

Securing Equitable Patient Access to Advanced Therapies across Europe

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FINAL REMARKS

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On the subject of Advanced Therapies Medicinal Products (ATMPs), in this period we are witnessing several interesting initiatives hosted by the European Parliament, which we have to thank for the sensitivity shown: days ago there was the TRANSFORM event with the Launch of the "Charter with Solutions to Enable Safe and Timely Patient Access to ATMPs in Europe"; today our initiative for which I again thank MEP Sokol, and on November 29 there will be the Alliance for Regenerative Medicine's initiative.

If we are going to say it, what is missing is a leading role of civic and patient associations, because too few are still aware of the issue. It may be because they are somewhat niche initiatives, bringing forward specific and complex proposals, but we must try to convey them in the everyday and concrete condition experienced by so many people in Europe, to bring to our side the largest number of actors who care about the issue of protecting patients' rights.

Hence the effort we are making, as Active Citizenship Network, to broaden the constituency of PAGs across Europe that are informed about the topic and then be promoters or in support of initiatives.

At the same time, the request we are making to the experts in the field is to make themselves available to the associations to better understand what is at stake. We will then all be more ready and active on the issue. To do what?

- First, to give a better and better account of the treatment expectations and access difficulties of patients in their own countries;
- For example, to encourage Parliamentarians in our home country to take inspiration to create in their own Parliament an aggregation of Parliamentarians as there is in Europe, as in the European Parliament

there is TRANSFORM, in the Italian Parliament there is the Interest Group "Sustainable Innovation in Healthcare" as very well described by its promoter, the Italian Parliamentary Daniela Manca.

- Promoting multi-stakeholder alliances and launching appeals like ours that gathered more than 40 associations among global/European/national civic & patients organizations that I still thank.

From today's meeting, as civil society stakeholders & patient associations, we take home first of all an increased awareness that all potentially eligible patients have the right to access care in particular ATMPs, and that national health budget constraints cannot be a barrier to patients to have access to advances therapies. How to leverage this message?

- We will continue our efforts to identify and carve out those spaces for participation and dialogue in which to bring the demands of patients potentially eligible for the new ATMPs and the proposal discussed today. I point out that in Italy, one of the last acts of the past government was that of October 3 when the General Secretariat of the Ministry of Health issued an act of guidance on how civil society, i.e., associations, companies, and organizations involved in health issues, can participate in the Ministry's decision-making processes.

- About the issue discussed today, individual patient associations could assign the ethics committees at the National Drug Agencies, as we will try to do in Italy where we are within the National Ethics Committee for clinical trials related to ATMPs at the Italian Drug Agency, established by Decree February 1, 2022, of the Minister of Health; in Europe, we will try to do with The Committee for Advanced Therapies (CAT) at EMA, which of course we had invited for today.

- Also at the European level, as an ideal next step of this meeting, I am pleased to announce that we will dedicate to the topic of advanced therapies the 17th European Patients' Rights Day, whose European celebrations are scheduled here in the European Parliament next April 26, 2023.

We will work for the European Day to be supported both by the MEPs Interest Group "European Patients' Rights and Cross-border Healthcare," which has already supported today's initiative and whom I thank in particular in the person of MEP co-chair Tomislav SOKOL and by the TRANSFORM MEP Interest Group with whom we have an appointment scheduled to share today's messages and better join efforts with their "Multi-stakeholder Alliance."

Certainly, we will continue to denounce the closures and work to avoid the rebound mentioned earlier: the Ministries of Health, in principle, are in favor of reasoning about the proposal but, on the other hand, are sending the ball back to Eurostat. In turn, Eurostat says that the issue is not within their competence but within the competence of the European Commission because underlying it is a policy choice that they are obliged to follow, so they defer to the Directorate General for Economic and Financial Affairs (ECFIN) headed by Commissioner Paolo Gentiloni, who is probably still unaccustomed

to dialogue with civil society and Patients' Advocacy Groups (PAGs) and who defers to DG Santè for issues like these.

In this context, we find on the one hand the fact that EMA is working to approve more and more ATMPs in the coming years, and on the other hand the patients from all over Europe with their legitimate expectations getting higher and higher and waiting for answers from the European institutions. A signal is also due to those European citizens who still believe in a Europe capable of putting first the concrete needs of its citizens, who in these dark times risk remaining totally invisible.

We are aware that the goal, but also the difficult one, is not to convince those who work in health care and are involved in public health, the practitioners are already (almost) all convinced. The challenge is mainly to convince those who have other parameters, those who see numbers before people, convinced that what we are going to propose is not a dream book or a proposal out of thin air or divorced from current contingencies. We are asking for innovations, that we rewrite certain accounting rules, etc. seemingly far removed from real life, and that instead determine less or more access to care. Therefore, I believe it is imperative to bring civic and patient sensitivities to this battle, which will not be short-lived.

We will have the perseverance to insist convinced that the time will come when even those who have responsibility for economic rather than health policies believe that we are not interlocutors or that we must take the demands for which we are fighting away from them, sooner or later will have to reconsider and listen to us. We will try to do that, as mentioned, starting with the next European Patients' Rights Day (where we will explore the possibility that the topic might become part of the Council Conclusions by the end of the next triptych) to which, of course, you are all invited.

Finally, as always, I have my list of acknowledgments (and now let me thank, as always, those who made this initiative possible)

- Once again, thanks to all the panelists, our moderator Mariam Zaidi, our media partner Health Europa and all the participants, connected and here in the room.
- Thanks to the Czech Presidency of the Council of the EU for the patronage.
- As always, thank you to the staff of Active Citizenship Network (Bianca, Maddalena, Daniela, Ginevra), our Event & Purchasing Department, and our communication office.
- Finally, let me remember you that the event has been realized with the unconditional support of #VITA - Value and Innovation of Advanced Therapies Coalition (which includes Bristol Myers Squibb, Gilead Sciences, Janssen, Pfizer, PTC Therapeutics, Roche, Vertex), Consortium which is coordinated by

LS CUBE Global Law Firm led by Rosanna that I thank together with her very valuable team and consultants.

For the ones interested to follow the Active Citizenship Network initiative, we'll be here again on November 15th to discuss AMR.

Meantime, stay safe and have a good night. Bye!