



## WELCOME

By Mariano Votta

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Good afternoon and welcome to everyone. It's always a pleasure to meet you in this Institutional venue, and for our first event in presence after the pandemic, I want to thank the Member of the European Parliament (MEP) Tomislav Sokol, always very sensitive when the topic affects the condition of patients across Europe and the protection of their rights.

As you know, today our attention will be paid to the opportunities and challenges linked with the Advanced Therapies Medicinal Products (ATMPs).

The **speed** at which research is advancing and the **projections** we have from the EMA regarding future approvals of new ATMPs jar with the **slow pace** of decisions for which every day of waiting deadens the more than legitimate expectations of a

growing number of patients across Europe. Today we are asking policymakers for a commitment to keep up, while we will leave it to experts to make a proposal on how to do so. As anticipated in our introductory documents, we will not talk today about research and clinical trials in the field of ATMPs nor about translational medicine, nor about the regulatory framework for AMTPs, nor about the identification of criteria and guidelines for the authorisation of centers for clinical trials of Advanced Therapy Medicinal Products. We will not deal with pre-market aspects today, but with the **sustainability of ATMPs** once the research is finished.

Let us project ourselves into a post-market dimension, with the therapeutic option coming onto the market and having to be reimbursed by National Health Systems. In this regard, when it comes to ATMPs, we speak of reimbursement in terms of potentially eligible population as opposed to budget constraints: a narrative that inevitably undermines **patients' fair access to such therapies** for reasons mostly related to cost containment. Hence the issue of sustainability and access to ATMP, which we will try to address today thanks to the experts we have invited and whom we thank in advance, not by chance experts first and foremost in economic issues, indispensable for approaching the specificity and complexity of the topic we wish to raise today.

They are going to illustrate a potential win-win economic-accounting solution for all stakeholders involved, of which I take no credit but am happy to contribute to making

it **known** to an audience of civic and patient association leaders, as was the case in May with an ad hoc seminar, to **disseminate it** with a positioning document, the call to Action “ATMPs revolution & the respect of the patients’ right to access to care” that you also received today, and, of course, to **present it for** the first time to European institutions and relevant stakeholders through today's meeting.

In particular, as also highlighted in the Call to Action, endorsed by 43 civic & patients organizations that I thank (some of them present here or connected), the issue of ATMPs is related at least to the following patients’ rights recognized by the European Charter of Patients’ Rights<sup>1</sup>, a milestone for those who work in advocacy for healthcare at the national and European level: the patients’ right to access to care<sup>2</sup>, the patients’ right to personalized treatment<sup>3</sup>, the patients’ right to Information<sup>4</sup> and the patients’ right to Innovation<sup>5</sup>. About it, 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. As we know, the costs of this

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<sup>1</sup> [https://ec.europa.eu/health/ph\\_overview/co\\_operation/mobility/docs/health\\_services\\_co108\\_en.pdf](https://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf)

<sup>2</sup> [www.activecitizenship.net/charter-of-rights/rights/351-2-right-of-access.html](http://www.activecitizenship.net/charter-of-rights/rights/351-2-right-of-access.html): *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.*

<sup>3</sup> [www.activecitizenship.net/charter-of-rights/rights/341-12-right-to-personalized-treatment.html](http://www.activecitizenship.net/charter-of-rights/rights/341-12-right-to-personalized-treatment.html): *Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.*

<sup>4</sup> [www.activecitizenship.net/charter-of-rights/rights/350-3-right-to-information.html](http://www.activecitizenship.net/charter-of-rights/rights/350-3-right-to-information.html): *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.*

<sup>5</sup> [www.activecitizenship.net/charter-of-rights/rights/343-10-right-to-innovation.html](http://www.activecitizenship.net/charter-of-rights/rights/343-10-right-to-innovation.html): *Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.*

technology are high so that access by patients is often hindered by public health budget limits: how to combine the above-mentioned patients' rights 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? More than ever, in order to avoid the risk that patients' needs remain totally invisible in this dark period we are going through, it is therefore time for a paradigm shift to which the institutions are called.

Of course, I would thank in advance those representatives of the institutions who accepted our invitation.

We believe that the relevance of these innovative therapies places them at the center of the discussion on health and health policy choices for the future and the sustainability of each National Health System (NHS) across Europe. This will pose very delicate problems of choice and rationing in terms of access to treatment for patients, which could result in the treatment of fewer patients than eligible and therefore potentially treatable.

A solution in terms of identifying the resources necessary to finance them must therefore be tackled today so as not to arrive unprepared tomorrow.

Bearing in mind once again the starting point of the today meeting is the fact that the traditional reimbursement and budgeting schemes are unable to amortize the value

of ATMPs, whose costs and benefits are not aligned, please let me thank in advance the moderator Mariam Zaidi, international news presenter, reporter and expert on the EU. So, she is the right person to chair our event today.

I wish you a fruitful meeting.