

“Patients right to access care”

COLLABORATE SUMMIT 2023

18-20 October 2023

Lisbon, Portugal



Cittadinanzattiva/Active Citizenship Network

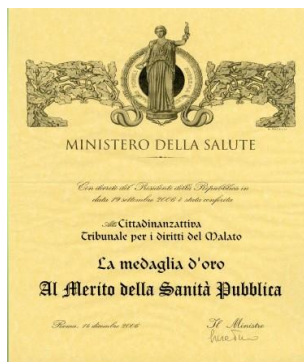
Network: a short introduction

Cittadinanzattiva

Italian NGO founded in Italy in 1978.

More than 30.000 members, 250 local assemblies and 84 Citizen Advisory Centres.

Mission: promote active participation of citizens and protection of their rights.



Active Citizenship Network

The European branch of Cittadinanzattiva, established in 2001.

One of the most widespread & informal network, able to involve in its initiatives 206 civic, patient & user organizations coming from 34 Countries, plus 22 European/Global networks/umbrella organizations.

Promote the point of view of European citizens in all public policies areas, focusing on healthcare, consumers and corporate social responsibility issues.



www.cittadinanzattiva.it

www.activecitizenship.net



European Charter of Patients' Rights

Visit the new section of the site where you can find everything that has been done and what you can do with it!

What is a "Charter of Rights" and what is needed for	Sites which host the Charter	The Charter in several languages	Articles, videos and public events	Institutional endorsement at the European and national level
	Books, studies and publications of the Charter	From the Charter to the Charters	The forerunners of the Charter	

1. Established in 2002 by Cittadinanzattiva-Active Citizenship Network, together with organizations from 15 EU countries;
2. It lists states 14 that should be guarantee to everyone, everywhere.
3. The rights stated in the European Charter of Patients have as the main starting point the European Charter of Fundamental Rights and several international declarations and recommendations.
4. Drafted in 22 languages, it has become a reference for EU citizens' rights in health care and a milestone for other Charters of rights.



"Charter for rare patients without a diagnosis" (promoted in 2023 in Italy by Fondazione Hopen Onlus, Ospedale Pediatrico Bambino Gesù, Orphanet-Italia, Osservatorio Malattie Rare)

European Charter of Patients' Rights



- 1 **Right to preventive measures**
Every individual has the right to a proper service in order to prevent illness.
 - 2 **Right of access**
Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.
 - 3 **Right to information**
Every individual has the right to access to all information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available.
 - 4 **Right to consent**
Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this information is a prerequisite for any procedure and treatment, including the participation in scientific research.
 - 5 **Right to free choice**
Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information.
 - 6 **Right to privacy and confidentiality**
Every individual has the right to the confidentiality of personal information, including information regarding his or her state of health and potential diagnostic or therapeutic procedures, as well as the protection of his or her privacy during the performance of diagnostic exams, specialist visits, and medical/surgical treatments in general.
 - 7 **Right to respect of patients' time**
Each individual has the right to receive necessary treatment within a swift and predetermined period of time. This right applies at each phase of the treatment.
 - 8 **Right to the observance of quality standards**
Each individual has the right of access to high quality health services on the basis of the specification and observance of precise standards.
 - 9 **Right to safety**
Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards.
 - 10 **Right to innovation**
Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.
 - 11 **Right to avoid unnecessary suffering and pain**
Each individual has the right to avoid as much suffering and pain as possible, in each phase of his or her illness.
 - 12 **Right to personalized treatment**
Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.
 - 13 **Right to complain**
Each individual has the right to complain whenever he or she has suffered a harm and the right to receive a response or other feedback.
 - 14 **Right to compensation**
Each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment.
- ⇒ **Rights of active citizenship**
The Charter sets forth 3 rights of active citizenship. They allow individuals and groups of organized citizens to promote and verify the implementation of patients' rights and as such, they are the necessary corollary of the Charter.
- Right to perform general interest activities
 - Right to perform advocacy activities
 - Right to participate in policy-making in the area of health



PATIENTS' RIGHTS HAVE NO BORDERS

2- The patients' right to access

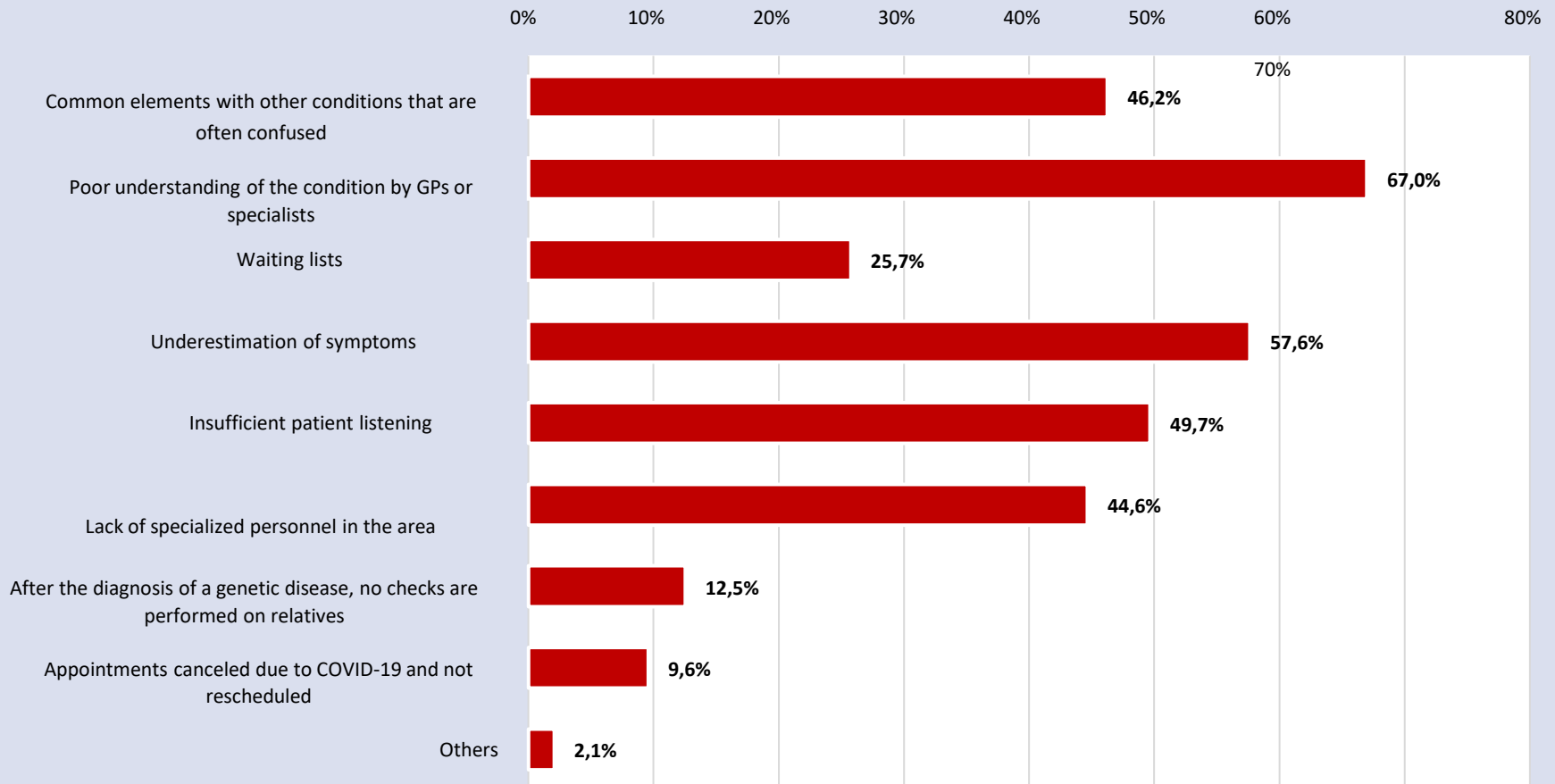
Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.

- An individual requiring treatment, but unable to sustain the costs, has the right to be served free of charge.
- Each individual has the right to adequate services, independently of whether he or she has been admitted to a small or large hospital or clinic.
- Each individual, even without a required residence permit, has the right to urgent or essential outpatient and inpatient care.
- **An individual suffering from a rare disease has the same right to the necessary treatments and medication as someone with a more common disease.**



What elements most hinder an early diagnosis of rare disease

Factors that most hinder an early diagnosis of the disease



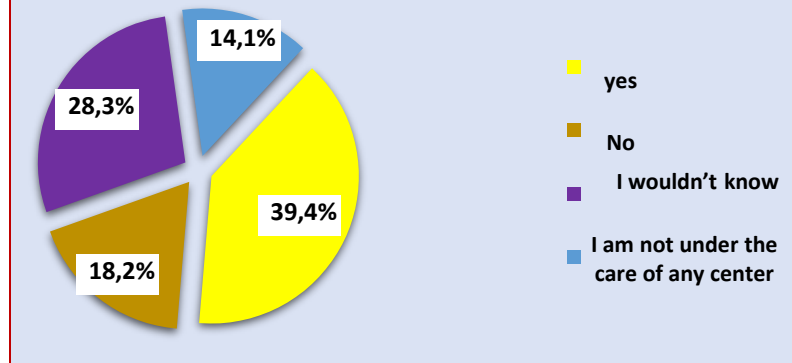
Source: 20th Chronicity Policy Report - Cnamc, Cittadinanzattiva, 2022

(Interviewed: 871 patients & leaders of 86 PAGs)

Snapshot from Italy: the voice of patients with rare diseases

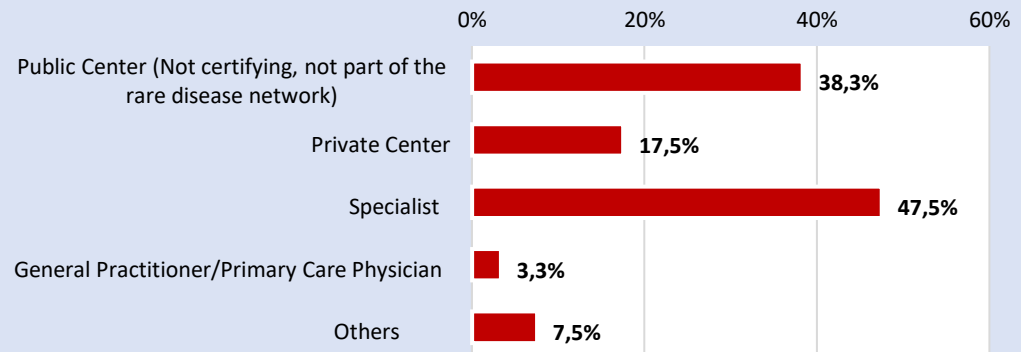
- In Italy, almost 2 millions people with rare diseases (up to 36 million people in the EU)
- In 2001 the first list of rare diseases eligible for co-pay exemption, updated in 2017.
- Only 39% of those who have a rare disease are treated at a centre that is part of the National Network of Rare Diseases (established in 2001); 28% do not know whether or not the centre is part of a network; 18% say it is not and 14% are not treated at any centre. It means, more than 60% of rare disease patients do not receive standardised care on the territory and a further 17,5% rely on a private centre.
- One in four (around 27%) is forced to travel to another region for treatment.
- Finally, waiting lists complicate matters further. For 60% it was a problem to get the first specialist examination and diagnostic tests, for 55% the check-up, while 43% had to postpone *sine die* the recognition of civil disability or accompaniment.

The centre where he is being treated is part of the regional rare disease network



Source: 20th Chronicity Policy Report - Cnamc, Cittadinanzattiva, 2022 (Interviewed: 871 patients & leaders of 86 PAGs)

Which centre/professional figure does it refer to:



Rare diseases in Italy: accessibility of medicines...

- 8.4 million doses of orphan medicinal products were dispensed in 2021, or just 0.03% of total pharmaceutical consumption;
- spending on orphan medicinal products in 2021 was €1,535 million, accounting for 6.4 percent of total pharmaceutical spending;
- the number of treatments for rare diseases included in the list of Law No. 648/1996 increased from 31 in 2018 to 45 in 2022 (there were just 13 in 2012);
- the number of people with rare diseases who have benefited from the AIFA fund (referred to in Law No. 326/2003, Art. 48) drops to 229 in 2022, after witnessing an exponential increase in previous years, from 20 people in 2016 to 1,361 in 2020;
- as many as 8 of the 16 Advanced Therapy Medicinal Products (ATMPs) with European approval (figure updated to May 2022), are currently reimbursed in Italy (the same number as in France and 2 less than Germany and England)

...and newborn screening

- At the end of 2022, the expanded neonatal screening program is active in all regions/autonomous provinces. There is also increasing homogenization of the number of diseases included in screening panels at the regional level;
- the DPCM January 12, 2017 "Definition and update of essential levels of care" in Art. 38 guarantees all newborns the necessary services for the early diagnosis of congenital deafness and congenital cataract.
- By the end of 2022, newborn hearing screening is active throughout the country. Similarly, neonatal ophthalmological screening is active throughout the country with the exception of two regions (in one region it is not active, in another it is being implemented);

Source: IX Report on the condition of people living with a rare disease in Italy. UNIAMO, 2023

Snapshot from Italy: rare diseases & HCPs

- Rare diseases affect all medical figures: more than 7 out of 10 doctors in their working lives have found it necessary to carry out diagnostic investigations for a suspected rare disease for one of their patients, while slightly more than 5 out of 10 doctors currently have at least one person diagnosed with a rare disease among their patients, especially GPs/pediatricians (70%).
- Awareness of the rare disease system is still low among doctors: only 2 out of 10 doctors have direct knowledge of ERNs, only half of doctors have heard of the new Italian law on Rare Diseases.
- Fragmentation of the care network for rare diseases: Of the 681 doctors who have at least one person with a rare disease in their charge, 147 (21.6%, one fifth) have no relationship with the Centres of Reference for Rare Diseases, while 3 out of 10 doctors are not in relation with the ASL (Social and Health District or other services).
- Clear view of the main problems related to the care of persons with rare diseases: absence/shortage of timely diagnosis (more than 7 out of 10 doctors), absence/shortage of continuity of care in the transition between hospital and territorial care (almost 5 out of 10 doctors) and absence/shortage of integration between primary care (GPs/pediatricians) and specialists at the centre of reference (4 out of 10 doctors, but almost 6 out of 10 GPs/pediatricians).

Source: "Rare diseases: Fact-finding survey addressed to general practitioners, pediatricians and specialist doctors" – UNIAMO 2022 (Tot. 1205 respondents)

Snapshot from Italy: Rare Diseases Act

This Law No. 175 of November 10, 2021, encompasses all the enforceable rights of patients to improve the quality of life of individuals affected by rare diseases and their families throughout the national territory. Its objectives are:

- To standardize the prevention, early diagnosis, and treatment of rare diseases across the entire national territory.
- To promote equity in care pathways in all regions.
- To advance research in the field of rare diseases, including incentivizing the production and research of so-called orphan drugs.

The provision consists of 16 articles and pursues the following objectives:

- Improved and free care for rare disease patients through the strengthening of the National Rare Disease Network.
- Implementation of personalized diagnostic and therapeutic pathways prepared by Reference Centers.
- Establishment of a structured pathway from pediatric to adult care.
- Update of the Essential Levels of Assistance (LEA).
- Enhancement of extended neonatal screening and early diagnosis.
- Creation of a solidarity fund for social support for the right to education and employment (although it may not cover all needs, it is an important start).
- Information campaigns for healthcare professionals and citizens.
- Increase in funding for research.
- Production of orphan drugs that are immediately available in all regions once approved by AIFA (Italian Medicines Agency).
- Availability of aids and innovative medicines.

Snapshot from Italy: new legislative framework

- First steps of the implementation of Law No. 175 of November 10, 2021, "Provisions for the treatment of rare diseases and the support of research and production of orphan medicinal products" which resulted in a decisive progress of the national rare disease network mainly due to:
 - Jan. 2023: establishment of the National Committee for Rare Diseases (CoNaMR);
 - July 2023: approval of the National Rare Diseases Plan 2023-2026 and the document for the "Reorganization of the National Rare Diseases Network" also linked with the development of the European Reference Networks (ERNs).
- The path of implementation of Law No. 175 of November 10, 2021, however, remains largely incomplete due to the failure to define the implementing measures of the specific measures (i.e. the solidarity fund for the support of the work of care and assistance of people with rare diseases).
- To date, moreover, not even the update of the "SNE panel" (Expanded Neonatal Screening) has been carried out.
- About screening, a hopeful sign comes from the many regions that are now implementing and/or experimenting with newborn screening also for other diseases not included in the current national panel.

How we cooperate to advocate for patients with rare diseases in Italy

National Coalition of Associations for Patients suffering Chronic & Rare Diseases (CnAMC)

Established in 1996 by Cittadinanzattiva, this network represents an example of crosscutting alliance between associations of people with chronic & rare diseases, for the protection of their rights. It has about one hundred members, 29 of them focused on rare diseases.

- From 2000, National Annual Report (cfr. XX Edition, Dic. 2022)
- Thematic dossier (i.e. on 2008) and website (www.malattierare.cittadinanzattiva.it)
- At the regional level, promoting alliances (i.e. Emilia, Veneto, Sicily, etc.) and new front-line services (i.e. Campania)
- At the national level, advocacy initiatives such as Civic Recommendation & Appeal on extended neonatal screening still blocked, to recognize the role of the caregivers, policy dialogue, surveys, etc.



CLICCA QUI >



**Ti hanno diagnosticato
una malattia rara
e non sai cosa fare?**



Directive 2011/24/EU on patients' rights in cross-border healthcare

- EU citizens have the right to access healthcare in any EU country and to be reimbursed for care abroad by their home country.
- [Directive 2011/24/EU on patients' rights in cross-border healthcare](#) sets out the conditions under which a patient may travel to another EU country to receive medical care and reimbursement. It covers healthcare costs, as well as the prescription and delivery of medications and medical devices.
- [European Reference Networks](#) (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on **complex and rare diseases** and represent the major achievement of the European spirit of collaboration, sharing and health investment in the field of rare diseases.
- [The Conclusions of the Council of the European Union on June 2017](#) have recognised that European Reference Networks, when fully developed, will represent an opportunity for the dissemination of knowledges and innovative practices in the **provision of specialised health services in the field of rare diseases**.



How we cooperate to advocate for patients with rare diseases at the EU level (I)

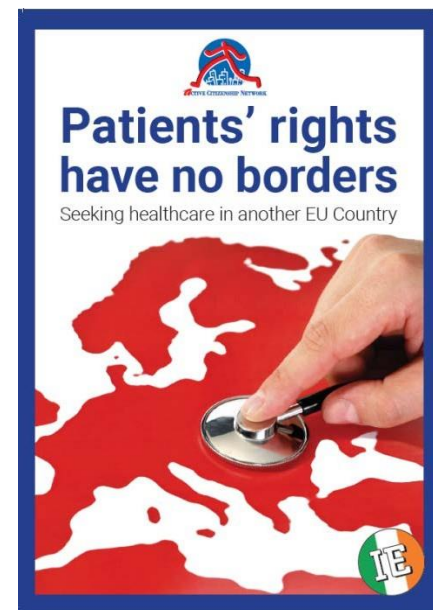


European Patients' Rights & Cross-Border Healthcare

Member of the European Parliament Interest Group

- AT  Lower Austrian Patient and Nursing Advocacy
- BE  Active Citizenship Network
- BG  Patients' Organizations "With You"
- CY  Cyprus Alliance for Rare Disorders
- CZ  [Klub pacientů mnohočetný myelom, z.s.](#)
- EL  Greek Alliance for Rare Diseases
- DE  Bürger Initiative Gesundheit e.V.
- DK  Rare Disease Denmark
- FI  [Association of Cancer Patients in Finland](#)
- FR  Inter-Association on health (CISS)
- EI  Irish Patients' Association
- ES  Plataforma de Organizaciones de Pacientes
- HR  Croatian Association for the Promotion of Patients' Rights
- HU  Hungarian Federation of People with Rare and Congenital Diseases
- IT  [Cittadinanzattiva](#) - Tribunal for patients' rights
- LT  Council of Representatives of Patients' Organizations of Lithuania
- NL  European Patients Empowerment for [Customised Solutions](#)
- MT*  Malta Health Network
- PL  Institute for Patients' Rights & Health Education
- PT  Azorean Chronic Pain Patients Association
- RO  Romanian National Alliance for Rare Diseases
- SL  SIBAHE Slovenian Foodbank; [Kultlab Celje Society](#);
Association for justice and control
- SK  Society of Consumer Protection
- UK  Pelvic Pain Support Network

- [Network of 26 organizations in 24 Countries](#) active in CBHC
- [Multi annual campaign on the implementation of the Directive 2011/24/EU](#)
- Policy dialogue initiatives at the Eu Parliament ([A](#) – [B](#) – [C](#))
- [Focus of the VII Edition of the EU Patients' Rights Day in Brux](#)
- Publications in peer review journals ([A](#) – [B](#))



How we cooperate to advocate for patients with rare diseases at the EU level (II)



Focus on Medical Sciences Journal
Feb 2021, Volume 7, Issue 1

Review Article

ERNs Multi-Stakeholder Forum to Enhance Patients' Rights and to Enhance Cooperation on Cross-border Healthcare

Mariano Votta ¹, Daniela Quaggia ², Michaela Papavero ³

¹ Director Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate 6, 00183 Rome, Italy

² Senior Project Manager Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate 6, 00183 Rome, Italy

³ Community & Fellowship Assistant at Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate 6, 00183 Rome, Italy

* Corresponding author: Mariano Votta, Director Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate 6, 00183 Rome, Italy. Phone: +3906367181; Fax: +3906 36718333; E-mail: mvotta@cittadinanzattiva.it

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Cross-border Healthcare
Health Disparities
European Health Union
PAGs
Civic Participation

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Abstract

Directive 2011/24/EU established a comprehensive set of patients' rights regarding access to health services in the EU. However, reports from both public actors (including the European Parliament and the European Court of Auditors) and private entities agree that the overall impact of such legislation on patients is still too limited. Until today, in the EU only 2% of citizens have planned treatment abroad. However, if properly adopted, the Directive can help reduce health inequalities not only among the Member States but within each country, benefitting the remaining 98% of the EU population. Against this background, the new EU4Health 2021-2027 program aims to boost the EU's preparedness for major cross-border health threats and, among other things, will try to expand successful initiatives like the European Reference Networks for rare diseases and continue to pursue international cooperation on global health threats and challenges. This will necessarily require a broader involvement of the actors engaged in cross-border healthcare. Given that the Directive's success depends highly on citizens being aware of their rights, it will be necessary to put citizens at the heart of decision-making by complementing the existing channels of engagement.

PUBLIC CONSULTATION

Roadmap "Cross-border healthcare – evaluation of patients' rights". Read Cittadinanzattiva-Active Citizenship Network's feedback about the Roadmap "Cross-border healthcare – evaluation of patients' rights" (February 2021)

139 | The European Files | Strengthening needs to engage through innovation a governance



MARIANO VOTTA
Director Active Citizenship Network

The value of investing in Advanced Therapy Medicinal Products: combining sustainability innovation and respect for patients' rights

Compared to the European Health Union, we probably also need to go beyond the current narrative concerning the European pharmaceutical innovation which – in synthesis – seems to be driven by the following equation: "The role of the pharmaceutical sector is to develop drugs that are profitable and sustainable". Taking about the future markets for the health sector, the European Commission (COM) has the most recent report about the health expectations of patients' when building up the health system and considering the overall role of the health sector. The overall picture of the health sector shows that the expectations are not only about the quality of the services, but also about the way of providing them. Traveling at different speeds, how can innovation and access be combined? To try to answer these questions, Cittadinanzattiva – through its EU Branch Active Citizenship Network – has recently organized a workshop in the European Parliament, moderated by Dr. Paolo Di Lorenzo, Director of the European Health Union, to discuss the role of the health sector in the future and to make proposals for a change in the institutional framework of the health sector.

All patients' rights patients have the right to access Advanced Therapy Medicinal Products and to be able to benefit from them. In addition, the health system can be an enabler to improve the value of ATMPs, reduce costs and benefits, and engage "new types of therapies" and also different patient and assisting parties, while ensuring the high quality and the safety and lasting benefits over time. For the patients and for national health systems, it is time to change the institutional framework. To do this, we need to coordinate the role of the patient and of the

as an investment and not as a cost, which is possible if a decision is made to invest. There are several elements – the current economic and financial conditions of the health sector, the cost of these therapies, the savings generated over time, in particular the cost of missed work or other – that can be used to justify the investment. The overall picture shows that the health sector is not only a provider of services, but also a provider of innovation. The overall picture shows that the health sector is not only a provider of services, but also a provider of innovation. The overall picture shows that the health sector is not only a provider of services, but also a provider of innovation.

It is also clear that the health sector is not only a provider of services, but also a provider of innovation. The overall picture shows that the health sector is not only a provider of services, but also a provider of innovation. The overall picture shows that the health sector is not only a provider of services, but also a provider of innovation.

AUOTORES
Globalize your Research

Journal of Women Health Care and Issues
Mariano Votta*

Open Access Review Article

Supporting Non-Communicable Disease Patients in Time of The Covid-19 Pandemic: From Motivating Them to Qualifying the Role of Their Caregivers

Mariano Votta ¹, Ana Avilés ², Rossana Di Renzo ³, Mariela Vimercati ³
¹ Junior Project Manager, Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate, 6 - 00183 Rome, Italy.
² Community & Fellowship Assistant, Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate, 6 - 00183 Rome, Italy.
³ Expert in narrative medicine, Responsible for Cittadinanzattiva-Emilia Romagna of the CRAMCRd - Regional Coordination of Chronic, Rare and Disability Disease Associations.

Corresponding Author: Mariano Votta, Junior Project Manager, Active Citizenship Network, c/o Cittadinanzattiva APS, Via Cerate, 6 - 00183 Rome, Italy.

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THE VALUE OF INVESTING IN ADVANCED THERAPY MEDICAL PRODUCTS

ALL patients' rights patients have the right to access Advanced Therapy Medicinal Products and to be able to benefit from them. In addition, the health system can be an enabler to improve the value of ATMPs, reduce costs and benefits, and engage "new types of therapies" and also different patient and assisting parties, while ensuring the high quality and the safety and lasting benefits over time. For the patients and for national health systems, it is time to change the institutional framework. To do this, we need to coordinate the role of the patient and of the

Wednesday, March 1st 2017
10:30 - 12:30
ROOM ASP7H1
European Parliament, Brussels
Hosted by MEP David Borrell, EFDD Group

For further information, please contact the secretariat:
Active Citizenship Network, Banca Farnesio - secretariat@activecitizenship.net

European Patients' Rights & Cross-Border Healthcare
Member of the European Reference Network Group

EXPLORING AREAS AND BENEFITS OF COOPERATION IN CROSS-BORDER HEALTHCARE TO PROTECT PATIENTS' RIGHTS

Wednesday, March 1st 2017
10:30 - 12:30
ROOM ASP7H1
European Parliament, Brussels
Hosted by MEP David Borrell, EFDD Group

For further information, please contact the secretariat:
Active Citizenship Network, Banca Farnesio - secretariat@activecitizenship.net

How we cooperate to advocate for patients with rare diseases at the EU level (III)

1. A “Call to Action” to try to make up ground for patients' right to access advanced therapies, calling for a change in institutional mentality to classify spending on ATMPs as an investment and not as a cost.

ATMPs revolution & the respect of the patients' right to access to care
43 associations from 12 countries signed the Call to Action



2. The cost of these therapies could be amortised over the years in relation to the savings generated over time. In particular, they could be included in the state budget over several years and not all in the year of expenditure.

3. This would significantly increase the financial sustainability of these costs by the public sector over time and promote greater and more equitable use of ATMP medicines in the population, without putting public finances at risk.

- Presented at Parliament in Oct. '22 & April 2023, + training seminar in April'22
- Endorsed by 43 Patients Advocacy Groups (PAGs)
- This proposal received an encouraging endorsement from the new Italian health minister in January 2023 and a signal of attention by the EU Health Commissioner last April 2023 (see the video)

How we cooperate to advocate for patients with rare diseases at the EU level (IV)



24 OCTOBER 2022 | Brussels: "Policy dialogue with Institutions at the EU Parliament on equitable patient access to advanced therapies across Europe"



26 April 2023 | The celebration of the 17th European Patients' Rights Day today at the European Parliament: Advanced Therapies in Europe between sustainability, innovation and patients' rights



"ATMPs give hope to patients where therapeutic options are currently lacking or non-existent and they must be able to reach patients sooner. Our priority is always to put patients' interest first". Watch the video message of the EU Health Commissioner Stella Kyriakides at the #EPRD23

#VITA
Value and Innovation of Advanced therapies
ATMPs revolution: empowering leaders of EU civic and patients' advocacy groups

EU online training seminar
24 MAY 2022 | 15:00 – 17:00 CEST

For further information, please contact: brussels@activecitizenship.net

The project was carried out with the unconditional contribution of Celgene - Bristol-Myers Squibb, Glaxo Sciences, Pfizer, PTC, Roche

Per te Seguiti

Ripostato da Natasha Azzopardi Muscat

Sandra Gallina @SandraG... 2g ...

But it's not all doom and gloom. The revision of EU pharma legislation can ensure equitable access to medicines. Thought-provoking question from @chrisfeame: 'shall we exempt health expenditure from budget deficit calculations?' health is an investment, not a cost. #ehfg2023

EU Health - #HealthUnion

10 21 1.603



Mariano Votta

Responsible EU Affairs at Cittadinanzattiva

Director Active Citizenship Network

m.votta@cittadinanzattiva.it

@marianovotta