

#VITA

Value and Innovation of Advanced therapies

ATMPs revolution: empowering leaders of EU civic and patients' advocacy groups

EU online training seminar

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WELCOME

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Good afternoon and welcome to everyone. It's always a pleasure to meet in these reserved but necessary meetings to explore issues that are particularly significant to us.

In my brief introduction, I would like to hint at some principle important to us that will let us try to figure out why we are involved in this issue.

To do that I have to refer to the European Charter of Patients' Rights¹ promoted by us in 2003 and still now a milestone for those who work in advocacy for health care at local, national, and European levels.

¹ www.activecitizenship.net/charter-of-rights.html

In particular, the issue of Advanced Therapy Medicinal Products I believe is related to the following patients' rights: the patients' right of access² to care (*"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.*), the patients' right to personalized treatment³ (*"Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs"*), the patients' right to Innovation⁴ (*Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations*) and the the patients' right to Information⁵ (*Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available*).

Those who usually follow us will remember that last April, during the XVI Edition of the European Patients' Rights Day⁶, among others, the topic of access to treatment for Advanced Therapy Medicinal Products has been introduced. Now we want to dedicate to this argument the importance that it deserves, without any doubt it is a complex issue in which information is still scarce among whole population and also several Patients' Advocacy Groups (PAGs).

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. www.activecitizenship.net/charter-of-rights/rights/351-2-right-of-access.html

³ 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. www.activecitizenship.net/charter-of-rights/rights/341-12-right-to-personalized-treatment.html

⁴ 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. www.activecitizenship.net/charter-of-rights/rights/343-10-right-to-innovation.html

⁵ Right to Information: Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available. www.activecitizenship.net/charter-of-rights/rights/350-3-right-to-information.html

⁶ www.activecitizenship.net/patients-rights/projects/418-european-patients-rights-day-2022-programme.html

For sure, innovation is an essential principle for anyone involved in health, and the principle of innovation is also inevitably linked to the principle of equity and homogeneity of access to care, access that must be equal throughout the territories: how to combine the above-mentioned patients' right in this new challenging context, characterized by health and humanitarian emergencies (fighting the pandemic and the war in Ukraine above all) with inevitable repercussions also on the financial resources of the countries of the European Union?

Today our attention will be paid to the opportunities and challenges of the new advanced therapies, which are expected to increase significantly over the next decade as the speakers I thank in advance will illustrate: an encouraging but equally challenging scenario, considering the high costs and public budget constraints faced by several EU countries: aspects that must be addressed today in order not to arrive unprepared tomorrow.

In fact, the volume of resources necessary to access these therapies and the methods of financing are - in perspective - the decisive junctions, because they will determine the lesser or greater availability of health systems to bear the cost. The persistence of the current situation would inevitably lead, for example, to the delay in access to advanced therapies by potential patients and the limitation of their use to subgroups of patients, within the approved indication. It is, therefore, necessary to prepare in time, to avoid having to face very delicate choice problems for the health service and phenomena of discomfort on the part of potential beneficiaries: which therapies can be reimbursed, given the resources available? Who and on the basis of what arguments will explain to potential patients that access to treatment is not possible for everyone? Who will decide the access thresholds and based on what criteria? What do we need to know in order not to be unprepared? And in what direction should we promote a change to guarantee the right of access to as many potentially

eligible patients as possible, avoiding forms of rationing or problems of financial sustainability?

In short, advanced therapies represent a new, yet another challenge for public health systems in all countries, and we are willing to learn more because, as always, to be well-informed and updated is often the better precondition to promote more activism, we are confident also in the area of the for Advanced Therapy Medicinal Products.

Thanks again for the attention. I wish you a fruitful seminar.