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<sup>14</sup> Recital 8 of the Implementing Directive.

<sup>15</sup> Consolidated Version of the Treaty on the Functioning of the European Union [2016] OJ L202/47.

<sup>16</sup> Recital 9 of the Implementing Directive.

<sup>17</sup> Point (c) of Article 11(2) of the CBC Directive.

<sup>18</sup> M Mäkinen and others, 'Electronic Prescriptions are Slowly Spreading in the EU' (2011) 17 *Telemedicine and eHealth* 217.

<sup>19</sup> R Baeten, L, and San Miguel 'Cross-Border Recognition of Medicines Prescriptions: Results from a Mystery Shopping Experiment' (2013) 19(4) *Eurohealth* 12.

<sup>20</sup> As recital 5 notes, medical devices do not have common names as medicinal products. Therefore the prescription should also include direct contact details of the prescriber which enable the dispensing professional, where necessary, to enquire about the prescribed medical device and correctly identify it.

(a) Common name as defined by the Community code relating to medicinal products for human use.<sup>21</sup> According to its Article 1(21) it is the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name.

(b) Brand name is only allowed in two cases. First, when the prescribed product is a biological medicinal product.<sup>22</sup> Secondly if the prescribing health professional deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name.

(c) Pharmaceutical formulation (tablet, solution, etc.), quantity, strength,<sup>23</sup> and dosage regimen.

#### 2.4 Comprehensibility of the information to patients

Even though Article 11(2) explicitly requires specific measures concerning the prescription and the instructions on the use of the product, including an indication of active substance and dosage, there is no innovative provision adopted within Implementing Directive regarding comprehensibility of the information to patients. This issue is especially important for the most vulnerable ones. In this regard, the preamble to the legal text simply mentions that the non-exhaustive list of elements to appear on the prescriptions should facilitate the comprehensibility of the information to patients.<sup>24</sup>

However, it should be noted that the list of elements is only including simple information without any additional tool to facilitate its comprehensibility. The preamble and Article 4 also highlight the important role of national contact points in order to provide patients with adequate information on the content and purpose of the non-exhaustive list of elements.<sup>25</sup> Nevertheless, this provision is not actually an additional measure since it had already been established in Article 6(3) of CBC Directive. The Implementing Directive seems to be aware that its content is not sufficient for a complete and adequate implementation since the preamble recognizes that 'the Commission will regularly review the situation in order to assess whether additional measures are necessary to help patients understand the instructions concerning the use of the product'. It is clear that certain obstacles continue to remain in place. This is evident in the case of the language of the prescription.<sup>26</sup> At the same time, we are missing some additional measures that could be implemented such as a standardised design of drug packaging, where the active ingredient is prominently displayed in the upper right-hand corner of the package. This would substantially increase patient recognition of products containing the same active substance, especially in case of elderly

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<sup>21</sup> Adopted by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 [2001] OJ L311/67.

<sup>22</sup> As defined in point 3.2.1.1(b) of Annex I (Part I) to Directive 2001/83 EC.

<sup>23</sup> As defined by Article 1(22) of the Directive 2001/83/EC ('the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form').

<sup>24</sup> Recital 6 of the Implementing Directive.

<sup>25</sup> Recital 7 of the Implementing Directive.

<sup>26</sup> Van den Steen (n 1).

patients.<sup>27</sup> In the light of this consideration, a patient-centred implementation continues to be a significant and pending challenge.

### 3. Cross-border ePrescriptions as tools to improve prescribing and dispensing processes

#### 3.1 Benefits and barriers

Both traditional prescriptions on paper and ePrescriptions should be mutually recognized according to Article 11 of the CBC Directive. However, the most typical application of this provision is related to electronic prescribing, since it makes extremely easy for patients to obtain a medicinal product within a different Member State.

As is well-known, ePrescriptions refer to prescriptions transferred prescriptions by electronic communication from the prescriber's IT system to a national repository or directly to a pharmacy chosen by the patient.<sup>28</sup> Different benefits of e-prescribing have been described from a medical, economic, and social point of view. From a clinical perspective, patient safety can be improved by increasing prescription legibility, decreasing the time required to prescribe medications and dispense them to patients, and decreasing medication errors and adverse events.<sup>29</sup> At the same time, it improves the patient medication adherence. Finally, it reduces redundant paperwork and allows electronic access to updated pharmacopeia information and patient medication record.<sup>30</sup>

From an economic view, e-prescribing also improves the efficiency of the prescribing process since it has the potential to save money due to reduced visits to primary care offices and emergency services.<sup>31</sup> In addition, substitution of generic medications or less costly formulary alternatives can reduce the cost to patients and insurance companies.<sup>32</sup>

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<sup>27</sup> See the proposal from the Standing Committee of the EFTA States, 'EEA EFTA Comment on the Public Consultation of the European Commission on measures for improving the recognition of prescriptions issued in another Member State' (9 February 2012) 4.

<sup>28</sup> KA Stroetmann, 'Cross-border ePrescriptions in the EU-Towards a European approach to univocally identify medicinal products' (Telemed Conference, Berlin, July 2016).

<sup>29</sup> J Kannry, 'Effect of E-prescribing Systems on Patient Safety' (2011) 78(6) Mount Sinai Journal of Medicine 827; A Dobrev and others, 'Interoperable eHealth is worth it - Securing benefits from electronic health records and ePrescribing' (2010 Office for Official Publications of the European Communities).

<sup>30</sup> M Samadbeik and others, 'A Comparative Review of Electronic Prescription Systems: Lessons Learned from Developed Countries' (2017) 6(1) Journal of Research in Pharmacy Practice 3.

<sup>31</sup> According to the 2012 Matrix study (n 7) 4, assuming that for each of the 1.28 million delayed prescriptions a visit to a local physician is required (estimated at €34 per visit), the associated costs amount to approximately €43.6 million per year. See further KA Stroetmann and others, 'eHealth is worth it: The economic benefits of implemented eHealth solutions at ten European sites' (2006 Office for Official Publications of the European Communities).

<sup>32</sup> A Porterfield, K Engelbert and A Coustasse, 'Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting' (2014) 11 Perspectives in Health Information Management 1.



In the context of social benefits, ePrescriptions may contribute to overall patient satisfaction with the health system. Another social benefit may also be a financial relief for society. Finally, e-prescriptions can improve social care for the elderly.<sup>33</sup>

Despite the described benefits, there are also barriers to implement ePrescriptions such as the cost of implementing an e-prescribing system, the new types of errors that can occur if an e-prescribing system has not been designed properly or concerns for patients and providers regarding privacy of patient information.<sup>34</sup>

### 3.2 Interoperability of ePrescriptions: functional, technical, legal and educational measures at soft law level

Regarding e-prescriptions, the goal of the CBC Directive is not too ambitious since it only sets up that the Commission shall adopt guidelines supporting the Member States in developing the interoperability of ePrescriptions.<sup>35</sup> In this regard, Guidelines on ePrescriptions dataset for electronic exchange<sup>36</sup> have been adopted in 2014 by the eHealth Network established under Article 14 of the CBC Directive. One major drawback of this approach is that, according to the primary responsibility of the Member States in the field of healthcare provision,<sup>37</sup> these guidelines are non-binding.<sup>38</sup> It is up to each Member State to implement the guidelines and hence ensure that ePrescriptions are suitable for both cross-border and domestic use. By contrast with the mandatory transposition of the rest of the legal measures laid down in Article 11 (2) of the CBC Directive, the interoperability of ePrescriptions is simply regulated at the soft law level.

It is also important to note that unlike the CBC Directive these Guidelines do not cover cross-border prescriptions of medical devices, but only medicinal products. The aims of implementing the ePrescription guidelines are, in line with the principles of cross-border care, to ensure access to safe and high-quality healthcare; to achieve a high level of trust and security; and to enhance the continuity of care for individual patients. In this way, Guidelines are supporting the Member States to achieve a minimum level of interoperability, taking considerations of patient safety and data protection into account, by defining minimum requirements for communication between National Contact Points for eHealth and for interfaces between national and European levels.<sup>39</sup> In short, the practical implication of these Guidelines is that pharmacists are allowed to dispense medicinal

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<sup>33</sup> U Deetjen, 'European E-Prescriptions: Benefits and Success Factors' (2016) 5 Working Paper Series-University of Oxford 1.

<sup>34</sup> *ibid* 5. See further L San Miguel, 'Obstacles to the cross-border recognition of medical prescriptions in the EU' (DPhil thesis, Universidad Nacional de Educación a Distancia 2015).

<sup>35</sup> Point b) of Article 11(2).

<sup>36</sup> eHealth Network, 'Guidelines on ePrescriptions Dataset for Electronic Exchange und Cross-border Directive 2011/24/EU', Release 1 (18 November 2014).

<sup>37</sup> Article 168 (7) of the TFEU.

<sup>38</sup> Article 1(2) and Article 3 of the Guidelines on ePrescriptions.

<sup>39</sup> Article 1(3) of the Guidelines on ePrescriptions.

products electronically prescribed in another Member State.<sup>40</sup> For this purpose, the Guidelines provisions could be classified in four different types: (a) functional and semantic; (b) technical; (c) legal; and (d) educational

Concerning functional and semantic provisions, the Guidelines establish a dataset for ePrescriptions taken from Implementing Directive and Draft International Standard DIS 17523. As an exception, if ePrescriptions are not ready for semantic interpretation by machines, may be rejected on grounds of patient safety/national legislation.<sup>41</sup> Likewise, Member States shall ensure that, for reasons of authentication, information is available at national, regional or any other level on the health professionals who are entitled to prescribe as well as on the health professionals/healthcare providers who are entitled to dispense according to national law. At the same time, Member States of affiliation are responsible for ensuring that ePrescriptions are issued only by registered persons (or, where relevant, organisations).<sup>42</sup> It must be underlined that prescription drugs may not be dispensed without appropriate identification of the recipient. Member States of treatment shall be responsible for communicating details of items dispensed back to the originating country according to national laws.<sup>43</sup>

Regarding technical provisions, Member States are free to choose the implementation of their ePrescription dataset. In case of cross-border exchange, the format of the document for exchange should be based on agreed international standards and profiles. However the eHealth Network explicitly recognizes that further work will be needed. In addition, some minimum technical commitments with regard to data security are required. Member States shall ensure that communication of identifiable personal health data is subject to secure communication and end-to-end security measures. In the same way Member States shall also assure logging of cross-border transactions and make logs available for legal purposes.<sup>44</sup>

With respect to the Guidelines legal provisions, four sticking points should be particularly commented: data protection, patient safety, substitution and storage periods. Privacy of patients and providers is likely to be one of the main challenges of the eHealth Network, taken into account the great diversity in the implementation of the old Data Protection Directive<sup>45</sup> across Member States. This is why the application of these Guidelines should at all times take place according to the provisions of relevant European and national legislation. Where such provisions do not exist or are not in force, Member States are

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<sup>40</sup> A den Exter, 'e-Health law: the final frontier?' in TK Hervey, CA Young and LE Bishop (eds), Research Handbook on EU Health Law and Policy (Edwar Publishing 2017) 251.

<sup>41</sup> Article 4 of the Guidelines on ePrescriptions.

<sup>42</sup> Article 5 of the Guidelines on ePrescriptions.

<sup>43</sup> Article 6 of the Guidelines on ePrescriptions. In case of eDispensations, the following data should be sent to the prescriber via the relevant National Contact Point for eHealth for the respective recipient: (a) identification number of the dispenser, (b) name of dispenser, (c) ISO 3166 country code of the dispenser, (d) address of the dispenser, (e) personal identification number of the patient, together with the ISO 3166 country code, (f) identification number of the prescription, and (g) items dispensed.

<sup>44</sup> Articles 7-8 of the Guidelines on ePrescriptions.

<sup>45</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31.

expected to implement, monitor and audit common policies, safeguards and measures representing agreements of the eHealth Network, as foreseen in its Multiannual Work Programme. Such agreements will apply to the exchange of health related data across borders in a generic way and they will include but are not limited to agreements on duties and responsibilities of the eHealth National Contact Points and on common identification, authentication and authorisation measures.<sup>46</sup>

Anyway, the 2014 Guidelines should be updated<sup>47</sup> in order to properly lay down the significant impact of the 2016 General Data Protection Regulation,<sup>48</sup> not only on health general issues but ePrescriptions as well. It has been remarked that cross border e-Prescriptions are still perceived as difficult since some of the Member States have varying interpretations and enforcement of data protection.<sup>49</sup> However, the new Regulation which shall apply from 25 May 2018 is supposed to deeply change the current national diversity concerning data protection since the Regulation shall be binding in its entirety and directly applicable in all Member States. It will be an excellent and challenging opportunity to increase standardisation of cross-border ePrescriptions.

Concerns for patient safety may be also perceived throughout the entire content of the Guidelines. There are two specific mentions to this issue within the set of legal measures. Such measures lie in the principles of trust and availability.<sup>50</sup> According to the first one, health professionals, patients and National Contact Points for eHealth may rely upon the information released by the National Contact Points for eHealth of other Member States. In the same way, principle of availability means that in the event of semantic transformation, both the transformed and the original documents shall for safety and audit reasons be available to all persons who are authorised to use this data.

Turning now to legal provisions on substitution, there is no common definition, process or set of rules across EU regarding the substitution of medication. Therefore it is recognised that the substitution is not within the scope of the eHealth Network other than in enabling appropriate information exchange to support the agreed policy. It is assumed that rules of the dispensing Member State shall apply and should be accepted by the prescribing country. In this regard, Member States are responsible for application of their rules regarding substitution. However, Member States will wish to ensure that agreements regarding substitution are reflected in the information flows to support cross-border ePrescriptions.<sup>51</sup> As explained before, cross-border substitution is a complex issue. Consequently, the eHealth

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<sup>46</sup> Article 9 of the Guidelines on ePrescriptions.

<sup>47</sup> According to Article 15 of the Guidelines the eHealth Network could include in its Multiannual Work Programme the necessary activities for collecting information on the approaches of Member States to implementing the guidelines; and updating the guidelines on a regular basis to reflect the evolution of the EU legal framework, functional and technological advances and lessons learned from their use by the Member States.

<sup>48</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EU [2016] OJ L119/1.

<sup>49</sup> P Kierkegaard, 'E-Prescription across Europe' (2013) 3 Health and Technology 205.

<sup>50</sup> Article 10 of the Guidelines on ePrescriptions.

<sup>51</sup> Article 11 of the Guidelines on ePrescriptions.

Network has acknowledged that it will need to be worked out for clarification of the consequences for both sides and proposed in the next version of the Guidelines.<sup>52</sup>

In the meantime some guiding principles have been proposed by the eHealth Network according to different national scenarios.<sup>53</sup> If therapeutic substitution is not allowed without formal prior consultation with the prescriber, it is clear that it will not be possible to substitute active ingredients, dose, pharmaceutical form and route of administration. In case of countries which do not allow generic substitution or countries which have put specific limitations on generic prescriptions, it is thus advisable to allow for substitution of package size and/or brand name in these situations: (a) in the event of shortages in the pharmacy, where the prescribed product is not available in the country (b) if the product is available in the country but the pharmacist does not have it at that moment and the patient needs it urgently, (c) if the brand name or size is not authorised or commercially available in country B, or (d) if the rules of substitution in country B force the change to be made. In such cases, country B will decide the brand name or package size to be dispensed according to their own rules of substitution.

Since there is no EU-wide agreement on minimum storage duration for ePrescription and dispensation records, national legislation applies to the rules regarding this issue.<sup>54</sup> Nevertheless, the eHealth Network has suggested three proposals: (a) ePrescriptions and personal data concerning dispensation of these ePrescriptions shall be kept for a minimum period of 24 months. (b) Data according to point a) above shall not be kept for more than 10 years, unless demanded by patients or required by law; and (c) Data in the log files is to be stored for the purposes of the pilot and for litigation purposes up to a maximum of 10 years. Regardless of these concrete minimum periods, it seems to be necessary to lay down an EU common standard concerning storage duration in the next future.<sup>55</sup>

Finally, some educational measures are provided.<sup>56</sup> In this way, Member States should take steps to engage in education, training and awareness raising. For this purpose, the Guidelines lay down measures such as common activities towards increasing awareness of the benefits of and need for interoperability and related standards and specifications for ePrescription services, and for electronic patient data exchange in general; recommendations addressed to policymakers and health professionals; education, training and dissemination of good practices in electronically recording and information; and last but not least awareness raising measures for all individuals, in particular patients.

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<sup>52</sup> eHealth Network, 'Guidelines on ePrescriptions Dataset for Electronic Exchange und Cross-border Directive 2011/24/EU', Release 1 (18 November 2014). Chapter 4 (supporting information), 25.

<sup>53</sup> *ibid* 26.

<sup>54</sup> Article 12 of the Guidelines on ePrescriptions.

<sup>55</sup> Guidelines Chapter 4 (supporting information) 26.

<sup>56</sup> Article 14 of the Guidelines on ePrescriptions.

#### 4. Concluding remark

As analyzed in previous sections, mutual recognition of cross-border prescriptions really improves patients' access to medicinal products and medical devices abroad. Since Article 11 of the CBC Directive is not comprehensive enough to eliminate all clinical barriers to cross-border prescriptions, some legal measures have been laid down by the Implementing Directive regarding key points, such as the authenticity of the prescription, identification of medicinal products or medical devices prescribed, and the comprehensibility of information to patients.

Furthermore, taken into account that mutual recognition is not only applicable to traditional prescriptions on paper but ePrescriptions as well, additional measures have been provided at the soft level through specific guidelines. These non-binding guidelines support Member States to achieve a minimum level of interoperability. For this purpose, the 2014 Guidelines include different provisions relating to functional, semantic, technical, legal and educational issues.

One may wonder if these provisions are sufficient to avoid the risks of e-prescribing and to foster the interoperability of cross-border ePrescriptions. In our view, critical challenges still remain and implementing legislation at the hard law level should be desirable. Accordingly, further harmonisation and standardisation would be more than welcome. Nevertheless, most of the measures laid down by EU law are undoubtedly important steps in the right direction.



# Chapter IX Patient mobility and Health SPAs in the EU: legal implications and future challenges for patients and users

Alceste Santuari

## 1. Introduction

European citizens are entitled to the right to health,<sup>1</sup> which both the European Union and Member States are responsible and held liable for.<sup>2</sup> In this perspective, within the broad notion of freedom of movement of people provided for by European law,<sup>3</sup> Directive 2011/24/EU has positively recognised also European citizens' right to cross-border care. The (high) expectations that Directive 2011/24/EU had triggered off, especially as to the potential European "free market" of patients, have progressively been largely frustrated by the implementation process of it in the single Member States<sup>4</sup> and by the international crisis that broke out in 2007/2008.<sup>5</sup> This in particular has tightened health expenditure: in some

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<sup>1</sup> See article 35 – Health care of the EU Charter of Fundamental Rights: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities".

<sup>2</sup> See R Cavallo Perin, *Il welfare state nell'Unione Europea in tempo di crisi economica e l'inesatta contrapposizione tra Stato e mercato*, in *Fenomenologia e Società*, n. 1/2013, XXXIV, p. 51.

<sup>3</sup> According to a recent survey, the main reasons why European citizens are willing to go abroad to access health care services are identified with the lack of treatments at home (71%) and higher quality of services abroad (53%). See European Commission, Special Eurobarometer 425: *Patients' Rights in Cross-border Healthcare in the European Union*, 18 May 2015, p. 14. See also R Baeten, *Cross-border patient mobility in the European Union: in search of benefits from the new legal framework*, in *Journal of Health Services Research & Policy*, 2014, 19.

<sup>4</sup> See A den Exter, A Santuari, T Sokol, *One Year After the EU Patient Mobility Directive: A Three-Country Analysis*, *European Law Review*, Vol. 40, No. 2, April 2015, p. 281; L Prudi, *Implementation of the Directive 2011/24/EU in the Czech Republic*, *European Journal of Health Law*, 2014, 2, 15; M Kattelus, *Implementation of the Directive on the Application on Patient's Rights in Cross-border Healthcare (2011/24/EU) in Finland*, *European Journal of Health Law*, 2014, 2, 23; MA Requejo, *Cross-border Healthcare in Spain and the Implementation of the Directive 2011/24/EU on the Application of Patient's Rights in Cross-border Healthcare*, *European Journal of Health Law*, 2014, 2, 79; LMH Bongers, DMR Townend, *The Implementation of the Directive on the Application of Patients' Rights in Cross-border Healthcare in the Netherlands*, *European Journal of Health Law*, 2014, 2, 65; M Schwebag, *Implementation of the Cross-border Care Directive in EU Member States: Luxembourg*, *European Journal of Health Law*, 2014, 2, 56; S Olsena, *Implementation of the Patients' Rights in Cross-border Healthcare Directive in Latvia*, *European Journal of Health Law*, 2014, 2, 46; T Vidalis, I Kyriakaki, *Cross-border Healthcare: Directive 2011/24 and the Greek Law*, *European Journal of Health Law*, 2014, 2, 33.

<sup>5</sup> The international economic and financial crisis has caused a worsening in the waiting lists, reduced the availability of health care facilities as well as the increase of out-of-pocket payments of health care treatments. See EUROFOUND, *Access to healthcare in times of crisis*, *Publications Office of the European Union*, Lussemburgo, 2014, 12 and 17. See also European Commission, *Evaluative study on the crossborder healthcare*

Member States, not only have national health authorities limited the right to cross-border health care;<sup>6</sup> they have even reduced the actual provision of some health care services.<sup>7</sup>

In some national health systems (Germany, Hungary, Austria and Italy), health SPAs<sup>8</sup> treatments fall within the health package that is ensured to all citizens. Therefore, health SPAs are facing the same challenges deriving from rationing health care services at large, including the possibility of being left out of the services included in the national health coverage. Health SPA treatments are naturally linked to transnational tourism policies and programmes, which maybe make the “natural” health care services falling within the legal framework of Directive 2011/24/EU.

Against this background, this chapter aims at analysing if there is any plausible future for health SPA treatments and if so, what kind of future.

## 2. Directive 2011/24/EU and health SPAs treatments

Over the years, the Court of Justice of the European Union (CJEU) has confirmed Member States’ responsibility in the health care sector but it has also stressed that patients are free to move cross-border to access health care services. In the leading case *Leichtle*,<sup>9</sup> the European judges had to establish whether a German patient, who benefited from a health SPA treatment abroad (Italy), was to be entitled to get the reimbursement of the expenses incurred.<sup>10</sup> The German employer did not authorise the reimbursement on three main accounts. Firstly, it stated that there was no medical evidence of a better state of health deriving from cross-border thermal treatment. Secondly, the number and the reputation of German health SPAs made it not reasonable for the patient to access cross-border care. Thirdly, the patient was expected to apply for prior authorisation before starting the

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*Directive (2011/24/EU) Final report* 21 March 2015; M Karanikolos, and others, *Financial Crisis, austerity and health in Europe*, *The Lancet* 381 (9874) 2013 1323-1331 (1325); A Maresso and others (eds), *Economic Crisis, Health Systems and Health in Europe: Country Experiences*, Copenhagen: European Observatory on Health Systems and Policies, 2015.

<sup>6</sup> See S Giubboni, *Cittadinanza europea, libertà di circolazione e solidarietà transnazionale: un riesame critico*, in *Politiche Sociali / Social Policies*, n. 1/2016, 169-184.

<sup>7</sup> See (Italian) Corte dei Conti, Sezioni Unite in sede di controllo, *Rapporto 2016 sul coordinamento della finanza pubblica*, 15 marzo 2016 (Del. N. 2/SSRRCO/RCFP/16), Presentazione, pp. 9-12.

<sup>8</sup> The term here expresses what is referred to, both at the European and at international level, to “thermae”, which many scholars regard as the acronym of the Latin word “*sanitas per aquas*”. Others, instead, are convinced that the word derives from the little village in Belgium called “Spa”, the hot springs of which used to be beneficial to Roman soldiers and their horses, especially after battles. Health SPAs are then based upon the existence of natural spring waters or sea waters. These treatments, rich of minerals, including thalassotherapy, have been historically identified with medical treatments, which are capable of restoring a wide range of bad health conditions. Such a healing effect has enabled most European national health authorities to refer medical SPA treatments to those services that the national health systems ensure to their citizens out of the general taxation.

<sup>9</sup> *Ludwig Leichtle v Bundesanstalt für Arbeit* (C-8/02), 18 March 2004.

<sup>10</sup> See A den Exter, *Patient Mobility in European Union: Health Spas in Ischia, Italy*, in *Croat Med. Journal*, 2005: 46(2): 197-200 (<http://www.cmj.hr>).



treatment. With respect to these reasons, both the Advocate General and the Court stated the following:

- prior authorisation must be regarded as a hindrance that prevent European citizens to access cross-border healthcare;
- there is no need for a scientific test that proves that thermal treatment is better at home rather than abroad;
- the accreditation of the thermal centre provided for in Italy must represent an “added value” for the German health care system. Like all health care services, health SPAs too have to comply with stringent regulations in order to be entrusted with the provision of services “on behalf” of the public welfare systems.

The CJEU, then, recognised that patients/users are free to move cross-border to benefit from health SPA provisions, without being bound to apply for prior authorisation. In this respect, the accreditation requirement that the European judges stressed is aimed at ensuring the health system of affiliation that the health system of destination supplies reliable, medicine evidence-based and effective treatments.

The aforementioned ruling, along with others, were incorporated in Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare. According to this Directive, Member States maintain responsible for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory (Article 4). Simultaneously, they have to respect basic legal principles. In case of cross-border care this means applying objective, non-discriminatory criteria which should be known in advance as well as providing access to a judicial review procedure in case granting cross-border health care is being refused, while taking into account all relevant circumstances.

In this context, although prior authorization violates the free movement principles, it can be justified for reasons of public interest, but only in case of hospital and high technology care (Article 8), since these services are potentially capable of jeopardising the financial balance of national healthcare systems. With respect to previous versions of the Directive, in which prior authorisation had been provided for only for hospital treatments, the final text provides for the necessity of granting prior authorisation under certain circumstances, which are up to the Member States to decide.<sup>11</sup> These circumstances may also include the decision of the national or regional health authorities not to grant authorisation since it might undermine the ensuring of a sufficient and permanent access to a balanced range of a high-quality treatment in the Member State, or it is regarded as essential to control over health expenditures or to avoid any waste of financial, human or technical resources. This means that health SPAs treatments too could actually be subject to prior authorisation in those national health systems in which they fall within the health services basket.

As to the reimbursement of cross-border healthcare, it is limited to services the insured person is entitled to in its country of affiliation. Should health SPA treatments be included in

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<sup>11</sup> See Article 8.

the national health basket ensured in the country of affiliation, then, patients are entitled to apply for reimbursement.

Finally, the Directive provides also for the “European reference networks” (Article 12) among healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks need to be based on voluntary participation by its members, which shall participate and contribute to the networks’ activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in the Directive.<sup>12</sup> This is a provision that could also apply to European health SPAs, especially to those which are well known to treat specific diseases (e.g. psoriasis).

### 3. Patient mobility and health budget restraints

Directive 2011/24/EU strikes a balance between the citizens’ rights to move freely cross border to access health care services and the need for the Member States to control over their health budgets. Accordingly, finance restrictions vs. freedom of choice seems to be the battle that nowadays health care systems are called upon to carry out. Might one state then that patients’ rights to access health care services depend upon Member States’ budgets? Are we facing a time in which the principle that defines many legal systems, especially European ones, according to which “everyone is entitled to access health care services regardless their wealth” is about to give way to financial sustainability only? Are we witnessing a setback of the “European healthcare union”?<sup>13</sup>

Undoubtedly, due to the current financial crisis, health SPAs, along with other health care provisions, can be subject to budget restrictions. Accordingly, whereas before the breaking out of the economic crisis health SPA treatments were thought as a natural field where to positively experiment the right to cross-border healthcare, at present these services run the same risk of other health care provisions, namely, to be cut off of the health provisions ensured by national health systems. In fact, these are facing a new health demand by citizens-patients in a context in which the traditional welfare systems are challenged by an ongoing crisis,<sup>14</sup> which is both economic and demographic. Accordingly, some Member States have adopted stringent austerity policies, which have ended up with reducing public health expenditure.<sup>15</sup> Among the negative effects of the economic crisis there are limitation

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<sup>12</sup> Also health SPAs can fall within this broad framework. It is noteworthy that in Austria, Italy, Hungary and Germany health SPA provisions do fall within those services and treatments that are paid for by the central or regional governments. In this respect, then, European health SPAs could greatly benefit from the provisions of the Directive. See par. 5.1.

<sup>13</sup> H Vollaard, D Sindbjerg Martinsen, The rise of a European healthcare union, in *Comparative European Politics* – March 2016.

<sup>14</sup> See I Begg, F Muschoevel, R Niblett, *The Welfare State in Europe. Visions for Reform*, Research Paper, Chatham House, The Royal Institute of International Affairs, London, September 2015.

<sup>15</sup> «Growth in health spending per capita fell in real terms in 2010 in almost all European countries, reversing a trend of steady increases. Namely, from an annual average growth rate of 4,6% per year

in the right to access health care services, increase in the level of co-payment of health care services by patients, the re-arrangement of hospital organisation and of other health providers, increase of the time in waiting lists, both for visits and surgical operations.<sup>16</sup> The prolonging of the financial crisis and the impact of it on European national health systems cause to wonder how fiscal austerity policies, which have been implemented over the last few years,<sup>17</sup> shall influence the survival of national health systems. Economic and welfare state crisis as well as austerity policies have made it rather difficult for MSs to ensure the same standards of care and the same values they were used to provide in the past. As a consequence of this incapability, MSs undergo many problems in promoting solidarity and equity in accessing health care.<sup>18</sup> Governments are challenged as to the negative effects deriving from austerity policies in a legal and institutional context, in which the right to healthcare at home overlaps with the right to cross-border access<sup>19</sup> provided for by both Directive 2011/24/EU and the European Charter of Fundamental Rights. Though with a different spirit, the two state that the entitlements that they provide for must comply with

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between 2000 and 2009, towards a fall in health spending per capita of 0,6% in 2010». G. Quaglio and others, *Austerity and Health in Europe*, in *Health Policy*, 113 (2013), p. 13.

<sup>16</sup> See Karanikolos (N 5) 1327 (box Panel 3: Greece).

<sup>17</sup> «Health spending continued to shrink in Greece, Italy and Portugal in 2013. Most countries in the European Union reported real per capita health spending below the levels of 2009. Outside of Europe, health spending has been growing at around 2.5% per year since 2010.» OECD, *Health Statistics 2015*, in <http://www.oecd.org/health/slow-growth-in-health-spending-but-europe-lags-behind.htm> (ultimo accesso in data 13 giugno 2016). Sugli effetti prodotti dalle politiche di austerità e dalla crisi economica sui servizi sanitari europei, si vedano; H Karger, *The Bitter Pill: Austerity, Debt, and the Attack on Europe's Welfare States*, *Journal of Sociology & Social Welfare*, June 2014, Volume XLI, Number 2, p. 48; EPHA (European Public Health Alliance), *Access to Healthcare and the Economic Crisis in Europe*, Bruxelles, novembre 2015; European Parliament, Directorate-General for Internal Policies. Policy Department Citizens's Rights and Constitutional Affairs, *The impact of the crisis on fundamental rights across Member States of the EU. Comparative Analysis. Study for the LIBE Committee*, 2015, p. 49; S Palasca, E Jaba, *Economic Crisis' Repercussions on European Healthcare Systems*, in *Procedia Economics and Finance* 23 (2015), pp. 525-533. Per un'analisi dell'impatto della crisi finanziaria sui sistemi sanitari nazionali di Spagna, Germania e Regno Unito, vedi L Giovannella, A Stegmüller, *The financial crisis and health care systems in Europe: universal care under threat? Trends in health sector reforms in Germany, the United Kingdom, and Spain*, in *Cadernos de Saúde Pública*, Rio de Janeiro, 30(11):2263-2281, nov. 2014. Alcuni osservatori hanno segnalato che «the most vulnerable groups who frequently are left invisible to official statistics and population surveys are at the forefront of feeling the consequences of the austerity.» M Karanikolos, A Kentikelenis, *Health inequalities after austerity in Greece*, in *International Journal for Equity in Health*, 2016 15:83, p. 1.

<sup>18</sup> «The important economic impact of health systems is more and more widely acknowledged[...] Also, Health 2020 makes clear that health and well-being are the most important goals of any society, and a significant resource that helps to promote the reciprocal relationship between health and development. Globally, health is an important sector of economy; countries spend a greater and greater part of their wealth on health as they get richer. The health sector also provides employment to large numbers of workers. The health sector employs about 6% of all workers in the EU, and accounts for about 10% of the EU GDP[...]» Address by Zsuzsanna Jakab, WHO Regional Director for Europe. *Health systems in times of global economic crisis: an update of the situation in the WHO European Region*, Oslo, Norway, 17 April 2013.

<sup>19</sup> See CJEU, C-617/10, decision of 26th February 2013: "That definition of the field of application of the fundamental rights of the European Union is borne out by the explanations relating to Article 51 of the Charter, which, in accordance with the third subparagraph of Article 6(1) TEU and Article 52(7) of the Charter, have to be taken into consideration for the purpose of interpreting it (see, to this effect, Case C-279/09 *DEB* [2010] ECR I-13849, paragraph 32). According to those explanations, 'the requirement to respect fundamental rights defined in the context of the Union is only binding on the Member States when they act in the scope of Union law'." (para 20).

single MSs' constitutions.<sup>20</sup> In this perspective, the combination of fundamental right to health and the MSs responsibility to ensure points out to the specific character of the provision of health care services and its exclusion from the internal market services rule<sup>21</sup> as provided for by Directive 2006/123/EU.

#### 4. Health tourism and health SPAs

Over the last decades, there has been an increased number of people who travel cross-border and over the oceans to access tourist as well as health care services. Such an increasing demand for well-being has brought to surface a new awareness relating to tourist attractions and services. According to some research data, tourism is presently characterised by the following trends:

1. the increase in the long-term demand;
2. the structural changes in the demand for tourism connected to demographic variations;
3. the re-arrangement of holidays in many countries around the world, which has led many tourists to prefer short breaks to long stays as it used to be in the past. This trend, especially if referred to "dead seasons", may have a positive impact on SPA resorts.

Hence, the very concept of "cure/treatment" has also been changing: its evolution has been influenced by a different approach to health matters. Indeed, health is no longer identified with a strictly medical healing of an illness but also with the possibility of redress, relax and an opportunity of preventing some state of mind.<sup>22</sup> In this respect, sports, wellness and SPA treatments have been more and more successful also because they are supported by specific and targeted marketing campaigns.<sup>23</sup> In other words, the traditional concept of "cure" has been enlarged, thus including modern approaches and tools, whereby people may actually experience a new and different way of facing their own demand for well-being.

In this context, over the years, health SPAs, along with the traditional supply of health services, started to develop also tourist-oriented policies and promotions. It is well known

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<sup>20</sup> See CJEU, C-399/11 of 26 February 2013.

<sup>21</sup> Hervey, 2016; T Hervey and J McHale, *Health Law and the European Union* (CUP 2004) 43.

<sup>22</sup> The following trends may be generally outlined:

1. the number of seniors who are willing to travel is increasing;
2. the seniors are healthier and wealthier than in the past;
3. most of them can count on early pension schemes;
4. the increase of the demand for quality, economic convenience and security;
5. the increase of the demand for easily accessible transports;
6. the increase of the demand for products and services targeted for singles;
7. the increase of the demand for tourism during the so called "dead Seasons" of the year;
8. a higher awareness by tourists concerning the aspects related to their own health, which accordingly has a great deal of influence on the choice of the destination and on the market behaviours during the stay;
9. the increase in the perception of the destination and the surroundings as distinctive aspects to choose a destination.

<sup>23</sup> Also governments have changed their attitude towards health tourism: see, Puczko' - Smith, *above*, p. 102.

that “thermae” has been changing from a “place” where to go in order to get cured to a “destination” where to find solutions to health and life expectations at large. The evolution of the cure concept has brought with it then a change in the way health SPAs too are perceived by patients and users. Along with the growth of their preventive role, health SPAs have also been regarded as a component of the overall “health market”. This market is wider than both thermal medicine and the wellness system only. The “health market” comprises of various and different aspects, such as sports, life style, food education as well “other” types of tourism. This evolution implies that SPAs are no longer regarded as a social phenomenon only. By contrast, SPA resorts are considered to be places where to spend individual and quite short stays, during which “tourists” get also cured but especially are taken care of. Whereas in the past health SPAs were used to be attended for relatively long periods of time and by ill people, nowadays they are visited for shorter periods of time and by “health tourists”. These are individuals, who are willing to exploit many or all the tourist opportunities that the area can offer to them after being treated. It is noteworthy that these treatments are no longer only strictly medical but they can also be (and it is often so) referred to a general state of health wellbeing.

This has progressively led to the recognition of health SPAs not only for the effectiveness of the health care services<sup>24</sup> provided but also because their locations are usually fascinating, the ancillary services provided are of a high quality standard and because they are easy to get to. Accordingly, the reputation of a thermal resort is actually capable of benefiting the whole surrounding area, thus strengthening the concept of tourist destination. In modern times, it is possible to point out that the quality of the services (i.e. health SPA resorts) along with the welcoming capacity and the perception of well-being are all characters that contribute to increase the appeal of the tourist destination in which the thermal resorts carry out their activities. Tourist packages are then to fully assess the “value added” represented by thermal resorts, both by means of a higher level of scientific validation and through the experimentation of new legal and organisational forms whereby to manage the resorts. Marketing at the local level together with the awareness that health SPAs represent essential assets are supposed to foster the growth of the resorts themselves. Accordingly, health SPAs are set to carry out positive and long-lasting co-operation between tourism promotion and health care services. In some cases, though, this evolution has ended up with shadowing the health character of health SPAs thus excessively enhancing their tourist side. This is the main reason why, especially in those Member States in which health SPA treatments come under the national health care services basket, health authorities question the listing of health SPA provisions among those guaranteed by the single NHS.

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<sup>24</sup> “In the early 1990s there was very little overlap between medicine and spas. That has changed dramatically over the last decade. More doctors have discovered that spa and wellness establishments can be allies in helping their patients make long-term lifestyle changes”. S Ellis, SpaFinder Wellness Trends, in L Puczko’- M Smith, *Health, Tourism and Hospitality. Spas, wellness and medical travel*, Routledge, 2014, second edition, Chapter 9, p. 239.

## 5. Health SPAs as natural “health destination management organisations”

At present, patients and users show a higher degree of sensitivity towards the quality of tourist offers than in the past.<sup>25</sup> In this respect, given their specific characteristics and role, health SPAs are then challenged to find out the most useful strategies to develop and enhance health tourism. They need to make it clear that wellness, well-being, prevention effectiveness of SPA treatments, as well as the necessity of innovating the thermal products, are parts of an overall strategy. The main goal of this strategy is the promotion of health, which can be reached, for example, by stressing the curing properties of health SPA treatments connected to a certain area. Hence, as a by-product, health SPAs can also support the sustainable development of tourism at the local level. In this respect, accordingly, tourist and local health authorities are to define joint actions and programmes aimed at promoting both health SPA provisions and tourist activities. These joint programming action plans need to get public bodies, private entrepreneurs, health authorities and SPA resorts involved. They are to agree upon a set of measures and tools so as to implement and develop the “offer” of that given area. As far as SPA resorts are concerned, their medical-based-evidence character is to go along with their capacity of providing a modern and requested environment to foster good life and health styles. The experience of many health SPAs and the worldwide health tourism trends clearly point out that also SPAs do fall within the concepts of territorial marketing and destination management, in the view of assessing and evaluating the thermal resort destination as a tourist one.

Tourist competition of a given area mainly derives from the resources that it possesses. However, it is not so unusual to find territories that despite their rich attractions factors and endowments are not able to face competition. This very much depends upon the insufficient capacity of integrating natural resources with an adequate mix of tourist services. Such a lack of integration does not allow then to promote co-operation and managerial behaviours, which are on the contrary among the most important aspects of a successful tourist destination policy. Accordingly, it is possible to underline that the capacity of attracting tourists does not stem out only from the actions of single territorial actors. It is rather the outcome of a system or network of actors which is capable of summing up all the stakeholders that operate and are involved in that particular territory so as to balance their interests.

In this perspective, health SPAs may become *Health Destination Management Organizations* (HDMO).<sup>26</sup> They act as local based agencies that supply health services and thus they

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<sup>25</sup> A specific research on spa-going respondents from 34 countries showed that the following as the primary reasons for visiting a spa: relaxation/stress management (88%); hair/nail/waxing maintenance (59%); improve appearance (47%); skin care (37%); gift (31%); pain management (22%); social experience (19%); other (3%); medical reasons (3%). See, Coyle Hospitality Group (2011), Global Spa Report, [www.discoverspas.com/news/newsstudies41.shtml](http://www.discoverspas.com/news/newsstudies41.shtml).

<sup>26</sup> DMO's role is crucial in promoting a health SPA: indeed, their main objective is to offer and introduce the available additional services and attractions in one given area. “In Europe, mainly historic spa towns or towns with an established clinic or major spa tend to label themselves as health or wellness destinations (e.g. Baden

manage facilities for recovering from sports injuries, for preventative medicine, for accommodation for the elderly. Such a recognition of health SPAs questions the very core of thermal treatments, namely, their medical aspects. Therefore, it is up to scientific research and the management of health SPAs to find out the most appropriate way whereby to strike a balance between patients' needs and medical treatments. Against this background, health SPAs' main goal is to build up a supply system of thermal wellbeing, which enables to balance the traditional concept of medical SPAs and the new trends connected to wellness. In this respect, a new approach towards the development of health SPAs is needed. This should include the following aspects: a) marketing; b) web positioning; c) information and communication; d) capacity of making different proposals; e) search for a high product quality; f) links between health SPAs and the area in which they are placed.

In order to achieve a better "strategic positioning" on the health market, health SPAs should devote more attention to patients and users so as to enable them to choose the "right" place to go. By complying with the specific treatment prescribed by practitioners or chosen on the basis of their individual health needs, users should not be left alone to decide which is the most adequate "place" to go for that treatment. In this respect, the management of health SPAs is expected to develop an effective information campaign so as to reach out for potential patients/users, including cross-border ones, by using the national or regional contact point provided for by Directive 2011/24/EU.

Within this promoting framework, SPAs should not be disconnected from the territory in which they operate. On the contrary, they are expected to be considered an added value to the area itself, so as to promote a mutual recognition between the two. By means of a network of relationships it is then possible to set up an integrated territorial supply system. The connections with the territory is indeed a valuable competitive advantage, which may allow health SPAs to supply a wide range of different services, thus being more appealing to patients and users.

## 6. Concluding remarks

Health care services are currently undergoing a number of challenges, especially due to budget restraints, which risk undermining cross-border healthcare too and accordingly patients' rights.

Over the years, the notion of "thermae" has been changing from a "place" where to go and get cured to a "destination" where to find solutions to health and life expectations at large. The evolution of the cure concept has brought with it then a change in the way thermal centres are perceived by the public.

Health SPA centres play a significant role in the preventive medicine and they are regarded as an important component of the overall "health market". This market is wider than both thermal medicine and the wellness system only. Indeed, the "health market" comprises of

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Baden in Germany). In other parts of the world, the health element typically is only one of the many image making elements or strengths". Puczko' - Smith, (n 24) 153.

various and different aspects, such as sports, life style, food education as well “other” types of health tourism.

This evolution implies that thermal centres are no longer deemed to be as a social phenomenon only. By contrast, SPA resorts are considered to be places where to spend individual and quite short stays, during which “tourists” get also cured but especially are taken care of. Indeed, whereas in the past thermal centres were used to be attended for relatively long periods of time and by ill people, nowadays thermal resorts are visited for shorter periods of time by “health tourists”. These individuals are willing to exploit many or all the tourist opportunities that the area can offer to them while and after being treated. It is noteworthy that these treatments are no longer only strictly medical but they can also be (and it is often so) referred to a general state of health wellbeing.

In the light of the aforementioned evolution, will health SPA centres be the same in the future? Will they be necessary – where applicable – dependent on national health systems? What if, against a background in which many European countries are facing significant financial and budget restraints, thermal centres will cease to be financed, at least partly, by the national health systems? Will they lose their health component? Will they be less attractive to users? Will they have to face an inevitable decrease both in economic and reputation terms? These are some of the questions, which thermal centres and those who are engaged in the sector are to face.

As to the government funds that thermal centres benefit from in some European countries, it is noteworthy that such a financial support has progressively been decreasing. This trend has caused health SPAs to supply their services onto a market in which private individuals are willing to pay for the treatments. However, to some extent these remain perceived as having an important health component, which is regarded as beneficial to individuals’ health needs. Therefore, any political measure that would exclude thermal treatments from those ensured by the national health systems does not per se necessarily imply the closing of thermal establishments. Those thermal centres that are capable of supplying high standard health services coupled with ancillary tourist services seem to have already partly balanced such a “loss”.

The international movement of persons willing to travel to find out the “right place” to go for their health has witnessed to the importance of singling out a proper strategy by which thermal centres can be viewed as that place. Indeed, thermal centres and resorts can offer health services of high quality and standards based on qualified professionals and a well rooted scientific validation of the cure properties.

Accordingly, the future of thermal centres cannot but be defined by the strengthening of scientific research aimed at showing the beneficial health implications of the services and provisions supplied. Likewise, investments are to be made to enlarge the range and variety of health provisions that individuals can find in thermal establishments. In this respect, for instance, a new role for preventative medicine should be explored, so as to test the potential of thermal centres to match individuals’ needs.



A renewed attention should be devoted to the modes and procedures by which thermal centres intend to be presented to the public. On the one hand, national and regional governments should promote the natural resorts where thermal centres are usually located better and more effectively. On the other hand, health authorities should foster and monitor the licensing process at the end of which thermal centres are registered in the single countries. As the European Court of Justice stated in the *Leichtle* case, the registration requirement is of a paramount importance to identify a medical SPA.

A positive evolution of thermal centres also requires a new organisational pattern: the representatives of thermal centres are expected to programme the services they supply as attractive to companies' funds and health insurance funds, which are seeking new health services to offer their members/insurers.

Is then a new pattern for thermal centres feasible and also desirable? The answer is in the affirmative, provided that all actors (politicians, health and tourist authorities, private investors) are given the adequate legal, organisational and financial frameworks by which to test and prove their partnership effective. Along with them, a new and fundamental role is to be played by the users of the services supplied by thermal establishments.

Given the legal provisions set out in Directive 2011/24/EU, I hereby intend to address some key questions concerning health SPAs so as to try to outline some future perspectives.

Firstly, health SPAs call for new partnerships between public bodies and private organisations, which are capable of foreseeing the strategic changes under way within society at large. In this respect, it is worthwhile stressing that health care systems are no longer based on public expenditures only. They are also defined by the existence of private investment funds or by private insurances that are progressively taking the lead in ensuring health care provisions.

Secondly, health SPAs are to support the connections between "public health" and "tourism". Tourism is facing important and crucial challenges worldwide. In particular, it is clear that an effective tourism promotion needs the partnership of various stakeholders (public authorities, private entrepreneurs, non governmental organizations). Furthermore, tourism does not require too much "red tape", given its free movement and free choice approach. Tourist actions need of coordination and especially at the local level they require monitoring and assessment schemes by which all the actors that in charge of its growth may be enabled to grasp trends and demands so as to define the right decisions.

Thirdly, health SPAs, both because of their very nature and by virtue of their connections with the environment in which they operate, are natural allies of a sustainable approach to tourism. This can be achieved by both promoting the attractions of a given area (environment, heritage, landscape, local traditions) and advance quality. Indeed, in the future a high standard tourism quality will be even more met by integrating environmental sustainability, natural assets and cultural heritage.

Fourthly, an adequate development of medical SPAs cannot but be reached by heavy investments in professional training. Thermal operators are called upon to be able to match

clients' demands and exigencies not only from the medical point of view but also by being ready to share and promote a marketing approach. The following agenda of possible actions may be drawn:

- to strengthen the networks among the different health SPAs;
- to promote and support a stronger integration between SPA resorts, health care and social care services;
- to foster the partnership with national and local tour operators so as to include the SPA services in specific all inclusive tourist packages for the international markets;
- to endow more resources to professional talent training programmes of thermal operators;
- to define a wide governance scheme which enables to include all aspects of health SPA treatments: from the cultural approach through the therapeutic value of water, also by means of new legal and organisational forms of management;
- to improve the management services that are implied in the carrying out of hot spring resorts;
- to foster tourist exchange programmes with other countries around the world;
- to set out legal provisions at the national level to recognise "free zones" for health SPAs with financial support and tax allowances for them.

Contrary to what it is usually the case, the renewal of health SPAs is closely linked to one of their most original and historical aspect, namely, water. It is indeed around water and its modern perception and use that relevant marketing programmes need to revolve. In this perspective, water becomes the key element that could allow for the change of some SPAs into medical ones. Moreover, water represents the common ground on which to foster scientific research and tourist promotion, without running the risk that the former wins the upper hand over the latter or the other way round.

The more effectively thermal centres will be capable of communicating their qualities and proving their health and scientific validation, the more users will benefit from them. Appropriate treatments along with preventative medicine can actually do some good to national health systems, especially if they are able to make the most out of the possibilities offered by cross-border health care.

# Chapter X Cross-border reproductive care: Low expectations from European (Union) law

André den Exter

## 1. Introduction

For centuries, mankind has been confronted with (the consequences of) infertility and searched for alternative ways of starting a family. A well known example of overcoming infertility was described in the Old Testament when Sarah, already in her nineties, encouraged Abraham to ‘visit’ her maid Hagar, who became pregnant with Ismael.<sup>1</sup> Such a ‘ménage à trois’ or surrogacy option has been observed in many cultures.<sup>2</sup> Nowadays, contemporary medicine and medical technology have developed more sophisticated methods for overcoming infertility. The first ‘test tube’ baby born by in vitro fertilisation (IVF) in the 1970s was generally considered a breakthrough in reproductive health: overcoming female infertility using medical or assisted reproductive technologies (ARTs). New methods at the interface of assisted reproduction and genetics have since been developed. These have enabled the selection of genetically ‘healthy’ embryos and modification of the genetic makeup, causing controversies on genetic selection and ‘designer babies’.

Each country has its own way of dealing with ARTs and is very much influenced by social, ethical, legal and religious norms and values. As a direct result of the diversity in regulatory frameworks on ART treatment, a new phenomenon has arisen: cross-border reproductive care (CBRC) or reproductive tourism. Apart from human rights concerns, such reproductive health services may also trigger free trade principles. ‘Repro’ health services fall within the scope of European Union law, i.e. the free movement of services treaty provision, whilst the outcomes (cells and embryos) may be regarded as health goods distributed on a free market. This raises new questions about the role and dynamics of EU law when donor gametes (sperm, oocytes or fertilised embryos) cross borders. What exactly is the EU’s role in cross-border access to reproductive care and is it possible to regulate this phenomenon at Union level? If not, are there any alternative options to promote universal access to ART treatment across Europe?

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<sup>1</sup> Old Testament, Book of Genesis 16(2): .. “The Lord has kept me (Sarah) from having children. Go, sleep with my slave; perhaps I can build a family through her”.

<sup>2</sup> E.g., in ancient Hindu society there existed a practice known as *Niyog Pratha*, wherein the wife was childless due to impotency of her husband. Here the brother in law was the surrogate father, quoted by AM Vyas, *Surrogacy: The only hope for a few* (2017) 3 *IJMSSR* (2017) p. 44.

## 2. Understanding cross-border reproductive care

Contemporary medical science offers various treatment options for overcoming male and female infertility. These include IVF and related treatment methods, such as preimplantation genetic diagnosis (PGD) and screening (PGS), intracytoplasmic sperm injection (ICSI) aimed at tackling male infertility, gamete donation, frozen embryo transfer, frozen oocyte replacement (cryopreservation) in the case of cancer patients or delaying motherhood, as well as posthumous reproduction and surrogacy arrangements with or without a genetic link between the gestating woman and the child. Future developments include genome-editing technologies (CRISPR) for infertility treatment and the idea of 'artificial wombs'.<sup>3</sup> Understanding the legal context of cross-border reproductive care, the analysis focuses on both human rights law and the internal market.

Access to assisted reproductive technologies (ARTs) rights: a human rights perspective  
In terms of human rights, access to reproductive health care is accepted as a subset of the human right to health care. Article 12 of the Convention on Economic, Social and Cultural Rights (ICESCR) interprets (sexual and) reproductive health as 'a set of freedoms and entitlements, including the freedom to make free and responsible decisions and choices ... over matters concerning ... reproductive health, and unhindered access to a range of health facilities, goods, services and information'.<sup>4</sup> Since then, such a right has constantly evolved, creating specific State obligations in terms of availability, accessibility, acceptability and quality of reproductive health services, as explained in the Convention's General Comment (GC) on the right to sexual and reproductive health (GC no. 22).<sup>5</sup> This means that States will take all necessary steps (legal and budgetary) to the maximum of available resources, to progressively realise the Convention's right to reproductive health.<sup>6</sup> Such reproductive health care services 'should be accessible to all individuals and groups without discrimination and free from barriers', whilst accessibility includes 'physical accessibility, affordability and information accessibility'.<sup>7</sup> In the case of ARTs, this means that States are under the immediate obligation to eliminate discrimination against individuals and groups, therefore lifting the ban on ARTs for same sex couples, single women and disabled persons. The GC also urges States 'to repeal or reform laws and policies that nullify or impair certain

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<sup>3</sup> E.g., JC Harper (ed) *Preimplantation Genetic Diagnosis* (2nd ed. CUP 2012); L Tang and others, CRISPR/Cas9-mediated gene editing in human zygotes using Cas9 protein, *Molecular Genetics and Genomics* (2017) DOI: 10.1007/s00438-017-1299-z; A Deglincerti and others, Self-organization of the in vitro attached human embryo, *Nature* 533, 251–254 (12 May 2016).

<sup>4</sup> See The Committee on Economic, Social and Cultural Rights (CESCR), General Comment (GC) no. 22 (2016) on the Right to sexual and reproductive health (Art. 12 of the International Covenant on Economic, Social and Cultural Rights), para 5, with references to GC no. 14 (2000): The Right to the highest attainable standard of health (Art. 12). As confirmed by other international human rights documents: Convention on the Elimination of All Forms of Discrimination against Women (1979), Art. 12; Convention on the Rights of the Child (1989), Art. 24(2)(d); and Convention on the Rights of Persons with Disabilities (2006), Arts. 23 and 25.

<sup>5</sup> The so-called AAAQ-approach: GC no. 22 (2016) on the Right to sexual and reproductive health, paras 11-21, based on GC no. 14; CEDAW General Recommendation (GR) no. 24: Article 12 of the Convention (Women and Health) A/54/38/Rev.1.

<sup>6</sup> *Ibid*, GCCC? para 33.

<sup>7</sup> *Ibid*, para 15

individuals' and groups' ability to realize their reproductive health right'.<sup>8</sup> Compliance with the Covenant further means that States abstain from 'retrogressive measures'. Examples of retrogressive measures in the context of reproductive rights are revoking public health funding and/or creating barriers to ARTs.<sup>9</sup>

Access to reproductive care can also be based on Article 3 of the Convention on Human Rights and Biomedicine (Oviedo Convention), imposing on States an obligation to achieve equal access to health care – including reproductive services - based on individual health needs and taking into account the available resources.<sup>10</sup> Here, individual health needs should be interpreted as objective medical needs as concluded by medical professionals rather than a patient's individual needs, which can be unlimited.<sup>11</sup>

Besides being an integral part of the right to health care, reproductive rights are also intrinsically linked with other human rights, such as the right to life, the right to private or family life, the prohibition of degrading treatment. Traditionally, classical civil rights protect the individual against arbitrary interference by public authorities (i.e. abstaining from such interference). In addition, such rights may also be interpreted as incorporating inherent positive measures (positive State obligations) such as facilitating reproductive rights, designed to secure civil rights. Notably the European Court of Human Rights (ECtHR) interprets ART cases under the Convention's right to private and family life (Article 8 ECHR), whether or not in combination with the non-discrimination principle (Article 14). As such, the Court clarified the nature and scope of positive obligations for particular groups.

For instance, in *Evans v UK*, the Court concluded that it is not disputed that the decision to become or not to become a parent by means of IVF treatment falls within the scope of Article 8 (private and family life).<sup>12</sup> Unfortunately for Natalie Evans, the Court's balancing of interests (i.e. competing positive obligations) ended unsuccessfully, as she was not allowed to use the embryo. The condition of mutual consent for the implantation of the embryo in the uterus was not considered a violation of her private life.<sup>13</sup> In another case, *S.H. and Others v Austria*, the Court accepted the prohibition of the use of donated gametes (ova and sperm) from donors for IVF purposes, as a lawful restriction of the applicants' private lives.<sup>14</sup> Unlike *Evans*, here the Court examined the case as 'interference with the applicants' right to respect their private and family lives, instead of a failure of the State to fulfil a positive

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<sup>8</sup> *ibid*, para 34.

<sup>9</sup> *ibid*, para 38. Retrogressive measures are in principle prohibited. In more detail, see A den Exter. The Right to Health Care, in A den Exter (ed) *European Health Law*, Maklu Press 2017, p. 113-114.

<sup>10</sup> Officially, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine: Convention on Human Rights and Biomedicine (also known as Oviedo Convention), ETS no. 164.

<sup>11</sup> Article 3 Biomedicine Convention and the Explanatory Report paras 24-25, as discussed by M Buijsen and A den Exter, 'Equality and The Right to Health Care' in A den Exter (ed), *Human Rights and Biomedicine* (Maklu 2010) 69-85. The medical needs concept is also applied by the EU Court of Justice in the prior authorization setting, interpreted as "an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition", such as "the history and probable course of his disease, the degree of pain he is in and/or the nature of his disability" (*Watts* C-372/04 paras 79 and 123).

<sup>12</sup> *Evans v UK*, Appl. no. 6339/05 (ECtHR, 10 April 2007) para 71.

<sup>13</sup> *ibid* paras 75-76 and 92.

<sup>14</sup> *S.H. and Others v Austria* Appl. no. 57813/00 (ECtHR 3 November 2011) GC para 89-116.

obligation in that respect', which was found compatible with Article 8 of the Convention (para 113). More successful was the *Costa Pavan* case, which challenged the Italian ban on ART and preimplantation genetic diagnosis (PGD) to avoid transmitting the genetic disorder - cystic fibrosis - to their offspring.<sup>15</sup> As the technique was only available to other categories of patients (infertile couples, HIV patients) to which they did not belong, they had no access to ART treatment, in addition to the blanket ban on PGD. Alternatively, the couple was allowed to abort the defective foetus, when it turned out to be affected by the disease (para 62). Such an inconsistency in Italian law on PGD was considered a disproportionate and therefore unlawful interference of the couple's private life (paras 64-71).

The latest ART case, *Parrillo v Italy*, diverges from the above cases as the ban concerned donated gametes through IVF for scientific research purposes.<sup>16</sup> After the unexpected death of her husband, Ms Parillo decided not to have the embryos implanted but requested – unsuccessfully - to release the cryopreserved embryos so that they could be used for stem cell research. The key issue was whether the Law prohibiting research on human embryos was incompatible with Parillo's right to a private life. According to the Court's standing case law, private life within the meaning of Article 8 of the Convention embraces, among others, the right to self-determination, meaning the freedom to choose whether to start a family or not.<sup>17</sup> In Parillo, the Court elaborates on that right, concluding that the right to self-determination also covers "the ability to exercise a [...] choice regarding the fate of her embryos not destined for implantation (para 159). This is based on the fact that "embryos contain the genetic material of the person in question" and accordingly represent a constituent part of that person's genetic material and biological identity" (para 158). But given the controversy and lack of consensus among Council of Europe member states on the donation of embryos not intended for implantation, domestic authorities enjoy a broad margin of discretion to enact restrictive legislation banning the donation of human embryos for scientific research. Taking into account the drafting process of the legislative ban, considering the different perspectives, the Court affirmed that Italy had not overstepped the wide margin of appreciation and that the ban was "necessary in a democratic society" under Article 8(2) of the Convention (para 197).

Other examples attempt to bring cross-border surrogate motherhood arrangements and reproductive techniques under Article 8 of the Convention (refusal to register a foreign birth certificate).<sup>18</sup> As the focus is more on the parent-child relationship, raising fundamental

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<sup>15</sup> *Costa and Pavan v Italy*, Appl. no. 54270/10 (ECtHR 11 February 2013).

<sup>16</sup> *Parrillo v Italy*, Appl. no. 46470/11 (ECtHR, 27 August 2015 [GC]).

<sup>17</sup> *Pretty v UK*, Appl. No. 4326/02 (ECtHR, 29 April 2002) para 61.

<sup>18</sup> E.g., *Menesson v France and Labassee v France* Appl. nos. 65192/11 and 65941/11 (ECtHR 26 September 2014) concerning the refusal to grant legal recognition to intended parents-child relationship that has been legally established in the US by gestational surrogacy; *D and Others v Belgium* concerning the initial refusal to authorise the arrival on its territory of a child who was born in the Ukraine from a surrogate pregnancy (Arts 3 and 8); *Paradiso and Campanelli v Italy* Appl. no. 25358/12 (ECtHR 25 January 2017): the placement of a nine-month-old baby in social service care who was born in Russia following a gestational surrogacy contract (Art. 8); *Foulon v France and Bouvet v France* Appl. nos. 9063/14 and 10410/14 (ECtHR, 21 October 2016) and *Laborie and Others v France* Appl. no. 44024/13, (ECtHR 17 January 2017).

questions of family law (i.e. maternity, paternity custody and children's rights, as well as the *mater semper certa est* principle), the transnational surrogacy cases are excluded from this analysis.

Outside Europe, in a landmark ruling the Inter-American Court of Human Rights (IACHR) applied treaty-based rights to annul a ban on performing IVF in Costa Rica.<sup>19</sup> In *Murillo and Others v Costa Rica*, the Court interpreted the scope of, among others, private and family life under the American Convention on Human Rights. Referring to other international human rights courts, the IACHR concluded that private life is a broad concept, "encompassing aspects of physical and social identity, the right to personal autonomy (...)", including "the decision whether or not to become a mother or father in the genetic or biological sense" (para 143).<sup>20</sup> Moreover, the right to private life is closely related to reproductive autonomy and access to reproductive services" (para 146), as confirmed by Article 16(e) of the Convention for the Elimination of All Forms of Discrimination against Women (CEDAW).<sup>21</sup> Therefore, the scope of private life and reproductive autonomy, ... give rise to the right to have access to the best health care services in assisted reproductive techniques (para 150). A ban on IVF can be regarded as interfering with a woman's private life because it hinders her right to control her fertility. Consequently, it violates a woman's reproductive autonomy and thus her right to private life. Furthermore, such a ban cannot be considered justified as it involves an arbitrary (i.e. discriminatory to infertile women) and excessive interference in private ... life that makes this interference disproportionate (para 316).<sup>22</sup> As a result, the Court ordered Costa Rica to legalise IVF and to take the necessary measures to safeguard equal access to IVF services whilst respecting the principles underlying reproductive rights, such as non-discrimination, information and education, high quality care, etc. (para 381). As such, the Court ruling echoes the core elements of reproductive rights as defined in international human rights treaties (e.g. Article 12 ICESCR, and Article 16 CEDAW) and treaty-related documents (e.g. the General Comment on Health and CEDAW Recommendation no. 24).

What becomes clear is the following. So far, both the European and the Inter-American Human Rights Courts have accepted the idea that the private life concept encompasses access to reproductive care. And thus obliges States to adopt positive measures securing the right to procreate by means of IVF technology (*Evans*). In the case of a contested measure

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<sup>19</sup> *Artavia Murillo and others v Costa Rica* Inter-Am. Ct.H.R. no. 257, Judgement of 28 November 2012, <http://corteidh.or.cr>.

<sup>20</sup> Here the Court made reference to the comparative European jurisprudence, referring to *Evans v UK*, *Dickson v UK*, and *S.H. and others v Austria*.

<sup>21</sup> According to which women enjoy the right "to decide freely and responsibly on the number of and spacing of their children and to have access to the information, education and means that enable them to exercise these rights", Art. 16(e) CEDAW.

<sup>22</sup> Not mentioned here but also interesting is the Court's interpretation of the Convention's right to life (Art. 4(1)) with respect to the prohibition on IVF. It raises the dispute when human life begins, and thus when the embryo requires protection within the scope of Convention. ... According to the Court, protection from the moment of conception should be understood as, the moment at which implantation in the uterus occurs, instead of from the moment of fertilization of the gametes. This means that prior to implantation Article 4 of the Convention is not applicable (para 264).

(e.g. ban on IVF and/or PGD), the analytical approach is similar: i) whether an interference is in accordance with the law and pursues a legitimate aim (e.g. protecting public morals or public health), and ii) to determine whether the measures taken were “necessary in a democratic society”, reviewing whether the reasons were relevant and sufficient for the purpose (not arbitrary or unreasonable).<sup>23</sup>

A new dimension to this approach will be added in the case of the denial of “medically assisted procreation” to same-sex couples, whether such a refusal results in discrimination based on sexual orientation (Art. 14 in conjunction of Art. 8 of the Convention).<sup>24</sup> Will the Court accept a same-sex couple’s controversial right to assisted procreation under the Convention? The Court will probably reiterate that ‘for the purpose of Article 14, a difference in treatment is discriminatory if it has no objective and reasonable justification, which means that it does not pursue a “legitimate aim” or that there is no “reasonable proportionality between the means employed and the aim sought to be realised”’.<sup>25</sup> And with regard to sexual orientation: ‘there is a need for particularly convincing and weighty reasons to justify a difference in treatment regarding rights falling within Article 8.’ In the Court’s option, refusing same-sex couples assisted procreation based solely on sexual orientation will be considered discriminatory and require very weighty reasons for denial when such services are available to heterosexual couples.

Cross-border reproductive care: a free movement issue under EU law?

Although the human rights approach dominates the access-to-ARTs debate, European Union law and the internal market principles in particular, they also play a (limited) role in facilitating *cross-border* access to ART treatment. A well known example is the case of Diane Blood, triggering the free movement of services, when exporting sperm of her deceased husband to another member state in order to be inseminated abroad.<sup>26</sup> In this national case, the English Court of Appeal agreed that the free movement provision (Art. 56 TFEU) was applicable and should have been taken into account in the decision to authorise the export.<sup>27</sup> Diane Blood is no exception, as recent studies show the growing popularity and thus emerging trend of ‘fertility tourism’ or infertile couples seeking cross-border reproductive care in other EU member states.<sup>28</sup> Reasons for crossing borders vary from avoiding legal restrictions in the resident country (e.g. fertility treatment for single or

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<sup>23</sup> *Knecht v Romania* Appl. no. 10048/10, ECtHR 2 October 2012, paras 56-60.

<sup>24</sup> Complaint lodged in 7 May 2015 by *Charron and Merle-Montet v France* Appl. no. 22612/15 (pending) in conjunction with Art. 8.

<sup>25</sup> *E.B. v France* Appl. no. 43546/02 (ECtHR, 22 January 2008) para 91.

<sup>26</sup> *R. v Human Fertilization and Embryology Authority*, ex parte Blood [1997] 2 All ER. 687.

<sup>27</sup> In more detail: TK Hervey and JV McHale, *European Union Health Law. Themes and Implications* (CUP 2015), p. 95.

<sup>28</sup> Although the exact data for cross-border reproductive care are unknown, there is some reliable evidence for an emerging trend based on a 2010 survey performed by the European Society for Human Reproduction and Embryology, F. Shenfield and others, ‘Cross-border reproductive care in six European countries’ (2010) 6 *Hum Reprod* p. 1361-1368. The study revealed some data on the frequency and destination countries estimating that there may be between 24,000-30,000 cycles of CBRC taking place in Europe per year, involving between 11,000-14,000 patients, at 1365.



lesbian woman in France), the expected better quality of care (e.g. better success rates abroad), to avoid waiting times at home (egg donation in the United Kingdom) or for less expensive treatment.<sup>29</sup> The reasons given illustrate patients' willingness to cross borders and therefore their reliance on the internal market rules.

Dealing with health care services, the first question raised is whether such services and ARTs in particular can be considered a 'service' under the Treaty on the Functioning of the European Union (Arts. 56-62 TFEU). Secondly, can national measures restricting health professionals providing health services abroad or patients in search of such services abroad be justified under EU law?

Apart from the confirmative answer given by the English Court of Appeal in the Diane Blood case, in the famous cases on *Decker* and *Kohll*, the European Court of Justice, renamed the Court of Justice of the European Union (CJEU), accepted that health services fall within the scope of 'services' under the treaty.<sup>30</sup> Health services are no different from other economic activities, where they are normally provided for remuneration' and thus have an economic nature. Despite the specific context in which health care is normally provided, the social security setting cannot deprive its economic nature of the health service in question (para 21). That being so:

'Article 49 EC (currently Art. 56 TFEU) applies where a patient ... receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services in subsequently sought operates.<sup>31</sup>

As a consequence, restrictions on the freedom of patients in search of cross-border (reproductive) health care services in another Member State are prohibited under EU economic law ... at least, in principle. In various rulings, the Court has been confronted with the delicate balance between Member States' autonomy to regulate and organise their health care system and upholding the basic freedoms applied in health care. To cope with that dilemma, any justification for restricting these freedoms must be necessary and proportionate. In the case of ART treatment, the main question concerns possible grounds for justified impediments. On several occasions, the Court reviewed the arguments presented to justify national restrictions on free movement. Starting with the restriction as such, it is clear that the refusal of reimbursement of health care services abroad is considered an important barrier to free movement. This is even more the case when the claimed service is covered by the national health care system. The justification is then based on the general or public interest argument raised in social security issues, i.e. the risk of uncontrolled health expenditure. Although purely economic reasons cannot justify any restriction of the fundamental freedoms, in *Kohll*, the Court accepted the argument that 'the risk of seriously undermining the financial balance of the social security system may

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<sup>29</sup> G Pennings and others, ESHRE Task Force on Ethics and Law 15: Cross-border reproductive care, (2008)10 *Hum Reprod* 2182-2184, at 2182; Shenfield (note 28), at 1363-64.

<sup>30</sup> *Kohll*, para 29.

<sup>31</sup> *Watts*, para 90 ECLI:EU:C:2006:325.

constitute an overriding reason in the general interest' justifying such a barrier (para 41). But in the case of the costs of dental treatment abroad, such a risk is unlikely. This would be different in the case of services provided in a hospital setting or using highly complex medical equipment and requiring a planning system. Here, the overriding risk of undermining the financial balance as well as wasting resources is more likely. Restricting free movement in the case of inpatient or 'high-tech' health services abroad can therefore be justified.<sup>32</sup> This reasoning was confirmed in the so-called Patient Mobility Directive (Directive 2011/24/EU) reading that 'the Member State of affiliation (i.e. the home state, *AdE*) may limit the application of the rules on reimbursement for cross-border health care based on overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources.'<sup>33</sup> The planning argument can be considered a public health justification and thus a reason of general interest: necessary to guarantee long term access for the entire population. But only as long as such restrictions are 'necessary and proportionate, and non-discriminatory'.<sup>34</sup> Article 8(2)(b)(c) includes another exemption: 'in case the treatment presents a particular risk for the patient or the population', or in the case of serious quality and safety concerns of the care provided abroad. Here, one may argue that innovative reproductive technologies using gene-editing techniques (e.g. CRISPR technology) may cause such a public health concern (risk of 'designer babies').

What should be emphasised is that Directive 2011/24/EU is only applicable to health services covered by the national benefit scheme to which the person is entitled (Art. 7(1)). In the case of a national ban on ARTs, the Directive and therefore reimbursement is not applicable. Nevertheless, EU citizens may receive these reproductive services abroad, but then at their own costs. This raises the question whether less fortunate infertile couples, when confronted with a national ban on ART treatment, could claim reimbursement of treatment abroad based on EU Charter rights?

### Cross-border reproductive care and "Charter shopping"

Since the Lisbon treaty, the EU Charter on Fundamental Rights has had the status of primary law, which rights can and must be invoked under both national courts and the Court of Justice.<sup>35</sup> Claiming access to ART treatment would be most likely be based on Article 35 providing that 'everyone has ... the right to benefit from medical treatment under the

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<sup>32</sup> See *Smits-Peerbooms* (Case C-157/99) ECLI:EU:C:2001:404; *Commission v France* (Case C-512/08), ECLI:EU:C:2010:579.

<sup>33</sup> Art. 7[9] Directive 2011/24/EU.

<sup>34</sup> Art.7(11)).

<sup>35</sup> FRA fundamental rights report 2016 on how national courts apply Charter rights. The FRA Case-law database provides a compilation of CJEU case law with direct reference to the Union Charter, such as *Brüstle* case (C-34/10)(human dignity), *Schrempfs* case (C-362/14) (private life); *Legér* case (C-528/13) (non-discrimination); *Weintor* (C-544-10)(public health), paras 42-59.

conditions established by nation laws and practices.<sup>36</sup> Challenging this right, one may argue that, according to contemporary human rights doctrine, the Charter rights create a positive obligation to provide and facilitate access to ART treatment. If accepted, this would mean an unprecedented infringement of the discretionary freedom of Member States to organise their own health care system. Most scholars, however, find it unlikely that the Charter right - or principle - to healthcare can be held justiciable.<sup>37</sup> This 'aspirational' norm leaves Member States a wide margin of appreciation on how to organise and to define the nature and scope of the health benefit scheme. And even when interpreted as a justiciable right, reading Article 35 more precisely, it has accepted such an ART ban by referring to 'the right benefit from medical treatment *under the conditions established by national law and practices.*'

Challenging the ART ban under the more 'individual rights' such as private and family life provisions (Art. 7) and gender-based non-discrimination (Art. 21(1))<sup>38</sup> also seems unlikely because neither rights are absolute, allowing restrictions set by law when necessary and proportionate. But in the absence of any case law, it is not known how the CJEU will interpret such a combined individual-social rights claim.<sup>39</sup> Moreover, and this is the most problematic hurdle when relying on the EU Charter Rights, the Charter refers to Union institutions and Member States only when they are implementing Union law (Art. 51(1)).<sup>40</sup> This is not the case with health care, as there is simply no EU health care system.<sup>41</sup> Although 'Union law and regulation on economic and fiscal governance is beginning to have an effect ... on national health care systems.'<sup>42</sup> But does this apply to ARTs? ART treatment is based on the use of human reproductive cells (sperm, eggs and embryonic stem cells), as covered by the Human Tissues and Cells Directive (Dir. 2004/23/EC, recital 7).<sup>43</sup> The Directive aims at standardising the quality and safety procedures of gametes, amongst others, as applied in

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<sup>36</sup> Either or not combined with other Charter rights, such as the right to private life (Art.7 corresponding to Art. 8 ECHR), and non-discrimination (Art. 21(1)).

<sup>37</sup> E.g., Hervey and McHale, Article 35, although the potential for a right to healthcare claim is there, particularly in case of vulnerable groups, in: S. Peers and others (eds), *The EU charter of fundamental rights: a commentary* (Hart 2014), p. 957; and linked with more individual rights, see Hervey and McHale p. 160, 176-7; the same line of reasoning, see N Koffeman, *Morally Sensitive Issues and Cross-border Movement in the EU. The cases of reproductive matters and legal recognition of same-sex relationships* (Diss.) (Intersentia 2015), p. 70-80; D Anderson and C Murphy, 'The Charter of Fundamental Rights', in A Biondi, P Eeckhout, S Ripley (eds), *EU Law after Lisbon* (OUP 2012), p. 161-2.

<sup>38</sup> Art. 21(1) including gender or sexual orientation-based discrimination of lesbian, bisexual and transgender women excluded from ART treatment.

<sup>39</sup> So far, available case law concerning Art.35 focusses on the protection of health then access to health care services, see CJEU C-544/10, *Deutsches Weintor*, 6 September 2012 (on marketing alcoholic beverages), CJEU C-570/07 and C-571/07 *Blanco Perez* (protection of public health) ECLI:EU:C:2010:300; C-267/10 and C-268/10 (selling tobacco products); CJEU C-343/09 Opinion A-G (interpreting precautionary principle). In *Stamatelaki* however, the A-G concluded that 'this right (to health care, AdE) is perceived as a personal entitlement, unconnected to a person's relationship with social security...'. Although the A-G considered the matter within the free movement of services context, he noted that 'citizens' right to health care are unjustifiably and disproportionately restricted (para 65). C-444/05, 11 January 2007.

<sup>40</sup> See also, e.g., case C-617/10 *Akerberg Fransson* [2013] ECR ECLI:EU:2013:105.

<sup>41</sup> Also Hervey (note 37).

<sup>42</sup> *ibid.*

<sup>43</sup> Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells, OJ L 102, 7 April 2004.

ARTs (Art. 1). Implementing the Directive's quality and safety standards in national measures would therefore 'trigger' the application of the Charter and thus the possibility of human rights review. At the same time, however, Article 51(2) does not extend the field of application *beyond* Union competences or establish any *new* power for the Union and therefore cannot be used as a gateway to general fundamental rights competence.<sup>44</sup> This is also confirmed by the Directive as it 'should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells' (recital 12). Only when 'any particular use of such cells is authorised in a Member State, will this Directive require the application of all provisions necessary to protect public health...' (recital 12). This means that Member States remain free to exclude ARTs from the health benefit scheme, and are thus excluded from the Charter's scope implementing Union law. But when approved, it should respect Union safety and quality norms, including donor rights such as informed consent and anonymity, respecting privacy and confidentiality and the non-discrimination principle.

Slightly different, but the similar result concerns the in vitro diagnostic medical devices Directive (IVDD), to be replaced by the new IVD Regulation.<sup>45</sup> The IVD Directive sets technical standards for manufacturers placing IVD products as applied for IVF treatments, on the market. Harmonisation of national legislation will remove existing barriers to free movement of IVD equipment within the EU. Although Member States will not create any obstacles to placing these devices on the market (Art. 4), the harmonising effect does not affect the Member States' exclusive competence to decide on the organisation and funding of IVD equipment under the public health or social insurance scheme (rec. 4). Revision of the IVDD under the forthcoming Regulation will not change this approach.<sup>46</sup> The trade-related approach of the IVDD/IVDR will therefore not support ART treatment claims under the EU Charter of Fundamental Rights.

### 3. Prospects for more coherence in regulating repro rights

Apart from harmonising safety and quality standards under the Human Tissues and Cells Directive, the analysis made clear that the availability, eligibility for treatment and requirements for reproductive health services remain the exclusive competence of Member States. This has resulted in a highly differentiated regulatory landscape of ART treatment,

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<sup>44</sup> The limited applicability of Union fundamental rights and the narrow approach taken by the Court of Justice so far, has also been criticized, see E Spaventa, *The interpretation of Article 51 of the EU Charter of Fundamental Rights: the dilemma of stricter or broader application of the Charter to national measures*, a study performed on behalf of DG for Internal Policies, 2016, p. 15 available at: [www.europarl.europa.eu/supporting-analyses](http://www.europarl.europa.eu/supporting-analyses).

<sup>45</sup> Directive 98/79/EC OJ L 331, 7.12.1998, as amended.

<sup>46</sup> *Idem* under the IVDR, Article 1(9): this Regulation shall not affect national legislation concerning the organisation, delivery or finance of health services and medical care, such as the requirement that certain medical devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or use certain devices or that their use is accompanied by specific professional counselling.

challenging women's reproductive rights in the EU.<sup>47</sup> The *Diane Blood* case made painfully clear that one can bypass more strict national regimes by invoking internal market principles. What's more, it reveals a new inequality: cross-border ART treatments for wealthy, well informed EU citizens in search of more advanced, more successful and less ethical(?) alternatives. EU law, however, seems unable to solve this inequality. Apparently, that is the price we pay for the lack of regulatory convergence in this field.<sup>48</sup>

The divergence in reproductive rights in Europe has been challenged by European Parliament. In a non-binding resolution on human rights, it was recognised that 'sexual and reproductive health and rights (SRHRs) are grounded in basic human rights and essential elements of human dignity, gender equality and self-determination', insisting 'on the role of the Union in awareness-raising and promoting best practices on this [women's reproductive health and rights, *AdE*] issue'.<sup>49</sup> Promoting best practices among Member States starts with collecting data on gender-based discrimination and reproductive health. This particularly applies for certain groups of women (lesbian, bisexual and transgender women) facing discrimination on the basis of their sexual orientation or gender identity. In the 2016 resolution, European Parliament repeated that call, but instead of incorporating gender in the EU Health Strategy, it called the Commission to include gender issues in all its policies, incorporating 'a systematic gender impact assessment as part of the fundamental rights compliance assessment'.<sup>50</sup> The systematic monitoring of progress in gender equality and reproductive health issues makes it possible to identify gaps at country level and to analyse progress. In a way, the Gender Equality Index 2015 already addresses women's health and gender equality but it does not differentiate in reproductive health issues.<sup>51</sup> Using reproductive health indicators (e.g. access and availability of reproductive health services, infertility rate, reproductive health rights legislation, accountability mechanisms, etc.)<sup>52</sup> with gender equality indicators<sup>53</sup> makes it possible to measure manifest gaps in reproductive rights and gender inequalities and to monitor a country's progress in improving access to reproductive services, including ART treatment. In this process, the European Institute for

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<sup>47</sup> K Berg Brigham and others, 'The Diversity of regulation and public financing of IVF in Europe and its impact on utilization' (2013) 3 *Hum Reprod* 666-675; European Society of Human Reproduction and Embryology (ESHRE), *Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies*, Final Report 2009 ESHRE p 20-26.

<sup>48</sup> M Frischhut, Legal and ethical issues of cross-border reproductive care from an EU perspective, in M.K. Smith and L Puczkó (eds), *The Routledge Handbook of Health Tourism* (Routledge, London 2017), pp. 203-218, at 213.

<sup>49</sup> European Parliament of 8 September 2015 on the situation of fundamental rights in the EU (2013-2014), (2014/2254(INI)), rec 69.

<sup>50</sup> European Parliament resolution of 13 December 2016 on the situation of fundamental rights in the EU in 2015, (2016/2009(INI)) Women's rights, para 78.

<sup>51</sup> [Eige.europa.eu/gender-statistics/](http://Eige.europa.eu/gender-statistics/).

<sup>52</sup> Measuring gender-related change in the field of access to reproductive health services over time between men and women, and special groups such as LGBTI in particular. There are a number of such indicators developed by inter alia, the World Health Organization (WHO Reproductive Health Indicators. Guidelines for their generation, interpretation and analysis for global monitoring, 2006), and the Guttmacher Institute, *Sexual and Reproductive Health and Rights Indicators for the SDGs* (2015) available at: [www.guttmacher.org](http://www.guttmacher.org).

<sup>53</sup> Including both international and national indicators such as the sustainable development goals (SDGs), developed at UN level, regional indicators, the 'OECD Gender Index' and UNECE 'Indicators of Gender Equality' (2015), and other national criteria.

Gender Equality (EIGE) should play a key role in selecting relevant indicators, reviewing the impact of national measures and actions taken to improve reproductive rights and access to reproductive services for marginalised groups in particular. The outcomes will trigger a national and European debate about raising awareness and promoting best practices on improving reproductive rights in Europe, as emphasised by European Parliament. The subsequent debate may hold countries accountable for identified gaps, promoting the ‘transferability’ of national achievements across Member States. This approach to measuring the progress of reproductive health rights does not necessarily harmonise the divergent regulatory frameworks in Europe but it certainly contributes to the underlying concepts on progressive realisation of reproductive rights and holding countries accountable for gender and health inequalities and gender-based discrimination in access to reproductive health services. In fact, the use of indicators, benchmarks and exchanging best practices may produce more coherence (and convergence?) of standards on reproductive rights, as observed in other fields.<sup>54</sup>

This ‘soft law’ method used as guidance for EU and national legislatures reflects the core elements of the ICESCR and CEDAW state obligations (e.g. taking steps to fulfil women’s right to health care according to the maximum available resources, measures to eliminate barriers to accessing reproductive health services, developing a reporting system to ensure equal access, etc.).<sup>55</sup> However, any future trend towards more coherence does not detract Member States to restrict reproductive health rights (e.g. by limiting access to ART treatment). But such limitations ‘should be justified on grounds of public order or public health’<sup>56</sup> and be strictly necessary for the promotion of the general welfare in a democratic society (Article 4). And, even more interestingly, although public health motivated restrictions can be justified, ... ‘they should be of limited duration and subject to review’ (para 29). Focusing on ART treatment, this means that permanently excluding certain groups (LGTBI) for reasons of public order or public health would be unjustified as this could be considered an act ‘aimed at the destruction of any of the rights ... recognised herein, or at their limitation to a greater extent than is provided for in the Covenant’ (Article 5 ICESCR).

Finally, the identified gaps and inequalities *between* Member States call for improving cross-border collaboration in the field of reproductive rights. As under the ICESCR international cooperation clause, all States, including EU Member States, are obliged to collaborate to comply with the full realisation of Article 12 as ‘gross inequalities in health status of the people ... are politically, socially and economically unacceptable, and therefore of common concern to all countries’ (para 38). This can be interpreted as an obligation to conclude bilateral agreements which facilitate cross-border access in the field of essential, and therefore reproductive, health services where possible and required.

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<sup>54</sup> Notably social security and social protection, see e.g, F Pennings and G Vonk, *Research Handbook on European social security law* (Edward Elgar Publishing, 2015), p 223-229; Although there is a fierce debate over the value of soft law. D Chalmers, and others, *European Union law* (3rd ed. CUP, 2010) 102-3.

<sup>55</sup> As referred in GC no. 14 (Art. 12 ICESCR) and GR no. 24 (Art. 12 CEDAW).

<sup>56</sup> CESCR interpretation of the Article 4 clause, GC no. 14, para 28.

#### 4. Final remarks

Reproductive health care services remain a non-harmonised area of EU law. Excluded from EU competences, the divergence in regulatory frameworks and reproductive rights has not triggered [national courts] or the CJEU to remove the barriers hindering the free movement of reproductive health services, and access to ART treatment in particular. Even under the Fundamental Rights Charter, this is unlikely to be changed because it does not establish any new power for the Union and cannot therefore be used to hold Charter rights justiciable.

Instead, filling the gaps in reproductive rights and improving access to ART treatment in particular, the use of soft law mechanisms on monitoring, measuring gender and reproductive health indicators and exchanging best practices may promote the use of a common set of principles or standards on reproductive health services and for holding Member States accountable for barriers to and new inequalities in access to reproductive treatment options.





# Chapter XI Rare diseases policies, European reference centers, and cooperation initiatives\*

Pilar Nicolás

## 1. Introduction

Rare diseases (RD) are defined as those which affect no more than 5 per 10 000 persons.<sup>1</sup> Although this low prevalence, as a whole, RD affect millions of people in Europe (between 27 and 36 million, 6-8 % of the population).<sup>2</sup> The European Union has been aware of the specific issues rose by this kind of conditions and the need to face them from a transnational perspective.

The first Programme of Community Action on RD start up took place in 1999 with the Decision No 1295/99/EC of the European Parliament and of the Council of 29 April adopting a programme of Community action on RD (1999-2003). The Decision provides that the Commission representative shall submit to the Committee an annual work programme indicating the priorities for action (Article 5(2b)). The priorities for action were: 1. General directions and balances of the programme Community added value giving priority “to projects and to networks with a substantial European dimension that are likely to make a significant contribution towards the attainment of the programme’s objectives; 2. Horizontal approach (taking into account that the budget allocation for the period was too limited to allow a disease specific approach -€1.3 million per year for more than 5.000 diseases- priority was given “to projects addressing or providing for action on rare diseases in general, important groups of diseases or at least a considerable number of them”); 3 Priority was given to the implementation of the European information network on RD.

One year later, Regulation (EC) No 141/2000 on orphan medicinal products was published, aimed at implementing measures to foster the development of medicinal products to diagnose, prevent or treat these conditions, as the cost would not be recovered (called orphan medicines).<sup>3</sup>

In 2008, the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on RD,

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\* This work has been generously supported by the Basque Government, ref. no. IT1066-16 (Basque University System Research Groups).

<sup>1</sup> Council Recommendation of 8 June 2009 on an action in the field of rare diseases [2009] OJ C 151/7. Recommendation II.

<sup>2</sup> European Commission Public Health web <[http://ec.europa.eu/health/rare\\_diseases/policy\\_en](http://ec.europa.eu/health/rare_diseases/policy_en)> accessed 2 May 2017.

<sup>3</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L 18/1.

identified the common strategy concerning RD as a Europe's challenge. The Communication reaffirmed that “the specificities of rare diseases - limited number of patients and scarcity of relevant knowledge and expertise - single them out as a distinctive domain of very high European added-value. European cooperation can help to ensure that scarce knowledge can be shared and resources combined as efficiently as possible, in order to tackle rare diseases effectively across the EU as a whole”.<sup>4</sup> The aim of the Communication was to clarify the direction of the activities in the field of RD oriented to three fields of work: improving recognition and visibility on RD, supporting policies on RD in the Member States and developing European cooperation, coordination, and regulation for RD. Some operational actions were described as “improving universal access to high-quality healthcare for rare diseases, in particular through development of national/regional centres of expertise and establishing EU reference networks”.<sup>5</sup>

In the first years of the XX century some other interesting documents, reports and studies were published emphasizing the need of a European approach in this field, and new initiatives were developed. A good summary can be found in the Recitals of the Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02). The Recommendation has been an important milestone in the adoption of transnational health strategies. It insisted on the need of a global European approach to optimize efforts in RD strategies: “because of their low prevalence, their specificity and the high total number of people affected, rare diseases call for a global approach based on special and combined efforts to prevent significant morbidity or avoidable premature mortality, and to improve the quality of life and socioeconomic potential of affected persons”. The Council recommends Member States, among other things, to establish and implement plans or strategies for RD; to contribute to the development of the European easily accessible and dynamic inventory of RD based on the existing networks; support specific disease information networks, registries and databases; identify ongoing research in the area of RD and improve the coordination programs for RD research; identify needs and priorities for basic, clinical, translational and social research; identify appropriate centres of expertise and consider supporting their creation; support the communication technologies to ensure distant access to the specific healthcare needed; and empower patient organizations; ensure the long-term sustainability of infrastructures developed in the field of information, research and healthcare for RD.

The Implementation Report of the Recommendation was published in 2014. This document states that a significant number of Member States had put in place RD National Plans since the Recommendation was adopted but that “there is still a long way to go to ensure that people suffering from a rare disease can obtain the right diagnosis and best possible treatment throughout the EU”.<sup>6</sup> The report mentions some important actions that Member

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<sup>4</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions on Rare Diseases: Europe's challenges (2008) 3.

<sup>5</sup> *ibid*, 5.

<sup>6</sup> European Commission, ‘Implementation report. Health and Consumers on the Commission Communication on Rare Diseases: Europe’s challenges and Council Recommendation of 8 June 2009 on an action in the field of rare diseases’ [2014] 12.

States should support, as “make use of the Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare to bring together European Reference Networks on rare diseases”.<sup>7</sup>

In fact, as one of the objectives of Directive 2011/24/EU is to foster a European cooperation for helping in the diagnosis and follow up of patients, it provides some mechanisms that can be useful in the concrete area of RD, were, at is has been said, the strategy to enhance diagnosis and treatment, must be a transnational one.

In this sense, the Directive states that “European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases [so it gives] “incentives to Member States to reinforce the continued development of European reference networks” (recital 54).

From the side of funding research, the sixth and the seventh framework programmes for research and development (years 2002-2006 and 2007-2013) as well as the Horizon 2020 (years 2014-2020) include research on RD as a priority so many RD initiatives have been funded from the European institutions.<sup>8</sup>

The principle of subsidiarity (Article 5.3 of the Lisbon Treaty) joined with the description of the Community health policies (Article 152 of the Treaty), justify the action of the EU in RD. In fact, it has been explained above that the objective of these actions is to ensure a high level of human health protection complementing national policies as the Union is the most appropriate level to face the strategy in the field of RD. Moreover, as said in the Public Consultation on RD: Europe’s challenges, by the European Commission Health and Consumer Protection Directorate-General: “Community strategy on rare diseases is also linked to implementation of European values, such as the fight against discrimination, including those based on disabilities, and the protection of human rights”.<sup>9</sup>

In the following pages some tools in the framework of RD policies will be described, and the Enerca Project and Eurobloodnet illustrate the practical development of networking.

## 2. Rare diseases policies: Fostering patient rights

Fostering patient rights (right to diagnosis and to clinical treatment), enhancing research and establishing Reference Centers are, in general and among others, three fundamental

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[http://ec.europa.eu/health/sites/health/files/rare\\_diseases/docs/2014\\_rarediseases\\_implementationreport\\_en.pdf](http://ec.europa.eu/health/sites/health/files/rare_diseases/docs/2014_rarediseases_implementationreport_en.pdf) accessed 2 May 2017.

<sup>7</sup> *ibid* 16.

<sup>8</sup> The projects can be found at <<https://ec.europa.eu/research/health/index.cfm?pg=projects>>.

<sup>9</sup> European Commission. Health & Consumer Protection Directorate General, Public Consultation Rare Diseases: Europe’s challenges [2008] 4

[http://ec.europa.eu/health/archive/ph\\_threats/non\\_com/docs/raredis\\_comm\\_en.pdf](http://ec.europa.eu/health/archive/ph_threats/non_com/docs/raredis_comm_en.pdf) accessed 2 May 2017

strategies in health care policies. In the particular case of RD these three strategies have a singular interest.

According to Article 13: “The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to: (a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks; (b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States, even for diagnosis and treatments which are not available in the Member State of affiliation”. In other words, the Europe institutions insist in the utility of the already implemented tools and ask for optimize their use. These three tools refer to the development of drugs and treatment, the design of new European structures, and the facilitation of cross border health care.

## 2.1 Orphanet, Orphan Drugs and clinical trials

In 1997 as an initiative of the French INSERM, a portal for information on RD and orphan drugs was created, Orphanet. This platform is supported by Inserm, the French Directorate General for Health, the European Commission and national institutions for national activities. Among its services, Orphanet offers an inventory of orphan drugs at all stages of development, as one of the main concern of the platform is to spread information to facilitate the diagnosis and treatment of RD.

One of the main concern in the field of RD is that, due to the small amount of population affected by one specific disease, the commercial benefit of the commercialization of medicinal products is very low, so it is the interest of the pharmaceutical industry in the research and development of these products (orphan medicines) as the cost would be not recovered.

From the legal perspective, two main European instruments are relevant for implementing measures facing this concern: the EU Regulation on orphan medicinal products (Regulation (EC) No 141/2000, mentioned above, and the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

To stimulate the research and development of orphan drugs, EU Regulation 141/2000 introduces several incentives, such as a product designation procedure free of charge, or fee waivers or long market exclusivity periods. The Regulation designated the Committee for Orphan Medicinal Products (COMP), as the European Medicines Agency's (EMA) committee responsible for recommending orphan designation of medicines for RD. COMP also advises and assists the European Commission on matters related to orphan medicines, as developing and establishing an EU-wide policy or drawing up guidelines. However, although

the number of products authorized has grown over the years, only 1% of RD is covered by authorized medicinal products in the EU,<sup>10</sup> so more effort was needed.

In this sense, Regulation (EU) No 536/2014 on clinical trials refers expressly to orphan drugs and states that clinical trials for the development of orphan medicinal and of medicinal products addressed to subjects affected by severe, debilitating and often life-threatening diseases affecting no more than one person in 50 000 in the Union (ultra-RD) should be fostered (recital 9). According to the Regulation, Member States should efficiently assess all clinical trials applications within the given timelines, but a rapid yet indepth assessment is of particular importance for clinical trials concerning medical conditions for which therapeutic options are limited or non-existent, as in the case of rare and ultra-rare diseases (recital 10). The assessment of applications for the authorisation of clinical trials should be conducted on the basis of appropriate expertise, and specific expertise should be considered when assessing clinical trials involving people suffering from rare and ultra rare diseases (recital 19 and Article 10.4).

## 2.2. European Reference Centers and Networks

Council Recommendation in the field of RD (2009), mentioned above, suggested that Member States identify appropriate centers of expertise throughout their national territory by the end of 2013, and considers supporting their creation (Recommendation number 11). Identification is the first needed step in order to implement a European cooperation in the diagnosis and treatment of RD, as these centers are the ones to integrate the future European Reference Networks. Identification of centers of expertise facilitates the organization of healthcare pathways for patients “through the establishment of cooperation with relevant experts and exchange of professionals and expertise within the country or from abroad when necessary” (Recommendation 13).

This challenge has been incorporated in Article 12 of the Directive 2011/24/EU. In fact, it encourages the Member States to facilitate the development of European reference networks through the adoption of the several strategies, among which it is mentioned “connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory” and “fostering the participation of healthcare providers and centres of expertise in the European reference networks”. According to Article 12, several actions must be taken in order to promote the creation of these Networks, both by the Member States and the Commission.

States shall connect healthcare providers and centres of expertise throughout their national territory and ensure the dissemination of information. National Reference Centres are recognized and authorized by a National authority generally linked to the Ministry of Health,

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<sup>10</sup> European Commission, Inventory of Union and Member State incentives to support research into, and the development and availability of, orphan medicinal products [2015] 4  
[https://ec.europa.eu/health/sites/health/files/files/orphanmp/doc/orphan\\_inv\\_report\\_20160126.pdf](https://ec.europa.eu/health/sites/health/files/files/orphanmp/doc/orphan_inv_report_20160126.pdf)  
accessed 2 May 2017.

according to the requisites established in national Laws, protocols or policies. In the case of RD, the establishment of these requisites has a common base agreed by Eucerd (European Union Committee of Experts Rare Diseases) in 2011. The requisites deal with expertise qualification (documented by the annual volume of referrals and second opinions, and through peer-reviewed publications, grants, positions, teaching and training activities), technical quality (the participation in internal and external quality schemes), organization parameters that assure the sustainability of the activities, the capacity of training other professionals, or the availability of systems that facilitate the collaboration (such as shared case management systems, expert systems for tele-expertise and shared repository of cases).<sup>11</sup>

The Commission shall take measures but not harmonize any laws or regulations of the Member States. It is stated that the Commission shall adopt a list of specific criteria and conditions that the European reference networks of national expert centers must fulfil. These criteria and conditions shall ensure, inter alia, that European reference networks: “a) have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes; b) follow a multi-disciplinary approach; c) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control; d) make a contribution to research; e) organise teaching and training activities; and f) collaborate closely with other centres of expertise and networks at national and international level”.

Article 12 includes a set of objectives, and establishes that European reference networks shall pursue, at least, three of them: a) to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies; b) to contribute to the pooling of knowledge regarding sickness prevention; c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare; d) to maximise the cost-effective use of resources by concentrating them where appropriate; e) to reinforce research, epidemiological surveillance like registries and provide training for health professionals; f) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of RD, within and outside the networks; g) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network; h) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

Following this strategy, the Commission took two decisions that entered into force in May 2014: A Delegated Decision setting out criteria and conditions that European Reference

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<sup>11</sup> European Union Committee of Experts Rare Diseases, ‘Recommendations quality criteria for centres of expertise for rare diseases in Member States’, [2011] *passim*  
[https://ec.europa.eu/health/sites/health/files/rare\\_diseases/docs/eucerd\\_centreexpertise\\_en.pdf](https://ec.europa.eu/health/sites/health/files/rare_diseases/docs/eucerd_centreexpertise_en.pdf) accessed 2 May 2017.

Networks and healthcare providers wishing to join a European Reference Network must fulfil,<sup>12</sup> and an Implementing Decision setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks.<sup>13</sup>

### 2.3. Cross border health care

As has been said, both research and clinical approach regarding RD should be addressed from a broad perspective, and not only within the national framework. In this sense, Directive 2011/24/EU on patients' rights in cross-border healthcare, seems to be a step forward, as it states the possibility to refer patients to other Member State for a better diagnosis and treatment. This is notably relevant for RD patients. In fact, the Directive refers to RD several times taking into account its singular characteristics but we should remind that Article 13 refers to the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with RD to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation. What is the meaning of this reference? How would Regulation 883/2004 benefit a RD patient? Does the Directive present any advantage for a RD patient regarding the diagnosis and treatment? The most frequent scenario is that a patient wants to visit a center in another country for diagnosis or treatment, since there is a greater knowledge of the disease, or a concrete technique is available abroad but not in his / her country. With this scenario in mind, there are some relevant issues to be taken into account in order to compare the two instruments.

First, the scope of the Directive and that of the Regulation differs from a sociological perspective. While the Regulation is based on the free movement of workers, the Directive is committed to the free movement of patients. Within the provisions of Regulation, all the European citizens in any Member State *where he is* because of professional or other reasons, have the right to healthcare in a framework of a the coordination between States. The Directive recognizes the right of the European citizens to choose the (health)service provider, so the concept of worker loses entity and the purpose is precisely to cover travel with the intention of receiving health care in another State.<sup>14</sup> In this sense, the Directive gives the opportunity to choose a center in other country, just because it is specialized in a concrete disease or treatment, and this is an important advantage for rare disease patients.

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<sup>12</sup> Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil [2014] OJ L 147/71.

<sup>13</sup> Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks [2014] OJ L 147/79.

<sup>14</sup> Joaquín García Murcia and Antonio Rodríguez Cardo 'Asistencia sanitaria transfronteriza en el ámbito de la Unión Europea: de la seguridad social de trabajadores migrantes a una regulación específica' (2014) 17(1) Foro. Nueva época 309, 324 <https://revistas.ucm.es/index.php/FORO/article/viewFile/48623/45412> accessed 2 May 2017

Second, the system in place in the Regulation is a *reimbursement of the cost between institutions* and the system in the Directive, is a *reimbursement to the patient* who had paid the service before.<sup>15</sup> The first system is more beneficial for patient.

Third, as the Regulation is based on the free movement of workers, only exceptionally allows the reimbursement of expenses in situations of travel with a specific purpose of receiving medical treatment: Article 20 states that a citizen can also travel to other country with the purpose of receiving a treatment when the treatment cannot be given in his country within a time-limit which is medically justifiable, taking into account his current state of health and the probable course of his illness. This restricts the services that can be reimbursed.

Forth, in this last exceptional case, the patient needs prior authorization and, contrary, the rule in the Directive is that no authorization is needed to receive the treatment in another country. However, Article 8 of the Directive states the condition of authorization in some particular cases (Member States can provide a regime of prior authorization in this case, and twenty-one Member States have introduced this system).<sup>16</sup> Among other circumstances, the need of overnight hospital accommodation for at least one night, or the use of highly specialized and cost-intensive medical infrastructure or medical equipment could justify the application of this requisite.<sup>17</sup> So, very often, both regimes of rare disease patients require prior authorization before travelling.

Fifth, in the Regulation, authorization can be denied when the treatment can be given in the country of the patient within a time-limit which is medically justifiable, taking into account his current state of health and probable course of illness. This reason does not justify the denial of the authorization in the Directive. In Spain, justification for refusal of the treatment within the provisions of the Regulation has been interpreted in a very restricted way in certain cases (before the entry into force of the Directive, must be noted). Based on the Community provisions on social security Regulation, the Social Court No. 1 of Toledo (Spain), in its decision of July 31, 2013, recognized the right to reimbursement of expenses of a patient who had been treated since 2003 in a German clinic with a previous authorization by the Health Service in Spain. In March 2012, however, he requested again the authorization to continue the treatment, but the request was denied because the

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<sup>15</sup> It has been said that "Given the evolution of the negotiations on the Directive, it is hard to avoid the conclusion that despite direct payment being included as option for Member States, they will systematically avoid this option. So far, there has been reluctance among Member States to address the technical aspects of using direct payment under the Directive due to a lack of demand, but the Commission hopes that as more patients begin to use the Directive and more data on take-up is gathered, it will be possible to assess the impact of the different options in the 2015 progress report". European Patient Forum 4th Regional Conference on the EU Directive on Cross-Border Healthcare Conference Report (2014) 12 [http://www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/cbhc\\_conf-report\\_4est-jul2014.pdf](http://www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/cbhc_conf-report_4est-jul2014.pdf) accessed 2 May 2017.

<sup>16</sup> Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (2015) 17 [http://ec.europa.eu/health/sites/health/files/cross\\_border\\_care/docs/2015\\_operation\\_report\\_dir201124eu\\_en.pdf](http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf) accessed 2 May 2017.

<sup>17</sup> "It is questionable whether this is in line with the criterion in Article 8(2)(a), which relates to the way treatment is provided in the Member State of affiliation rather than the Member State of treatment" *ibid*, 4.



Spanish authority considered that there was possibility of treatment in Spain. The court declared that there is a right of Community workers and members of their families to receive, in the other Member States of the Union, a health treatment which the Member State of residence is obliged to provide, when treatment cannot be dispensed in the state of residence. This right extends both to cases in which treatment cannot be provided in the territory of the State of residence and in which treatments are simply more effective in the other State of the Union than in the territory of the Member State of residence. In this particular case, the treatment could not be given in Spain because it was a complex, rare, serious and an infrequent disease, for which there are no specialized centers in the country.<sup>18</sup>

Sixth, as the Directive does not deal with the coordination of the public health systems, but with the freedom of movement and services within all the Union, and the right to choose a service in any Member State, the service abroad can be given by a public or private institution. The expert networks of centers in RD (see epigraph 2.2) are the framework to facilitate sharing knowledge and patients and the nets are made up of public and public centers. Including the possibility to go to private centers benefit rare disease patients.

Seventh, in both legal instruments, regarding the reimbursement, it is required that the treatment is under the benefits provided in the Member State of the person (in the benefit basket in the home country). Rare disease patients seek diagnosis or treatment in another country because it is not available in their home country or because there is professional or a center specialized in that concrete disease in a certain country. In case of diagnosis, most tests are generally covered in the National health systems, so the authorization to undergo the test abroad cannot be denied.<sup>19</sup> The problem is when the patient needs a treatment that is not described in the basket of benefits in his home country. There is an important margin of discretion concerning this issue because, among other reasons, the level of explicitness of the benefits basket varies significantly among Member States.<sup>20</sup>

In short, the scenario described above, which motivates travel to a patient with a rare disease, is more accurately reflected in the Directive, fits better in its conception. Why then does the Directive itself refer to another Regulation for the case of patients with RD? The answer seems to lie in the advantages of the reimbursement system, but it will be necessary to make a flexible interpretation of the provisions of the Regulation to benefit ER patients, and to keep in mind that private institutions are left out. Consultation with the National Contact Point on the best option in each case is crucial. The duty laid down in Article 13 of

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<sup>18</sup> Vicente Lomas Hernández, 'Comentario sobre el Real Decreto 81/2014, de 7 de febrero por el que se establecen normas para garantizar la asistencia sanitaria transfronteriza, y por el que se modifica el RD 1718/2010, de 17 de diciembre, sobre receta médica y órdenes de dispensación' (2014) 9 Revista CESCO de Derecho de Consumo 177, 178 <<https://www.revista.uclm.es/index.php/cesco/article/view/481/417>> accessed 2 May 2017.

<sup>19</sup> European Patient Forum 4th Regional Conference on the EU Directive on Cross-Border Healthcare Conference Report (n 15) 12.

<sup>20</sup> Reinhard Busse and others, 'Benefit baskets and tariffs' in Matthias Wismar and others (eds.), Cross-border Health Care in the European Union. Mapping and analysing practices and policies (European Observatory on Health Systems and Policies 2011) 94 <[http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0004/135994/e94875.pdf](http://www.euro.who.int/__data/assets/pdf_file/0004/135994/e94875.pdf)> accessed 2 May 2017

the Directive, according to which States should ensure that professionals and patients are aware of all the possibilities that can be exploited, should also be emphasized. The Networks, to which I will refer below, can also play a very important role in this regard. They can draft catalogues of diagnosis and treatment procedures, identify the best centers in Europe for each one of them, and transfer to the National Authorities the options that are better for the patients in each case, with accredited scientific support.

### 3. Cooperation initiatives. Enerca Project and Eurobloodnet

For many years, initiatives have been led in the field of RD by health professionals. The support of the European institutions has been crucial in their development. All the instruments cited above have provided a framework for this awareness. The role of patients associations must be also mentioned, the implication of Eurordis? has been notably important. These joined efforts, as pilot projects, have been the essential basis for more ambitious networks.

The European Network for Rare and Congenital Anaemias (ENERCA) is a good example of this activity.<sup>21</sup> Enerca is a consortium created in 2002 that has been developed in four phases. Its main objective was the establishment of a European Network of Expert Centres in Rare Anaemias (RA). The consortium has been integrated out by 48 partners, covering the majority of Member States.

ENERCA partners have developed different activities to promote the harmonization of procedures for diagnosis, treatment and follow up of patients with RA, to provide a tool for epidemiological surveillance of RA in Europe, to improve continuous medical education in order to ensure the provision of the highest quality services for patients with RA, to increase patients and public awareness about RA, and to promote research and cooperation between experts and expert centers in RA.

Others actions concern the publication of a white book of Recommendations for Centres of Expertise in Rare Anaemias,<sup>22</sup> the creation of a telemedicine platform, the organization of courses, and dissemination of educational material stand out. The Chair in Law and the Human Genome (through the University of Deusto and through the University of the Basque Country) has been a partner, assessing about the ethical and legal issues of these activities.

Enerca partners realise that the model of the European Reference Networks (ERNs) is a major challenge to overcome specific problems of: scarcity of patients, resources and expertise. ERNs “allow the rare disease community the possibility of reaching a larger number of patients and a more diverse range of rare diseases”.<sup>23</sup> So ENERCA and the

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<sup>21</sup> See <https://www.enerca.org>.

<sup>22</sup> Joan Luis Vives-Corróns and others, ENERCA recommendations for centres of expertise in rare anaemias A WHITE BOOK (2014).

<sup>23</sup> Maria del Mar Mañú Pereira and Victoria Gutiérrez Valle, ‘From ENERCA to the establishment of a European Reference Network of centres of expertise in Rare Hematolo-gical diseases: potential ethical issues impacting on its implementation’ (2016) 44 *Revista de Derecho y Genoma Humano* / *Law and the Human Genome Review* 33, 46.

European Haematology Association (EHA) prepared a common application and now they integrate a Rare Haematological Diseases European Reference Network, known as EuroBloodNet.<sup>24</sup> As the other European reference networks, Eurobloodnet started its activities on March 1, 2017. The Commission provides support to the Network's coordinator, but the main contribution comes from the healthcare centers and national health authorities.

One important perspective that will be crucial for the success of the network is the analysis of the ethical and legal implications of its activities.<sup>25</sup> The transfer of data (clinical records) and biological samples will be needed in order to receive a treatment abroad, but could also facilitate that patients could stay in their country while the professionals in the net would assess the diagnosis and treatment. The exchange of data and samples through the members of the net will enhance the opportunities for develop research projects and patient registries. This legal analysis must be carried out within the framework of the Regulation (EU) 2016/679 on the processing of personal data,<sup>26</sup> and the Convention of the Council of Europe on Human Rights and Biomedicine and its Additional Protocols. Other legal issues concern the rights and duties of health professionals involved in cross border health services, and the claims of patients to receive access to treatment and being reimbursed.<sup>27</sup>

For this reason, risks related to legal and ethical issues are included as a specific topic in the risk management plan of EuroBloodNet and experts in biolaw have been appointed as members of the advisory board.<sup>28</sup>

#### 4. Conclusion

Since the nineties, the European Union has been aware of the specific issues rose by RD. A common action is needed to achieve a better perspective for these patients. Fostering patient rights (the right to diagnosis and to clinical treatment), enhancing research and identifying Reference Centers are, in general and among others, three fundamental strategies in health care policies. In the particular case of RD, these three strategies have a singular interest and are the basis of creating and promoting European Reference Networks (ERN), the main tool of European rare diseases policy.

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<sup>24</sup> Joan Lluís Vives Corrons, 'EuroBloodNet: From Rare Anaemias to Rare Haematological Diseases, a Transitional Proposal for European Reference Network (ERN)' (2016) 2 J Rare Dis Diagn Ther., p. 4. doi:10.21767/2380-7245.100047 <http://raredisorders.imedpub.com/eurobloodnet-from-rare-anaemias-to-rare-haematological-diseases-a-transitional-proposal-for-european-reference-network-ern.php?aid=9948> accessed 2 May 2017.

<sup>25</sup> *ibid.*

<sup>26</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1.

<sup>27</sup> Mañú Pereira and Gutiérrez Valle, 'From ENERCA to the establishment of a European Reference Network of centres of expertise in Rare Hematological diseases: potential ethical issues impacting on its implementation' (n 23) 48-49.

<sup>28</sup> *ibid.*, 50 – 51.

ERN will play a crucial role guiding patients to choose better options in cross border health care (either Directive 2011/24/EU or Regulation 883/2004). ERN will also improve RD clinical research bringing together patients and professionals from different countries, and fostering the legal advantages for clinical trials. As ERNs will facilitate the collaboration between professionals and institutions, they will enhance the quality of health services.

For these reasons European institutions and Member States must make efforts to support the networks, as their sustainability cannot be the responsibility of health professionals only.

Another important action regarding the success of the networks is to address several ethical and legal issues, such as sharing data and biological samples, and the rights and duties of health professionals involved. Despite of some particularities, most of these issues are common to all ERNs, therefore a common analysis and guidelines are required.

# Chapter XII Health Technology Assessment and its Relevance to Cross-border Healthcare in Europe

Verena Stühlinger, Petra Schnell-Inderst, Uwe Siebert

## 1. Introduction

Innovation and new health technologies play a critical role in modern societies. On the one hand they can be highly valuable, generating important jobs, improving health or saving lives.<sup>1</sup> On the other hand, new health technologies can be harmful or even life-threatening and can represent high costs for health systems.<sup>2</sup> In times of slowing economic growth and budgetary constraints across Europe, there is a need for thorough reflection on how healthcare costs can be reduced and on how health budgets are spent. Thus, a systematic assessment of new health technologies, especially high cost investments, is crucial to ensure the sustainability of health systems and equitable access to innovative health technology.

Since the mid-1960s, technology assessment has been used in the USA to systematically evaluate the effects – both intended and unintended – of innovative products, including some healthcare technologies. In 1965, US congressman Emilio Daddario stated that “[t]echnical information needed by policymakers is frequently not available, or not in the right form. A policymaker cannot judge the merits or consequences of a technological program within a strictly technical context. He has to consider social, economic, and legal implications of any course of action (US Congress, House of Representatives 1967)”.<sup>3</sup> In 1973 the first US congressional “Office of Technology Assessment (OTA)” was founded, establishing a health program in 1975.<sup>4</sup> Since then, the use of HTA spread world-wide, building a bridge between decision-makers and researchers.<sup>5</sup> The term “Health Technology

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<sup>1</sup> See e.g. Egon Jonsson, David Banta, ‘Management of health technologies: an international view’ [1999] *BMJ* 319: 1293, p 1, stating radiography, computed tomography, antibiotics or coronary artery bypass grafting as examples for effective new health technologies.

<sup>2</sup> See e.g. Jonsson, Banta (n 1) p 1, stating mass screening for prostate cancer or treatments used to immobilise patients with back pain as examples for technologies doing more harm than good.

<sup>3</sup> Clifford S Goodman, *HTA 101: Introduction to Health Technology Assessment*, (Bethesda, MD: National Library of Medicine (US), 2014), <[www.nlm.nih.gov/nichsr/hta101/HTA\\_101\\_FINAL\\_7-23-14.pdf](http://www.nlm.nih.gov/nichsr/hta101/HTA_101_FINAL_7-23-14.pdf)> accessed 27 December 2016, citing Emilio Daddario, US Congress, House of Representatives 1967, at p I-2.

<sup>4</sup> The OTA had to close its doors in 1995 due to budgetary restrictions - see Warren E Leary, *Congress’s Science Agency Prepares to Close Its Doors*, [1995] *New York Times*, September 24. <[www.nytimes.com/1995/09/24/us/congress-s-science-agency-prepares-to-close-its-doors.html](http://www.nytimes.com/1995/09/24/us/congress-s-science-agency-prepares-to-close-its-doors.html)> accessed 27 December 2016. For a directory of Health Technology Organizations see <[www.ispor.org/htadirectory/index.aspx](http://www.ispor.org/htadirectory/index.aspx)> accessed 27 December 2016.

<sup>5</sup> At an international level, the International Network of Agencies for Health Technology Assessment (INAHTA) is linking activities and developments in this sector. For more information on INAHTA see <[www.inahta.org/](http://www.inahta.org/)>.

Assessment (HTA)“ increasingly appeared in the titles of both scientific articles and the press,<sup>6</sup> indicating the rising profile of HTA among the scientific community and the general public.

In the 1970s, Health Technology Assessment also began to develop in different European states, initially at regional/local and then at national level. Spain and France were the first countries to establish HTA bodies at regional/local level, while Sweden was the first EU-Member State to establish a national HTA agency in 1987. Since then, several Member States started to establish HTA-strategies and agencies or provided funding for HTA research as part of their national health policies.<sup>7</sup>

At the European level, health policy was not initially an explicit EU competence. The emphasis of the six founding Member States was the promotion of peace and stability in Europe through stable economic cooperation and the establishment of a common market. However, European health policy has existed implicitly since the 1960s, with food safety legislation being a notable example.<sup>8</sup> Nowadays health is an established EU policy area.<sup>9</sup> It is explicitly stated in Article 168 (1) of the Treaty on the Functioning of the European Union (TFEU)<sup>10</sup> - Public Health - that a “[...] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”. In certain domains, such as safety of medicines and medical devices, European health law already has a significant impact on the laws of Member States through binding regulation.<sup>11</sup> However, many of the remaining health policy domains still depend heavily on voluntary cooperation, soft law and coordinative governance processes. Indeed, according to Article 168 (7) TFEU the “organisation and delivery of health services and medical care [...including] the allocation of the resources assigned to them [...]” remains explicitly the responsibility of the Member States. This means that the organisation and financing of healthcare systems is up to Member States, including reimbursement decisions or the procurement of new health technologies, for which HTA forms an important basis to decision making.<sup>12</sup>

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<sup>6</sup> Cyril Benoit, Philippe Gorry, ‘Health Technology Assessment: the Scientific Career of a Policy Concept’, [2017], *International Journal of Technology Assessment in Healthcare*; 33(1):128-134.

<sup>7</sup> Marcial Velasco-Garrido, Reinhard Busse, *Health technology assessment, An Introduction to Objectives, Role of Evidence and Structure in Europe*, (WHO European Centre for Health Policy on behalf of the European Observatory on Health Systems and Policies, Brussels, Belgium, 2005)

<[www.euro.who.int/\\_\\_data/assets/pdf\\_file/0018/90432/E87866.pdf](http://www.euro.who.int/__data/assets/pdf_file/0018/90432/E87866.pdf)> accessed 29 December 2016.

<sup>8</sup> Tamara K Hervey, Jean V McHale, *European Union Health Law: Themes and Implications*, (Cambridge, Cambridge University Press, United Kingdom, 2015), pp 30-33.

<sup>9</sup> See e.g. Council of the European Union, specifying two actual topics under health policy: “Modernising EU rules for medical devices” and “Novel foods”, <[www.consilium.europa.eu/en/policies/?top%5B%5D=284](http://www.consilium.europa.eu/en/policies/?top%5B%5D=284)>, accessed 27 February 2017.

<sup>10</sup> Consolidated Version of the Treaty on the Functioning of the European Union (TFEU) [2016] OJ C 202/01.

<sup>11</sup> According to Art. 168 (4) TFEU, “[...] the European Parliament and the Council [...] shall” adopt legislation “in order to meet common safety concerns: (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures; (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.”

<sup>12</sup> See e.g.: Giuditta Callea and others, ‘The Impact of HTA and Procurement Practices on the Selection and Prices of Medical Devices’, [2017] *Social Science & Medicine*, 174, pp 89-90.

Based on voluntary cooperation, the European Union started to support several cross-border HTA-coordination and -cooperation initiatives between national HTA agencies or bodies and EU institutions since the 1990s.<sup>13</sup> As a result, a European HTA-network supporting national Member States and promoting cooperation has been established. This network even gained an explicit legal basis in 2011: in line with TFEU Articles 168 (1) and 114 TFEU – Approximation of Internal Market Rules –, Art. 15 (1) Directive 2011/24/EU – Cooperation on health technology assessment – states that “[t]he Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States”.<sup>14</sup>

Before elaborating potential future perspectives in HTA and its relevance for cross border care in Europe (CBC), it is necessary to specify what is meant by a ‘collaborative HTA approach’ and how far this approach is consistent with existing EU-Member States’ HTA-policies.

## 2. Health Technology Assessment in Europe

### 2.1. What is Health Technology Assessment (HTA)?

Generally speaking, HTA provides relevant decision makers in the healthcare system (policy decision makers, health professionals, healthcare administrators, etc.) with evidence-based, scientific and transparent decision support for the development, uptake and diffusion of new health technologies. Some authors even argue for HTA being a platform to enable more patient involvement when it comes to the implementation of new health technologies.<sup>15</sup> De facto, HTAs conducted by HTA organisations provide the basis for reimbursement and pricing decisions by competent (national) authorities in the healthcare sector.<sup>16</sup>

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<sup>13</sup> Marcial Velasco Garrido and others, Health Technology Assessment and Health-Policy Making in Europe, Current Status, Potential and Challenges, (World Health Organization (on behalf of the European Observatory on Health Systems and Policy, Observatory Studies Series No 14), United Kingdom 2008), <[www.euro.who.int/\\_\\_data/assets/pdf\\_file/0003/90426/E91922.pdf](http://www.euro.who.int/__data/assets/pdf_file/0003/90426/E91922.pdf)> accessed 28 December 2016; see also: Helga Sigmund, Finn Børlum Kristensen, Brigitte Bonnevie, ‘HTA – Clarifications and Planning’, in Finn Børlum Kristensen, Helga Sigmund (eds), Health Technology Assessment Handbook, (Copenhagen: Danish Centre for Health Technology Assessment, National Board of Health, 2007) <[www.sst.dk/~media/ECAAC5AA1D6943BEAC96907E03023E22.ashx](http://www.sst.dk/~media/ECAAC5AA1D6943BEAC96907E03023E22.ashx)> accessed 27 December 2016, pp 14-33; Velasco-Garrido and Busse (n 7) .

<sup>14</sup> Directive of the European Parliament and of the Council 2011/24/EU of 9 March 2011 on the Application of Patients’ Rights in Cross-border Healthcare [2011] OJ L 88/45.

<sup>15</sup> Janet L Wale and others on behalf of HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG), ‘Strengthening international patient advocacy perspectives on patient involvement in HTA within the HTAi Patient and Citizen Involvement Interest Group – Commentary’, [2017] Research Involvement and Engagement, 3:3 pp 2-10.

<sup>16</sup> Michael F Drummond and others, ‘Key principles for the Improved Conduct of Health Technology Assessments for Resource Allocation Decisions’ [2008], International Journal of Technology Assessment in Health Care, 24(3): 244-58; discussion 362-8.

When further defining HTA, it is necessary to elaborate on the approach and methods used. The development of HTA methods is closely linked with methodological advances in evidence synthesis, economic evaluation and evidence-based medicine (EBM). However, while EBM focuses on individual decision support for patients and physicians,<sup>17</sup> HTA is a broader, multi-method concept, primarily aimed at decision makers and – as stated by Luce et al [2010] – “including the following questions:

- ‘Whether a new health technology does work (Effectiveness)?’,
- ‘Whether the new health technology is worth it (Economic Value)?’ as well as
- ‘Whether the new health technology is worth being implemented or covered by the public system’ (coverage by public system).

[It is] a method of evidence synthesis that considers evidence regarding clinical effectiveness, safety, cost-effectiveness and, when broadly applied, includes social, ethical and legal aspects of the use of health technologies”.<sup>18</sup> In order to answer these questions, different methods are used, including systematic reviews and meta-analysis, modelling for clinical or economic evaluations or comparative and content analysis.<sup>19</sup>

Several other definitions of HTA exist. Some are very specific and refer to the methods used, while other definitions are more general. In the European context, the prevailing definition is that used by the European Network for Health Technology Assessment (EUnetHTA), which describes HTA as “a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.”<sup>20</sup> In other words: through a multidisciplinary process HTA shall provide the basis for the formulation of safe, effective, transparent and patient-centred health policies, thereby contributing to sustainable health systems.<sup>21</sup>

The health technologies subject to HTA vary. EUnetHTA broadly mentions “healthcare and prevention” and lists “diagnostic and treatment methods, medical equipment, pharmaceuticals, rehabilitation and prevention methods [as well as] organisational and

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<sup>17</sup> See Bryan R Luce and others, ‘EBM, HTA, and CER: Clearing the Confusion’ [2010] *The Milbank Quarterly*, Vol. 88, No. 2 (pp. 256-276) p 271: “Evidence-based medicine (EBM) is an evidence synthesis and decision process used to assist patients’ and/or physicians’ decisions. It considers evidence regarding the effectiveness of interventions and patients’ values and is mainly concerned with individual patients’ decisions, but is also useful for developing clinical guidelines as they pertain to individual patients.”

<sup>18</sup> Luce (n 17) pp 271-272.

<sup>19</sup> For further elaborations of methods used for HTAs see EUnetHTA: <[www.eunethta.eu/tools](http://www.eunethta.eu/tools)> or Jennifer M Stephens, Bonnie Handke, Jalpa Doshi, ‘International Survey of Methods used in Health Technology Assessment (HTA): Does Practice meet the Principles proposed for Good Research?’, [2012] *Comparative Effectiveness Research*, 2, (pp. 29-44).

<sup>20</sup> European Network for Health Technology Assessment, EUnetHTA <[www.eunethta.eu/faq/Category%201-0#t287n73](http://www.eunethta.eu/faq/Category%201-0#t287n73)> accessed 3 February 2017.

<sup>21</sup> European Commission, ‘Strengthening of the EU cooperation on Health Technology Assessment (HTA), Inception Impact Assessment’, SANTE.B4, 14/09/2016, (indicative planning: Q4 2017) <[ec.europa.eu/smart-regulation/roadmaps/docs/2016\\_sante\\_144\\_health\\_technology\\_assessments\\_en.pdf](http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf)> accessed 3 February 2017.



supportive systems within which healthcare is provided” as examples for technologies subject to HTA.<sup>22</sup>

A recent study conducted by the World Health Organisation (WHO) among responsible experts in health ministries of all Member States<sup>23</sup> identified that the following types of technologies are subject to HTA: medical devices, medicines, surgical interventions, service delivery models, population health interventions, clinical interventions and vaccines. In Europe, medicines were the health technologies most often listed for conducting HTAs, followed by medical devices, vaccines, surgical interventions, population-level health interventions (prevention and promotion), clinical interventions and service delivery models. For low-income countries, HTA was rather used for population-level health interventions than for medicines or other health interventions.<sup>24</sup> This difference in focus most likely arises from the fact that health systems in low-income countries are predominately financed by out-of-pocket spending. Whereas medicines and health technologies – including medical devices – are predominantly publicly financed for most European countries.<sup>25</sup> The following chart (Fig. 1) visualizes different technologies and frequencies of health technology assessments by region and country income.

**CHART 2.4:** Type of technologies or interventions assessed, proportion of countries by (a) region and (b) country income

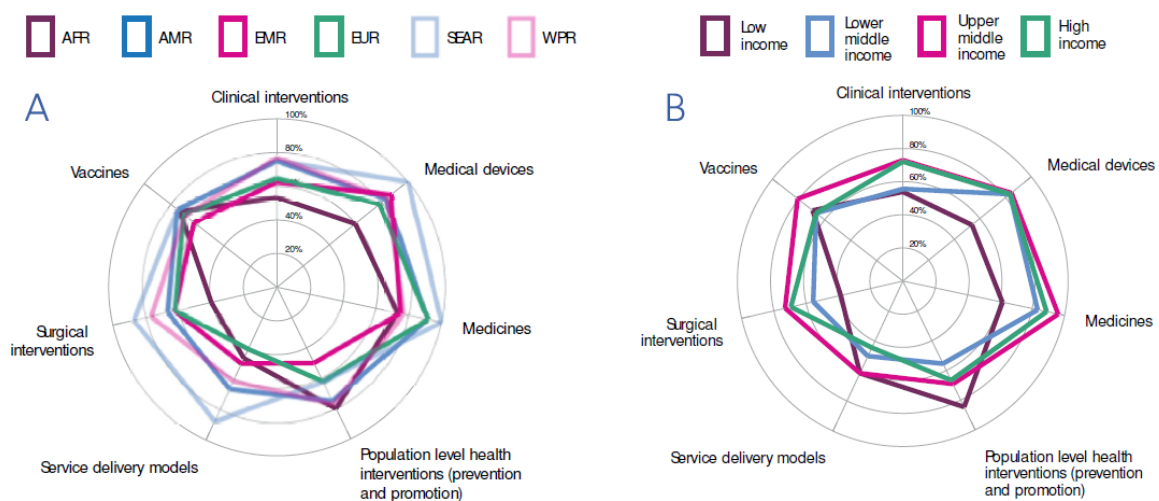


Figure 1: WHO, 2015 Global Survey on Health Technology Assessment by National Authorities, Main Findings, World Health Organization, Geneva, Switzerland, 2015, p 9.<sup>26</sup>

<sup>22</sup> EUnetHTA (n 20).

<sup>23</sup> WHO, 2015 Global Survey on Health Technology Assessment by National Authorities, Main Findings (World Health Organization, Geneva, Switzerland, 2015) <[www.who.int/health-technology-assessment/MD\\_HTA\\_oct2015\\_final\\_web2.pdf?ua=1](http://www.who.int/health-technology-assessment/MD_HTA_oct2015_final_web2.pdf?ua=1)> accessed 28 December 2016, at p 3: overall response rate: 56,2 % - 111 of 194 Member States responded to the survey questionnaire; for Europe the response rate has even been higher: EUR: 79,2 %.

<sup>24</sup> WHO, 2015 (n 23), at p 9.

<sup>25</sup> In this context see: Pablo Gottret and George Schieber, Health Financing Revisited, A Practitioner’s Guide [2006], The International Bank for Reconstruction and Development/The World Bank <[siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf](http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf)> accessed 29 March 2017.

<sup>26</sup> Reprinted from WHO (2015) (n 23) with permission of WHO dated 10/08/2017.

Having clarified the term ‘Health Technology Assessment’, its focus and methods used, the following two sections shall outline HTA policies: first at EU-Member State-level, followed by the European collaborative approach.

## 2.2. Health Technology Assessment (HTA) in EU-Member States

HTA is not an explicit EU policy domain or competence. The origins of HTA in Europe can be traced back to developments in certain Member States. However, since Directive 2011/24/EU promotes cross-border cooperation by Member States or Member States’ HTA-bodies, the following chapter shall also elaborate on potential common ground for this cooperation by exploring the status quo in Member States.

Up to now, all EU-Member States developed some kind of HTA-strategy and committed themselves to HTA as an “[...] important tool for achieving sustainable healthcare systems [...]”.<sup>27</sup> However, the structures, processes and methods used by Member States to conduct HTA differ widely.<sup>28</sup> These differences reflect “the different health-care and political systems with different mandates, financing mechanisms and roles in policy formulation”.<sup>29</sup> In a recent publication by Olga Löblová (2016), the evolution of existing European HTA agencies and bodies has been systematically collected, thereby trying to draw conclusions from actual developments. Even though it seems inaccurate to compare

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<sup>27</sup> Press Release: Council of the European Union, ‘Council Conclusions on Strengthening the Balance in the Pharmaceutical Systems in the EU and its Member States’, 17/06/2016, <[dsms.consilium.europa.eu/952/Actions/Newsletter.aspx?messageid=5902&customerid=31372&password=en\\_c\\_3167363863553131746E5932\\_enc](https://dsms.consilium.europa.eu/952/Actions/Newsletter.aspx?messageid=5902&customerid=31372&password=en_c_3167363863553131746E5932_enc)> accessed February 3 2017; see also: Press Release: Council of the European Union, ‘Council Conclusions on Innovations for the Benefit of the Patients’, 01/12/2014 <[www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lsa/145978.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/145978.pdf)> accessed February 3 2017.

<sup>28</sup> See e.g.: Ruth Schwarzer and Uwe Siebert, ‘Methods, Procedures, and Contextual Characteristics of Health Technology Assessment and Health Policy Decision Making: Comparison of Health Technology Assessment Agencies in Germany, United Kingdom, France, and Sweden’ [2009] *International Journal of Technology Assessment in Health Care* 25:3, 305–314; for a still ongoing, comprehensive analysis see FB Kristensen, ‘Mapping of HTA methodologies in EU, Work in Progress’, SANTE/2016/B4/026, presented at the 8th meeting of the HTA-Network, Brussels, 29 March 2017, <[ec.europa.eu/health/sites/health/files/technology\\_assessment/docs/ev\\_20170329\\_co03\\_en.pdf](http://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20170329_co03_en.pdf)> accessed May 20 2017.

<sup>29</sup> Marcial Velasco Garrido and others, ‘Health Technology Assessment in Europe – Overview’, in Marcial Velasco Garrido and others (eds), *Health Technology Assessment and Health Policy Making in Europe. Current Status, Challenges and Potential*, pp 79-108, p 83 (Observatories Studies Series No 14 World Health Organization on behalf of the European Observatory on Health Systems and Policies, Observatory Studies Series No 14, 2008), <[www.euro.who.int/\\_\\_data/assets/pdf\\_file/0003/90426/E91922.pdf](http://www.euro.who.int/__data/assets/pdf_file/0003/90426/E91922.pdf)> accessed February 1, 2017. Health systems in Europe are traditionally divided in Bismarck-Systems (mandatory social health insurance financing systems based on economic activity) and Beveridge-Systems (systems financed by general government revenues through national health services based on citizenship or residency). However, this distinction nowadays does not reflect reality, since no European health system solely corresponds to either financing system. Rather, there exist health systems that include more or less elements of planned economies, constrained competition/modified liberalism or neo-liberalism – see e.g.: Joseph Kutzin, ‘Bismarck vs. Beveridge: is there increasing convergence between health financing systems?’ 1st annual meeting of Working Party of Senior Budget Officials (SBO) network on health expenditure 22 November 2011, Paris, OECD <[www.oecd.org/gov/budgeting/49095378.pdf](http://www.oecd.org/gov/budgeting/49095378.pdf)> accessed 30 December 2016; for further information on Health Systems in Europe see WHO, European Observatory on Health Systems and Policies, *Health System Reviews (HiT Series)*, <[www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)>; see also: Hervey and McHale (n 8), p 222.

HTA bodies and agencies of different Member States – since their function very much depends on the respective health system – it is interesting to compare key developments.<sup>30</sup> According to Löblová (2016), Member States fall into one of three categories regarding the creation of HTA agencies: those which had already developed HTA agencies by the 1990s (“Forerunners”), those that developed HTA agencies within the time-period 2004 to 2011 (“Mainstreamers”) and those Member States with no specific HTA agencies (“Non-adopters”), who developed no formal agencies, despite adopting certain HTA strategies, e.g. within health ministry units<sup>31</sup>). The three categories with the respective Member States are seen in Table 1.

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<sup>30</sup> Nicola Allen and others, ‘Development of archetypes for non-ranking classification and comparison of European national health technology assessment systems’ [2013] *Health Policy*, 113, 305-312.

<sup>31</sup> Olga Löblová, ‘Three Worlds of Health Technology Assessment: Explaining Patterns of Diffusion of HTA Agencies in Europe’ [2016] *Health Economics, Policy and Law*, 11, 253-273.

Table 1. Chronological taxonomy of HTA agencies in Europe

Forerunners	Mainstreamers	Non-adopters
Sweden (SBU, 1987)	Belgium (KCE, 2004)	<b>Bulgaria</b>
Finland (FinOHTA, 1995)	<b>Croatia</b> (AAZ, 2009)	Cyprus
Denmark (DACEHTA, 1997)	France (HAS, 2004)	<b>Czech Republic</b>
United Kingdom (NICE, 1999, SMC, 2002)	Germany (IQWiG, 2004)	<b>Estonia</b>
Spain	<b>Hungary</b> (GYEMSZI, 2004)	Greece
(COHTA - Catalonia, 1991)	<b>Poland</b> (AHTAPol, 2005)	<b>Lithuania</b>
Osteba – Basque, 1992	Austria (LBI, 2006)	Luxembourg*
AETS – central, 1993)	Netherlands (CVZ, 2006)*	Malta
AETSA – Andalusia, 1996)	Ireland (HIQA, 2007)	Portugal
	Italy (AGENAS 2006)	<b>Romania</b>
	<b>Latvia</b> (VEC, 2009-11)*	<b>Slovakia</b>
		<b>Slovenia</b>

Legend: \* outlier, specific case – see description below for short discussion; Former communist countries in bold. Source: own compilation.

Table 1: O. Löblová, 'Three worlds of health technology assessment: explaining patterns of diffusion on HTA agencies in Europe', Health Economics, Policy and Law, p 257.<sup>32</sup>

This paper states that no answer was found as to which type of health system (centralized or decentralized, higher or lower resource, tax or health-insurance financed etc.) best supported an 'institutionalization' of HTA strategies.

Analysing different forms of institutionalization, Sorenson, Drummond and Kanavos describe the HTA-bodies as follows: "Broadly speaking, such bodies fall into two categories: (1) independent (arms-length) review bodies that produce and disseminate assessment reports on a breadth of topics, including health technologies and interventions; and (2) entities under government mandates (e.g. from health ministries) with responsibilities for decision-making and priority-setting, typically pertaining to the reimbursement and pricing of health technologies. The latter serve an advisory or a regulatory function."<sup>33</sup> There is also heterogeneity of the legal bases for the establishment of HTA agencies and whether they have decision making power.<sup>34</sup> In some European countries, HTA agencies determine reimbursement and coverage decisions on a legal basis – at least for some health technologies such as pharmaceuticals (e.g. the United Kingdom's National Institute for Health and Care Excellence (NICE)). In other countries, HTA agencies have a more advisory function with no statutory incorporation of decision making power (e.g.: Germany's Institute for Quality and Efficiency in Healthcare (IQWiG) or Croatia's Agency for Quality and Accreditation in Healthcare and Social Welfare (AZZ)).<sup>35</sup> In countries with heavily decentralized healthcare systems, several agencies may be commissioned with HTA tasks. Some have decision-making power, such as Sweden's Dental

<sup>32</sup> Reprinted from Löblová O [2016] (n 31) with permission of author dated 25/07/2017.

<sup>33</sup> Corinna Sorenson, Michael Drummond, Panos Kanavos, Ensuring value for money in health care. The Role of Health Technology Assessment in the European Union (Observatories Studies Series No 11 World Health Organization on behalf of the European Observatory on Health Systems and Policies, Observatory Studies Series No 11, 2008), p 8 <[www.euro.who.int/\\_\\_data/assets/pdf\\_file/0011/98291/E91271.pdf](http://www.euro.who.int/__data/assets/pdf_file/0011/98291/E91271.pdf)> accessed February 1, 2017.

<sup>34</sup> International Working Group for HTA Advancement, Peter J. Neumann and others, 'Are Key Principles for Improved Health Technology Assessment Supported and Used by Health Technology Assessment Organizations?' [2010], International Journal of Technology Assessment in Health Care, 26(1):71-78.

<sup>35</sup> Löblová (n 31).

and Pharmaceutical Benefits Agency (TVL),<sup>36</sup> while others do not, like the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU).<sup>37</sup>

Even though there are fundamental differences in the use, level of institutionalization and legal basis for HTA in Europe, there are at least some similarities: all agencies conduct assessments on safety and clinical effectiveness and many perform assessments on cost-effectiveness and budget impact. Ethical, legal or social aspects are rarely considered.<sup>38</sup>

### 2.3. Health Technology Assessment at EU-level – towards an Intensified Collaboration

Starting in 1965, Member States in Europe started to develop strategies against rising healthcare costs (though this was compounded by the financial crisis of 2008).<sup>39</sup> New health technologies do not always represent good value for money. HTA is one strategy Member States use in order to critically assess innovations in health, thereby referring to scientific evidence. A certain health technology may enter the market of several Member States simultaneously or in short succession. Although HTA agencies agree that they must consider their country-specific policy context, there is also a clear agreement that an intersection exists for generating, collecting and assessing the evidence in a coordinated European-wide fashion.<sup>40</sup> A transparent and coordinated HTA-approach at the EU level could contribute to an efficient use of resources and avoid the unnecessary duplication of work.

HTA collaborations first appeared in Europe in the late 1970s. In the beginning, collaborative initiatives depended on proactive national experts and stakeholders such as the Swedish Planning and Rationalization Institute of Health Services (SPRI) as well as some European organizations like the Organization of European Medical Research Councils, which organized and sponsored HTA conferences across Europe. These activities contributed to European involvement in the establishment of the International Journal of Technology Assessment in Healthcare as well as the International Society on Technology Assessment in Healthcare (ISTAHC, since 2004 Health Technology Assessment International (HTAi)). In the 1980s, cooperation at the European level intensified, stressing the need for closer coordination mechanisms.<sup>41</sup>

Since the 1980s, the European Commission (EC) funded several studies on HTA, mostly under the Program on Health Services Research. In the EU Maastricht Treaty, responsibility for Public Health was included in the EC's mandate for the first time. From the 1990s onwards, the EC recognised HTA as a key instrument for the efficient use of healthcare resources and intended to strengthen

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<sup>36</sup> Dental and Pharmaceutical Benefits Agency 2017: Gunilla Rönholm and Peter Skiöld: PPRI Pharma Profile Sweden <[www.tlv.se/Upload/English/PPRI\\_Pharma\\_Profile\\_Sweden\\_2017.pdf](http://www.tlv.se/Upload/English/PPRI_Pharma_Profile_Sweden_2017.pdf)> accessed 25 July 2017.

<sup>37</sup> Mans Rosén and Sophie Werkö, 'Does Health Technology Assessment affect Policy-making and Clinical Practice in Sweden?' [2014], *International Journal of Technology Assessment in Health Care*, 30(3), 265-272.

<sup>38</sup> WHO (2015) (n 23).

<sup>39</sup> Katharina Böhm and Claudia Landwehr, 'The Europeanization of Health Care Coverage Decisions: EU-Regulation, Policy Learning and Cooperation in Decision-Making', [2014] *European Integration*, Vol. 36, No. 1, 17-35.

<sup>40</sup> EUnetHTA: EUnetHTA Strategy 2012 and beyond, <[www.eunetha.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20Strategy%202012%20and%20beyond.pdf](http://www.eunetha.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20Strategy%202012%20and%20beyond.pdf)> accessed 25 July 2017.

<sup>41</sup> Banta David and others, 'A History of Health Technology Assessment at the European Level' [2009], *International Journal of Technology Assessment in Health Care*, 25(S1), 68-73.

European collaboration between HTA agencies. Between 1993 and 2002, three projects funded by the EC supported collaboration in a European HTA network, but the network was discontinued when its funding was cut. Meanwhile, the political process on cross-border healthcare had started and the need for a sustainable network for HTA had been expressed by the High Level Group on Health Services and Medical Care of DG SANTE in 2004.<sup>42</sup> The next step to achieve this goal was the funding of a further 3-year project to establish EUnetHTA by the EU Public Health Program from 2006-2008.<sup>43</sup> In 2009 the EUnetHTA partners financed the continuation of the work for a year (EUnetHTA Collaboration) until the EC and EU Member States decided to continue the establishment of EUnetHTA through the funding of a Joint Action (JA) on HTA.<sup>44</sup> In contrast to competitive scientific projects, project participants in JAs have to be nominated by the competent authorities of Member States.<sup>45</sup> Since 2010, three EUnetHTA JAs have been implemented with a total budget of € 35.5 million (see Table 2). The current and third JA will run until 2020 with 79 partner organisations that consist mostly of regional and national HTA bodies from 29 participating countries.<sup>46</sup>

In parallel within the EU's Research and Innovation funding program FP7 (2007-2013)<sup>47</sup> and under the Public Health Programmes<sup>48</sup> of the European Parliament, the European Council and the Health Programme of the EC, a call for "new methodologies in HTA" was launched in 2011. Running until 2013, this provided additional support for European HTA activities by advancing methodology.<sup>49</sup>

The financing of these JAs by the EC demonstrates that collaboration at the European level is expected to deliver added value at the national and regional level. In Table 2 we give an overview of all EU projects and related JAs to build a sustainable scientific European HTA network, their aims and – if publicly available – the size of any subsidies granted.

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<sup>42</sup> European Union. Health and Consumer Protection Directorate- General. High Level Group on Health Services and Medical Care. High level process of reflection on patient mobility and healthcare developments in the European Union. Outcome of the reflection process, 9 December 2003. Available at: <[ec.europa.eu/health/ph\\_overview/Documents/key01\\_mobility\\_en.pdf](http://ec.europa.eu/health/ph_overview/Documents/key01_mobility_en.pdf)>, accessed 25 July 2017.

<sup>43</sup> Banta (n 41).

<sup>44</sup> <[www.eunethta.eu/activities/EUnetHTA%20Collaboration%20%282009%29/eunethta-collaboration-2009](http://www.eunethta.eu/activities/EUnetHTA%20Collaboration%20%282009%29/eunethta-collaboration-2009)>, accessed 25 July 2017.

<sup>45</sup> See EU Ref. Ares(2015)2353033 - 05/06/2015, Annex 1: Submission of Nominations for Participation in Joint Actions, <[ec.europa.eu/chafea/documents/health/nomination\\_procedure\\_for\\_joint\\_actions.pdf](http://ec.europa.eu/chafea/documents/health/nomination_procedure_for_joint_actions.pdf)> accessed February 1, 2017.

<sup>46</sup> GN Fracchia and M Theofilatou, 'The European Community's Research Projects in the Field of Health Services', [1993] *International Journal Of Technology Assessment In Health Care*, Fall; Vol. 9 (4), pp.554-63.

<sup>47</sup> Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) [2006] OJ L 412, 30.12.2006, p 1.

<sup>48</sup> Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) [2002] OJ L271, 9.10.2002, p 1; Decision 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) [2007] OJ L 301, 20.11.2007, p 3.

<sup>49</sup> Finn Borlum Kristensen, 'Development of European HTA: from Vision to EUnetHTA', [2012], *Michael*, 9,147-156

Years	Project	Goals
1994-1997	Project on Coordination and Development of Healthcare Technology Assessment in Europe (EUR-ASSESS) <sup>50</sup>	Improve methods of priority setting, to develop and formulate HTA methodologies, to ensure that effective dissemination strategies were being used throughout European agencies, and to improve decision making by stimulating wider use of technology assessments. EU Budget: **
1997-1998	HTA-Europe	Investigation of emerging technologies, internationally coordinated assessments, measurement of outcomes in technology assessment, role of HTA in future healthcare systems in the European countries. EU Budget: **
1999-2001	European Collaboration for Health Technology Assessment/Assessment of Health Interventions (ECHTA/ECAHI) <sup>51</sup>	<i>"To develop and strengthen the network(s) (of HTA organisations) in the EU by promoting co-operation between the various centres and activities concerned with assessments of health interventions in the member states."</i> EU Budget: **
2006-2008	European Network for Health Technology Assessment Project (EUnetHTA Project)	Establishment of an effective and sustainable European network for HTA that informs policy decisions EU Budget: € 3 233 858
2009	European Network for Health Technology Assessment Collaboration (EUnetHTA Collaboration)	The EUnetHTA Collaboration was launched to continue the work of the EUnetHTA Project. It was funded by the contribution of its participants <sup>52</sup>
2010-2012	European Network for Health Technology Assessment Joint Action 1 (EUnetHTA JA 1)	To put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level EU Budget: € 6 000 000
2012-2015	European Network for Health Technology Assessment Joint Action 2 (EUnetHTA JA 2)	To strengthen the practical application of tools and approaches to cross-border HTA collaboration in Europe. EU Budget: € 9 500 000
2016-2020	European Network for Health Technology Assessment Joint Action 3 (EUnetHTA JA 3) <sup>53</sup>	To support voluntary cooperation at scientific and technical level between HTA bodies to validate the model for joint work to be continued after EU funding ends. EU Budget: € 20 000 000

\*\* information not traceable through print or online publication.

Table 2: Overview of co-funded EU-projects and one project funded by EUnetHTA Founding Partners aiming to enable HTA cooperation in Europe; own compilation, based on Banta [2009], Kristensen [2012], the EUnetHTA homepage, European Commission, Inception Impact Assessment, 14/09/2016<sup>54</sup> and respective project websites.

EUnetHTA's work aims to promote the scientific and technical cooperation between HTA agencies and therefore it developed common processes and methodologies for conducting HTA to support joint production of HTA information that can be adapted and taken up by regional and national HTA agencies. A special focus is on Rapid Relative Effectiveness Assessments (REA) – first applied to pharmaceuticals with the sole intention of producing assessments within a time frame of 90 days. Due to the requirements of the European Transparency Directive (Directive 89/105/EEC) they are also performed for other technologies such as medical devices or screening programs since JA 2. REAs comprise only a description of the health problem and the technology under assessment as well as the assessment of effectiveness and safety. REAs utilise a short checklist to indicate whether issues in other assessment domains (such as cost-effectiveness, organizational, social, legal and

<sup>50</sup> Banta and others (n 25).

<sup>51</sup> <[ec.europa.eu/health/ph\\_projects/1999/monitoring/fp\\_monitoring\\_1999\\_frep\\_09\\_en.pdf](http://ec.europa.eu/health/ph_projects/1999/monitoring/fp_monitoring_1999_frep_09_en.pdf)>, accessed 29 March 2017.

<sup>52</sup> [www.eunethta.eu/activities/EUnetHTA%20Collaboration%20%282009%29/eunethta-collaboration-2009](http://www.eunethta.eu/activities/EUnetHTA%20Collaboration%20%282009%29/eunethta-collaboration-2009) accessed 25 July 2017.

<sup>53</sup> <[www.eunethta.eu](http://www.eunethta.eu)>.

<sup>54</sup> European Commission, Inception Impact Assessment (: 'Strengthening of the EU cooperation on Health Technology Assessment' 14/09/2016 (indicative planning: Q4 2017), <[ec.europa.eu/smart-regulation/roadmaps/docs/2016\\_sante\\_144\\_health\\_technology\\_assessments\\_en.pdf](http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf)> accessed 2 January 2017.

ethical aspects) could also be relevant for an assessment.<sup>55</sup> Full HTA Assessments comprise all mentioned aspects in depths. Until the end of JA2 EUnetHTA has published three pilot assessments, twelve REAs and five full assessments. For JA 3, 80 joint or collaborative assessments are planned.

Several tools, methodological guidelines and processes were developed to support the conduction of joint assessments and to facilitate the collection and production of evidence from the manufacturers:<sup>56</sup>

- At the centre of HTA production stands the HTA Core Model<sup>®</sup> which provides an ontology. In other words, it provides the questions that an assessment should answer, methodological guidance on how to answer the questions and a common reporting structure for the results.
- The Planned and Ongoing Projects (POP)-Database allows EUnetHTA partners to share information on their projects to facilitate collaboration of future joint assessments.
- The main goal of the EVIDENT database is to facilitate collaboration on the generation of further evidence when assessments have already been performed by an HTA agency. It allows storage and sharing of information on reimbursement and coverage status and on further evidence requirements already requested.
- EUnetHTA Evidence Submission Templates comprise the evidence requests for reimbursement from the manufacturers of all HTA agencies in EUnetHTA.
- Methodological guidelines aim to help assessors of the evidence to process, analyse and interpret relevant data.
- The goal of Early Dialogues between HTA bodies from several countries and manufacturers is to improve the quality and relevance of initial evidence generation in order to facilitate the HTA process and support coverage decisions. National and regional reimbursement differences can be taken into account when giving input on the clinical development program of new technologies in such a multi-HTA Early Dialogue with European HTA bodies and companies.<sup>57</sup>

In previous JAs, the uptake of the recommendations from joint assessments on the regional and national level was scarce, with parallel national and regional HTA production continuing. Therefore, JA 3 emphasises joint production, uptake and implementation in regional and national HTA production.

In order to explore the European strategy beyond 2020, the EC launched an Inception Impact Assessment on 'Strengthening of the EU cooperation on Health Technology Assessment (HTA)' on 14th September, 2016.<sup>58</sup> Inception impact assessments are usually initiated during the preparation phase of a proposal for a new law in order to assess economic, social, administrative and other impacts of different options for actions at the EU level. According to this document, the EC basically sees five options when it comes to cooperation in the field of HTA beyond 2020. These are outlined in Table 3.

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<sup>55</sup> EUnetHTA. Joint Action on HTA 2012-2015. HTA Core Model for Rapid Relative Effectiveness. Nov 2015 <[www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/JA2%20WP5%20-%20HTA%20Core%20Model%20for%20Rapid%20REAs.pdf](http://www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/JA2%20WP5%20-%20HTA%20Core%20Model%20for%20Rapid%20REAs.pdf)> accessed 2017-07-19> accessed 25 July 2017.

<sup>56</sup> <[www.eunethta.eu/tools](http://www.eunethta.eu/tools)> accessed 2 January 2017.

<sup>57</sup> EUnetHTA Joint Action on HTA 2012-2015. Consolidated Procedure for Early Dialogues (drug and non-Drug), Dec 2015 <[www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20early%20dialogue%20consolidated%20procedure\\_%20November%202015.pdf](http://www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20early%20dialogue%20consolidated%20procedure_%20November%202015.pdf)> accessed 25 July 2017.

<sup>58</sup> European Commission (n 19).



	<b>Option</b>	<b>Specification</b>
1	<b>Status quo – voluntary cooperation until 2020</b>	Since no further EU-funding is foreseen after 2020, further cooperation at EU-level would be at risk or rather depend on national procedures and budgets. No legislative changes required
2	<b>Long-term voluntary cooperation (financed by the EU beyond 2020)</b>	Continuation of the current cooperation model (voluntary cooperation and voluntary uptake for a limited number of new technologies, parallel national HTA processes) but on a long-term financing mechanism that ensures the sustainability based on Article 15 Directive 2011/24/EU [2015], co-funded e.g. by the Public Health Programme. No legislative changes required
3	<b>Cooperation on collection, sharing and use of common tools and data</b>	Introduction of a legal framework how data is collected, shared and used to enable that efforts by national bodies are compatible. Voluntary cooperation, voluntary uptake but compulsory use of tools (e. g. POP database, HTA Core model, Early Dialogues). Mixed funding model of EU budget, the Member States and industry contribution). Legislative changes required
4	<b>Cooperation on production of joint Rapid REA reports and their uptake (cooperation on clinical/medical matters)</b>	Member States jointly produce REAs on the relative effectiveness in terms of clinical/medical benefits. Assessment of non-clinical domains remains under national responsibility. Two sub-options are considered: (1) voluntary participation of Member States in REA production, but if opted in then compulsory uptake (2) participation and uptake of joint REA mandatory. Permanent EU funding for organisational structure for REA production. Financial contribution from Member States for tools and services and fees from industry. (mixed funding model). Legislative changes required
5	<b>Cooperation on production of joint Full HTA reports and their uptake (cooperation on cost-effectiveness)</b>	Member States jointly produce Full HTA reports including economic, legal, social, organisational and ethical domains. Same two sub-options as in option 4. Organisational structure and funding as in option 4, but with higher costs. Legislative changes required

Table 3: Overview – Option Mapping according to EC Inception Impact Assessment ‘Strengthening of the EU cooperation on Health Technology Assessment (HTA)’; own compilation, based on EC Inception Impact Assessment on ‘Strengthening of the EU cooperation on Health Technology Assessment (HTA)’.

In the course of the impact assessment, the EC started a public consultation process.<sup>59</sup> One of the tools used for this process was an open public stakeholder consultation, running from 21st October 2016 to 13th January 2017. Two questionnaires have been sent out. One was addressed to citizens and another one to administrators and economic stakeholders, including pharmaceutical and

<sup>59</sup> For further information on this process see Stakeholder Consultation Strategy: [ec.europa.eu/health/sites/health/files/technology\\_assessment/docs/20161013\\_strategyhta\\_en.pdf](http://ec.europa.eu/health/sites/health/files/technology_assessment/docs/20161013_strategyhta_en.pdf) accessed May 20, 2017.

medical technology industries, small and middle-sized enterprises (SME) as well as associations representing other stakeholders (patients and consumers, healthcare providers, payers, etc.).

The recently published report indicated a total of 249 replies of which 63 (25%) are from individuals and 186 (75%) from administrations, economic stakeholders, associations or organisations. Of the 186 non-individual contributions, 36 replies were received from SME. The large majority of the individual respondents have expertise and work experience in areas relevant for the consultation (healthcare, HTA, public administration, health technologies industry). Of all replies, industry (SME, big commercial operators, trade associations) contributed 52%, public administration (consisting mainly of HTA bodies, Ministries of Health and payers) 14%, patient and consumer associations 13% and healthcare provider organisations and scientific societies 13%.

The results show that most participants are aware of EU-funded involvement (67 %). 30% find cooperation at EU-level useful, while 39% find this to some extent useful (39 %). 87 % of respondents think that EU cooperation should continue after 2020. However, the report also discloses many obstacles for further cooperation and the production of joint assessments: most respondents think that different socio-economic realities in Member States, differences in HTA methodologies and knowledge gaps by key stakeholders (including patient/consumer organisations or clinicians) prevent partners from taking on joint work. Even among respondents who considered the current EU cooperation on HTA useful, there were reports that the uptake of joint work remained low.<sup>60</sup>

Trying to summarise collaborative initiatives at the EU level, it seems that EU involvement has established a common platform of knowledge and information exchange. Some authors even argue that a new policy field has been successfully launched.<sup>61</sup> Although a permanent and intensified HTA-collaboration promises efficiency gains for HTA bodies and may strengthen evidence-based decision making (which can be considered an important precondition for better healthcare services in all EU Member States), there remain substantially sceptical views on a centralized European HTA production and uptake. These views largely arise from concerns over the differences in healthcare systems, legislation and the role of HTA in decision-making, as well as the remaining socio-economic gradient across countries. A permanent scientific and technical HTA network with secured funding can further support collaboration by producing high quality HTA information using clear and commonly accepted methodologies. It may also create a European infrastructure and transparent processes for appropriate evidence generation along the lifecycle of new technologies. Knowledge gaps disclosed by the recent open stakeholder consultation show that considerable information and education efforts will be necessary and will have to accompany this process.

Thus, the hurdles for cooperation on the scientific and technical level will have to be overcome, if Europe is to be adequately prepared for a future opportune time, when societal preconditions are met and the decision makers in Member States decide for a more integrated European HTA collaboration. The EU legislator recognized that the scientific and technical network alone will not be able to promote adequately the role of HTA in healthcare decision-making in Member States. It complemented the network at the strategic level with a HTA network (HTAN), connecting national

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<sup>60</sup> European Commission, Directorate General for Health and Food Safety, 'Strengthening the EU Cooperation on Health Technology Assessment (HTA)', Online public consultation report, Ref.Ares(2017)2455149 – 15/5/2017, pp 16-19  
<[ec.europa.eu/health/sites/health/files/technology\\_assessment/docs/20161020\\_frep\\_en.pdf](http://ec.europa.eu/health/sites/health/files/technology_assessment/docs/20161020_frep_en.pdf)> accessed May 20, 2017.

<sup>61</sup> Böhm and Landwehr (n 39).

authorities or bodies responsible for HTA in the Cross-border Healthcare Directive 2011/24/EU Art 15 (4) and the Commission Implementing Decision of 26th June 2013, (2013/329/EU). Membership in the HTAN is voluntary. It “shall focus its activities on strategic issues relevant for EU cooperation on HTA. It shall provide strategic recommendations to the scientific and technical cooperation mechanism which shall carry out its work in scientific independence and shall aim at synergies with Network’s activities.”<sup>62</sup> All Member States are represented in this network and meet on a regular basis. Additionally, Iceland and Norway have sent observer members and key stakeholders are represented.<sup>63</sup>

### 3. Cross-border Healthcare and Health Technology Assessment

#### 3.1. Cross-border Healthcare in Europe – Development, Definition, Basic Facts and Challenges

Over the last few decades, an increasingly mobile population led to a rise in those seeking healthcare in a member state other than that of their primary residence. Out of the ‘freedom of movement for workers’ and, later on, the ‘freedom of services’, entitlement to receive healthcare in another member state was established. First this applied to employees and their family members, then also to those travelling for the primary purpose of seeking healthcare (patients). An increasingly interconnected Europe supported this mobility. By adopting Directive 2011/24/EU, the EU legislator implemented decisions of the European Court of Justice (CJEU) and amended the existing social security and health insurance regime.<sup>64</sup> These developments strengthened patients’ rights<sup>65</sup> in cross-border healthcare and – to some extent – opened the healthcare systems of Member States to EU citizens. Official commitments by the Council of Europe,<sup>66</sup> national health ministers and other key stakeholders<sup>67</sup> towards common values and principles in European Union Health Systems finally led to a European regulatory system, enabling patients to access healthcare across borders.

According to Article 3 (e) of the Directive 2011/24/EU, ‘cross-border healthcare’ is defined as “healthcare provided or prescribed in a Member State other than the Member State of affiliation”. The ‘Member State of affiliation’ can either be:

- the Member State competent to grant prior authorisation for treatment other than the Member State of residence, or

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<sup>62</sup> European Commission, Rules of procedure of the Health Technology Assessment Network adopted by the HTA Network on 10 November 2016 <[ec.europa.eu/health/sites/health/files/technology\\_assessment/docs/ev\\_20161110\\_co03\\_en.pdf](http://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co03_en.pdf)> accessed July 20, 2017.

<sup>63</sup> For a full list see of Members of the HTA-Network see <[ec.europa.eu/health/technology\\_assessment/policy/network\\_en](http://ec.europa.eu/health/technology_assessment/policy/network_en)>.

<sup>64</sup> See Hervey and McHale (n 8), pp 184 ff: Chapter 8: ‘Rights: mobile patients’ rights as human rights’.

<sup>65</sup> However, as Hervey and McHale stress, “patients’ rights are in practice probably more closely related to consumerism than to human dignity”, since, patients basically are only entitled to comprehensive healthcare abroad in emergency situations and in situations where they have the money to pay for healthcare in advance - see Hervey and McHale (n 8), pp 208-210.

<sup>66</sup> Council Conclusions on Common values and principles in European Union Health Systems, OJ C 146/1, 22.6.2006.

<sup>67</sup> Martin Mc Kee and Paul Belcher, ‘Cross border health care in Europe’, [2008] BMJ, Jul 19, 337:a610, pp 124-125.

- the Member State, in which the person is either insured or has the rights to sickness benefits.<sup>68</sup>

There are basically two closely linked, parallel systems for reimbursement or coverage claims of patients as recipients of health services: one based on Regulation (EC) 883/2004<sup>69</sup> on the coordination of social security systems – for planned (elective) and necessary (emergency) healthcare (via European Health Insurance Card) – and another one based on Directive 2011/24/EU – for planned healthcare only. In practice, the relation between these two systems is quite complex and rather difficult to understand, both for patients and other key stakeholders.<sup>70</sup> Implementation efforts of Member States in this field are supported by the Directorate General for Health and Food Safety<sup>71</sup> as well as by the Cross-border Healthcare Expert Group compounded of representatives of all 28 Member States.<sup>72</sup> Other chapters in this book will cover patient mobility in greater depth.<sup>73</sup> As such, these two systems shall not be further outlined in this chapter.

To elucidate the relevance of HTA for cross border healthcare, it is important to first explore the actual relevance of cross-border healthcare in Europe and its potential for development. By showing relevant developments, points of reference for HTA cooperation can be reflected upon.

Reliable data on cross-border healthcare in Europe is rare and some Member States do not monitor patient flows on a central basis.<sup>74</sup> In the 2015 report of the EC to the European Parliament and the Council on the operation of Directive 2011/24/EU, the Commission holds that “[p]atient flows for healthcare abroad under the Directive are low.”<sup>75</sup> These findings are based on the following three studies investigating data on cross-border healthcare and published by the EC in 2015:

- Evaluative Study on the Cross-border Healthcare Directive 2011/24/EU (published in 2015);<sup>76</sup>
- Member State Data on Cross-border Healthcare following Directive 2011/24/EU, (published in 2015);<sup>77</sup>

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<sup>68</sup> Article 3 (c) (i) and (ii) of the Directive 2011/24/EU.

<sup>69</sup> Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems ) [2004] OJ L 166, 30.04.2004, replacing Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community [1971] OJ L 149, 05.07.1971.

<sup>70</sup> See e.g.: European Commission, Final Minutes of meeting Cross-border Healthcare Expert Group [2016], 11 March 2016, Ref. Ares(2016)6412521-14/11/2016, at p 2, where “a better clarification on the relationship between Regulation 883/2004 and Directive 2011/24” came up; see also: G. Zucca and others, Evaluative study on the cross-border healthcare Directive 2011/24/EU [2015], European Commission, Directorate-General for Health and Food Safety, Brussels, at p. 157: “Since patients cannot always know the differences between EU policies, insurers often decide on their own which rules are the most favorable for patients.”

<sup>71</sup> <ec.europa.eu/health/cross\_border\_care/policy\_en> accessed February 8, 2017.

<sup>72</sup> <ec.europa.eu/health/cross-border-healthcare-expert-group/201610242\_en> accessed February 8, 2017.

<sup>73</sup> E.g., Chs.1-3, and 9.

<sup>74</sup> See e.g.: Zucca (n 70) at p 60: “It is important to underline the point that whilst the Directive is at its early stages of implementation, data available for analysis is scarce. This limitation is due to the fact that Member States have yet to begin appropriately monitoring patient inflows and outflows.” However, cross-border healthcare did not start with the implementation of the Directive 2011/24/EU – it is at least an issue since 1971, when Council Regulation (EEC) No 1408/71 has been enacted. Thus, it could also be argued that the missing monitoring of patient-flows either mirrors the limited relevance of this issue for Member States’ governments or the diversity of power and administration in the health sector.

<sup>75</sup> European Commission, Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare [2015], COM(2015) 421 final, p 7.

<sup>76</sup> Zucca (n 70).

<sup>77</sup> Jonathan Olsson Consulting, Member State Data on cross-border healthcare following Directive 2011/24/EU, EC (Year 2015).

- Patients' Rights in Cross-border Healthcare in the European Union (published in 2015).<sup>78</sup>

All three studies collected data in 2014 (Zucca et al, Special Eurobarometer) and 2015 (Olsson Consulting). Besides literature review (including website analysis), Zucca et al. gathered information from an online survey conducted with National Contact Points (NCPs), from 'pseudo-patient' investigation of NCPs and from stakeholder interviews (NCPs, healthcare provider organisations, individual healthcare insurance providers, patient groups, trade unions, ombudspersons and healthcare inspectorate/audit bodies of twelve Member States).<sup>79</sup> Jonathan Olsson Consulting collected data by means of a survey sent to all responsible stakeholders in Member States (stakeholders from 23 Member States replied).<sup>80</sup> Special Eurobarometer interviewed 27,868 people in twenty-eight Member States at home.

Around 50 % of the people interviewed in the course of the Special Eurobarometer-study would be willing to seek cross-border care, but only 5 % experienced medical treatment abroad. Usually, in border regions the issue of cross-border treatment is more relevant and specific cooperation agreements between Member States promote cross-border treatments. Thus, additional political (and legal) support in terms of specific cooperation agreements is crucial for claiming cross-border treatment.

To some extent, the apparently low level of cross-border patient flows might also be related to the fact that knowledge about existing possibilities is lacking. For instance, the stakeholders surveyed by Jonathan Olsson Consulting only received a few hundred information requests on cross-border treatment in 2015.<sup>81</sup> All studies indicate that information on the possibility to receive treatment abroad for stakeholders as well as for patients is hardly available or insufficient.

Results of studies mentioned above basically show that there are more factors impeding cross-border healthcare than supporting it. The biggest challenges to overcome in the context of cross-border healthcare are linked to the following issues:

- transparent information (including availability of cross-border healthcare, quality of care, waiting times, patient rights);
- clear political commitment and coordinated national health strategies for healthcare planning by Member States (including central monitoring of patient-flows as a basis for healthcare strategies and planning);
- clear and easily applicable legal rules (including rules supported by healthcare agreements for specific regions);
- support for financial planning (including information about treatment costs, simple reimbursement application procedures, insurance-coverage for treatments abroad and travel costs).

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<sup>78</sup> Special Eurobarometer 425, Patients' Rights in Cross-border Healthcare in the European Union, EC, Directorate-General for Health and Consumers (SANCO) and co-ordinated by Directorate General for Communication (published May 2015).

<sup>79</sup> Austria, Belgium, France, Germany, Hungary, Italy, Lithuania, Malta, the Netherlands, Slovenia, Spain and Sweden.

<sup>80</sup> No replies were received from Austria, Finland, France, Iceland, Latvia, Lithuania and Portugal.

<sup>81</sup> Only Poland has received outstanding 31.736 information requests, see Jonathan Olsson Consulting (n 77).

Table 4 gives an overview of all studies investigating data on cross-border healthcare, summarising data sources and the main findings.

Study	No of Member States (MS) involved	Data source	Main findings	
			factors impeding cross-border healthcare	factors supporting cross-border healthcare
Zucca G et al [2015]	12	<ul style="list-style-type: none"> <li>online survey conducted with National Contact Points (NCPs)</li> <li>pseudo-patient investigation of NCPs</li> <li>stakeholder interviews of NCPs, healthcare providers, organizations, individual healthcare insurance providers, patient groups, trade unions, ombudspersons, healthcare inspectorate/audit bodies</li> </ul>	<ul style="list-style-type: none"> <li>unavailable / low quality of information about cross-border treatment possibilities</li> <li>uncertainty about quality of care in other MS</li> <li>(difficult) prior authorization process</li> <li>upfront payment</li> <li>difficult reimbursement procedures</li> <li>uncertainty about treatment costs in other MS</li> <li>additional billing and translation costs in context of reimbursement procedures</li> <li>travel costs</li> <li>administrative issues</li> <li>difficulties regarding access to patient files</li> <li>unavailability of list of treatments subject to prior authorisation</li> </ul>	<ul style="list-style-type: none"> <li>healthcare cooperation agreements between MS</li> <li>long waiting time for treatments in MS of affiliation</li> <li>low quality of treatments in MS of affiliation</li> <li>border regions</li> </ul>
Special Eurobarometer [2015]	28	interviews with 27.686 people in different MS	<ul style="list-style-type: none"> <li>satisfaction with (quality of) treatment on country of affiliation</li> <li>treatment far from place of residence</li> <li>knowledge about cross-border prescription procedures</li> <li>language issues regarding treatment in other MS</li> <li>prior authorization of treatment on other MS</li> <li>unavailable information about quality of care on other MS</li> </ul>	<ul style="list-style-type: none"> <li>treatments not available in MS of affiliation</li> </ul>
Jonathan Olsson Consulting [2015]	23	questionnaire to stakeholders in MS	<ul style="list-style-type: none"> <li>Mechanisms to limit access to cross-border healthcare according to Article 4(3) of the Directive 2011/24/EU</li> </ul>	<ul style="list-style-type: none"> <li>healthcare in bordering MS</li> <li>50.2 % of requests for prior authorization were authorized.</li> <li>treatments in Germany</li> <li>78 % of the requests for reimbursement were granted</li> <li>request for reimbursement for treatments in Germany or Spain</li> </ul>
Study	No of Member States (MS) involved	Data source	Main findings	
			factors impeding cross-border healthcare	factors supporting cross-border healthcare

Zucca G et al [2015]	12	<ul style="list-style-type: none"> <li>• online survey conducted with National Contact Points (NCPs)</li> <li>• pseudo-patient investigation of NCPs</li> <li>• stakeholder interviews of NCPs, healthcare providers, organizations, individual healthcare insurance providers, patient groups, trade unions, ombudspersons, healthcare inspectorate/audit bodies</li> </ul>	<ul style="list-style-type: none"> <li>• unavailable / low quality of <b>information about cross-border treatment</b> possibilities</li> <li>• <b>uncertainty about quality of care</b> in other MS</li> <li>• (difficult) <b>prior authorization process</b></li> <li>• <b>upfront payment</b></li> <li>• <b>difficult reimbursement procedures</b></li> <li>• <b>uncertainty about treatment costs</b> in other MS</li> <li>• <b>additional billing and translation costs</b> in context of reimbursement procedures</li> <li>• <b>travel costs</b></li> <li>• <b>administrative issues</b></li> <li>• difficulties regarding <b>access to patient files</b></li> <li>• <b>unavailability of list of treatments subject to prior authorisation</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>healthcare cooperation agreements</b> between MS</li> <li>• <b>long waiting time</b> for treatments in MS of affiliation</li> <li>• <b>low quality of treatments</b> in MS of affiliation</li> <li>• <b>border regions</b></li> </ul>
Special Eurobarometer [2015]	28	interviews with 27.686 people in different MS	<ul style="list-style-type: none"> <li>• <b>satisfaction with (quality of) treatment</b> on country of affiliation</li> <li>• <b>treatment far from place of residence</b></li> <li>• <b>knowledge about cross-border prescription procedures</b></li> <li>• <b>language issues</b> regarding treatment in other MS</li> <li>• <b>prior authorization</b> of treatment on other MS</li> <li>• <b>unavailable information about quality of care on other MS</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>treatments not available</b> in MS of affiliation</li> </ul>
Jonathan Olsson Consulting [2015]	23	questionnaire to stakeholders in MS	<ul style="list-style-type: none"> <li>• Mechanisms to limit access to cross-border healthcare according to Article 4(3) of the Directive 2011/24/EU</li> </ul>	<ul style="list-style-type: none"> <li>• healthcare in <b>bordering MS</b></li> <li>• <b>50.2 % of requests</b> for prior authorization were <b>authorized</b>.</li> <li>• treatments in <b>Germany</b></li> <li>• <b>78 % of the requests for reimbursement</b> were <b>granted</b></li> <li>• request for <b>reimbursement</b> for <b>treatments in Germany or Spain</b></li> </ul>

Table 4: Studies investigating data on of cross-border healthcare, published by the EC in 2015, own compilation based on indicated studies.

Study results show that cross-border healthcare is currently an issue of marginal relevance. Probably also due to major discrepancies in healthcare spending and supply in different Member States, political commitment to enhance cross-border care and smooth out those discrepancies seems rather low.<sup>82</sup> Countries with relatively high health expenditure per capita (e.g. Germany) are in some way target countries for those seeking cross-border healthcare in the public sector.<sup>83</sup> This fact might indicate that treatments in countries with a high healthcare spending per capita are more attractive for those seeking healthcare. Findings like this support a common fear by Member States, namely that higher standards in national health systems are taken advantage of by citizens of countries with

<sup>82</sup> Hervey and McHale (n 8), p 210.

<sup>83</sup> Whereas for out of pocket healthcare services countries with rather cheaper health services might be chosen (e.g. Austrian patients seeking dental treatments in Hungary).

lower standards. Without political commitment to reduce such inconsistencies, further development of cross-border healthcare seems doubtful.

It shall now be explored, whether and how an intensified European collaboration in the field of HTA could affect cross-border healthcare in the future, thereby potentially promoting patients' rights in Europe.

### 3.2. The Impact of enhanced Coordination in Health Technology Assessment (HTA) on Cross-Border Healthcare (CBC)

As outlined in chapter 2.2, every State in Europe has its own HTA-policy and each State determines its own HTA-strategy, including the performance of HTAs and their impact. Thus, the impact of HTA bodies and agencies vary to a great extent. With respect to considerable variations in health systems, including health expenditures per capita, these conditions are comprehensible. Accordingly, Art. 168 (7) TFEU explicitly states that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care." Thus, health-coverage, pricing and reimbursement decisions are in the competence of Member States.

Coming back to the three questions, HTA intends to analyse ('Whether a new health technology does work (Effectiveness)?', 'Whether the new health technology is worth it (Economic Value)?' as well as 'Whether the new health technology is worth being implemented or covered by the public system' (coverage by public system)). The third question mainly lies within the remit of each Member State. Only very selective procedural issues in the area of pharmaceutical pricing are coordinated and regulated through the Transparency Directive (Council Directive 89/105/EEC<sup>84</sup>) at the European level. According to this directive, transparent and comprehensive criteria for pricing strategies such as fixed time limits and adequate legal remedies for companies to appeal against procurement decisions have to be implemented.

In line with these principles, the legal basis for a common HTA-strategy is Art. 15 (4) Directive 2011/24/EU providing for the management and organisation of a "functioning network of national HTA-agencies and bodies", thereby "assuring the exchange of scientific information." This mechanism per se does not really constitute a strong tool at the European level. It is a rather soft instrument, requiring a lot of convincing in order to lead Member States to more cooperation. Due to collaborative funding efforts at the European level, starting in the 1990s, a European HTA-network (EUnetHTA) has now been established, supporting endeavours for closer coordination of HTA work. The main objectives of these coordination activities are to:

- share information on HTAs conducted in Member States,
- develop alliances with contributing fields of research to support a stronger and broader evidence base for HTA while using the best available scientific competence

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<sup>84</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems [1988], L 40/8, 11.2.1989. Since the European pharmaceutical market has changed since 1989 the Commission issued a revised proposal for an updated directive in March 2012 (Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance system, COM (2012) 84 final, 2012/0035 (COD)). However, due to resistance by Member States the Commission withdrew the proposal in March 2015 (OJ, C 80/08, Volume 58, 7 March 2015).



- coordinate and develop common methods and to
- support the conduct of joint HTAs (REAs and full HTAs).

Basically, all four objectives might have effects on cross-border care. However, so far no study has been conducted to investigate the potential impact of enhanced HTA-coordination on cross-border care. Some studies focusing on the impact of HTA on national resources reveal potential benefits for health budgets in Member States.<sup>85</sup> By exchanging and sharing information on HTAs – thereby providing decision basis for more Member States – such effects might also have benefits for health budgets in other Member States – not only through avoidance of duplication of HTA work, but also through influencing health-coverage, reimbursement or pricing decisions. In this case, HTAs conducted in one Member State might have an indirect impact on cross-border care by aligning the decisions made, thereby reducing discrepancies between different levels in healthcare supply.

In addition to this indirect effect, a more direct impact on sustainable healthcare across national borders is possible. There is an initiative of smaller countries to proceed from joint HTA production to joint procurement and price negotiations. This initiative aims to ensure access to innovative drugs for patients at affordable prices. Patients then will have access to medicines at the same time in several countries. The BeNeLuxA–collaboration on procurement of pharmaceuticals for rare diseases for instance was launched by Belgium and the Netherlands in April 2015, joined by Luxemburg in September 2015 and by Austria in June 2016.<sup>86</sup>

The coordination and further development of common methods in HTA will facilitate application and increase acceptance of HTAs conducted by one Member State, but also of joint HTAs, which might be of particular relevance for cross-border care in border regions. A recent study on better cross-border cooperation for high-cost capital investments assessed six cross-border cooperation examples.<sup>87</sup> In all cases, border regions coordinated and shared the use of high cost medical equipment. While political support for coordinated high-cost investments is currently weak, this study reveals potential economic advantages for several Member States. Among other recommendations, the study states that HTAs should consider pooling options for high-cost medical equipment: “HTA reports should be used for assessing effectiveness and safety of (new) and expensive medical equipment including economic analyses (e.g. budget impact analysis) pointing out economic aspects of potential Cross-border cooperation’s pooling variants.”<sup>88</sup> In cases of HTA in cross-border in border regions, the specific conditions of more than one Member State could also have a direct effect on cross-border healthcare by providing the basis for rational investment decisions and enhanced cooperation.

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<sup>85</sup> European Commission, Inception Impact Assessment, 2016 (n 54), p 2.

<sup>86</sup> J. Espin and others, ‘How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?’ [2016], Health System and Policy Analysis, available at <[www.eu2017.mt/Documents/Programmes/PB21.pdf](http://www.eu2017.mt/Documents/Programmes/PB21.pdf)> accessed July 20, 2017.

<sup>87</sup> European Commission, Study on better cross-border Cooperation for high-cost Capital Investments in Health, Final Report, November 2016, <[ec.europa.eu/health/sites/health/files/cross\\_border\\_care/docs/hci\\_frep\\_en.pdf](http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/hci_frep_en.pdf)>, accessed June 20, 2017.

<sup>88</sup> European Commission, Study on better cross-border Cooperation for high-cost Capital Investments, 2016 (n 87), p 13.

## 4. Conclusions

Within the past few decades, both HTA and cross-border healthcare have developed in Europe. Patients are entitled to cross-border healthcare under certain conditions, thereby making use of health technologies in other Member States.<sup>89</sup> States in Europe began to develop HTA strategies and -bodies in the late 1980s. Almost all national or regional HTA-bodies assess safety and clinical effectiveness of new health technologies and frequently perform assessments on cost-effectiveness and budget impact. However, since variations in different health systems are great and the organisation and delivery of healthcare is in the competence of Member States, developments vary across the continent.

European coordination activities in the field of HTA started in the 1990s. However, collaboration very much depends on voluntary initiatives and Member States' willingness to support corresponding health policies in the strategic HTA network and its scientific and technical counterpart, EUnetHTA. Collaborative efforts can contribute to the efficient use of resources and avoid duplication, and can help to improve evidence generation for new health technologies, thereby contributing to high quality and access to healthcare. However, according to the recently initiated inception impact assessment by the EC, "[...] the benefits of EU cooperation on HTA are not fully exploited (there is no comprehensive uptake of joint work) and the long-term sustainability of the EU cooperation is not guaranteed. The fragmentation of national HTA systems (procedures and methodologies) leads to duplication of efforts and diverging outcomes across the EU. According to industry, the lack of business predictability has also an adverse impact on the investment climate. From the Member States' perspective, there is also a risk of misallocation of resources. Ultimately, all these shortcomings impact market and patient access to health technologies, leading to delays and health inequalities."<sup>90</sup>

Further steps would be necessary to move towards more stable and financially secured cross-border collaboration in this field. For reasons of predictability and stability, collaboration thereby should have a legal framework basis, providing for voluntary or even mandatory cooperation. An important prerequisite for achieving such collaboration would be a consensus on financing mechanisms (EU budget, Member States' contribution, industry contribution).<sup>91</sup> From a current perspective, a stable financing mechanism for a joint HTA policy at the European level might not be the easiest task to realise. And at the moment, joint HTAs, do not have a large impact on Member States' healthcare planning decisions.<sup>92</sup> Sustainability of EUnetHTA activities is therefore still challenged.

Despite convincing arguments for collaboration, heterogeneous healthcare systems with different roles of HTA in decision-making and the socio-economic gradient in European Member States are an obstacle. Thus, efforts are necessary to enhance European HTA collaboration and facilitate financing mechanisms. One factor in this context could be the enhancement and consideration of cross-border care for healthcare planning, especially in the field of high cost investments in health and particularly in border regions. Financial pressure on Member States is high, which presents a challenge to investment in high-priced medicines and medical devices. At the same time, access to health services is a fundamental right, guaranteed in Article 35 of the Charter of Fundamental Rights of the European Union.<sup>93</sup> Equal access to high quality healthcare is thus a major matter for all EU policies.

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<sup>89</sup> Art. 168 (7) TFEU (n 10).

<sup>90</sup> European Commission, Inception Impact Assessment, 2016 (n 54), p 13.

<sup>91</sup> European Commission, Inception Impact Assessment, 2016 (n 54).

<sup>92</sup> European Commission, Inception Impact Assessment, 2016 (n 47), p 13.

<sup>93</sup> Charter of Fundamental Rights of the European Union, OJ 2000/C 364/01), 18.12.2000.

Enhanced European coordination in the field of HTA can thereby have direct and indirect impacts on access to healthcare, especially on cross-border healthcare in border regions. By considering economic conditions in more than one Member State, for example in a border region, HTA can provide the potential basis for healthcare planning and cooperation decisions, thereby having a direct impact on cross-border care. In cases where a single Member State or region would decide not to invest in high-cost medical equipment, a joint-HTA could consider cross-border pooling options. As a result, HTA collaboration activities could promote equal access to high quality care, endorsing a patient's right to receive treatments in other Member States. Furthermore, by sharing information on HTAs, indirect impacts on cross-border care are possible. Sharing knowledge in this way may affect healthcare decisions in more than one Member State. It follows that healthcare resources might be better aligned, health inequalities could be diminished and divergences in access to healthcare reduced. In order to enhance collaboration of Member States and increase confidence in cross-border healthcare planning, further research is necessary to demonstrate clearly the added value of such impacts for different Member States, as well as ways to reduce obstacles for closer cooperation.



# Chapter XIII Data Protection and Patient Mobility in Europe\*

Jean Herveg

## 1. Introduction

As for the Directive on the application of patients' rights in cross-border healthcare,<sup>1</sup> patient mobility means the possibility for a person to benefit from healthcare in a Member State other than the Member State of affiliation. In this context, the Directive insists, rightly, on the necessity to protect patient's personal data.<sup>2</sup> Protecting patient's personal data implies that any patient who benefits from cross-border healthcare is entitled to expect that one's personal data will not be processed by anyone in any way e.g. when using electronic medical records or transferring data for reimbursement purposes or for scientific research. In addition, it means that the patient is entitled to see his or her rights recognized on his or her personal data. The patient is also entitled to expect that specific mechanisms and bodies will contribute to ensuring the effectiveness of data protection. In other words, a patient receiving healthcare in a Member State other than the Member State of affiliation is entitled to expect to enjoy the same level of data protection as in his Country of affiliation, all other things being equal. That being said, we still have to agree on the significance and properties of this right to data protection to which the patient could claim in cross-border healthcare, both in its affirmation and in its implementation through the new European General Data protection Regulation.

## 2. Recognition of a right to data protection in European Law

At the level of the Council of Europe, the issue of data protection has been formally raised at the end of the 1960s. It was within the framework of reflections on the subject of human rights and modern scientific and technological achievements that the Council of Europe supported work more specifically focused on data protection. The results of this work were presented at a Conference in Salzburg on 9-12 September 1968. Based upon these results, the Committee of Ministers subsequently adopted the first two recommendations on automatic processing of personal data which shaped the first outline of the legal framework for ensuring data protection in Europe. The first of these recommendations concerned

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\* This work has been done with the financial support from the European Union's Horizon 2020 research and innovation program under Grant Agreement no. 730953 (Inspex) and in part by the Swiss Secretariat for Education, Research and Innovation (SERI) under Grant no. 16.0136 730953. This paper only reflects the author's view and does not engage the Commission.

<sup>1</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (see the consolidated text).

<sup>2</sup> Cf. Recital no. 25, Article 2 (c), Article 4.2 (e) and (f), and Article 14 of Directive 2011/24/EU.

databases in the private sector<sup>3</sup> and the second, databases in the public sector.<sup>4</sup> The continuation and development of the Council of Europe's activities in data protection resulted in the adoption of the 28 January 1981 Convention for the protection of individuals with regard to automatic processing of personal data (Treaty no. 108)<sup>5</sup> as well as numerous sectoral or thematic recommendations.<sup>6</sup>

Relatively early in time several cases related to data protection were brought before the European Court of Human Rights. When assessing the necessity of an interference in a democratic society in the famous *Z v Finland* judgment of 25 February 1997, the Court explicitly stressed the importance and need to protect personal data for the exercise of the right to respect for private and family life.<sup>7</sup> Since then, the Court has repeatedly and consistently proclaimed that:

- The protection of personal data (and health information are not the least) plays a fundamental role in the exercise of the right to respect for private and family life.
- Respecting the confidentiality of health information is an essential principle of the legal system of all Contracting Parties to the Convention; it is essential not only to protect patients' privacy but also to preserve their confidence in the medical profession and health services in general. Without such protection, persons requiring medical care could be discouraged from providing the personal and intimate information necessary to get the appropriate treatment and even to consult a doctor. That could end up jeopardizing their health or, in case of communicable diseases, that of the community.
- Domestic legislation should therefore provide appropriate safeguards to prevent the use of personal data and in particular any communication or disclosure of personal data relating to health, which does not comply with the guarantees provided by Article 8 of the Convention.

In addition to this assertion of the importance and need to protect personal data for the exercise of the right to respect for private and family life,<sup>8</sup> the European Court of Human Rights has developed a substantial case-law in many areas interesting data protection:<sup>9</sup>

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<sup>3</sup> Council of Europe, Resolution (73) 22 on the protection of the privacy of individuals vis-a-vis electronic data banks in the private sector, adopted by the Committee of Ministers on 26 September 1973 at the 224<sup>th</sup> meeting of the Ministers' Deputies.

<sup>4</sup> Council of Europe, Resolution (74) 29 on the protection of the privacy of individuals vis-a-vis electronic data banks in the public sector, adopted by the Committee of Ministers on 20 September 1974 at the 236<sup>th</sup> meeting of the Ministers' Deputies.

<sup>5</sup> This Convention is under revision.

<sup>6</sup> Recommendation 97 (5) on the protection of medical data is also under revision.

<sup>7</sup> *Z v Finland* (ECtHR, 25 February 1997), appl. no 22009/93, para 95.

<sup>8</sup> On the basis of which it could already be argued that each State has a positive obligation to protect personal data.

<sup>9</sup> Without prejudice to the question of the relationship between personal data and the sphere of private life (do all personal data fall within the private sphere?) and the question between interference and data processing (does any processing of data amount to an interference with the exercise of the right to respect for private life?). These are difficult and unresolved questions to date in the case-law of the European Court of Human Rights. Regarding the case-law of the Court to date (until 31 December 2016), it does not seem possible to say that all personal data fall within the private sphere within the meaning of Article 8.1 or that any processing of data constituted an interference with the exercise of the right to privacy within the meaning of Article 8.2. On the other hand, there are sufficient indications in the Court's decisions and judgments, as well

- surveillance of individuals and protection of their communications;
- personal identity and filiation;
- protection of reputation;
- systematic collection of public data;
- collection, conservation and use of data;
- protection against disclosure of data;
- protection of medical data;
- medical records;
- medical records security;
- access right (including the right to get a copy);
- data security;
- the right to one's image;
- genetic testing;
- collection and retention of data by the police;
- taking and preservation of fingerprints, human cellular substantive, and realization and conservation of DNA profiles;
- criminal records and files of sexual offenders;
- search and seizure of computer data;
- national security;
- protection against hidden cameras;
- motor vehicle registrations;
- records of bankrupts;
- protection of bank data.

At the level of the European Community (now the European Union), the issue of data protection was formally embraced by the European Parliament on 8 April 1976. At that date, it instructed its Legal Committee to report on the Community actions to be taken or pursued with a view to ensuring the protection of human rights in relation to the development of technical progress in the field of informatics.<sup>10</sup> This Legal Committee then set up a subcommittee on "Informatics and Human Rights". The latter organized a public debate on

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as in some dissenting opinions, to support the opposite view. In any event, the principle adopted in the context of the assessment of the necessity of the interference in a democratic society makes it possible not to have to decide.

<sup>10</sup> Resolution adopted on 8 April 1976 OJ C 100, 3 May 1976 p. 27.

informatics and human rights in early 1978. This work resulted in the adoption on 5 June 1979 of a Resolution on the protection of human rights in the face of the development of technical progress in the field of informatics.<sup>11</sup> Then, after the adoption of the OECD Guidelines for the Protection of Privacy and Transborder Data Flows on 23 September 1980, the European Community adopted on 24 October 1995 the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.<sup>12</sup> Its objective was to harmonize data protection legislations across the European Community and to state the principle of the free movement of personal data within the common market.<sup>13</sup> As from 25 May 2018, data protection will be ensured in Europe by the General Data Protection Regulation.<sup>14</sup>

But fundamentally, beyond the recognition of the importance and need to protect data for the exercise of the right to respect for private and family life, beyond the Member States' positive obligation to ensure data protection, beyond the development of the European Court of Human Rights case-law on data protection, and beyond the establishment of a specific legal framework to ensure data protection (at the level of the Council of Europe or the European Union), it was not until the adoption of the Charter of Fundamental Rights of the European Union on 7 December 2000 that the existence of a right to data protection was explicitly and formally recognized as a fundamental right at the European level. Since then, Article 8 of this Charter provides that:<sup>15</sup>

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<sup>11</sup> OJ 5 June 1979 no. C 140/34.

<sup>12</sup> OJ L 281 23 November 1995 p. 31 (take into account the consolidated text).

<sup>13</sup> This legal framework has been supplemented by Regulation (EC) no 45/2001 of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, Directive 2002/58/EC of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), Commission Regulation (EU) no 611/2013 of 24 June 2013 on the measures applicable to the notification of personal data breaches under Directive 2002/58/EC of the European Parliament and of the Council on privacy and electronic communications, Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC (the latter has been declared invalid by the Court of Justice of the European Union in a judgement of 8 April 2017 in joined cases C-293/12 and C-594/12).

<sup>14</sup> Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119 4 May 2016 p. 1. This Regulation was adopted at the same time (and as a prerequisite), on the one hand, that Directive (EU) 2016/680 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA and, on the other hand, that Directive (EU) 2016/681 of 27 April 2016 on the use of passenger name record (PNR) data for the prevention, detection, investigation and prosecution of terrorist offences and serious crime. The General Data Protection Regulation is applicable in 28 countries and concerns directly more than five hundred million people (without taking into account its indirect effects notably in the matter of transfers of personal data to third countries or international organizations). On the Regulation, see: S Gutwirth, R Leenes and P De Hert (eds.), *Reforming European Data Protection Law*, Law, Governance and Technology Series, Issues in Privacy and Data Protection, volume 20, Springer, 2015.

<sup>15</sup> Charter of fundamental rights of the European Union, 2016/C 202/02. See Working Party on the Protection of Individuals with Regard to the Processing of Personal Data *Recommendation 4/99 on the inclusion of the*



1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

If the Charter had no legal value at the time of its adoption, it is now legally binding on the same basis as all the Union Treaties<sup>16</sup> since the entry into force of the Treaty of Lisbon in December 2009. The provisions of the Charter are addressed to the institutions, bodies, offices and agencies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law (which includes national authorities as well as regional or local authorities or public bodies).<sup>17</sup> They all have to respect the rights, observe the principles and promote their application in accordance with their respective powers and respecting the limits of the powers of the Union as conferred on it in the Treaties.

On the other hand, the *Treaty on the Functioning of the European Union* also recognizes, under its provisions of general application, the right to data protection:<sup>18</sup>

1. Everyone has the right to the protection of personal data concerning them.
2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall lay down the rules relating to the protection of individuals with regard to the processing of personal data by Union institutions, bodies, offices and agencies, and by the Member States when carrying out activities which fall within the scope of Union law, and the rules relating to the free movement of such data. Compliance with these rules shall be subject to the control of independent authorities. The rules adopted on the basis of this Article shall be without prejudice to the specific rules laid down in Article 39 of the Treaty on European Union.

It is to this extent that any patient who comes under the jurisdiction of a Member State<sup>19</sup> has the right to claim the protection of his or her personal data in cross-border healthcare<sup>20</sup>

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*fundamental right to data protection in the European catalogue of fundamental rights* WP 26 7 September 1999.

<sup>16</sup> This is confirmed by Article 6 of Treaty on the European Union.

<sup>17</sup> On this, see the Explanatory Report on Article 51 of the Charter. It follows that the Charter of Fundamental Rights of the European Union does not apply in a general and undifferentiated or unconditional way.

<sup>18</sup> See Article 16.

<sup>19</sup> In the meaning of the first Article of the European Convention on Human Rights to which Article 52 of the Charter of Fundamental Rights of the European Union refers.

<sup>20</sup> That is confirmed by Recital no 25 of Directive 2011/24: "The right to the protection of personal data is a fundamental right recognized by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patients' health. These personal data should be able to flow from one Member State to another, but at the same time the fundamental rights of the individuals should be safeguarded." Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data establishes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any

due to the fact that, on the one hand, the European Union have a competence in cross-border healthcare and, on the other hand, the patient's right to data protection concerns, at least, the implementation of European law in the matter of cross-border healthcare.

All this means that data protection must be ensured in the context of cross-border healthcare provided to a patient by a health professional in a Member State other than the Member State of affiliation. This also means that the patient has the right to claim the benefit of this protection in the context of cross-border healthcare. It is therefore not only an obligation on the part of the health professional or the Member State but also, and above all, a right which the patient can claim against them.<sup>21</sup>

It remains to agree on the content of this protection as it is implemented in the new European General Data Protection Regulation,<sup>22</sup> either in terms of substantive and territorial scope, applicable substantive rules governing data processing, data subject's rights, obligations of data controller and processor, and data protection specific authorities and mechanisms ensuring data protection effectiveness.

### 3. Scope of the General Data Protection Regulation

In order to claim the benefit of the General Data Protection Regulation, the patient's personal data must be automatically processed, in whole or in part, or at least be included in a file, and the situation has to fall within the territorial scope of the General Data Protection Regulation.

#### 3.1 Material scope of the General Data Protection Regulation

As it was already the case with Directive 95/46/EC, the General Data Protection Regulation applies<sup>23</sup> to the processing<sup>24</sup> of personal data wholly or partly by automated means and to

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treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.

<sup>21</sup> On the right to data protection, see: G Gonzalez Fuster, *The Emergence of Personal Data Protection as a Fundamental Right of the EU*, Law, Governance and Technology Series, Issues in Privacy and Data Protection, volume 16, Springer, 2014; B van der Sloot, 'Legal Fundamentalism: Is Data Protection Really a Fundamental Right?', in R Leenes, R van Brakel, S Gitwirth and P De Hert (eds), *Data Protection and Privacy: (In)visibilities and Infrastructures*, Law, Governance and Technology Series, Issues in Privacy and Data Protection, volume 36, Springer, 2017, p. 3.

<sup>22</sup> The provisions of which apply from 25 May 2018.

<sup>23</sup> See Article 2 for the material scope of the Regulation. See the exclusion for activities falling outside the scope of Union law and purely personal or household activities (Recital no. 18: "This Regulation does not apply to the processing of personal data by a natural person in the course of a purely personal or household activity and thus with no connection to a professional or commercial activity. Personal or household activities could include correspondence and the holding of addresses, or social networking and online activity undertaken within the context of such activities. However, this Regulation applies to controllers or processors which provide the means for processing personal data for such personal or household activities").

<sup>24</sup> Processing means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or

the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system.<sup>25</sup>

The definition of *personal data* remains substantially unchanged except for the description of the elements likely to help to identify the data subject.<sup>26</sup> It should be recalled that, in accordance with Directive 95/46/EC, the General Data Protection Regulation and the case-law of the Court of Justice of the European Union, the concept of *personal data* must be interpreted as widely as possible. However it has been suggested, but to no avail so far, to set contextual limits on the possibility of identifying the data subject, in order to respond to the criticism, partially justified, that by giving an excessive and somehow unlimited scope to the legislation,<sup>27</sup> it ends up covering almost any kind of situations even when there is no informational content or when no one involved in the data processing is able to reasonably identify the data subject. It is possible to wonder whether this does not proceed from an operational difficulty in distinguishing the data or the processing which really matters.

However, whatever the controversies surrounding the notion of personal data,<sup>28</sup> it is likely that in almost all situations the patient's data in cross-border healthcare will be subjected to an automated processing, in whole or in part, or will be included in a file, as it should be in a modern and state-of-the-art practice of healthcare.

### 3.2 Territorial scope of the General Data Protection Regulation

The General Data Protection Regulation applies first of all to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not.<sup>29</sup> It is thus beyond doubt that the processing of patient's data carried out by a healthcare professional providing cross-border healthcare to a patient falls under the scope of the Regulation.<sup>30</sup>

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otherwise making available, alignment or combination, restriction, erasure or destruction (Article 4.2 of the Regulation).

<sup>25</sup> The filing system means any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralized or dispersed on a functional or geographical basis (Article 4.6 of the Regulation).

<sup>26</sup> Personal data means any information relating to an identified or identifiable natural person (data subject); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. The data subject does not have to be identified. It only has to be possible to identify the data subject. (Article 4.1 of the Regulation).

<sup>27</sup> Like data which does not yet qualify as personal data but which could become so in the light of technological developments.

<sup>28</sup> And they will be solved gradually as the Regulation is implemented and enforced.

<sup>29</sup> Article 3.1 of the Regulation.

<sup>30</sup> If the data controller or processor is not established in the Union, the Regulation applies to the processing of personal data of data subjects who are in the Union where the processing activities are related to the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or the monitoring of their behavior as far as their behavior takes place within the Union (Article 3.2). But the Regulation does not specify what is meant by a person who is on the territory of the European Union. This concept may cover accidental or tourist presence, transit, mere residence, domicile or principal or

#### 4. Main actors in Data Protection

Like the Convention of 28 January 1981 or Directive 95/46/EC, the General Data Protection Regulation does not explicitly determine its personal scope. However, the Regulation identifies the main actors in data protection. As in Directive 95/46/EC, the [data] controller is the person who, alone or jointly with others, determines the purposes and means of the data processing<sup>31</sup> and the processor is the one who processes personal data on behalf of the [data] controller.<sup>32</sup> The Regulation also identifies the recipient,<sup>33</sup> the third party,<sup>34</sup> the representative,<sup>35</sup> the enterprise<sup>36</sup> and the group of undertakings.<sup>37</sup>

However, as with Directive 95/46/EC, the General Data Protection Regulation still does not provide a formal definition of the data subject even though the latter is supposed to be at the heart of the regulatory system. Whatever, the Regulation insists on the point that the protection applies irrespective of the nationality or residence of the data subject.<sup>38</sup>

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secondary establishment in the territory of the European Union [within the territory of a Member State of the European Union]. Moreover, these notions do not have necessarily the same meaning in all the Member States. Finally the Regulation applies to the processing of personal data by a controller not established in the Union, but in a place where Member State law applies by virtue of public international law.

<sup>31</sup> The [data] controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law (Article 4.7 of the Regulation). See Article 29 Data Protection Working Party *Opinion 1/2010 on the concepts of "controller" and "processor"* WP 169 16 February 2010.

<sup>32</sup> The processor means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller (Article 4.8 of the Regulation).

<sup>33</sup> The recipient means a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing (Article 4.9 of the Regulation).

<sup>34</sup> The third party means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorized to process personal data (article 4.8 of the Regulation).

<sup>35</sup> The representative means a natural or legal person established in the Union who, designated by the controller or processor, represents the controller or processor with regard to their respective obligations (Article 4.8 of the Regulation).

<sup>36</sup> The enterprise means a natural or legal person engaged in an economic activity, irrespective of its legal form, including partnerships or associations regularly engaged in an economic activity (Article 4.8 of the Regulation).

<sup>37</sup> The group of undertakings means a controlling undertaking and its controlled undertakings (Article 4.8 of the Regulation).

<sup>38</sup> See recital 14. The protection extends to persons who are not nationals of any Member State and who do not reside in the territory of any Member State but whose data are processed by a data controller subject to the Regulation. In any case, this protection is expressly excluded for legal persons (see recital 14). The Regulation is, however, once again ambiguous. Indeed, it states that "This Regulation does not cover the processing of personal data which concerns legal persons and in particular undertakings established as legal persons, including the name and the form of the legal person and the contact details of the legal person". This last sentence seems to imply a form of derogation, which would mean that there would be some form of

In any case, all these actors must be properly identified when a health professional provides healthcare to a patient from a Member State other than the Member State of affiliation. This can lead to some problems in particular in the context of Internet platforms for patient's data communication, cloud computing services<sup>39</sup> or mobile applications (mHealth).<sup>40</sup>

## 5. Substantive rules applicable to the processing of patient's personal data

The processing of patient's personal data may be subject to two types of substantive rules: on the one hand, the common uniform substantive rules laid down by the General Data Protection Regulation and, on the other hand, additional national substantive rules laid down by Member States.

### 5.1 Common uniform substantive rules applicable to the processing of personal data

The Regulation enumerates and details the principles applicable to all data processing. The principles are not that substantially different from the rules previously laid down in Directive 95/46/EC.

#### *Principles relating to the processing of personal data*

There are seven principles relating to the processing of personal data:

- i) Personal data must be processed lawfully, fairly and in a transparent manner in relation to the data subject (principles of *lawfulness, fairness and transparency*);
- ii) Personal data must be collected for specified, explicit and legitimate purposes and not further processed in a manner that is *incompatible* with those purposes (principle of *purpose limitation*).<sup>41</sup> Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should not be considered as incompatible with the initial purposes provided that it is subject to appropriate safeguards for the rights and freedoms of the data subject. These guarantees must ensure that technical and organizational measures are set in place to ensure compliance with the data minimization principle.<sup>42</sup> Whenever

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protection for other data related to enterprises. In theory, this would be inaccurate, but this recital brings unnecessary doubt.

<sup>39</sup> See Article 29 Data Protection Working Party *Opinion 05/2012 on Cloud Computing* WP 196 1<sup>st</sup> July 2012.

<sup>40</sup> See Article 29 Data Protection Working Party *Opinion 02/2013 on apps on smart devices* WP 202 27 February 2013.

<sup>41</sup> See Article 29 Data Protection Working Party *Opinion 03/2013 on purpose limitation* WP 203 2 April 2013.

<sup>42</sup> These measures may include pseudonymization, to the extent that these purposes can be achieved in this way. Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure

- possible, further processing should not or no more allow for the identification of the data subject.
- iii) Personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (principle of *data minimization*).
  - iv) Personal data must be accurate and, where necessary, kept up to date. Every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (principle of *accuracy*).
  - v) Personal data must be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed (principle of *storage limitation*). Personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes provided that it is subject to appropriate safeguards for the rights and freedoms of the data subject. These guarantees must ensure that technical and organizational measures are set in place to ensure compliance with the data minimization principle.<sup>43</sup> Whenever possible, further processing should not or no more allow for the identification of the data subject.
  - vi) Personal data must be processed in a manner that ensures an appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures (principle of *integrity and confidentiality*).
  - vii) The controller is responsible for the compliance with the principles applicable to the processing of personal data. The controller must also, and that is formally new, be able to demonstrate that the data processing is compliant with these principles (principle of *accountability*).<sup>44</sup>

### *Data processing lawfulness*

The General Data Protection Regulation lists the categories of situations in which it is a priori, lawful, that is to say, as permitted by law, to process personal data.<sup>45</sup> It is assumed, for each of these situations, that it is legitimate in general to process personal data. To put it another way, each of these categories is supposed to represent a situation in which the interests involved are in an acceptable balance. The interests to be taken into consideration are those of the data controller, the data subject and the community. In line with the legitimization mechanisms set up in Directive 95/46/EC, it is of course necessary to verify in each individual case for each data processing taken and considered separately and

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that the personal data are not attributed to an identified or identifiable natural person (Article 4.5 of the Regulation).

<sup>43</sup> *ibid.*

<sup>44</sup> See Article 29 Data Protection Working Party *Opinion 3/2010 on the principle of accountability* WP 173 13 July 2010.

<sup>45</sup> See Article 6 of the Regulation and the possibility of special arrangements for processing imposed by law or carried out in the public interest or in the exercise of official authority by the controller and the flexibility of the criterion for the compatibility of further data processing.

individually whether there is a fair balance between these three kind of interests *in concreto* and not only *a priori* and *in abstracto*. In this respect, changing the balance of interests over time will have the effect of removing the legitimacy of the data processing for the future. The data processing will have to be stopped except for a solution to satisfactorily rebalance the interests involved. It must be reiterated that the assessment of the legitimacy of data processing is sensitive to other aspects of the implementation of data protection, such as the level of confidentiality and security of the data processing, the level of control exercised by the national supervisory authority, the degree of necessity of the purpose pursued, and so on.

The rule regarding the processing of sensitive data is well known and has not changed: the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health<sup>46</sup> or data concerning a natural person's sex life or sexual orientation are prohibited.<sup>47</sup> This prohibition does not apply in the situations detailed in the Regulation,<sup>48</sup> without prejudice to the need to verify *in concreto* the existence of a fair balance between the interests involved in each processing.

If the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller is no more be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the General Data Protection Regulation.<sup>49</sup> In addition, the Regulation provides that, if possible, the controller will inform the data subject when it is able to demonstrate that it is not in a position to identify the data subject (sic). In such cases, the data subject must provide additional information to enable the data controller to control his or her identity identify for the purpose of exercising his or her right of access, to rectify, to cancel, to limitation of treatment, to notification of rectification or deletion of data or limitation of processing, or to data portability.<sup>50</sup>

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<sup>46</sup> Data concerning health means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status (Article 4.15 of the Regulation). Recital 35 of the Regulation provides that “Personal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test”.

<sup>47</sup> Article 9.1 of the Regulation.

<sup>48</sup> Article 9.2 of the Regulation.

<sup>49</sup> Article 11.1 of the Regulation.

<sup>50</sup> See Article 11.2 of the Regulation.

None of this prevents the data controller from being, for the rest, subject to all the other obligations arising from the General Data Protection Regulation.

## 5.2 Additional national substantive rules applicable to the processing of personal data related to health

Surprisingly, while one of the objectives of the reform of the legal framework for data protection was to eliminate inconsistencies between Member States regarding the processing of personal data relating to health, the General Data Protection Regulation provides that, in respect of the subsidiarity principle, Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.<sup>51</sup> It follows that the differences between Member States, which have been strongly condemned, are likely to increase in the matter of personal data related to health.

It remains, of course, that, in any case, Member States are bound by the common legal framework that emerges from the case-law of the European Court of Human Rights in the field of data protection and by the rights therefore granted to individuals in terms of data control (situations in which the Court considers that the person is entitled to expect that data will not be disclosed without his or her consent), data access (including access to medical records) or medical records security, for example.

It should be noted that the General Data Protection Regulation does not lay down criteria for delimiting the territorial scope of the national provisions that Member States might adopt regarding the processing of genetic data, biometric data or health.<sup>52</sup>

## 6. Patient's rights on the processing of personal data

Where Directive 95/46/EC formally recognized three rights (right of access, right to object to data processing and right not to be subject to individual automated decisions), the General Data Protection Regulation grants data subject with eight rights (right to information, right of access, right to rectification, right to erase, right to limit treatment, right to data portability, right to object to data processing and right not to be subject to automated individual decisions).<sup>53</sup>

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<sup>51</sup> Article 9.4 of the Regulation.

<sup>52</sup> Article 9.4 *in fine* of the Regulation.

<sup>53</sup> See the limits which may be imposed on these rights by Union law or by the law of the Member State to which the controller or processor is subject, by means of legislative measures, in accordance with Article 23 of the Regulation. These limits are permissible only if they respect the essence of fundamental rights and freedoms and are necessary and proportionate measures in a democratic society to guarantee one of the objectives listed in this provision.



In particular, the right to data portability<sup>54</sup> means that, where the data are processed on the basis of the data subject's consent or a contract and by automated means, the data subject has the right to request and receive in a structured, commonly used and machine-readable format, the data he or she has provided to the data controller. The data subject is then entitled to forward these data to another data controller. The data subject may also ask the first controller to send them directly to another data controller if technically feasible.<sup>55</sup> This right inevitably brings to mind the situation in which the patient's medical record is communicated between healthcare professionals in order to ensure the continuity of care. The implementation of this newly formalized right may therefore not be a problem in the health sector as long as it is extended to data not provided by the patient.<sup>56</sup>

That being said, the real challenge is to know how these rights will really and effectively prosper in the light of the debates around cloud computing services, big data and mobile applications,<sup>57</sup> and whether this formal increase in the number of rights will improve data protection and the benefit to the patient from the information society participation. Doubt is permitted.

## 7. Additional obligations of the data controller and processor

Beyond the uniform substantive rules laid down by the General Data Protection Regulation and the substantive rules that national law of each Member State could add, the data controller (and the processor)<sup>58</sup> is subject to another series of general obligations which represent as many new uniform substantive rules to comply with.

### *Implementation of technical and organizational measures*

The data controller (and processor) must implement appropriate technical and organizational measures to ensure and to be able to demonstrate that the data processing is performed in accordance with the General Data Protection Regulation. In doing so, the data controller has to take into account the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons. Those measures must be reviewed and updated where necessary. Where

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<sup>54</sup> Article 29 Data Protection Working Party *Guidelines on the right to data portability* WP 242 13 December 2016.

<sup>55</sup> See Article 20 of the Regulation. This right is without prejudice to the right to erasure or to be forgotten. That right does not apply to processing necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. In addition, it cannot adversely affect the rights and freedoms of others.

<sup>56</sup> In any case, Article 4.2 (f) of Directive 2011/24/EC provides that "in order to ensure continuity of care, patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC".

<sup>57</sup> What about algorithmic governance in healthcare?

<sup>58</sup> See Article 26 of the Regulation for the case of joint data controllers, Article 27 for the representative of data controllers or processors who are not established in the territory of the European Union and Article 28 for the special rules applicable to processors.

proportionate in relation to processing activities, these measures must include the implementation of appropriate data protection policies by the data controller.<sup>59</sup>

#### *Privacy by design*

The data controller (and processor) must implement, both at the time of the determination of the means for processing and at the time of the processing itself, appropriate technical and organizational measures (such as pseudonymization) which are designed to implement data-protection principles (such as data minimization) in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements of General Data Protection Regulation and protect the rights of data subjects. In doing so, the data controller has to take into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of natural persons posed by the processing.<sup>60</sup>

#### *Privacy by default*

The data controller (and processor) must implement appropriate technical and organizational measures for ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed. That obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility. In particular, such measures must ensure that by default personal data are not made accessible without the individual's intervention to an indefinite number of natural persons.<sup>61</sup>

#### *Processing on instruction*

As a rule, the processor and any person acting under the authority of the data controller or processor who has access to personal data cannot process these data unless instructed by the data controller, unless a legal duty to do so imposed by Union law or the law of a Member State.<sup>62</sup>

#### *Records of processing activities*

Due to a lack of understanding of its use in the daily enforcement of the data subject's rights, the General Data Protection Regulation regrettably has ended the obligation to hold a public registry which was easily accessible on line by everyone. This public registry has been replaced by the data controller obligation to maintain a record of processing activities.<sup>63</sup> This means that a unique public registry has been replaced by a multitude of private registries which are not freely and unconditionally accessible. Moreover, this

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<sup>59</sup> See Article 24 of the Regulation. The application of an approved code of conduct or approved certification mechanisms may serve as a means of demonstrating compliance with the obligations of the data controller.

<sup>60</sup> On this, see Article 25.1 of the Regulation. An approved certification mechanism may serve as an element to demonstrate compliance with these requirements.

<sup>61</sup> See Article 25.2 of the Regulation. Again, an approved certification mechanism can serve as an element to demonstrate compliance with these requirements.

<sup>62</sup> Article 29 of the Regulation.

<sup>63</sup> See Article 30 of the Regulation. This register may be in written or electronic form. It must be made available to the supervisory authority on request.

obligation does not apply to an enterprise or an organization employing fewer than 250 persons unless the processing is likely to result in a risk to the rights and freedoms of data subjects, the processing is not occasional or the processing includes special categories of data or personal data relating to criminal convictions and offences.<sup>64</sup>

Similarly, and under the same conditions as the data controller, each processor and, where appropriate, the processor's representative, must maintain a record of all categories of processing activities carried out on behalf of the data controller.

#### *Cooperation with supervisory authorities*

The data controller and the processor and, where applicable, their representatives, must cooperate, on request, with the supervisory authority in the performance of its tasks.<sup>65</sup>

#### *Security of personal data*

The data controller and processor must implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk. They must take into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons. In assessing the appropriate level of security, they must take into account in particular the risks presented by the data processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to personal data transmitted, stored or otherwise processed.<sup>66</sup>

In any case, the data controller and processor must take steps to ensure that any natural person acting under the authority of the controller or the processor who has access to personal data does not process them except on instructions from the controller, unless required to do so by Union or Member State law.

#### *Notification of personal data breach to supervisory authorities and data subjects*

In the case of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed (known as *personal data breach*),<sup>67</sup> the data controller must without undue delay and, where feasible, not later than 72 hours after having become aware of it,<sup>68</sup> notify the personal data breach to the competent supervisory authority.<sup>69</sup> The data

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<sup>64</sup> See Article 30.5 of the Regulation.

<sup>65</sup> Article 31 of the Regulation. The application of an approved Code of Conduct or an approved certification mechanism may serve as an element to demonstrate compliance with data processing security requirements.

<sup>66</sup> See Article 32 of the Regulation.

<sup>67</sup> Article 4.12 of the Regulation. See Article 29 Data Protection Working Party Working Document 01/2011 on the current EU personal data breach framework and recommendations for future policy developments WP 184 5 April 2011 and Opinion 03/2014 on Personal Data Breach Notification WP 213 25 March 2014.

<sup>68</sup> See Article 33 of the Regulation. Where the notification to the supervisory authority is not made within 72 hours, it has to be accompanied by reasons for the delay. Where, and in so far as, it is not possible to provide the information at the same time, the information may be provided in phases without undue further delay.

<sup>69</sup> The notification must, at least: i. describe the nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned; ii. communicate the name and contact details of the data

controller is exempted when the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. But, in any case, the data controller must document any personal data breaches, including the facts relating to the personal data breach, its effects and the remedial action taken. That documentation must enable the supervisory authority to verify the compliance with the obligations applicable to the data controller.

Similarly, the processor must notify to the data controller without undue delay after becoming aware of a personal data breach. It must be assumed that it is also required to document any data breaches even if this is not expressly foreseen in the Regulation.

Asymmetrically in relation to the obligation to notify the supervisory authority, the data controller must only communicate the personal data breach to the data subject if the breach is likely to result in a high risk to the rights and freedoms of natural persons. The communication must be done without undue delay. The communication to the data subject must describe in clear and plain language the nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned. It must also contain the name and contact details of the data protection officer or any other contact point where more information can be obtained, the likely consequences of the personal data breach, the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

However, even in the event of a high risk to rights and freedoms, this communication is not always required. Furthermore, if the data controller has not already communicated the data breach to the data subject, the supervisory authority may, after examining whether this data breach is likely to result in a high risk, require the data controller to do the communication or decide that the controller is in one of the situations in which he is exempted to do so.<sup>70</sup>

#### *Privacy impact assessment*

Prior to the processing, the data controller must carry out an assessment of the impact of the envisaged processing operations on the protection of personal data<sup>71</sup> where a type of processing, particularly when using new technologies, and taking into account the nature, scope, context and purposes of the processing, is likely to result in a high risk to the rights

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protection officer or other contact point where more information can be obtained; iii. describe the likely consequences of the personal data breach; iv. describe the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

<sup>70</sup> Article 34 of the Regulation.

<sup>71</sup> See: D Wright and P De Het (eds), *Privacy Impact Assessment*, Law, Governance and Technology Series, volume 6, Springer, 2012 and Article 29 Data Protection Working Party *Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679* WP 248 4 April 2017.

and freedoms of natural persons. The controller will seek the advice of the data protection officer, where designated, when carrying out a data protection impact assessment.<sup>72</sup>

The data controller will consult the supervisory authority prior to processing where a data protection impact assessment indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk.<sup>73</sup>

Where the supervisory authority is of the opinion that the processing would infringe the General Data Protection Regulation, especially when the data controller has insufficiently identified or mitigated the risk, the supervisory authority must, within period of up to eight weeks of receipt of the request for consultation, provide written advice to the controller and, where applicable to the processor, and may use any of its investigating powers, correcting powers, advisory powers or any other power conferred by its national law.<sup>74</sup>

### *Data protection officer*

The obligation to appoint a data protection officer is one of the measures that has received particular attention. Beyond the situation in which that this designation is required under organizational measures to ensure the security and confidentiality of data processing, the

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<sup>72</sup> See Article 35 of the Regulation. A single assessment may address a set of similar processing operations that present similar high risks. The controller shall seek the advice of the data protection officer, where designated, when carrying out a data protection impact assessment (leaving open the question of the obligation to do so when the controller had no obligation (formally or in the framework of technical and organizational measures) to designate one but still did it).

The supervisory authority must establish and make public a list of the kind of processing operations which are subject to the requirement for a data protection impact assessment. The supervisory authority must communicate those lists to the European Data Protection Board. The supervisory authority may also establish and make public a list of the kind of processing operations for which no data protection impact assessment is required. The supervisory authority shall communicate those lists to the European Data Protection Board. Prior to the adoption of the lists, the competent supervisory authority will apply the consistency mechanism where such lists involve processing activities which are related to the offering of goods or services to data subjects or to the monitoring of their behavior in several Member States, or may substantially affect the free movement of personal data within the Union.

Compliance with approved codes of conduct by the relevant controllers or processors must be taken into due account in assessing the impact of the processing operations performed by such controllers or processors, in particular for the purposes of a data protection impact assessment.

Where appropriate, the data controller must seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of processing operations.

<sup>73</sup> When consulting the supervisory authority pursuant to paragraph 1, the controller shall provide the supervisory authority with (Article 36.3 of the Regulation): i) where applicable, the respective responsibilities of the controller, joint controllers and processors involved in the processing, in particular for processing within a group of undertakings; ii) the purposes and means of the intended processing; iii) the measures and safeguards provided to protect the rights and freedoms of data subjects pursuant to this Regulation; iv) where applicable, the contact details of the data protection officer; v) the data protection impact assessment; vi) and any other information requested by the supervisory authority.

<sup>74</sup> See Article 58 of the Regulation.

data controller and the processor are in any case obliged to designate a data protection officer<sup>75</sup> in three cases:<sup>76</sup>

- the processing is carried out by a public authority or body, except for courts acting in their judicial capacity;<sup>77</sup>
- the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope or purposes, require regular and systematic monitoring of data subjects on a large scale;
- the core activities of the controller or the processor consist of processing on a large scale of special categories of data and personal data relating to criminal convictions and offences.

## 8. Specific data protection bodies, mechanisms and remedies

In order to ensure data protection effectiveness, provision was made to create specific data protection authorities as well as specific mechanisms and remedies.

### 8.1 Supervisory authorities

At the level of the Member States, each Member State must provide for one or more independent public authorities to be responsible for monitoring the application of the General Data Protection Regulation, in order to protect the fundamental rights and freedoms of natural persons in relation to processing and to facilitate the free flow of

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<sup>75</sup> Article 37 of the Regulation: the data protection officer must be designated on the basis of professional qualities and, in particular, expert knowledge of data protection law and practices and the ability to fulfil its tasks. The data protection officer may be a staff member of the controller or processor, or fulfil the tasks on the basis of a service contract. See Article 29 Data Protection Working Party *Guidelines on Data Protection Officers ('DPOs')* WP 243 rev.01 5 April 2017. The data controller or the processor must publish the contact details of the data protection officer and communicate them to the supervisory authority.

<sup>76</sup> See Article 37 of the Regulation. A group of undertakings may appoint a single data protection officer provided that a data protection officer is easily accessible from each establishment. Where the controller or the processor is a public authority or body, a single data protection officer may be designated for several such authorities or bodies, taking account of their organizational structure and size. When there is no obligation to appoint a data protection officer, the data controller or processor or associations and other bodies representing categories of data controllers or processors may or, where required by Union or Member State law must, designate a data protection officer. The data protection officer may act for such associations and other bodies representing controllers or processors.

<sup>77</sup> There remains to found a justification for this discrimination all the more astonishing at a time when justice tries to reach the 21<sup>st</sup> century.

personal data within the Union.<sup>78</sup> Each supervisory authority must act with complete independence in performing its tasks and exercising its powers.<sup>79</sup>

At the level of the European Union, the European data protection Board replaces the Working Party on the protection of individuals with regard to the processing of personal data (the Working Party).<sup>80</sup> The Board is composed of the head of one supervisory authority of each Member State and of the European Data Protection Supervisor, or their respective representatives. The Board must act independently when performing its tasks or exercising its powers. In the performance of its tasks or the exercise of its powers, the Board will neither seek nor take instructions from anybody. The Board will draw up an annual report regarding the protection of natural persons with regard to processing in the Union and, where relevant, in third countries and international organizations. The European data protection supervisor will provide the secretariat of the Board.<sup>81</sup>

## 8.2 Data subject's remedies

### Right to lodge a complaint with a supervisory authority

Without prejudice to any other administrative or judicial remedy, every data subject has the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the data subject considers that the processing of personal data relating to him or her infringes the General Data Protection Regulation.<sup>82</sup>

### Right to an effective judicial remedy against a supervisory authority

Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a supervisory authority concerning them.<sup>83, 84</sup>

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<sup>78</sup> See Article 51 of the Regulation on the principle of independence and Article 55 on the issue of the competence of the supervisory authority (cf. Article 4.22 of the Regulation for the definition of the *supervisory authority concerned*). It is expressly provided that the supervisory authorities are not competent to review the processing operations carried out by the courts in the exercise of their judicial function (Article 55.3 of the Regulation). The duties and powers of the supervisory authorities are detailed in Articles 57 and 58 of the Regulation. See Article 29 Data Protection Working Party *Guidelines for identifying a controller or processor's lead supervisory authority* WP 244 13 December 2016.

<sup>79</sup> See Article 52 of the Regulation.

<sup>80</sup> See Article 68 of the Regulation. Article 70 lists its missions.

<sup>81</sup> The European Data Protection Supervisor is also the supervisory authority for EUROPOL.

<sup>82</sup> It is not easy to argue that this right exists in the case of a breach of a rule which would be imposed by a Member State within the scope of the discretion which would be accorded to the State for the implementation of a particular provision of the Regulation. See Article 80 on the question of the representation of data subjects.

<sup>83</sup> Directive 95/46/EC already provided that *Decisions by the supervisory authority which give rise to complaints may be appealed against through the courts* (Article 28.3, *in fine*).

<sup>84</sup> See Article 78.1 of the Regulation. Proceedings against a supervisory authority must be brought before the courts of the Member State where the supervisory authority is established. Where proceedings are brought against a decision of a supervisory authority which was preceded by an opinion or a decision of the Board in

Without prejudice to any other administrative or non-judicial remedy, each data subject shall have the right to an effective judicial remedy where the supervisory authority which is competent does not handle a complaint or does not inform the data subject within three months on the progress or outcome of the complaint.<sup>85</sup>

#### Right to an effective judicial remedy against a controller or processor

Without prejudice to any available administrative or non-judicial remedy, including the right to lodge a complaint with a supervisory authority, each data subject shall have the right to an effective judicial remedy where he or she considers that his or her rights under the General Data Protection Regulation have been infringed as a result of the processing of his or her personal data in non-compliance with the General Data Protection Regulation.<sup>86</sup>

#### Right to compensation and liability

Any person who has suffered material or non-material damage as a result of an infringement of the General Data Protection Regulation has the right to receive compensation from the controller or processor for the damage suffered.<sup>87</sup> Any data controller involved in processing is liable for the damage caused by processing which infringes the General Data Protection Regulation. A processor is liable for the damage caused by processing only where it has not complied with obligations of the General Data Protection Regulation specifically directed to processors or where it has acted outside or contrary to lawful instructions from the data controller. A data controller or processor is exempt from liability if it proves that it is not in any way responsible for the event giving rise to the damage. Where more than one data controller or processor, or both a data controller and a processor, are involved in the same processing and where they are responsible for any damage caused by processing, each data controller or processor is liable for the entire damage in order to ensure effective compensation of the data subject.<sup>88</sup>

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the consistency mechanism, the supervisory authority shall forward that opinion or decision to the court (Article 78.4 of the Regulation).

<sup>85</sup> See Article 78.2 of the Regulation. Proceedings against a supervisory authority must be brought before the courts of the Member State where the supervisory authority is established. Where proceedings are brought against a decision of a supervisory authority which was preceded by an opinion or a decision of the Board in the consistency mechanism, the supervisory authority shall forward that opinion or decision to the court (Article 78.4 of the Regulation).

<sup>86</sup> See Article 79.1 of the Regulation. Proceedings against a controller or a processor must be brought before the courts of the Member State where the controller or processor has an establishment. Alternatively, such proceedings may be brought before the courts of the Member State where the data subject has his or her habitual residence, unless the controller or processor is a public authority of a Member State acting in the exercise of its public powers.

<sup>87</sup> Court proceedings for exercising the right to receive compensation must be brought before the courts competent under the law of the Member State where the data controller or processor has an establishment. Alternatively, such proceedings may be brought before the courts of the Member State where the data subject has his or her habitual residence, unless the controller or processor is a public authority of a Member State acting in the exercise of its public powers.

<sup>88</sup> See Article 82 of the Regulation. Where a controller or processor has, in accordance with paragraph 4, paid full compensation for the damage suffered, that controller or processor shall be entitled to claim back from the other controllers or processors involved in the same processing that part of the compensation corresponding to their part of responsibility for the damage.



## Administrative fines and penalties

Depending on the circumstances of each individual case, each supervisory authority may impose effective, proportionate and dissuasive administrative fines<sup>89</sup> in addition or in place of corrective measures.<sup>90</sup>

Member States must lay down the rules on other penalties applicable to infringements of the General Data Protection Regulation in particular for infringements which are not subject to administrative fines. They must take all measures necessary to ensure that these penalties are implemented [and enforced]. Such penalties must be effective, proportionate and dissuasive.<sup>91</sup>

## 9. Conclusions

Data protection must be guaranteed in the context of cross-border healthcare provided to a patient by a health professional in a Member State other than the Member State of affiliation. That means that the patient has the right to claim the benefit of this protection in the context of cross-border healthcare. It is therefore not only an obligation on the part of the health professional or the Member State but also, and above all, a right that the patient can claim against them.

The European Union and Member States have maintained the decision to implement a common legal framework for data protection at the European level when adopting the General Data Protection Regulation. However, in the same time, Member States may add national rules for the processing of personal data concerning health. Regarding the specificities and powers of each Member State in the matter of public health, we could wonder whether this decision should not be reversed and whether we should not have instead distinct national legal frameworks with common restrictive rules applicable to the transfer of personal data related to health between Member States. That being said, the right to data protection had to be recognized at the European level especially when considering that some Member States still do not recognize data protection as a fundamental right.

The scope of the General Data Protection Regulation is not clearer than before and regarding the new uniform substantive rules applicable to the processing of personal data, differences between Member States (which have been strongly condemned) are likely to increase in the matter of personal data related to health since Member States may maintain or introduce further conditions, including limitations, with regard to the processing of data concerning health. Of course, Member States are still bound by the common legal framework that emerges from the case-law of the European Court of Human Rights in the field of data protection and by the rights therefore granted to individuals in terms of data

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<sup>89</sup> On all of this and in particular the factors to be taken into account in each individual case, see Article 83 of the Regulation.

<sup>90</sup> See the list of corrective measures in Article 58.2, a) to h), and j) of the Regulation.

<sup>91</sup> See Article 84 of the Regulation.

control (situations in which the Court considers that the person is entitled to expect that data will not be disclosed without his or her consent), data access (including access to medical records) or medical records security, for example. In any case, we should consider imposing that personal data concerning health are not be subtracted from the effective physical and jurisdictional powers of the data subject excluding therefore the possibility to store and process them in another country without very strict and serious justifications and constraints.

On the other hand, one cannot but, wonder how to reconcile the general principles applicable to data processing such as transparency, fairness, minimization, accuracy, storage limitation, integrity and confidentiality, and accountability, in the light and reality of cloud computing services, big data and mobile applications that are heavily promoted in the same time by the European Union.

Some may acclaim the fact that the General Data Protection Regulation recognizes more rights to the data subject. But maybe it should have been better to find new ways to enforce already existing data subject rights before adding some new ones. In other words, recognizing new rights will not help enforcing previous rights largely and voluntarily ignored such as the basic but fundamental right of access including the right to get all the needed information about the data processing.

Because the real problem does not lie in the legal framework but well in the effective enforcement of data protection rules. We need information and sensibilization campaigns about data protection. We need fairness and transparency on data processing especially in the matter of eHealth and mHealth. We have to oppose so-called health applications promising anything and everything only to get access to personal data concerning health for commercial purposes. However, in the same time, we have to strongly promote the development of all information and communication technologies that could improve healthcare and patient's rights while respecting the distribution of powers between the European Union and the Member States in the matter of public health.

# Chapter XIV The relevance of Directive 2005/36 on the recognition of professional qualifications\*

Miek Peeters

## 1. Introduction

Cross-border healthcare covers all situations, different from the one the patient is treated in his own Member State (the one he is socially insured in) by a local healthcare provider (established in that Member State).

The phenomenon of cross-border healthcare is mostly associated with patient mobility. However, patients moving across the borders in order to receive medical treatment (or purchase pharmaceuticals or medical devices), represent only one form of cross-border healthcare.

In the case of patient mobility, the patient moves to another Member State than the one in which he is socially insured. He can also receive healthcare services or purchase medical products in that other Member State without actually moving (telemedicine) e.g. medical consultations through the internet or telephone, examinations or analyses from distance or telesurgery.

European secondary legislation facilitating patient mobility is Directive 2011/24 concerning patients' rights in cross-border healthcare.<sup>1</sup> This Directive contains provisions on the reimbursement of costs, the responsibilities of the Member States and their mutual cooperation in healthcare.

In case of healthcare professional movement, it is the health professional that moves (physically or virtually) to another Member State than the one he is established in with the purpose of treating one or several patients. This movement can occur on a temporary or on an occasional basis.

European secondary legislation facilitating this kind of cross-border healthcare is Directive 2005/36 on the recognition of professional qualifications<sup>2</sup> with its system of diploma

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\* The views expressed in this contribution are solely those of the author in her private capacity and do not in any way represent the views of the EFTA Surveillance Authority.

<sup>1</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L 088/45.

<sup>2</sup> Directive 2005/36 /EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [2005] OJ L 255/22.

recognition and coordination of rules concerning the pursuit of the profession. It was recently amended by Directive 2013/55.<sup>3</sup>

Although both Directives have the same objective i.e. facilitating cross-border healthcare, their history and therefore their content is different. Both Directives should nevertheless be looked at as a whole. Together they represent the EU's legislative framework for cross-border healthcare and they both contain relevant provisions for (moving) patients and (moving) health professionals.

This contribution comments on the relevance of Directive 2005/36 for moving patients and also on the relevance of Directive 2011/24 for moving health professionals. It becomes clear that the impact of both Directives reaches far beyond patient and healthcare professional mobility. This is preceded by a delineation of the origin of both Directives and an introduction of Directive 2005/36 as, contrary to Directive 2011/24, it has not been commented upon in this book.

## 2. Origin of both Directives

The political incentive for creating a Directive on patient mobility emerged during the legislation process of the Services Directive 2006/123<sup>4</sup> nicknamed the "*Bolkestein Directive*",<sup>5</sup> in which the European Parliament succeeded in excluding healthcare from the scope of application, arguing that the Directive was not suitable for something as specific as healthcare. As a consequence, increasing calls arose for a Directive adapted to the particular characteristics of healthcare. Such a Directive was expected to act as a counterweight to the jurisprudence of the European Court of Justice that, whilst safeguarding the internal market principles of the Treaty on the Functioning of the European Union, seemed to restrict national policy makers in organizing their healthcare systems in an increasing way.

Although the Directive owes its existence to the exclusion of healthcare from the scope of application of the Services Directive, it does not fill in that gap. Directive 2011/24 is not a sectoral version of the Services Directive. The latter aims to facilitate *market access* for self employed and undertakings wanting to offer their (economic) services in another Member State than the one in which they are or were established. Therefore the Directive obliges the Member States to screen their requirements, applicable for candidates wanting to offer services on their territory in the light of the internal market principles. It may be so that healthcare is excluded from the Services Directive, the internal market principles of the Treaty remain fully applicable to healthcare. European case law<sup>6</sup> had determined already

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<sup>3</sup> Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ( 'the IMI Regulation') [2013] OJ L 354/132.

<sup>4</sup> Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market [2006] OJ L 376/ 36.

<sup>5</sup> After the name of former Commissioner of internal market, Frits Bolkestein.

<sup>6</sup> E.g., cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, case C-159/90 *Society for the Protection of Unborn Children Ireland/Grogan* [1991] ECR I-4685 and case C-158/96 *Kohll* [1998] ECR I-1931.

more than twenty years ago that healthcare services are economic services and therefore fully subject to the freedom of establishment and the free movement of services. This is however not the topic of this contribution.

So, despite of the political aim of creating a sectoral version of the Services' Directive, Directive 2011/24 became a legal framework for cross-border moving patients, 13 years after the famous *Kohll* and *Decker* rulings.<sup>7</sup>

Whereas Directive 2011/24 is quite new, the origin of the Directive 2005/36 on the recognition of professional qualifications goes way back in history. The directives on the professional qualifications have been part of very early European secondary legislation crystallizing the free movement of persons together with Regulation 1612/68<sup>8</sup> fighting discrimination and Regulation 1408/71<sup>9</sup> coordinating the different social security systems.

The European legislator had realised soon that the free movement of persons for regulated professions could never be realised without specific legislation on the mutual recognition of diplomas and titles. This was especially the case for healthcare professions as healthcare is a highly regulated sector. It is therefore not surprising that doctors have been the primary target group of the directives on recognition of professional qualifications. The first Doctors' directives 75/362/EEC and 75/363/EEC were consequently used as a model for the directives of other medical and pharmaceutical professions: nurses responsible for general care, dentists, veterinary surgeons, midwives and pharmacists.

Until 2005, the legal framework on recognition of diplomas consisted out of two types of directives: sectoral and general ones. In 2005, all directives were merged into one, Directive 2005/36. The same recognition systems continued to apply. This remained unchanged in 2013 when the Directive was modernised by Directive 2013/55.

### 3. Directive 2005/36: an introduction

As mentioned in the introduction, Directive 2005/36 does not only serve the mutual recognition of diplomas, certificates and professional qualifications – which regulates the access to the profession – but also the coordination of the rules concerning the pursuit of the profession, such as disciplinary rules, the requirement of documents, etc. The scope of Directive 2005/36, contrary to Directive 2011/24, is not limited to healthcare (professions) but includes all regulated professions. Nevertheless, as will be explained, it clearly highlights the special nature of healthcare professions.

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<sup>7</sup> Case C-158/96 *Kohll* [1998] ECR I-1931 and case C-120/95 *Decker* [1998] ECR I-1831.

<sup>8</sup> Regulation 1612/68 of the Council of 15 October 1968 on freedom of movement for workers within the Community [1968] OJ L 257/2. This Directive has been replaced by Regulation 492/2011 of the European Parliament and of the Council of 5 April 2011 on freedom of movement for workers within the Union [2011] OJ L 141/1.

<sup>9</sup> Regulation 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1971] OJ L 149/2. This Directive has been replaced by Regulation 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems OJ L 166/1.

Until 2005, the legal framework on recognition of diplomas consisted out of two types of directives: sectoral and general ones. The general directives were characterised by a mutual – but not automatic – recognition of diplomas and other titles of qualification, without prior harmonisation of training requirements. It gave the host Member State the freedom to decide each case separately and to impose compensating measures like an aptitude test or an adaptation period if appropriate. The sectoral directives concerned a specific regulated profession and provided an automatic recognition of diplomas for which the required training met certain minimum requirements, listed in the directives. This procedure of automatic recognition obliges every Member State to act positively upon every request for recognition. This implies that these Member States have to grant the same legal consequences to those diplomas, listed in the directive and corresponding to the minimum training requirements as they have in their home country. This automatic recognition system is – still today - only applicable for seven professions whereof six from the healthcare sector (doctors including doctor-specialists,<sup>10</sup> nurses responsible for general care, midwives, dentists including dental specialists,<sup>11</sup> pharmacists, veterinary surgeons and architects).

In 2005, all directives were merged into and replaced by Directive 2005/36. The same recognition systems continued to apply and also a recognition system on the basis of professional experience for certain professional activities was introduced.<sup>12</sup> This remained broadly unchanged in 2013 when the Directive was modernised by Directive 2013/55. Besides modernising the minimum training requirements, Directive 2013/55 dedicates attention to continuous professional development (CPD) by obliging the Member States to encourage CPD in accordance with their own specific procedures for those professions, falling under the scope of the automatic recognition system. They must report about these measures to the Commission (Article 22.b).<sup>13</sup>

Directive 2013/55 consolidated the possibility of partial recognition or partial access to the profession when certain conditions are met (Article 4f), created by the European Court of Justice rulings.<sup>14</sup> First, the professional must be fully qualified in his own Member State to exercise the professional activity. Second, the differences between the professional activity exercised in the home Member State and the regulated profession in the host Member

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<sup>10</sup> Currently, there are 54 specialties of doctors, listed in Annex V, 5.1.3 and 2 dental specialties, listed in Annex V, 5.3.3. To insert a new speciality to the system of automatic recognition, the medical or dental specialties should be common to at least two fifths of Member States. However, the Directive does not prevent Member States from agreeing amongst themselves on automatic recognition for certain medical and dental specialties common to them but not automatically recognised within the meaning of this Directive, according to their own rules (Preamble, no. 20, Articles 26 and 35).

<sup>11</sup> *ibid.*

<sup>12</sup> As this system is not relevant for healthcare professions, it will not be discussed here.

<sup>13</sup> A mapping and review of continuous professional development and lifelong learning for doctors, nurses, dentists, midwives and pharmacists in the 28 member countries of the EU and EFTA countries is to be found in *“Study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU”*, Final Report, October 2013, [http://ec.europa.eu/health/sites/health/files/workforce/docs/cpd\\_mapping\\_report\\_en.pdf](http://ec.europa.eu/health/sites/health/files/workforce/docs/cpd_mapping_report_en.pdf)

<sup>14</sup> Case C-330/03 *Colegio de Ingenieros de Caminos, Canales y Puertos* [2006] ECR I-801 and case C-575/11 *Nasiopoulos* ECLI:EU:C:2013:430.

State must be so large that the application of compensation measures would amount to requiring the professional to complete the full education and training required in the host Member State. Third, the differences of the professional activity can objectively be separated from other activities falling under the regulated profession in the host Member State. Partial access may however be rejected if it is justified by overriding reasons of general interest, suitable for securing the attainment of the objective pursued, and does not go beyond what is necessary to attain that objective.

The Directive later excluded partial access for all professions, falling under the scope of the automatic recognition system (Article 4f, 6). It deprives therefore most health professionals from partial access. Paramedical professions however could in principle, when all conditions are met, benefit from partial access. In the case *Nasiopoulos*,<sup>15</sup> the Court had analysed the situation of a Greek national who, after having obtained a German qualification of “medical masseur-hydrotherapist”, asked for authorisation to access the profession of physiotherapist in Greece, as “medical masseur-hydrotherapist” is no regulated profession in Greece and the nearest profession is that of physiotherapist. According to the Court, the Greek legislation excluding partial access to the profession of physiotherapist is an infringement on the freedom of establishment and goes beyond what is necessary to protect consumers and public health. Less restrictive means in order to protect consumers could be applied such as the obligation to use the professional title of origin. Concerning the protection of public health, the Court emphasizes the profession of physiotherapist and masseur fall within the paramedical sector and the provision of their services merely consist out of therapy prescribed by a doctor.

One of the key features of Directive 2013/55 was the introduction of the European professional card (EPC), an electronic certificate issued to professionals interested in working in another Member State, using a new electronic recognition procedure, through the Internal Market Information System (IMI).<sup>16</sup> It is intended to promote the free movement of professionals and make the system of recognition of professional qualifications between competent authorities in Member States more efficient and transparent. So far, the EPC is only available for five professions (nurses for general care, physiotherapists, pharmacists, real estate agents and mountain guides).<sup>17</sup> It might be extended for other professions in the future.

For the sake of transparency (Article 59), Directive 2013/55 created a transparency and a mutual evaluation exercise. Article 59 obliges the Member States to notify to the Commission a list of existing regulated professions, specifying the activities covered by each profession, a list of regulated education and training, a list of professions for which a prior check of qualifications is necessary under Article 7.4 including a specific justification for the inclusion of each of those professions on that list.

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<sup>15</sup> Case C-575/11 *Nasiopoulos* ECLI:EU:C:2013:430.

<sup>16</sup> On 24 June 2015, the EU Commission adopted the Implementing Regulation 2015/983 of 24 June 2015 on the procedure for issuance of the European Professional Card and the application of the alert mechanism pursuant to Directive 2005/36/EC of the European Parliament and of the Council [2015] OJ L 159/27.

<sup>17</sup> See Annex to Regulation 2015/983.

Member States also have to examine on a regular basis – and report the Commission about their findings - about their (current, new and removed) requirements restricting the access to a profession or its pursuit to the holders of a specific professional qualification, are compatible with the following principles: they must be neither directly nor indirectly discriminatory on the basis of nationality or residence, they must be justified by overriding reasons of general interest and suitable for securing the attainment of the objective pursued and must not go beyond what is necessary to attain that objective.

On 10 January 2017, the Commission launched a proposal for a Directive on a proportionality test before adoption of new regulation of professions.<sup>18</sup> The results of the mutual evaluation process of Article 59 had revealed a lack of clarity as regards the criteria to be used by national competent authorities when assessing the proportionality of requirements restricting access to or pursuit of regulated professions. To avoid fragmentation of the internal market and eliminate barriers to taking-up and pursuit of professional activities, the Commission considered it necessary to establish a common approach at Union level, preventing disproportionate measures from being adopted. The proposal holds the obligation for Member States to ensure that, before introducing new provisions restricting the access to or pursuit of regulated professions or amending existing ones, an assessment of their proportionality in accordance with the rules laid down in the Directive is undertaken.

The Pharmaceutical Group of the European Union (PGEU), the Council of European Dentists (CED) and the Standing Committee of European Doctors (CPME) have expressed their concerns about a “proportionality test” for the sake of quality and safety of healthcare services. They are convinced that regulation of healthcare professionals should be excluded from the proportionality test.<sup>19</sup>

Directive 2013/55 strengthened the language requirements for healthcare professionals applying for the recognition of their qualification wishing to establish themselves in another Member State (Article 53). In the old Directive provision, host Member States had to make sure that health professionals acquired the language skills, necessary to communicate with their patients. The rule allowed – although not explicitly – that host Member States required from candidates certain language skills in order to be allowed to practise the profession. Directive 2005/36 now explicitly allows the host Member State to impose language controls on applicants who wish to access a profession which has patient safety implications. These language controls can only be carried out after the applicant’s qualification has been recognised and his EPC has been issued and is restricted to only one official language used in

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<sup>18</sup> Proposal for a Directive of the European Parliament and of the Council on a proportionality test before adoption of new regulation of professions of 10 January 2017, COM(2016) 822 final 2016/0404 (COD).

<sup>19</sup> PGEU, CED and CPME statement on proportionality in professional regulation, 15 September 2016, [http://doc.cpme.eu:591/adopted/2016/CPME\\_AD\\_EC\\_15092016\\_079\\_FINAL\\_EN\\_CED\\_PGEU\\_CPME\\_Joint\\_statement\\_proportionality\\_professional\\_regulation.pdf](http://doc.cpme.eu:591/adopted/2016/CPME_AD_EC_15092016_079_FINAL_EN_CED_PGEU_CPME_Joint_statement_proportionality_professional_regulation.pdf) See also press release of January 2017, [http://doc.cpme.eu:591/adopted/2017/CED\\_PGEU\\_CPME\\_joint\\_PR\\_January\\_2017.pdf](http://doc.cpme.eu:591/adopted/2017/CED_PGEU_CPME_joint_PR_January_2017.pdf).



the host Member State. According to case law of the European Court of Justice, the proportionality principle should be respected.<sup>20</sup>

To ensure that patients are adequately protected, Directive 2013/55 installed a legal duty on national authorities to share fitness to practise decisions proactively by adopting an alert mechanism (Article 56a). This mechanism obliges the competent authorities to send an alert to other authorities immediately through the IMI-system when health professionals, established in their country, have been prohibited or restricted from practising the profession or have used falsified diplomas for the recognition of their qualification. The alert must be sent within three days of a final decision being taken and will contain key information relating to the professional. This information will include their identity, profession, the scope of the restriction or prohibition and the period involved. The Directive does not address the issue of what the host Member State is supposed to do with the received information.<sup>21</sup>

Directive 2005/36 dedicates a specific chapter (Title II) to the provision of services. In order to facilitate the free movement of services, persons, who go temporarily or occasionally to another Member State in order to provide their services while being established in another Member State, are subject to a more flexible system. The host Member States cannot restrict the free provision of services for any reason relating to professional qualifications, if the service provider is legally established in another Member State and if he has pursued the profession in one or more Member States during the last 10 years when the profession is not regulated in the Member State of establishment (Article 5). For health care professionals, however, it remains possible to check qualifications and to oblige the candidate to take an aptitude test to check whether the candidate has the knowledge, skills and competence that seems to be lacking after an analysis to see whether there is a substantial difference between the qualifications of the candidate and the required training in the host Member State. The latter is obviously only possible for health professions, falling under the scope of the general system.

Service providers are subject to professional rules of the Member State (Article 5.3). More specifically, that are subject to 'professional rules of a professional, statutory or administrative nature which are directly linked to the professional qualifications such as the definition of the profession, the use of titles and serious professional malpractice which is directly and specifically linked to consumer protection and safety as well as disciplinary provisions which are applicable in the host Member State to professionals who pursue the same profession in that Member State'. It appears that the latter professional rules should be interpreted strictly. In the case of *Konstantinides*, the European Court of Justice had to determine whether the German code of professional conduct for doctors was applicable to a Greek doctor that performed operations on an occasional basis in Germany.<sup>22</sup> The Court reiterated that the rules at stake i.e. the rules about reasonable fees and the prohibition for

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<sup>20</sup> Case C-424/97 *Haim* [2000] ECR 2000 I-05123 and case E-01/11 *dr. A* [2011] EFTA Ct. Rep. 484.

<sup>21</sup> See Miek Peeters, Free Movement of Medical Doctors: The new Directive 2005/36/EC on the Recognition of Professional Qualifications (2005) 11 *European Journal of Health Law*, p. 382-383.

<sup>22</sup> Case C-475/11 *Konstantinides* ECLI:EU:C:2013:542.

doctors to engage in unprofessional advertising, do not fall within the scope of Directive 2005/36 as they could not be considered as directly linked to professional qualifications. Therefore they had to be examined only in the light of Article 56 TFEU by the national court.

Member States may require a written declaration from the service provider before he offers his services for the first time in that Member State (Article 7). This declaration shall be renewed every year. Member States may require that the declarations be accompanied by documents such as proof of nationality, evidence of professional qualifications and an attestation of legal establishment, certifying the service provider is not prohibited from his activities, even temporarily. On top of the latter attestation, Directive 2013/55 provided the Member States the possibility to ask for professions in a.o. the healthcare sector an attestation confirming the absence of criminal convictions.<sup>23</sup> Only for health professionals (“professionals that have patient safety implications”), Member States can ask also a declaration about the applicant’s language knowledge necessary for practising the profession in the host Member State.

In order to enlighten the administrative burden for the service provider, there are also some forbidden registration requirements (Article 6). The Directive stipulates explicitly that the host Member State will exempt service providers from an authorization or membership of, or registration with, a professional organization or body. Nevertheless, an automatic temporary registration or membership pro forma with the professional organisation remains possible. The competent authority will therefore send the written declaration and required documents to the professional organisation and it shall count as an automatic registration or pro forma membership.

The Directive forbids also the compulsory registration with a public social security body,<sup>24</sup> required for the settlement with insurance bodies of accounts relating to services rendered. The doctor must however, inform this body, in advance or, in urgent cases, subsequently, concerning the services provided.

Article 8 about administrative cooperation obliges the host Member State to exchange information necessary to pursue complaints against a service provider. It also foresees the possibility for the national authorities of the host Member State to ask the national authorities of the Member State of establishment information about the service provider’s training courses of the applicant, the legality of his establishment and good conduct and the absence of disciplinary or criminal sanctions of a professional nature.

#### 4. Relevance of Directive 2005/36 for (cross-border) healthcare

Although the scope of Directive 2005/36 is wide, including all regulated and not just healthcare professions, it certainly highlights the specific nature of healthcare professions. This shows out of the fact that healthcare professions constitute the major part of the

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<sup>23</sup> The same possibility for establishment is foreseen in Article 50.3a.

<sup>24</sup> See Miek Peeters, ‘Free Movement of Medical Doctors: The new Directive 2005/36/EC on the Recognition of Professional Qualifications’ (2005) 11 European Journal of Health Law, p. 383-384.

professions under the scope of the automatic recognition system with its minimum training requirements and its obligation to encourage continuous professional development. The latter professions are also excluded from the possibility of partial access.

Healthcare professions are also under the scope of the alert mechanism and the more liberal system for the provisions of services holds exceptions for healthcare professionals. They are also the only ones under the scope of the (lately reinforced) language requirements.

Obviously, Directive 2005/36 is not only relevant for moving health professionals but even so for (moving) patients. When consulting a health professional abroad which profession does not fall under the scope of the automatic recognition system, patients will have to rely upon the training of that specific Member State as there is no minimum harmonisation of their training. In case of a doctor, nurse for general care, dentist, midwife and pharmacist, however, the moving patient can count on the fact that their training complies with the EU minimum training level through the (recently updated) minimum training requirements of the Directive. In the cases *Kohll* and *Decker*, the European Court of Justice had judged that the minimum criteria for the training of medical doctors and dentists, guaranteed a sufficient level of quality of healthcare providers. The argument of Luxembourg stating that the authorisation procedure for the reimbursement of cross-border healthcare was necessary for reasons of public health, was therefore rejected by the Court. Later on, the European legislator added in Directive 2011/24 some “safeguards” in the authorisation procedure for the reimbursement of cross-border healthcare for the “quality” of the health professionals, treating the patient abroad.<sup>25</sup>

First, Member States are given (in Article 8.2) the possibility to install the obligation to ask for an authorisation in case of ‘concerns about the healthcare provider: healthcare is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union’. It is however not clear to what extent Member States can question the quality and safety of healthcare provided in another Member State. It appeared for example from the *Stamatelaki* case<sup>26</sup> that reimbursement of *private* cross-border care cannot be excluded simply because of the fact this is the case for private care provided in the Member State of affiliation. The possibility to install a prior authorisation system does not exist for healthcare ‘which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union’. The legislator probably refers to possible future European legislation, providing a minimum harmonisation of quality and safety criteria of healthcare services.

Member States were also given (in Article 8.6) the opportunity to refuse the authorisation in case of ‘concerns about the healthcare provider: this healthcare is to be provided by a

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<sup>25</sup> See also Miek Peeters, ‘Free Movement of Patients: Directive 2011/24 on the Application of Patients’ Rights in Cross-Border Healthcare’ (2012) 1 European Journal of Health Law, p. 38-39.

<sup>26</sup> Case C-444/05 *Stamatelaki* [2007] ECR I-03185.

healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment'. One could imagine a situation whereby the healthcare provider is no(t) (longer) entitled to the right to practise. It seems that this ground for refusing the reimbursement has rarely been used by the Member States so far.<sup>27</sup> In this context, Directive 2011/24 had created an obligation for Member States to exchange information on healthcare providers' right to practise upon request (Article 10.4), a few years before Directive 2013/55 installed the proactive obligation to exchange this information through the alert mechanism in Directive 2005/36.

The reverse is also true. Directive 2011/24 is also relevant for (moving) health professionals. Health professionals, whether they are treating patients in the Member State they are established in or in another Member State, they must respect the patient's rights, created by Directive 2011/24 (in its chapter "Responsibilities of the Member States with regard to cross-border healthcare). Besides providing "cross-border" patient rights, specifically related to patients crossing borders (such as the right not to be discriminated on the basis of nationality concerning access to and the price of healthcare and the right to remote access to their medical record), Directive 2011/24 created also "classic" patient rights. These rights are applicable to all patients, whether they have moved to another country to be treated or not. These rights include the right to receive information and to provide informed consent, clear invoices and clear information on prices, transparent complain procedures and mechanisms to seek for remedies when suffering harm arising from the healthcare received, systems of professional liability insurance, privacy with respect to the processing of personal data and the right to a medical record to ensure continuity of care.

Second, Directive 2011/24 may not contain any quality or safety standards for healthcare services, the attention it dedicates to standards and guidelines on quality and safety is

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<sup>27</sup> According to Article 8.6, the reimbursement can be refused on the basis of five reasons: '(1) This healthcare can be provided on its territory within a time limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each patient concerned'; (2) The healthcare is not included among the national healthcare benefits of the Member State of affiliation"; (3) The patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare;(4) The general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question, and (5) This healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment.' On the basis of data, collected in 15 Member States in 2015, the reimbursement was refused 214 times whereof only 6 times on the basis of the last three reasons; it was not specified how many requests for refusal were based on reason five (concerns concerning the healthcare provider); see Commission, "*Member State Data on cross-border healthcare following Directive 2011/24/EU, Year 2015*", p. 16, [http://ec.europa.eu/health/sites/health/files/cross\\_border\\_care/docs/2015\\_msdata\\_en.pdf](http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_msdata_en.pdf)

nevertheless undeniable. This could contribute to the pressure health professionals might feel to improve the safety and quality of the services they deliver.

Directive 2011/24 foresees that the so-called “national contact points for cross-border healthcare” (of the Member State of treatment) have to inform patients on standards and guidelines on quality and safety. This includes information on supervision and assessment of healthcare providers and information on which healthcare providers are subject to these standards and guidelines. Information about the quality and safety of the healthcare must also be provided in the relationship patient vs. healthcare provider, in order to help the patient to make an informed choice.

The result of these information obligations is an increase of the patients’ knowledge about the existence and the type of standards and guidelines in the different Member States which influences national debates on quality and safety of healthcare. Furthermore, the assertive and critical patient is able to compare healthcare services throughout the Member States and claim his entitlements to qualitative and safe care.

Finally, health professionals are the subjects of the chapter of Directive 2011/24 on cooperation in healthcare. This includes their obligation to recognize prescriptions issued in another Member State for medicinal products, the possibility to participate in European networks of reference centres spreading scientific knowledge and good practices, in an e-health network and health technology assessment network.

## 5. Conclusion

Although both Directives have a different history and content, Directive 2011/24 and 2005/36 both facilitate cross-border healthcare and should therefore be looked at as a whole. Together they represent the EU’s legislative framework for cross-border healthcare and they both contain relevant provisions for moving patients and moving health professionals.

Analysing the impact of both Directives, it becomes clear that their impact reaches far beyond patient and healthcare professional mobility. They influence the position of all European patients and healthcare professionals, even the ones that do not move. Directive 2011/24 creates “classic” patients’ rights, pays attention to the quality and safety of healthcare services and creates an excessive structure of cooperation in the field of healthcare and Directive 2005/36 contains a minimum training level for the most healthcare professions.

Both directives address considerable attention to quality and safety of healthcare services, although the internal market is the legal ground of both directives. As described above, Directive 2011/24 is so much more than the mere consolidation of the *Kohll* and *Decker* rulings on the reimbursement conditions for moving patients. By adding patient rights and creating a framework for cooperation in healthcare, it showed great ambition aiming at contributing to a better healthcare for all EU patients.

Directive 2005/36 initially focussed on the mere recognition of the diplomas to make the free movement possible. Throughout the years, it added more and more safeguards for patient safety, as the recent modernisation through Directive 2013/55 has proved once again with its alert mechanism, its attention of continuous professional development and its reinforced language requirement for health professionals.

# Chapter XV Comparing the American and European Experiences with Medical Tourism: Legal and Ethical Issues

Ariel Teshuva and I. Glenn Cohen

## 1. Introduction

What drives someone to become a medical tourist? The answer to that is complicated; it could be that the procedure is not available at home, or not available at a sufficiently high enough quality, or available but is just too expensive. But importantly, the ways in which that answer is complicated will differ depending on the medical tourist's country of origin. It may seem intuitive, but a patient's home country determines the kind of medical services available to them, as well as the cost and quality of those services. Patients from different home countries often weigh very different considerations in making the decision to go abroad to seek care. In what ways do the obstacles for American and European medical tourists differ depending on their home country, and in what ways are they the same?

This chapter seeks to answer that question by looking at a few discrete areas. To give a few examples: For American medical tourists, key facets of the United States' malpractice law combines with procedural hurdles mean that American medical tourists will face a very different chance and amount of recovery should they get treatment at home versus abroad. European medical tourists, on the other hand, are more likely than American to seek care abroad for fertility services not available at home because of stricter access controls in Europe. And unlike European medical tourists, who have access to some forms of medical tourism funded by insurance, most Americans cannot use public or private health insurance to finance medical tourism. But though the challenges may be unique to each nation, they still have lessons to offer each other and for other nations looking to grapple with the changing world of medical tourism.

## 2. Medical Malpractice

Consider two hypothetical American patients, each without health insurance, who need to undergo a quadruple bypass surgery. Jenna chooses to undergo the procedure in Milwaukee, paying \$73,000 out of pocket.<sup>1</sup> Tina, on the other hand, decides to get the exact same surgery in the Bumrungrad Hospital in Thailand for \$10,000. Tina's cost savings have to be balanced against the effect on medical malpractice. If that both patients suffer from a

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<sup>1</sup> This will vary depending on the hospital. See Guy Boulton, *States Push for Hospital Price Lists, Initiatives Aim to Clarify Billing for Consumers*, Milwaukee J. Sent., Oct. 15, 2007, at 1A.

stroke months after the procedure, and both believe that the stroke was the result of medical error during the surgery, what happens? Jenna, whose surgery was in the United States, could bring a medical malpractice suit against the domestic hospital. But Tina might face barriers to recovery that would not have been there had she gotten the procedure done in the United States.<sup>2</sup>

This challenge is not unique to American patients, but for them, it is perhaps more acute. Why? There are two parts to the answer. First, American medical malpractice tort law (“med-mal”) allows plaintiffs to recover far more in damages than would be available in other nations.<sup>3</sup> Second, the uninsured, along with the underinsured, are those perhaps most likely to be attracted to the cost savings of medical tourism.<sup>4</sup> And as of 2015, 28.4 million Americans were without insurance.<sup>5</sup> Medical malpractice is intended to accomplish two goals: compensate patients for the harm caused to them by medical errors, and deter medical professionals from committing those errors in the first place. While the debate on how well med-mal manages to accomplish both goals remains open,<sup>6</sup> the fact is that given that most users of medical tourism will be without insurance, they are likely to be particularly badly off should medical error result and they cannot get adequate compensation. If Jenna, the home-treated patient, can recover more than Tina, the foreign-treated patient, then Jenna may in fact be better off than Tina although she paid more at the outset.

And there are very good reasons to believe that patients who travel abroad for treatment face heavy barriers to care. Although we have few examples of real lawsuits to guide us, American rules on personal jurisdiction, forum non conveniens, choice of laws, and enforcement of judgments combine to make it very difficult for Americans suing foreign doctors to succeed. And even if an American plaintiff succeeds in bringing suit, less favorable foreign laws are likely to apply, further reducing likelihood of recovery.

## 2.1 Personal Jurisdiction

U.S. courts are constitutionally required to have personal jurisdiction over the defendant before a plaintiff can sue. Each state also has an individual statute that authorizes jurisdiction; these “long-arm statutes” may be as broad as the Constitution would allow, or

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<sup>2</sup> See I Glenn Cohen, *Patients with Passports* 80–81 (2015) for an expanded version of this hypothetical.

<sup>3</sup> See Cohen (n 2) 80; Nathan Cortez, ‘Patients without Borders: The Emerging Global Market for Patients and the Evolution of Modern Health Care’, (2008) 83 *Ind. L.J.* 71, 106–07 (citing Mark Roth, ‘A Cheaper Alternative for Those with Minimal Health Insurance, Getting Surgery Abroad May Be a Sound Option’, *Pittsburgh Post-Gazette* (Sept. 10 2006), at G1).

<sup>4</sup> See Cohen (n 2) 3–8 for a discussion of this population.

<sup>5</sup> *Health Insurance Coverage*, Ctrs. Disease Control (Oct. 7, 2016), [www.cdc.gov/nchs/fastats/health-insurance.htm](http://www.cdc.gov/nchs/fastats/health-insurance.htm).

<sup>6</sup> See Philip G Peters, ‘Health Courts?’ (2008) 88 *B.U.L. L. Rev.* 227; Paul C Weiler, ‘Reforming Medical Malpractice in a Radically Moderate—and Ethical—Fashion’, (2005) 54 *DePaul L. Rev.* 205, 215 (arguing for alternative mechanisms of compensation); Janet Currie and W Bentley MacLeod, ‘First Do No Harm? Tort Reform and Birth Outcomes’, (2008) 123 *Q.J. Econ.* 795 (arguing that med-mal doesn’t adequately deter actual harm to patient).



they may allow jurisdiction over a narrower class of defendants. A plaintiff must show that jurisdiction is consistent with both the long-arm statute and the Constitution. The U.S. Supreme Court has held that the defendant must have minimum contacts with the forum state for jurisdiction to be consistent with the Due Process Clause of the Fourteenth Amendment.<sup>7</sup> To establish “general” personal jurisdiction, the plaintiff must show that the defendant is domiciled in the forum state, or that the defendant corporation has such systematic and continuous contacts as to have made itself at “home” in the forum state.<sup>8</sup> It is unlikely that either a foreign hospital or physician would clear the high bar, typically that the U.S. state be a principal place of business or place of incorporation for the entity. “Specific” personal jurisdiction, which requires the plaintiff to show that the defendant has “purposefully availed” themselves of the forum state,<sup>9</sup> may also be difficult to establish against the foreign doctor. If the foreign hospital did reach out to solicit patients or American patients more generally, the plaintiff would have a better case for specific personal jurisdiction based on that solicitation.<sup>10</sup>

Even if the Constitution allows jurisdiction, some states have passed long-arm statutes that are narrower than the constitutional grant; and some may pose a problem to patients seeking to maintain a suit against a foreign defendant.

## 2.2 Forum Non Conveniens

The doctrine of forum non conveniens, a discretionary doctrine that allows courts to dismiss a case when another forum would be better suited for it, poses an additional hurdle for a would-be med-mal plaintiff like Tina. If jurisdiction is proper in the alternative forum, the controlling test weighs the burdens to the plaintiff and defendant of litigating in the other forum against the public interest.<sup>11</sup> In the med-mal context, jurisdiction will often be proper in the destination country. That, as we will see, the destination country will often provide less favorable remedies to the plaintiff does not make the alternative forum improper; the U.S. Supreme Court has cautioned court not to give that factor “conclusive or even substantial weight,”<sup>12</sup> and when plaintiffs have argued against forum non conveniens based on the lower damages available in the other forum, courts have not been receptive.<sup>13</sup> The part of the test weighing the burden to the defendant, too, would seem to cut in favor of dismissing the case (and thus against med-mal plaintiffs) on this ground: Foreign physicians

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<sup>7</sup> *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).

<sup>8</sup> *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924 (2011); *see also Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 415 (1984).

<sup>9</sup> *See, e.g., Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475–76 (1985).

<sup>10</sup> *See Zippo Mfg. Co. v. Zippo Dot Com, Inc.*, 952 F. Supp. 1119, 1123–26 (W.D. Pa. 1997). Given the way that websites advertising medical tourism typically operate, many courts may refuse to find specific personal jurisdiction, but it will depend on how much targeting of U.S. patients they do. *See Cohen*, note 2, at 84–85; Kerrie S Howze, Note, ‘Medical Tourism: Symptom or Cure?’, (2007) 41 *Ga.L.Rev.* 1013, 1031–32.

<sup>11</sup> *See Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 257–61 (1981); *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508 (1947).

<sup>12</sup> *Piper*, 454 U.S. at 247.

<sup>13</sup> Howze (n 10) 1035–36 (citing *Gonzalez v. Chrysler Corp.*, 301 F.3d 377, 382 (5th Cir. 2002) (finding that the extremely low damages available in Mexico did not make the forum “unsatisfactory”).

and hospitals are likely to have difficulty gathering the proof and legal resources needed to litigate in the U.S., and are likely to find needing to do so difficult and burdensome. These are all factors that courts have found dispositive.<sup>14</sup> Thus, forum non conveniens would make it more difficult for American plaintiffs to litigate.

### 2.3 Choice of Laws and Barriers to Litigation

Even if Tina did manage to persuade a court that it had personal jurisdiction over the defendant and that the court should not dismiss the case under the doctrine of forum non conveniens, a question remains: whose law applies? That question could determine whether litigation is even economically feasible, because many destination countries have med-mal laws that are far less favorable to plaintiffs than the U.S.<sup>15</sup> Unlike in the U.S., where “damage awards for medical negligence can be in the millions,” medical negligence claims in India “are rare, and multimillion dollar awards are nonexistent.”<sup>16</sup> In Thailand, too, medical malpractice awards are small and “do not compensate for pain and suffering.”<sup>17</sup> Mexican courts have also been criticized for not providing recourse for med-mal victims, and some have characterized Malaysian and Singaporean med-mal law as being overly deferential to physicians both in determining the standard of care and deciding whether it was breached.<sup>18</sup>

The main reason that Tina may want to litigate in the U.S. (aside from convenience), therefore, is that American law would be more favorable to her claim than Thailand’s. But choice-of-law doctrine may mean that even if Tina sues in the U.S., Thai law will apply. The most common approach to choice-of-law questions in the U.S. is to apply a state-interest analysis.<sup>19</sup> Essentially, the rule is that the law of the place last necessary for the wrong to have occurred will apply unless some other forum has a more significant interest. Courts look at such factors as where the injury occurred, where the conduct that caused it occurred, where the residence, nationality, or place of incorporation of the parties involved is located, and where the parties’ relevant relationship is centered.<sup>20</sup>

The place where Tina’s wrong occurred is Thailand, so that will be the default choice. The multifactor test is unlikely to lead to a divergence: the injury occurred in Thailand, as did the conduct that caused it, and the doctor-patient or hospital-patient relationship is centered in Thailand also. While the third factor is neutral, it seems likely that Thai law will apply. This will likely be true in most med-mal cases where the court must decide between the

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<sup>14</sup> *Gulf Oil*, 330 U.S. at 508–09.

<sup>15</sup> For efficiency, we have chosen to focus on the laws of several common destination countries; nonetheless, it should be noted that several destination countries have med-mal systems more similar to the United States.

<sup>16</sup> Howze, note 10, at 1030 (citing Malcolm Foster and Margie Mason, ‘Insurers Looking at Surgeries Overseas’, *Desert Morning News* (Salt Lake City, Utah), Nov. 10, 2006, at A01).

<sup>17</sup> See Cortez (n 3) 106–07.

<sup>18</sup> *ibid.*, 106.

<sup>19</sup> See Kermit Roosevelt III, ‘The Myth of Choice of Law: Rethinking Conflicts’, (1999) 97 *Mich. L. Rev.* 2448, 2466.

<sup>20</sup> Restatement (Second) of Conflict of Laws § 164, §6.

American state's and the foreign nation's law; indeed, it has been in the few such cases that have been litigated.<sup>21</sup>

And even if Tina cleared all of those hurdles and got a favorable judgment, there is still the matter of enforcing the judgment abroad. The Thai court might be reluctant to enforce the American judgment; foreign courts often are, claiming that the U.S. allows for jurisdiction too liberally. They might also be reluctant to enforce a large award for pain and suffering when their system does not allow for it.<sup>22</sup> Given all of this, then, Tina may not even try to litigate in the U.S.; the procedural hurdles in getting a court to entertain her claim, the likelihood that unfavorable foreign law will apply (reducing her damage award), and the possibility the foreign court will refuse to enforce the judgment all reduce her incentive to sue in the first place. Tina's only remaining option, then, is to sue in Thai court. But given the inconvenience of litigating abroad when she lives in the U.S. (including the difficulty in getting representation there), and of the lower damage available under Thai substantive law, that is also not likely to be worth it.

Let's return to Jenna, the American patient who chose to get the surgery in Wisconsin. Jenna will have no trouble convincing the court that it has personal jurisdiction over the physician, a domiciliary of Wisconsin, or the local hospital, incorporated there. A motion for forum non conveniens would likely fail. As the surgery occurred in Milwaukee, Wisconsin's med-mal laws would apply. And as the American court has the power to enforce its own judgment, all Jenna must do to recover is prove her claim. If she does so, and if the jury chooses to award high damages, she will end up better off as compared to Tina and her ostensibly cheaper surgery. Thus there is a real trade-off between the cost savings of going abroad (enjoyed by Tina) and the compensatory (and perhaps deterrence value) of staying at home (enjoyed by Jenna). This trade-off as to medical tourism, while not unknown in Europe, remains one of the key policy questions for U.S. medical tourism. It might lead policy-makers or private ordering to try to solve the problem, including through agreements to arbitrate or victim's compensation funds.<sup>23</sup>

### 3. Circumvention Tourism

In the previous section, our hypothetical patients were deciding between getting the procedure at home, where it was legal but expensive, and getting it abroad, where it was affordable but carried the risk of less compensation in the event of medical error. But what happens when the procedure is not legal in the patient's home country? Whether a patient chooses to engage in circumvention tourism, or tourism to access medical services illegal at home but legal in some destination country, is a choice deeply shaped by the range of services legally available in their home country. Common forms of circumvention tourism

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<sup>21</sup> See, e.g., *Chadwick v. Arabian Am. Oil Co.*, 656 F. Supp. 857, 858, 860 (D. Del. 1987) (finding Saudi med-mal law to apply in case where a Florida patient sued a doctor who, though working for a Delaware corporation and its subcontractor, treated the patient in Saudi Arabia).

<sup>22</sup> See, e.g., Jenny S Martinez, 'Towards an International Judicial System', (2003) 56 *Stan. L. Rev.* 429, 511.

<sup>23</sup> See Cohen (n 2) 108–19 (discussing possibilities for regulatory intervention).

include tourism for organ transplants (a form of circumvention tourism for patients from most countries, as organ sale is illegal everywhere except Iran, who heavily regulates the practice), assisted suicide, abortion, and stem cell treatments. But the focus of this chapter will be fertility tourism, or tourism for the purpose of using reproductive technologies for creating life.

It is important to emphasize here that circumvention tourism is tourism undertaken for *legal* reasons. While many Americans might travel abroad for surrogacy due to the cost savings available in other countries,<sup>24</sup> few would think to do so for legal reasons<sup>25</sup>—in fact, the United States is a major destination country for fertility tourism.<sup>26</sup> Many European patients, on the other hand, must travel abroad not because they want to realize the cost savings, but because fertility services are not legally available at home.

### 3.1 Prevalence

How prevalent is circumvention tourism for fertility purposes within Europe? While it is difficult to put a number on it, a 2010 study by the European Society of Human Reproduction and Embryology gives some gauge.<sup>27</sup> The study collected information at almost fifty clinics during a one-month period in six nations thought to be prime destinations for fertility tourism. The clinics see an estimate of eleven to fourteen thousand distinct patients per year. Though the patients came from forty-nine different home countries, four origin countries made up the bulk of the clinics' flow: Italy (31.8 percent), Germany (14.4 percent), the Netherlands (12.1 percent), and France (8.7 percent). When asked why they chose to travel, 70.6% of Italian, 80.3% of German, 64.5% of French, and 71.6% of Norwegian patients said that they were traveling abroad for legal reasons; that is, engaging in circumvention tourism.

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<sup>24</sup> Paid surrogacy in the U.S., for instance, is twice as expensive as in India, Thailand, and Mexico. Tamar Lewin, 'Coming to U.S. for Baby, and Womb to Carry It', *N.Y. Times* (July 5, 2014), [www.nytimes.com/2014/07/06/us/foreign-couples-heading-to-america-for-surrogate-pregnancies.html?\\_r=0](http://www.nytimes.com/2014/07/06/us/foreign-couples-heading-to-america-for-surrogate-pregnancies.html?_r=0). Of course, as with all cost estimates as to medical tourism they should be taken with a grain of salt.

<sup>25</sup> See Faith Merino, *Adoption and Surrogate Pregnancy* 53 (2010) (observing that "[m]ost American couples who travel abroad for fertility treatments do so not to avoid strict regulations but crippling high costs."). There is no national law on surrogacy in the United States. Approaches in the U.S. vary widely. While some states, like California, are very accepting of surrogacy, other jurisdictions go so far as to ban and criminalize it; still others have no laws regulating surrogacy at all. See Martha A Field, 'Compensated Surrogacy', (2014) 89 *Wash. L. Rev.* 1155, 1165–67 (discussing state approaches). But even in particular states where surrogacy is prohibited, intra-national medical tourism is legally *available*: "residents can use the services of nearby states. They may not even have to travel to do so." *ibid.*, 1165. Within-country medical tourism raises different legal and ethical issues than those discussed below.

<sup>26</sup> Field (n 25) 1166 (citing Lewin, note 24).

<sup>27</sup> The following data all come from this study: F Shenfield and others, 'Cross Border Reproductive Care in Six European Countries', (2010) 25 *Hum. Reprod.* 1361.

### 3.2 Surrogacy: A Case Study

When patients go abroad for circumvention purposes, what are their legal consequences at home? Surrogacy, which by its nature involves prolonged and ongoing legal consequences, is a useful case study.

While an exhaustive listing of European prohibitions on the various forms of fertility tourism is beyond the scope of this chapter, several nations do prohibit paid surrogacy altogether.<sup>28</sup> France both bans and penalizes surrogacy.<sup>29</sup> In Italy, reproductive technologies may only be used by heterosexual infertile women of “potentially fertile age” who are married or in a stable relationship; it also prohibits the use of donated sperm or eggs.<sup>30</sup> In Germany, while “surrogacy in itself is not explicitly prohibited or punishable,” it is illegal to facilitate surrogacy. Surrogacy contracts are also “ineffectual and unenforceable.”<sup>31</sup> And the Netherlands allow parties to make private arrangements under certain circumstances, but prohibit engaging in or encouraging commercial surrogacy.<sup>32</sup>

Few nations have actually passed laws criminalizing the use of reproductive technologies *abroad*, though the French have extended the criminal ban on surrogacy to those who travel for surrogacy services.<sup>33</sup> But that doesn’t mean that there are no legal complications at home for parents who choose to use foreign surrogates. Particularly, complex questions arise around the resulting child’s potential citizenship.

At the outset it is important to distinguish between two major types of principles that nations use to decide birthright citizenship questions. Some nations use the “*jus soli*,” or “right of the soil,” principle, which holds that any child born in that country’s territory is a citizen of that territory. Other nations operate under the “*jus sanguinis*,” or “right of the soil,” principle, in which citizenship is based on the parents’ nationality. Some nations adopt both principles.<sup>34</sup> If the child is born in a country that recognizes *jus soli* citizenship, then at the very least, the child will not remain stateless even if they do not get the home country’s citizenship. But what happens when the destination country adopts a *jus sanguinis* rule?

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<sup>28</sup> For an aggregate view of global surrogacy practices, see Alex Finkelstein and others, ‘Surrogacy Law and Policy in the U.S.: A National Conversation Informed by Global Lawmaking’, Columbia Law School Sexuality and Gender Law Clinic (May 2016), [https://web.law.columbia.edu/sites/default/files/microsites/gender-sexuality/files/columbia\\_sexuality\\_and\\_gender\\_law\\_clinic\\_-\\_surrogacy\\_law\\_and\\_policy\\_report\\_-\\_june\\_2016.pdf](https://web.law.columbia.edu/sites/default/files/microsites/gender-sexuality/files/columbia_sexuality_and_gender_law_clinic_-_surrogacy_law_and_policy_report_-_june_2016.pdf).

<sup>29</sup> Civil Code, arts. 16-7; French Penal Code, art. 227–13, art. 511–24; Louis Perreua-Saussine and Nicolas Sauvage, *France*, in Katarina Trimmings and Paul Beaumont (eds), *International Surrogacy Arrangements: Legal Regulation TT the International Level* (2013) 119, 120–22.

<sup>30</sup> I Glenn Cohen, ‘Regulating Reproduction: The Problem with Best Interests’, (2011) 96 *Minn. L. Rev.* 423, 450.

<sup>31</sup> Laurence Brunet and others, *A Comparative Study on the Regime of Surrogacy in EU Member States* 106–07, Directorate General for Internal Policies, Policy Department C: Citizens’ Rights and Constitutional Affairs (2013).

<sup>32</sup> Brunet (note 31) 302–03.

<sup>33</sup> Myriam Hunter-Henin, ‘Surrogacy: Is There Room for a New Liberty between the French Prohibitive Position and the English Ambivalence?’, in (2008) 11 *Law and Bioethics: Current Legal Issues* 2008, at 329, 334 & n.29 (Michael Freeman ed.).

<sup>34</sup> See Cohen (n 2) 403 (citing Tina Lin, Note, ‘Born Lost: Stateless Children in International Surrogacy Arrangements’, (2013) 21 *Cardozo J. Int’l and Comp. L.* 545, 556.

Depending on the home country's laws, there is a real possibility that the child will remain stateless.

A recent French case illustrates the point. As previously mentioned, France has banned paid surrogacy since 1991. Until recently, couples who used a foreign surrogate were considered to have falsified their birth certificate; France would recognize only a "biological connection between the male partner and the child."<sup>35</sup> But a recent case has forced France to reconsider its approach. The case arose when French officials in Los Angeles refused to provide a couple, the Mennessons, a passport for their American-born children on suspicion that the couple had used a surrogate. When the family travelled to France (with the children using American passports), French officials tried to charge the parents with fraud and set aside their entry in the official parents' register (thus depriving the children of French citizenship). The French court blocked the charge, finding that France did not have extraterritorial jurisdiction over events occurring in the U.S.. But though the judge recognized the Menessons' parental rights over their children, he refused to grant the children French citizenship. The Menessons could not legally adopt their children, as French law prohibited them from adopting the children after having circumvented the surrogacy law. After prolonged litigation, the French Cour de Cassation ruled that the children were not French citizens.<sup>36</sup>

The Menessons appealed to the European Court of Human Rights (ECHR).<sup>37</sup> The ECHR found that France was in violation of the children's rights under Article 8 of the European Convention on Human Rights, which guarantees the right to respect for private and family life. The parents' rights, the court found, were invaded, but not insurmountably so; they were still able to settle in France with the children. But the children, the court said, were thrust into a state of legal uncertainty. Another country had recognized the twins as the Mennessons' children, but France nonetheless denied them that recognition. This undermined the children's identity in French society. Indeed, the uncertainty over their nationality would negatively impact the children's sense of their own identity.

Note that the Menessons' children were never stateless; they had U.S. citizenship by virtue of their birth. What if it had been the other way around, though? Let's consider a hypothetical American couple (we'll call them the "Hansons") who go to India for cost saving reasons. The Hansons have two routes for attaining citizenship for their children: they could either apply while abroad, in which case the Secretary of State has jurisdiction and her interpretation of the state in the Foreign Affairs Manual will govern, or they could return to

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<sup>35</sup> Richard F Storrow, "The Phantom Children of the Republic": International Surrogacy and the New Illegitimacy, (2012) 20 *Am. U. J. Gender Soc. Pol'y and L.* 561, 567. This account was written prior to the European Court of Human Rights' ruling, discussed below.

<sup>36</sup> *ibid*, at 599.

<sup>37</sup> Registrar of the Court, European Court of Human Rights, Press Release, *Totally prohibiting the establishment of a relationship between a father and his biological children born following surrogacy arrangements abroad was in breach of the Convention* (2014).

the U.S. and raise citizenship as a defense in a removal proceeding, in which the U.S. federal courts will ultimately decide the case, applying case law.<sup>38</sup>

The trouble is that the decisionmakers here have adopted conflicting rules, leading to different outcomes for children depending on the decisionmaker. The statute reads, in pertinent part, that “a child born abroad out of wedlock to a U.S. citizen mother will automatically receive U.S. citizenship, while “a child born abroad out of wedlock to a U.S. citizen father will receive citizenship only if certain conditions are met, one of which requires that ‘a blood relationship between the person and the father is established by clear and convincing evidence.’”<sup>39</sup> The Ninth Circuit Court of Appeals has interpreted the statute not to require a blood relationship between a child born *in* wedlock and a U.S. citizen parent.<sup>40</sup> But the Secretary of State has reached the opposite conclusion, requiring a blood relationship even for children born in wedlock.<sup>41</sup> The result, then, is that where and when the U.S. decides on the citizenship of Baby Hanson will determine the baby’s citizenship. That this can happen in the United States is a quirk of its system of government. In the U.S., the executive has plenary power to enforce the immigration laws. Given that, when the executive directs an interpretation of the law, that interpretation controls.<sup>42</sup> In Europe, on the other hand, the European Court of Human Rights, to an extent, centralizes the interpretation of immigration policy. This gives member states parameters within which their interpretation of the law must fall, lessening the risk of different actors interpreting the same law in different ways.<sup>43</sup>

These cases show the legal consequences that can follow decision to use circumvention tourism even in the absence of sanctions. Surrogacy makes the questions particularly poignant, because the consequences are not visited on the parents themselves, who had chosen to go abroad, but on their children. These consequences, which will of course differ based on a patient’s home country, can deeply shape a patient’s decision to utilize circumvention tourism in the first place.

#### 4. Financing Medical Tourism

When patients go abroad, who pays? Both American and European patients struggle with that question. Both have the option of paying out-of-pocket, of course. But depending on the patient’s home country, the patient may also be able to rely on insurers to finance medical tourism. In the United States, where private insurance predominates, several

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<sup>38</sup> Victoria Degtyareva, Note, ‘Defining Family in Immigration Law: Accounting for Nontraditional Families in Citizenship by Descent’, (2011) 120 *Yale L.J.* 862, 871–73.

<sup>39</sup> *ibid*, at 874 (citing and quoting 8 U.S.C. § 1409 (2006)).

<sup>40</sup> *ibid*, at 875–76 (citing *Scales v. INS*, 232 F.3d 1159, 1166 (9th Cir. 2000) and 7 Foreign Affairs Manual § 1131.4-1 (1998)).

<sup>41</sup> *ibid*, at 878.

<sup>42</sup> Jon Feere, *Plenary Power: Should Judges Control U.S. Immigration Policy?*, *Cen. Immigr. Stud.* (Feb. 2009).

<sup>43</sup> See generally Yannis Ktistakis, *Protecting Migrants under the European Convention on Human Rights and the European Social Charter* (2013), [http://www.coe.int/t/democracy/migration/Source/migration/ProtectingMigrantsECHR\\_ESCWeb.pdf](http://www.coe.int/t/democracy/migration/Source/migration/ProtectingMigrantsECHR_ESCWeb.pdf).

private insurers have experimented with coverage for medical tourism to cut costs. Meanwhile, in the European Union, as discussed in depth elsewhere in this volume, public insurers will pay for services abroad under certain circumstances; while this currently not true in the U.S., some have suggested the possibility that it could be in the future. The way a patient will finance their medical tourism, then, is also a choice shaped by their country of origin.

#### 4.1 Private Insurance

Private insurance is the dominant form of health insurance in the United States. In recent years, private insurers have begun experimenting with coverage for medical tourism. In 2011, the four largest private insurers in the U.S. had either introduced or considered pilot programs for medical tourism coverage. BlueCross BlueShield of South Carolina, for instance, contracted with a Thai hospital to perform certain surgeries, and two hundred U.S. employers offer employees access to a network of foreign providers.<sup>44</sup> Following the passage of the Affordable Care Act, some speculated that demand for medical tourism coverage by private insurers was likely to increase; as the Act introduced an “individual mandate” that requires all non-exempt citizens to purchase health insurance meeting certain regulatory criteria, it was thought that demand for low-cost health insurance products would increase.<sup>45</sup> With the results of the recent U.S. election, the faith of the Affordable Care Act looks less certain than ever; however, it is entirely possible that efforts to replace the ACA could also increase the demand for low-cost insurance products and thus create an incentive for private insurers to experiment with medical tourism.<sup>46</sup>

Cost has largely been the motivating factor for those private insurers looking to experiment with medical tourism. Insurers, just the same as patients, can realize significant cost savings by inducing covered patients to use medical tourism rather than purchasing health from U.S. providers at a premium. It is hard to estimate just how much they would save, however. Insurers pay much less for domestically performed procedures than patients who would pay out of pocket (due to their ability to negotiate with providers given their patient volume). But in some cases, even the lowest negotiated rate will be much more expensive for the insurance than the rates available in some destination countries,<sup>47</sup> enabling American insurers to realize significant cost savings were they to incorporate medical tourism into their coverage.

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<sup>44</sup> Nathan Cortez, ‘Embracing the New Geography of Health Care: A Novel Way to Cover Those Left Out of Health Reform’, (2011) 84 *S. Cal. L. Rev.* 859, 882–83.

<sup>45</sup> I Glenn Cohen, ‘Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument’, (2010) 95 *Iowa L. Rev.* 1467, 1541–42; Cortez, note 44, at 879–80, 889.

<sup>46</sup> Proposals from Trump administration officials have included getting rid of the individual mandate and replacing it with tax incentives to purchase insurance. See Robert Pear, ‘Tom Price, H.H.S. Nominee, Drafted Remake of Health Law’, *N.Y. TIMES* (Nov. 29, 2016), [www.nytimes.com/2016/11/29/us/tom-price-trump-health-secretary.html](http://www.nytimes.com/2016/11/29/us/tom-price-trump-health-secretary.html). That, too, could increase demand for low-cost insurance products by those seeking to take advantage of the new tax benefits; but it is difficult to speculate without a more concrete picture of what the ACA’s possible successor will look like.

<sup>47</sup> See Cohen (n 2) 138 for several examples.



But will they be able to, as a matter of law? To answer that question, it is useful to get an understanding of the legal landscape governing health insurance. In the U.S., health insurance has historically been a matter of state law. One way states have regulated health insurance has been through the design of insurance plans. Two are particularly relevant for our purposes: health maintenance organizations (HMOs) and preferred provider organizations (PPOs). HMOs traditionally limit reimbursements only for patients who use providers with whom the plan contracts. PPOs, on the other hand, do have a provider network, but only apply deductibles and copayments for patients who go out of network.<sup>48</sup>

HMOs are subject to both federal and state law requirements; PPOs, in comparison, are subject only to state law requirements. Some HMO requirements are compatible with some forms of medical tourism; others are in direct conflict. For instance, the federal HMO statute requirement that “care be available and accessible to each of its members in a manner which assures” continuity within the area served by the HMO (a requirement also found in many PPO statutes) could be a problem for any kind of private insurance plan that *mandates* that the patient use medical tourism and perhaps even some plans that provide incentives for using medical tourism. This uncertainty makes it difficult for any insurer to offer coverage for medical tourism aside from through a plan that gives medical tourism as an option, but does not incentivize it; this kind of plan is the least desirable, in terms of cost savings.<sup>49</sup> What experimentation there has been can be credited more to a quirk of federal law that allows federal law to preempt state-level regulation for employers that self-insure.<sup>50</sup> This loophole means that state-level regulation does not apply to the large number of Americans who work for self-insuring employers; but it remains an obstacle for the remainder of Americans who have private health insurance.

But the more important question is: should that obstacle be removed? That is, is it desirable for private insurers, driven as they are by a profit motive, to subsidize medical tourism? Removing regulatory obstacles and allowing more insurers to incorporate medical tourism into their products would have several effects: these plans would likely be lower cost, so there is a population of individuals who previously did not have coverage who will now be able to buy it. There is also a population of those already currently insured on a domestic-only plan who would switch to a plan that offered medical malpractice in order to realize the cost savings. If we think insurer-prompted medical tourism plans are good value for their money, provide adequate protections to patients, and do not pose problems for insurance pools, then both effects are good news. If, on the other hand, we have some concerns about insurer-prompted medical tourism then we face a trade-off – we may increase the number of insured individuals (good) but also prompt some insured individuals to shift to plans we think pose problems (bad), and one would want to know how the two vectors compare.<sup>51</sup>

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<sup>48</sup> *ibid*, at 479–81.

<sup>49</sup> Cohen (n 2) 140, 143.

<sup>50</sup> See *ibid*, at 143–44; Allison Overbay and Mark Hall, ‘*Insurance Regulation of Providers That Bear Risk*’, (1996) 22 *Am. J.L. and Med.* 361, 380.

<sup>51</sup> See Cohen (n 45) 1547 n.292.

Should we be concerned about plans that incorporate medical tourism? One common rejoinder is that while medical tourism does increase risk, it is the consumer's right to choose to take on that added risk, especially for cost savings. Advocates of these "consumer sovereignty" type arguments say that consumers, when fully informed, are the best "judges of what will promote their own welfare."<sup>52</sup> However, it is difficult for consumers to be fully informed in the medical tourism context, given high information costs and evidence that patients are very bad at choosing insurance plans.<sup>53</sup>

One might think insurers, as repeat players, could mitigate these concerns about poor patient choices; if insurers (or employers that provide health insurance) bear the cost of continuing care from medical error, and if that cost exceeds the insurer's savings from using medical tourism, then insurers have an incentive to select high quality care providers abroad or use a domestic provider at home. But that incentive assumes that insurers have an interest in the long-term health of their customers; they may not. Recent empirical work shows that Americans switch insurers frequently,<sup>54</sup> thus reducing the likelihood that an insurer ends up on the hook for their customers' long-term maladies.

These types of issues, and many others we do not have the space to discuss, should lead us to be hesitant in our bullishness to encourage insurer-sponsored medical tourism. One of us has suggested the adoption of a "channeling regime" to limit the unacceptable risks of medical tourism while allowing consumers to realize its benefits.<sup>55</sup> Policymakers seeking to maximize consumer welfare while respecting consumer agency and reducing costs should seriously consider it as a compromise between competing values.

#### 4.2 Public Insurance

The European Union has struggled for decades with the question of how public insurers should treat medical tourism when a citizen of a member state receives care in another member state. This volume has covered at length the operation of the Crossborder Care Directive, and it is unnecessary to repeat that discussion here. To put it fairly generally, under some circumstances, EU nations will reimburse their citizens for care received in another member state. That is not currently true of the American system. But there are inklings of the possibility. In 2006, for instance, West Virginia considered (but ultimately failed to pass) a bill that would have encouraged state employees to use medical tourism through offering generous financial incentives.<sup>56</sup> One writer has suggested that the Affordable Care Act, which authorizes states to create alternative programs for those not eligible for Medicare and Medicaid, could act as a vehicle for incorporating medical tourism

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<sup>52</sup> Christine Jolls and others, 'A Behavioral Approach to Law and Economics', (1998) 50 *Stan. L. Rev.* 1471, 1541.

<sup>53</sup> See Cohen, note 2, at 104–06; 154–55.

<sup>54</sup> Bradley Herring, 'Suboptimal Provision of Preventive Healthcare due to Expected Enrollee Turnover among Private Insurers', (2010) 19 *Health Econ.* 438, 442.

<sup>55</sup> See Cohen (n 2) 158–61.

<sup>56</sup> See H.B. 4359, 77th Leg., 2d Sess. (W. Va. 2006), [http://www.legis.state.wv.us/Bill\\_Text\\_HTML/2006\\_SESSIONS/RS/Bills/hb4359%20intr.htm](http://www.legis.state.wv.us/Bill_Text_HTML/2006_SESSIONS/RS/Bills/hb4359%20intr.htm); see also Mark Roth, Surgery Abroad an Option for Those with Minimal Health Coverage, *Post-Gazette.Com*, Sept. 10, 2006, <http://www.post-gazette.com/pg/06253/719928-37.stm>.

to American public insurance<sup>57</sup>— though, again, the recent U.S. election could change things.

But if Medicare and Medicaid covered medical tourism, what would it look like? Many of the risks discussed in the previous sections would still exist—inability to recover for malpractice committed abroad and selection of high quality foreign providers, for instance. But solutions would be far easier to implement than in the private insurer context, because here, the payer and the regulator are the same actor. Medicare could require that foreign hospitals implement solutions to these problems before they reimburse care; indeed, they impose similar conditions on domestic care providers all the time.<sup>58</sup> Since the Medicare/Medicaid business is sizeable enough that foreign providers would be interested in it, strings attached, the care enhancements would also have significant “spillover” benefits for those who finance out-of-pocket or through private insurers.

But to realize cost savings, Medicare would have to do more than offer to cover medical tourism; it would have to create financial incentives for patients to accept medical tourism over domestic options. Though this could be criticized as coercive, given that patients enrolled in Medicare or Medicaid typically have few other options for financing health care, it is not necessarily. For one, if adequate safeguards are in place to ensure that the medical services abroad are safe, then incentivizing medical tourism is no less coercive than limiting coverage to a few select domestic providers. Moreover, Medicare and Medicaid costs are unsustainable at their current level; if savings from medical tourism could help save the programs without reducing services, then that might be a preferable outcome. Indeed, competition from medical tourism could incentivize domestic providers to offer better and more cost-efficient services to retain customers; there’s some evidence that patient mobility in the EU has had a similar effect.<sup>59</sup>

The recent U.S. election makes the possibility of Medicare-funded tourism even more remote (it was politically unlikely no matter who won the election). President Trump, who ran on a protectionist platform,<sup>60</sup> might be reluctant to support a program that could be perceived as outsourcing American jobs using public money. But depending on the ultimate impact of the dramatic changes that his administration has proposed for health care coverage,<sup>61</sup> the administration may not have the choice but to look for cost savings where they can find them.

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<sup>57</sup> Cortez (n 44) 892.

<sup>58</sup> See *ibid*, at 911 (discussing the Conditions of Participation that Medicare imposes on domestic hospitals prior to allowing reimbursements).

<sup>59</sup> See Tamara K Hervey and Jean V McHale, *Health Law and the European Union* (CUP 2004) 142.

<sup>60</sup> See Katie Allen, ‘Trump's Economic Policies: Protectionism, Low Taxes, and Coal Mines’, *The Guardian* (Nov. 9, 2016), <https://www.theguardian.com/us-news/2016/nov/09/trumps-economic-policies-protectionism-low-taxes-and-coal-mines>.

<sup>61</sup> See Pear (n 46).

## 5. Conclusion

The decision to travel for medical services is, in many dimensions, a decision about risk. When a patient travels for services, she is making the determination that the potential benefits from receiving care abroad outweigh the risks of not receiving that care at home. But what are the risks? As we have seen, an American patient choosing to use medical tourism may take on the risk that, should medical error occur, she will not be compensated for the harm caused. A European patient engaging in fertility tourism, meanwhile, might take on the risk of legal consequences at home for him or for his children. And both public and private insurers, and those that regulate them, make all sorts of choices about how to allocate the risks of medical tourism. Though the risks may be different, the way that nations have chosen to address them could still offer valuable lessons for policymakers. They would do well to heed them when they look for answers to the questions raised by a globalizing world and the possibilities for medical services that it offers.

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