



# The right to information and free choice in a European perspective

## “Patients' Rights Have No Borders”

23 October 2013



**The right to information and free choice  
in a European perspective  
“Patients' Rights Have No Borders”**

**INDEX**

1. The Directive on Cross Border Care	3
2. The “Manifesto for the implementation of the Right of European Patients to make an informed choice”	6
3. The patient involvement in the transposition of the Directive: the state of the art from the patients ‘association point of view.	8
4. Current concerns and possible future scenarios	22
5. Involvement of the organisations: a first assessment	23
6. Recommendations	24
ANNEX I	26



## 1. The Directive on Cross Border Care<sup>1</sup>

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare aims to establish clear rules to facilitate access to safe and high quality health services in the European Union, guaranteeing mobility of individuals/patients seeking health services in a Member State different from that of origin.

The EU calls on the Member States to uniform standards, facilitate access to innovation and encourage the choice of the healthcare structures. The logic which governs this choice refers to the principles which govern the EU, most notably that of the single market and the free movement of goods, people and services. Furthermore, especially in recent years, the Court of Justice has ruled in favour of the freedom of citizens to choose healthcare structures and after receive financial coverage provided by their own health system. The Directive also fully fits in with the EU strategy to put European citizens in a stronger position *vis a vis* rules and regulations issued by the Member States, thus facilitating greater uniformity in terms of guarantees.

Most of the content in the Directive derives also from the debate among the Commission, through the European Commissioner for Health and Consumer Policy, the European Parliament and the citizens' associations, including Active Citizenship Network, which has fought to have the contents of the European Charter of Patients' Rights included in the Directive.

### **The facilitation of mobility for healthcare**

The aim of the Directive is to facilitate the mobility of people/patients within the European Union to access health services in all Member States. In practical terms, the Directive intends to standardize procedures and facilitate those for the requests for healthcare services in a EU Member State different from that of origin. Healthcare services are all those facilities and services provided by healthcare structures and healthcare professionals in order to assess, maintain or restore the health of the patient.

### **The request for healthcare products**

The Directive does not only apply to situations in which a patient coming from the Member State A requires reimbursement for care provided by the health services of the Member State B, but it is also applicable to prescriptions, distribution and supply of medicines and medical devices when they are provided within the scope of the healthcare services. In particular, reimbursement for medicines and medical devices is foreseen when reimbursement is claimed in a Member State different from that of residence or in the Member State in which the

---

<sup>1</sup> Excerpt from the "Civic Observatory on federalism in healthcare, 2011" by Cittadinanzattiva.

prescription is given, which means that a patient may request a refund for products prescribed in his/her country of residence and purchased abroad as well as prescribed and purchased in a Member State different from that of residence.

### **Responsibilities of the countries providing the healthcare services**

The text of the Directive establishes that the Member States and healthcare facilities operating in their territory and providing healthcare services should provide :

- correct information upon patient's request regarding standards and guidelines on the supply of healthcare services;
- information on the availability, quality and safety of services;
- a clear and transparent invoicing ;
- clear and transparent information about prices;
- clear information on the authorization granted to the healthcare facility;
- respect of the fundamental right to privacy;
- a copy of the medical reports once the healthcare services have been provided.

The Directive recognizes the principle of non-discrimination in access to care. The Member States which provide the treatment must not discriminate patients on the basis of their origin, both as regards the conditions for the supply of the treatment and the definition of the prices for the services. For patients from other Member States conditions and prices must be the same as those available to patients in their own country.

### **The Member States of origin of patients requiring treatment abroad**

Member States are responsible for reimbursement of the cost of cross-border healthcare services and must provide all necessary information regarding the type of services that the individual can request abroad according to the type of health insurance held in the country of origin.

Each Member State must also provide assistance to patients through the identification of "National Contact Points".

### **Reimbursement**

Article 8 of the Directive establishes that the Member State of origin of the patient who requires medical or healthcare products abroad must ensure repayment of the cost of the required services and products. The refund will be made within the limits of the healthcare insurance benefits held by the patient and in any case cannot exceed the cost of the services received abroad should this be less than the amount established for the same service in the country of origin. For example: a spirometry test in France is reimbursed at 100 Euros and in Italy at 120 Euros. If an Italian patient requires a spirometry test in France the reimbursement will be 100 Euros not 120 Euros. When implementing the Directive, the Member State of the



patient requesting treatment abroad must adopt such regulations which would guarantee to the said patient the same rights as those he/she would have requested and received - in a comparable situation - in his/her country of origin.

Article 10 establishes that Member States, when implementing the Directive on cross-border healthcare, must also implement administrative procedures for the use of treatment abroad and the request for the relevant reimbursement. These procedures must be objective and non-discriminatory, clear, accessible and properly publicized thus all healthcare services required abroad and covered by a healthcare insurance are available to the patient and therefore do not require an *ad hoc* authorization for each performance. A patient can forward the request, receive the service and ask for a refund in the country of origin. There are however exceptions dealt with in Article 9, which require "prior" authorization for those healthcare services which include:

- overnight hospital accommodation of the patient for at least one night;
- services which require the use of highly specialized and costly infrastructures or medical equipment;
- treatments which entail high risks for the patient.

The Directive establishes that the cross-border healthcare provisions should not affect the laws and regulations of the Member States regarding the organization and financing of healthcare services which do not concern situations of cross-border care.

It also does not compel, in any way, a Member State to reimburse the costs for services provided by private institutions which are not part of the public system or which are not included in the public social security system. In the event of litigation the case falls under the jurisdiction of the Member State in which treatment is provided. It is clear from the text of the Directive that the right to apply for cross-border healthcare cannot be applied to those healthcare services which relate to medium-long term assistance of the chronically ill, or to organ transplantation. In addition, prior authorization as dealt with by Article 9 could limit the reimbursement of highly expensive services. This exception is reinforced by the possibility of a Member State to limit the reimbursement if it significantly impairs the economic and financial balance of the social welfare model of the state of origin of the patient.

### **The National Contact Points**

The new law establishes that "National Contact Points" be set up in each country in order to assist citizens regarding the services and treatments which can be accessed in other Member States and to understand the different circumstances and situations presented by users as well as for settling any disputes or litigations. The number of contact points and their location (which can be incorporated also into existing information centres) will be set up independently by each single country. In addition to national offices, there will also be regional or local



information points, so as to foster cooperation among the healthcare systems of the various Member States.

## 2. The “Manifesto for the implementation of the Right of European Patients to make an informed choice”

The 7th European Patients’ Rights Day, organized by Active Citizenship Network (ACN) has been an occasion for the representatives of national patient organizations, European platforms, EU and national institutions, healthcare providers etc. to share opinions and experiences on the Directive 2011/24/EU on cross border care and on patients' involvement in health policies on a multi-stakeholder basis. The on-going transposition of the Directive, is, in fact, a unique occasion to enhance the collaboration between national institutions and representatives of patients and users to agree on implementation measures as much adapted as possible to the needs and expectations of citizens in each country.

In this occasion ACN drafted the “Manifesto for the implementation of the Right of European Patients to make an informed choice”, because it believes that the implementation of this principle, contained in the Directive (art. 4 § 1.b), shall allow all patients to access services better adapted to their personal requirements, both abroad and in their own country/region.

Patients’ right to "make an informed choice" officially recognizes the "**right to free choice**"<sup>2</sup> and the "**right to information**"<sup>3</sup> included in the European Charter of Patients' Rights drafted in 2002 by 15 associations part of the ACN network. The Charter is based both on the experience of the Tribunal for Patients' Rights (in particular on previous Charters for Patients' Rights promulgated in Italy at national, regional and local level) and on the Charter of Fundamental rights of the European Union. The Charter brings together the inalienable rights of every patient which each EU country should protect and guarantee. Article 6 § 1 of the Directive establishes that "Member States shall ensure that the national contact points consult with patient associations, healthcare providers and health insurance agencies", recognizing and enhancing also the ultimate principle of the European Charter of Patients' Rights, namely the "right to participate in policy-making in the health area."

---

<sup>2</sup> "Everyone has the right freely to choose among different treatments and suppliers on the basis of adequate information."

<sup>3</sup> "Everyone has the right to access all information regarding their health status, health services and their use and all that scientific research and technological innovation provides."

## The “Manifesto for the implementation of the Right of European Patients to make an informed choice”

### What does Active Citizenship Network ask for?

1. Citizens’ organisations representing patients and users must be **involved** in the transposition process in all Member States. They shall have their say on all national provisions implementing the text, especially those regarding information of citizens and the reimbursement of costs of cross-border healthcare, which both heavily condition the effectiveness of the right to make an informed choice.
2. All the **information** mentioned in the Directive should be **directly accessible** through the national contact points, including information on treatment options, on the availability, quality, safety and prices of the healthcare services supplied by the different providers in the Member State of treatment.
3. Information on **waiting lists and on humanisation of care**, which are not mentioned in the Directive but are key issues in the determination of patients’ choice, should also be available through the national contact points.
4. Beyond the web portals, the contact points shall set up a service of personalized information for citizens through **telephone and email**.
5. All the information provided by the national contact points should be available in **several languages**, including English. The web portals of the national contact points should promote graphic presentations of data, which do not require specific language skills.
6. The content, presentation and organisation of information on the web portals of the national contact points should be agreed with the representatives of patients and users, so that it shall be **easily accessible and understandable by citizens**.
7. The **effectiveness of the supply of information** through the national contact points should be assessed and reviewed in collaboration with the representatives of patients and users on a regular basis.
8. **Information campaigns** aimed at raising the attention of citizens on their rights deriving from the Directive and on the existence of the national contact points shall be organised in occasion of the entry into force of the national implementation measures in every Member State and no later than 25 October. These campaigns shall involve citizens’ organisations representing patients and users.

The Manifesto has been subscribed up to now by 31 associations<sup>4</sup> and 2 EU Networks (Pain Alliance Europe and the European Union of Private Hospitals UEHP).

---

<sup>4</sup> The complete list is in the ANNEX I.



### 3. The patient involvement in the Directive transposition: the state of the art from the patients 'association point of view.

As many of the provisions of the Directive are optional or leave room for interpretation by the Member States, much depends on the way the Directive is implemented. In order to make sure that the Directive is implemented so as to be an added value for patients, it is essential that patients' organisations at national level be actively involved!

For these reasons, a number of associations from ACN's network from different European countries and other stakeholders (such as the European Union of Private Hospitals - UEHP) deemed of paramount importance to work together in order to be involved by their national institutions and to actively monitor the processes of adopting and implementing the Directive using as a common tool for lobbying the **"Manifesto for the implementation of the Right of European patients to make an informed choice"**.

In order to share all activities a short questionnaire has been created asking each association the following:

- a) if the association was involved in the recognition and implementation of the Directive and in which way;
- b) if there is an existing national law implementing the Directive in the country and if the association was consulted during drafting;
- c) if and how the National Contact Point was organised and become operational and if the association was consulted (as required by the Directive);
- d) the association's main concerns;
- e) if the association has enacted any information/communication activities, or intends to do so;
- f) if and how the "Manifesto for the implementation of the Right of European patients to make an informed choice" was disseminated and signed in the country.

Here follows the information collected between July and September 2013 divided by country. Some has been written in the third person, while the rest (shown as quotes) refers to what was written by the associations.

What emerges in general from the point of view of the associations is that the recognition process has been slow and the involvement of citizens' organizations is not deemed a priority for most of the countries surveyed.



## AUSTRIA

**Organization:** Lower Austrian Patient and Nursing Advocacy<sup>5</sup>

**The organization's involvement:** “we were invited to give our opinion on the draft for the implementation of the law. When the new law has an effect on patients' interests or rights we are usually involved in the legal evaluation process”.

**The transposition law:** “there is an existing draft of the transposition of law EU-PMG (EU-Patienten-Mobilitätsgesetz / Federal Act on Patients' Mobility in the EU) available at the Austrian Parliament website<sup>6</sup>. Statements had to be sent to the Ministry of Health by August 19 at the latest (end of the legal evaluation process). The drafting is still in process as far as we know. The EU-PMG modifies 18 federal acts: the federal act on hospitals, the federal act on pharmacies, the federal acts on public state insurances, laws on professionals in the medical field (for example doctors' professional law) and the federal act on the “Gesundheit Österreich GmbH” (national research and planning institute for healthcare and competence, and funding centre for health promotion)”.

**The National Contact Point (NCP):** “this will be managed by the “Gesundheit Österreich GmbH”(GÖG). GÖG is a limited liability company established in 2006 on the basis of a federal statute as a national research and planning institute for healthcare and competence, and funding centre for health promotion. GÖG has not yet requested our advice”.

**Principal concerns:** “Our statement firstly refers to Art. 4/2/a of the Directive. The EU-PMG does not include regulations concerning standards and guidelines referring to the information about quality and safety of healthcare. There should be specific evaluation models to provide the essential information, for example information about the quality of a specific healthcare unit.

Furthermore, the National Contact Point should supply detailed information about the possibility of enforcement of patient rights and compensation out of court (for example Patient Advocacies).

The EU-EMP establishes that reimbursement is not possible if there is a high risk from the medical treatment. We propose that this risk must be weigh up against the prospect of success”.

<sup>5</sup> <http://www.patientenanwalt.com/>

<sup>6</sup> [http://www.parlament.gv.at/PAKT/VHG/XXIV/ME/ME\\_00540/fname\\_314261.pdf](http://www.parlament.gv.at/PAKT/VHG/XXIV/ME/ME_00540/fname_314261.pdf)

The “Manifesto for the implementation of the Right of European Patients to make an informed choice” has been shared with associations and the Ministry of Health and subscribed by 7 organizations.<sup>7</sup>

## FINLAND

**Organization:** Suomen Kipu ry<sup>8</sup>

**Organization involvement:** the Ministry of Social Affairs and Health have informed patients’ organisations about the change of the legislation. It has sent press releases of the issue to all the media, both social and traditional. Furthermore, information of these changes can also be found on the homepage of their website<sup>9</sup>.

## CROATIA

**Organization:** Croatian Association for Patients’ Rights<sup>10</sup>

**The organization’s involvement:** there has been a strong and hostile attitude and lack of information. Despite having sent several official letters to the Ministry of Health (May-June, 2013) the association was not involved in any way. The request for information on the status of implementation, after an initial period of total silence, was answered with "We have many activities in place", but did not specify any.

**The transposition law:** “to last letter of request for information at the beginning of September 2013 the Ministry replied that two laws had been passed to implement the Directive in Croatia at the end of June 2013, clearly without consulting any patients’ association”.

**The National Contact Point (NCP):** the Ministry announced that the NCP will be set up by the "National Health Insurance (HZZO)" although further information is not available as yet. The association was not consulted.

<sup>7</sup> Lower Austrian Patient Advocacy; Working Group Kidney Austria; Working Group Self-help Austria; Community of Interests for Epilepsy; Austrian Laryngectomees; Austrian Diabetics Association; Austrian Heart Association.

<sup>8</sup> <http://www.suomenkipu.com/>

<sup>9</sup> <http://www.stm.fi/en/pressreleases/pressrelease/-/view/1863388#en>

<sup>10</sup> <http://www.pravapacijenata.hr/eng/default.asp>



**Principal concerns:** "in our opinion, in Croatia there is not an efficient way to protect the rights of patients because there is no opportunity to work independently and impartially regarding complaints and lawsuits. In the case where foreign patients find their rights infringed in Croatia they would be able to pursue their rights and this would have an economic impact on Croatian citizens because the compensation would still be paid through the national budget. Moreover Croatia is a tourism oriented country and health services cost much less than in other countries, thus it could become a favourite destination for longer stays mostly of elderly citizens from Northern Europe and adversely affect the ability to access services for Croatians".

**Information and communication activities about the Directive:** on September 24, 2013 the association organized a small public forum in Split preceded by a press conference in which its representatives spoke about the Directive and the lack of information and involvement from the institutions.

**The "Manifesto for the implementation of the Right of European Patients to make an informed choice":** the Manifesto translated into Croatian was published in the official Bulletin of the Association (no.65). The document has not been shared with the institutions because until now they have not shown a real interest in collaborating with patient organizations in this field.

## ESTONIA

**Organization:** Estonian Patient Advocacy Association (EPAA)<sup>11</sup>

**The organization's involvement:** the Ministry of Social Affairs has involved EPAA in the implementation of the Directive. EPAA has already expressed its opinion about the law and has been involved in the workgroups.

**The transposition law:** "implementation of the Directive will bring about change in several laws. Most important is the obligation to provide the mechanism for the protection of patients and for seeking remedies in the event of damaging events. Also important is the obligation to gather information regarding safety and quality standards and which healthcare providers are subject to these standards. This means that these issues have to be discussed again. It should also be mentioned that up to now there has not been an independent and transparent complaints procedure or mechanism for patients in order to claim damages against any harm

---

<sup>11</sup> <http://www.epey.ee/index.php?page=3>



arising from the treatment. At the moment the only way to obtain redress is through the court system. Moreover, there is not an all-over professional liability insurance system”.

**The National Contact Point (NCP):** no available information.

**Principal concerns:** “seen from our point of view EPAA considers the lack of resources the main problem (specialists, time etc). We could be involved in the process but we do not have enough time or enough specialists to deal with it. Finally, we have great expectations for a change in our healthcare system. Hopefully there will be important changes thanks to the adoption of the Directive. We are glad to be involved in the implementation process but there is still a long way to go to obtain the expected results”.

## FRANCE

**Organization:** Le Collectif Interassociatif sur la Santé (CISS)<sup>12</sup>

**The organization’s involvement:** the CISS has been consulted on the implementation of the Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State, which implements points (a), (c) and (d) of Article 11(2) of the Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare. “The Ministry of Health sent us the draft decree implementing the directive at the beginning of August 2013, asking for our comments and observations. We have not been consulted yet on any other implementing measure”.

**The transposition law:** “there is a law proposal<sup>13</sup> which shall implement several EU requirements in the field of health, including one provision of the Directive 2011/24/EU, i.e. article 4 2° (d), which states “*The Member State of treatment shall ensure that: (...) 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 the extent of the risk, are in place for treatment provided on its territory*”. This proposal was submitted to the Parliament at the beginning of August but the Ministry of Health told us it is not expected to be voted rapidly. We asked when and how the other provisions of the Directive would be implemented and the said Ministry just answered that they are currently working on it (5 October 2013)”.

---

<sup>12</sup> [www.leciss.org/](http://www.leciss.org/)

<sup>13</sup> <http://www.assemblee-nationale.fr/14/projets/pl1336.asp>

As regards the draft decree our 2 main comments were the following:

1. We expressed our surprise that the decree did not mention art. 4 of Directive 2012/52/UE, which is essential for the respect of patients' right to information:

Article 4

**Information requirements**

Member States shall ensure that the national contact points referred to in Article 6 of Directive 2011/24/EU inform patients about the elements to be included, pursuant to this Directive, in prescriptions issued in a Member State other than the Member State where they are dispensed.

2. We also reminded the Ministry of Health that the question of language shall be the main obstacle to the recognition of medical prescriptions, even if the Directive does not oblige Member States to adopt any provisions regarding this issue. The CISS therefore suggested to include a new paragraph, asking the prescriber to write the prescriptions in English, or at least to translate into English the main elements, so that it could be understandable by a pharmacist from any other Member State who does not speak French.

**The National Contact Point (NCP):** “We have no information in this regard, since we asked when and how the provisions of the Directive on the National Contact Points would be implemented, asking specifically to be consulted on that question, but we have not received any answer yet.”

**Principal concerns:** Informing patients on their rights deriving from the Directive does not seem to be the main concern of the Ministry of Health, which apparently dealt with technical issues first. Apparently, the provisions on the National Contact Points have not been implemented yet and we wonder when and how the French authorities will do it and whether they intend to involve patient and user organisations in any manner in this process.

**GERMANY**

**Organization:** Deutsche Gesellschaft für Versicherte und Patienten e.V. (DGVP)<sup>14</sup>

**The organization's involvement:** DGVP has not been involved.

---

<sup>14</sup> <http://www.dgvp.de/>

**The transposition law:** there is no one-to-one transposition of the directive and there is nothing such as a separate law on it. Major parts of the directive have already been implemented in German national law such as the right to obtain reimbursement of costs on health services within the EU – implemented in 2004.

- Planned treatments in EU hospitals: have to be approved by the insurance beforehand. Other treatments do not necessarily have to be approved in advance, however it usually makes sense to speak with one's insurance company on planned treatments before starting them. In cases of emergency there is no need to receive an approval.
- Regulations on reimbursement: are clearly specified. In most countries showing your insurance card is enough.
- Other parts of the Directive have been implemented by the new patients' rights law and due to this are now part of the German Civil Code (advanced information on documentation by the doctors in favour of the patients (§§630c, 630f BGB) or right to have an insight into one's own patient file (§630g BGB) or are part of certain operating rules (advanced information to be provided by pharmacists, §20 Abs. 3 Apothekenbetriebsordnung).
- Rules in cross-border medical prescriptions: are part of the pharmaceutical prescription order<sup>15</sup> and the pharmacy operating rules<sup>16</sup>.

**The National Contact Point (NCP):** this will be located at the *Deutsche Verbindungsstelle Krankenversicherung Ausland (DVKA)* which is part of the GKV *Spitzenverband* (The National Association of the Statutory Health Insurance and Long-Term Care Insurance Funds) at federal level in accordance with section 217 a of Book V of the German Social Code (SGB V). Legally it is called *Körperschaft des öffentlichen Rechts* (public body). It generally functions as a service partner for health insurances, patients, international and national organizations. It has been the partner for international issues for years and therefore will continue to work in this field. The GKV *Spitzenverband* closely works with the statutory health insurances as well as with the Ministry of Health. They do not ask for patients organizations' advice. As far as I know, not even members of the *Unabhängige Patientenberatung UPD* - which was set up a couple of years ago by the GKV *Spitzenverband* in cooperation with the Ministry of Health and which receives its entire funding from the statutory health insurances – are consulted in matters regarding the NCP.

The NCP will receive information and input by the *Deutsche Krankenhausgesellschaft* (German Hospital Federation), the *Kassenärztliche Bundesvereinigung* (National Association of Statutory Health Insurance Physicians), the *Kassenzahnärztliche Bundesvereinigung* (National

---

<sup>15</sup> Arzneimittelverschreibungsverordnung (AMVV)

<sup>16</sup> Apothekenbetriebsordnung (ApBetrO)



Association of Statutory Health Insurance Dentists) as well as from private insurance companies. *Bundesärztekammer* (German Medical Association) and *Bundeszahnärztekammer* (German Dental Association) can be called upon for consultations whenever necessary.

Basically, they will continue doing the work they already do. On their web site they briefly describe what their work is about<sup>17</sup>.

The “**Manifesto for the implementation of the Right of European Patients to make an informed choice**” has been translated in German and published on the association’s website.

## ITALY

**Organization:** Cittadinanzattiva Onlus<sup>18</sup>

**The organization’s involvement:** “we are not informed about any formal involvement of associations of citizens and patients by the Ministry”.

**The transposition law:** The adoption has not yet been formalised<sup>19</sup>. The guidance issued by the Ministry of Health in the workshop organized by the Project “*Mattone Internazionale*”<sup>20</sup> goes towards the Legislative Decree for the adoption of the Directive 2011/04 EU. The Decree, based on “interim regulations” (those rules which apply to the regions until the entry into force of the specific regional regulations) will have a uniform national framework on which the regions may intervene and regulate regarding particular permissions, refunds, rates etc. The process is still long as there will be a series of steps in the State-Regions Conference before the Decree can be approved in Parliament. This will be followed by regional regulations.

**The National Contact Point (NCP):** At present it appears that the Ministry of Health has identified the National Contact Point at the Ministry of Health and that notice has been given to the European Commission. The National Contact Point is not operative yet (at least for citizens). There is no web page or link, not even on the website of the Ministry of Health. The documents of the “*Progetto Mattone Internazionale* (Dir-Mi)” indicate the presence of agreements for the establishment of other regional contact points (in Veneto, Liguria, Trento and Valle d’Aosta).

<sup>17</sup> <http://www.dvka.de/oeffentlicheSeiten/Fremdsprachen/Englisch.htm>

<sup>18</sup> [www.cittadinanzattiva.it](http://www.cittadinanzattiva.it)

<sup>19</sup> 30 September 2013

<sup>20</sup> [http://progettomattoneinternazionale.it/servizi/notizie/notizie\\_homepage.aspx](http://progettomattoneinternazionale.it/servizi/notizie/notizie_homepage.aspx)



**Principal concerns:** there is still debate about the "rules of the game" while citizens should have already had access to clear, simple and transparent information and preferably to procedures which do not differ from region to region. This information would allow citizens to be "ready" and more aware at the date of 25 October when it will be possible to choose the country in which one wants to be treated.

The establishment of a European reference network and the identification of centres of excellence, which for citizens are the first step towards the identification of healthcare places and structures, will be set up step by step. The Ministry will collect information regarding networks and centres of excellence to present specific proposals to the European Commission.

The **"Manifesto for the implementation of the Right of European Patients to make an informed choice"** has been shared on the web page of the association and signed by 4 associations part of the Italian Union of Associations for Patients suffering from Chronic Diseases, CNAMC (a network of Cittadinanzattiva) and 160 individuals on the on-line petition.

## LATVIA

**Organization:** Patients' Ombud Office<sup>21</sup>

**The organization's involvement:** definitely not efficient. We tried several times to contact our Ministry of Health and even had promising meetings where we proposed our ideas regarding the new Directive which we consider very important in order to share information with the public and healthcare providers. We were promised to be consulted in some of the communication plans by the Ministry but to no avail from this.

**The transposition law:** at last there will be changes in several laws, especially as regards our patients' compensation system. This was planned very long time ago. As the patients' representatives we have been campaigning for the setting up of this system for many years and now, only thanks to the new Directive, it will at last be established. The problem lies with the fact that all legislation changes are rushed through at the very last moment and very quietly so that we are not at the moment able to peruse the latest version.

**The National Contact Point (NCP):** the service, run by the National Health Service is already operative but at the moment provides very little information.

---

<sup>21</sup> <http://www.pacientuombuds.lv/>





**Principal concerns:** “We consider the new Directive as a new opportunity for patients and a for a better quality of healthcare throughout the EU. However, it is also our opinion that our healthcare management might find it difficult to understand the need to be more welcoming to patients from other countries; there is also the need to have safer healthcare services for our patients and in this respect much more information is needed.

We have been in contact with many Latvian hospitals which are interested to learn more about health risk insurance services but we frankly feel that much more information is needed. The new Directive has been implemented only for the past two weeks and we have noticed that information in this respect is wanting and there is also a certain lack of direct commitment, not to mention there is not an appropriate financing plan from the government to make the Directive properly operative.

Hospitals and other healthcare providers are interested to learn more about the new system they will be a part of, but there is not enough information from the Government. The Ministry of Health is only now planning to divulge information and distribute publications, but since the new legislation will be in force as of October 25, this action is going to be a bit late in the day. Finally, there will be provisions to compensate patients in the case of damages received during healthcare treatment but this model seems to need already quite a lot of improvements”.

**Information and communication activities about the Directive:** “Since we realised that there is no intention to really cooperate on this issue, we are organising a conference<sup>22</sup> independently and we have invited the EU Commission to send a representative. More details about our conference plan can be viewed on our website. Also our Minister of Health has accepted to say some introductory words, but at this moment we are not sure of the Ministry’s real involvement. This is a great challenge for us”.

**The “Manifesto for the implementation of the Right of European Patients to make an informed choice”** The Manifesto has been translated and will be disseminated during and after the conference <http://poconferences.org/en>.

---

<sup>22</sup> <http://poconferences.org/en/>

## MALTA

**Organization:** Malta Health Network (MHN)<sup>23</sup>

**The organization's involvement:** the Malta Health Network was involved in 2 meetings held at the end of 2011 and 2012 with the Health Authorities although proceedings were still at their initial stages. In June 2013 MHN held an information seminar with the participation of the Minister of Health, a representative from the UK and other speakers. The meeting was well attended by MHN members and other patient organisations. This September there was a public information session also attended by MHN.

**The transposition law:** "there is a new Health Law in second reading in Malta and the government plan to include relevant parts of the Directive in this law. However we have not been formally involved or invited to any consultation or discussions but we managed to obtain a draft of the law privately and not officially".

**UPDATE** (October 2013): The new health Act is now public and can be accessed publicly from the Malta Bills section in the Laws of Malta website.

**The National Contact Point (NCP):** "the NCP will definitely be activated within the Ministry of Health and will work under the direct responsibility of the health authorities but for the moment no steps have been taken".

**UPDATE** (October 2013): "We have been informed in a public session that the ministry has assigned this role to the office which is currently dealing with entitlement for specialised treatment abroad and they are updating website over the coming days".

**Principal concerns:** "on paper many things are being said but in practice we are still not seeing anything being done. The reply to our questions and queries is that the Ministry will be there on time but how and when is a big question mark".

**Information and communication activities about the Directive:** in June 2013, the association organized an information seminar with the participation of the Minister of Health and a number of patients' associations<sup>24</sup>.

---

<sup>23</sup> <http://maltahealthnetwork.org/>

<sup>24</sup> European Citizens' Rights, Patients' Rights, involvement and Cross-border Care, 24 thJune 2013



The “Manifesto for the implementation of the Right of European Patients to make an informed choice” was released during the seminar held in June 2013, sent to all members and contacts and posted on the website and on the Facebook profile of the association.

## PORTUGAL

**Organization:** Chronic Disease Associations Network in Azores (RIADCA)

**The organization's involvement:** none.

**The transposition law:** “the Directive is in the process of transposition in the Health Department therefore, at the moment we do not have any information”.

**UPDATE October 2013:** there is a Preliminary Document in public discussion for one month, The Health Minister can receive all the reports of Citizens and Associations or other Organizations:<http://www.portaldasauade.pt/portal/conteudos/a+saude+em+portugal/politica+da+saude/discussao/cuidados+transfronteiricos.htm>

**The National Contact Point (NCP):** “the information will surely be made available on the Patient Portal<sup>25</sup>, which is a software application accessible to all citizens, which is being developed and has currently several functions to aid users in contacting with the healthcare system”.

The “Manifesto for the implementation of the Right of European Patients to make an informed choice” : we have sent the Manifesto to 67 Patients’ Associations and we are receiving several subscriptions.

## ROMANIA

**Organization:** Myeloma Euronet Romania (MeR)<sup>26</sup>

---

<sup>25</sup> <http://www.portaldasauade.pt/portal/conteudos/informacoes+uteis/taxas+moderadoras/requerimento+isencao.htm>  
<https://servicos.min-saude.pt/utente/portal/paginas/default.aspx>

<sup>13</sup> <http://www.myeloma.ro/>



**The organization's involvement:** Romania, along with Poland and Spain initially vetoed the approval of the Directive. They subsequently signed it by introducing some amendments promoted by their associations and the Romanian Ministry of Health.

**The transposition law:** "Romanian Government signed the Directive with the special provision that endorsement for treatment abroad undertaken by Romanian citizens should be made only under the following circumstances:

- when treatment is not available in Romania
- when the level of the reimbursement is equal/compatible to the Romanian reimbursement system
- when the patient undertakes to personally cover any additional costs (care providers, family support etc).

**The National Contact Point (NCP):** "it will be managed directly by the National House of Health, a Governmental Agency. In a way, it is a legitimate decision because management of this service involves substantial funding. However, despite our efforts, patients' organizations will have no significant role in this instance except in the assistance granted to the patient in the process of identifying the most suitable medical location for his/her treatment abroad".

**Principal concerns:**

Reimbursement.

The ambiguous statements of the Directive: there are too many cases where it is stated that "the State should/could" rather than "the state must". This can give rise to a free interpretation of the Directive and justify possible decisions by the national authorities to the detriment of the patients."

**Information and communication activities about the Directive:** MeR has disseminated the Directive among several patient groups.

**NORWAY**

**Organization:** Norwegian Cancer Society<sup>27</sup>

**The organization's involvement:** in January 2013 Norway held a national hearing about patients' rights and the implementation of the Directive on Patients' Rights in Cross Border

<sup>27</sup> <https://kreftforeningen.no/en/main-priorities/>



Care. The Norwegian Cancer Society attended the hearing. In our answer, we stated that we are generally positive about the implementation of the directive, but fear that only a small percentage of patients will use the opportunity to obtain medical care abroad. The Norwegian Cancer Society has also participated in a consultation network organised by the Ministry of Health where one of the topics was The Directive on Patients' Rights in Cross Border Care.

**The transposition law:** in accordance to a new provision in the Act relating to national insurance and national regulations, planned treatments in EU hospitals have to be approved by HELFO beforehand to get reimbursement. There are also requirements for the service in the new regulatory provisions. In accordance to a new provision in the act relating to specialized healthcare service, foreign nationals who come to Norway must initially pay health expenses themselves, and then claim reimbursement from their insurance company in their home country.

**The National Contact Point (NCP):** “in Norway the National Contact Point will be part of the Norwegian Health Economics Administration (HELFO) which is a sub-ordinate institution directly linked to the Norwegian Directorate of Health. Please find more information about HELFO at their website<sup>28</sup>.

As far as we know they have not asked for advice from patients' organizations. We have recently invited HELFO to a meeting, prior to the implementation of the Directive, to give us an overview about how they will be organized and what help the users of the service may expect. We will make plain what our expectations from the service are.

**Principal concerns:** “firstly, we fear that too much responsibility is placed on the patient regarding self-orientation. Secondly, we disagree with the decision that each patient must advance and pay the cost of the treatment abroad, and apply for reimbursement afterwards”.

**Information and communication activities about the Directive:** we will express our concerns and explain the importance of the main points of the "**Manifesto for the implementation of the Right of European Patients to make an informed choice**" during the meeting with HELFO.

---

<sup>28</sup> <http://www.helfo.no/omhelfo/Sider/about-helfo.aspx>.

#### 4. Current concerns and possible future scenarios

Patients' associations have clearly shown that the innovative potential expressed by the Directive is strong and thus they are committed to work for its implementation.

The opportunity to access quality information, the guarantee of safety in healthcare, the right to compensation and alternative forms for dispute resolution are just some of the aspects that will bring about major breakthroughs in many countries by strengthening the rights not only for those who travel for health reasons, but also for people who live in any Member state and use its healthcare system.

In view of this potential, however, the associations express some **concerns**:

- the transposition process has been slow and almost "in the dark";
- the involvement of citizens' organizations is yet to be considered a priority and a way of ordinary governance of the National Public Health system;
- information to the public in general and to patients in particular on their rights under the Directive is currently lacking, as well as communication strategies which should inform the population as effectively as possible.
- Member States seem much more concerned with technical and legal issues related to the adaptation and revision of the national legislation than with the management of the short term practical implications of these provisions. This is demonstrated by the following arguments:
  - the knowledge that in several countries, e.g. Estonia, Latvia and Austria (where the transposition law changes as many as 18 Federal Acts), the transposition of the Directive requires a substantial adaptation of the existing legislation;
  - albeit partial, the involvement of patients' associations and the protection of their rights has been recorded only in the transposition phase of the Directive, against a total lack of consulting the associations by the National Contact Points, although expressly provided for by the Directive.

This being the case, the associations foresee that only a small percentage of patients will request treatment abroad.



In addition to these general concerns there are more detailed ones, specifically related to both the transposition of the Directive and its practical impact.

Concerns regarding the transposition of the Directive:

- The Directive leaves Member States too much discretion: in fact there are too many cases where it is stated that "the State should/could" rather than "the State must". This can give rise to a liberal interpretation of the Directive from country to Country.
- In some cases, the law does not mention aspects of national implementation which are an important part of the Directive, such as those regarding information.

Concerns regarding practical implications:

- the cuts to public health and the current lack of investment funds are likely to prevent the principles of the Directive being implemented and respected.
- the provisions of the Directive may be hindered by a cultural approach since health workers should be the first to be more open and available to patients from other countries.
- language is the main obstacle in reading/understanding medical prescriptions since the Directive does not indicate that Member States adopt specific rules about it.
- associations believe that patient self-guidance in the choice is a possible critical issue.
- they disapprove of the fact that each patient should anticipate the cost of treatment abroad and then ask for reimbursement.
- countries which are economically disadvantaged or live on tourism (particularly attractive for older people who may decide to spend their retirement in a country other than their own) fear the depletion of the health service for nationals, too much debt or longer waiting lists.

Finally, the changes introduced by the implementation of the Directive affect also the patients' organizations, since in some cases the main concern lies not in the fact of being involved in the implementation per se but in the lack of internal resources specialized in the topic and able to offer citizens all the relevant information they may need.

## **5. Involvement of the organisations: a first assessment**

A brief summary of the information produced by associations clearly shows that the behaviour of the various Member States, compared with **the involvement of citizens and patients' organizations** can be classified into three types:



- **Formalized:** public consultations, dissemination of the transposition measures to acquire the opinions and the views of associations etc. as in the case of Austria, Estonia, France and Norway.

- **Informal:** relationships between the ministry and civic associations/organizations which are based on spontaneous interviews and meetings and most of the time required by the same associations but which do not become a binding force nor a proper intervention. Involvement therefore depends on the willingness of individual associations which decide to "put pressure" to enter the transposition process in the Member States. See the example of Italy.

- **Absent or almost absent:** are those situations in which the associations, after having forwarded specific requests, have discovered that their institutional partner (Ministers or similar) has dropped the submissions, downplayed the importance of the issue, has not responded or has clearly indicated that the issue is not a priority of the Ministry.

Seven out of twelve associations have begun a more or less formalized form of collaboration with their national institution of reference; this situation gets worse when you consider the number of active and available National Contact Points for citizens: only one has been set up in Latvia, although providing very little information to citizens. In other instances or the associations know little about the issue or have not been involved in the implementation process, or the service still does not offer any services to citizens.

An emblematic example is that the National Contact Point, which should be a top service for citizens, is not involving the associations which could offer both their knowhow and experience.

## 6. Recommendations

At European level, Active Citizenship Network addresses the EU Institutions so that they become facilitators and guarantors in:

- building a network of National Contact Points;
- begin a proper dialogue between the National Contact Points and the various stakeholders identified by the Directive as necessary interlocutors and at the same time striving to involve associations for patients and for the protection of rights;
- promote opportunities for discussion and debate on the subject, for example within the EUHPF in order to disseminate awareness and maintain high attention to the important changes introduced by the Directive;





- monitor the problems citizens may encounter while dealing with cross-border healthcare;
- ensure that the development of e-health, urged by the Directive, may be safely carried out and without exposing the Member States to the risks of scams and frauds;
- convey a European-oriented message built upon these new rights and provisions in healthcare which would help strengthen the sense of belonging to the European community.

## ANNEX I

The "Manifesto for the implementation of the Right of European Patients to make an informed choice" has been subscribed by:

### 31 ASSOCIATIONS in 13 Countries:

1. Lower Austrian Patient und Nursing Advocacy, Austria
2. Working Group Kidney, Austria
3. Working Group Self-help, Austria
4. Community of Interests for Epilepsy, Austria
5. Austrian Laryngectomees, Austria
6. Austrian Diabetics Association, Austria
7. Austrian Heart Association, , Austria
8. National Patients' Organization, Bulgaria
9. Croatian Association for Patients' Rights, Croatia
10. Estonian Patient Advocacy Association (EPAA), Estonia
11. Finnish Pain Association - Suomen Kipu ry, Finland
12. Le Collectif Interassociatif sur la Santé (CISS), France
13. Deutsche Gesellschaft für Versicherte und Patienten e.V. (DGVP), Germany
14. Cittadinanzattiva Onlus, Italy
15. Associazione Diabetici Parma - A..I.D, Italy
16. AMICI Onlus, Associazione Nazionale per le Malattie Infiammatorie Croniche dell'Intestino, Italy
17. F.A.I.S. Onlus - Federazione Associazioni Incontinenti e Stomizzati, Italy
18. Simba Onlus Italian Behcet's patients association, Italy
19. Patients' Ombud Office, Latvia
20. Malta Health Network (MHN), Malta
21. Chronic Disease Associations Network in Azores (RIADCA), Portugal
22. APOROS – Associação Nacional contra a Osteoporose, Portugal
23. APAHE – Associação Portuguesa de Ataxias Hereditárias, Portugal
24. ADSMSM – Associação de Diabéticos de São Miguel e Santa Maria, Portugal
25. Escola Superior de Enfermagem de Ponta Delgada, Portugal
26. Associação Seniores São Miguel, Portugal
27. ANEM – Associação Nacional de Esclerose Múltipla, Portugal
28. Associação Atlântica de Apoio ao Doente Machado-Joseph, Portugal
29. ADRNP – Associação dos Doentes Renais do Norte de Portugal
30. Myeloma Euronet Romania (MeR), Romania
31. Norwegian Cancer Society, Norway



## 2 EUROPEAN NETWORKS:

32. European Union of Private Hospitals · UEHP
33. Pain Alliance Europe · PAE

✓ We have also launched an on line petition<sup>29</sup>.

---

<sup>29</sup> <http://www.change.org/it/petizioni/european-states-governments-make-them-informed-ask-your-state-to-inform-citizens-on-eu-health-rights#news>