

Strengthening the European Ecosystem for Equitable Patient Access to Advanced Therapy Medicinal Products

4 July 2024 • 14:00-16:00 CEST

On-line EU meeting



Media partners:  

The event is realized with the unconditional support of the #VITA Coalition, which is coordinated by LS CUBE Global Law Firm



Introduction

Mariano Votta, Head of European Affairs, Cittadinanzattiva-Active Citizenship Network

Good afternoon and welcome to everyone. Thank you once again for accepting our invitation. It is always a pleasure to take part in these meetings, which are necessary to explore topics of special significance for us and, more in general, for the patient community at European level.

As you know, even better than I do, access to advanced therapies is extremely complicated. It is precisely this situation that motivates us to find solutions, or at least to explore new ways to enable as many patients as possible to have access to them.

Those of you who follow us regularly will remember that the 17th edition of the European Patients' Rights Day - organised at the European Parliament in April 2023 - was entirely dedicated to the theme of access to treatment for Advanced Therapy Medicinal Products.

On that occasion, EU Health Commissioner Stella Kyriakides stated that *“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”*¹. Today, we start from this statement in order to understand how to guarantee eligible patients faster but also wider access to care: in which direction should we move and how should the newly elected European institutions act in order to make the right to care within the context of ATMPs enforceable?

For my part, in this brief introduction, I would like to emphasise some principles that are important to us, which will help to understand why we are involved in this issue. To do so, I must refer to the European Charter of Patients' Rights², which we promoted in 2002 and which is still a milestone for those involved in healthcare advocacy at local, national and European level.

In particular, the topic of Advanced Therapy Medicinal Products I believe is linked to the following patients' rights: 1) the right to access care³ (*“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, etc.”*); 2) the right to personalized treatment⁴ (*“Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs”*); 3) the right to information⁵ (*Every individual has the right to access to all kind of*

¹ <https://www.youtube.com/watch?v=-BpxcyJ21IU>

² www.activecitizenship.net/charter-of-rights.html

³ <https://www.activecitizenship.net/charter-of-rights/rights/127-2-right-of-access.html>

⁴ <https://www.activecitizenship.net/charter-of-rights/rights/117-12-right-to-personalized-treatment.html>

⁵ <https://www.activecitizenship.net/charter-of-rights/rights/126-3-right-to-information.html>

information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available); and 4) the right to innovation⁶ (Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations).

Certainly, innovation is an essential principle for anyone concerned with health, and the principle of innovation is also inevitably linked to that of equity and homogeneity of access to care. Travelling at different speeds, how can innovation and access be combined?

We all know that there is product innovation, but there is also process innovation: often the first, if not accompanied by the second, risks not expressing its full potential. And this, I believe, is also the case for ATMPs. Not surprisingly, for example, the Alliance for Regenerative Medicine recently denounced that *“If the EU HTA process does not modernize its approach, the reviews will fail to capture the clinical value of ATMPs and jeopardize patient access to transformative therapies in the coming years”⁷*. An analysis by ARM found that nearly 90% of the ATMPs licensed and used in Europe would have been rejected if a standard HTA methodology had been applied⁸.

Even though it is not related to the new HTA regulation, the proposal we will hear shortly from Prof. Marè on the topic of access to ATMPs has in some ways to do with an innovation not of product, but of building a new framework, to strengthen - as also described by the title of today's meeting - the European ecosystem for equitable

⁶ <https://www.activecitizenship.net/charter-of-rights/rights/119-10-right-to-innovation.html>

⁷ <https://alliancerm.org/wp-content/uploads/2023/06/20230608-V5-HTA-Advocacy.pdf>

⁸ <https://alliancerm.org/press-release/joint-clinical-assessment-methodology/>

patient access to Advanced Therapy Medicinal Products (ATMPs).

An institutional mindset change is needed, which has already been called for by 43 Patient Advocacy Groups (PAGs) from 12 Member States through a call to action⁹ aimed at unlocking the potential of advanced therapies for a large number of European citizens , while respecting the budget constraints that healthcare has for some time now, in almost all of Europe.

In all this, the role of Cittadinanzattiva-Active Citizenship Network is to facilitate discussion and exchange of knowledge among the various stakeholders at the European level. In coherence with our mission to protect and advocate the enforcement of rights through greater civic participation in public policies, we are committed to the ultimate goal of seeing the right to access to care, including advanced therapies, recognised. For this reason, we have decided to collaborate with the #VITA (Value and Innovation for Advanced Therapies coalition) consortium committed on this front in a dimension that is not only national.

In short, advanced therapies represent a new, yet another challenge for public health systems in all countries, and we want to know more about it because, as always, being well-informed and up-to-date is often the best prerequisite for promoting greater activism.

Thank you again for your attention. I wish you a fruitful meeting.

⁹ <https://www.activecitizenship.net/insights/406-advanced-therapies-medicinal-products-revolution-the-respect-of-the-patients-right-to-access-to-care-a-call-to-action.html?highlight=WyJhdG1wcyJd>