EUROPEAN PATIENTS' RIGHTS DAY 2023

Advanced Therapy Medicinal Products in Europe: combining sustainability, innovation and respect for patients' rights

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FINAL REMARKS

Domenica Taruscio
MD, Former Director - National Centre for Rare Diseases, Italian National Institute of Health; Co-Founder - Undiagnosed Diseases Network International (UDNI); International Rare Diseases Research Consortium (IRDiRC) FCC Member

I would like to thank for the invitation to this important event dedicated to 17th European Patients' Rights Day.
During this meeting, invited patients, patients' representatives, professionals and Institutional authorities presented, from diverse angles and perspectives, activities and experiences existing at a European level on Advanced Therapies Medicinal Products (ATMPs).
The event highlighted a widespread interest toward ATMPs, many promising aspects, as well as some remarkable steps forward at scientific level.
Meanwhile, many obstacles still exist to the development of and access to these therapies, leading to significant issues of innovation, sustainability, equity and full respect of patients' rights.
Opportunities and barriers have been highlighted.

Let's consider **weakness** and **strengths**, **threats** and **opportunities** that have emerged from this meeting.

Weakness
-ATMPs require **high investment costs**: they are personalized therapies with high complexity
-there is a lack of regulatory uniformity and transparency
- lack of public funds
-there are inequalities of access (multidimensional)

Strengths
there is an incresing interest and commitment by stakeholders, as highlighted by this event at the EU Parliament
Advanced therapies are becoming **not only a dream, a hope, but a reality of cure** for patients suffering from serious diseases who have not yet found a concrete therapeutic answer.
They are one-shot therapies, that is, they are administered with a single treatment, unlike traditional drugs, which provide for repeated and regular treatments, with an evident temporal misalignment between current costs, concentrated in the short term, and future benefits, spread over a longer time horizon;
-they cure (even otherwise fatal diseases) or significantly transform the clinical history of the patient who has no therapeutic alternative, intervening directly on the causes of the disease, improving the quality of life of the patient and his family.

Threats
-Lack of attention to equity and sustainability
-Need to maintain attention also toward safety

Opportunity
ATMPs offer great opportunities for innovative treatment and personalized medicine to patients, since they are treatments that start from the patient's cells and therefore act on the genetic cause at the origin of the diseases, also in some cases even with a single administration the ability to offer benefits to the patient forever.
Therefore, a favorable momentum can lead to :
-promoting a clear, transparent, and adequate regulation regarding ATMPs,
-increasing investment in research related to ATMPs
-improving data sharing and patients registries
- reducing health inequalities in access to ATMPs at EU level, among Member States (MS) and inside a MS.
In particular, the increasing committment and active participation of patients to all steps can be **a main driving force.**

In conclusions

- Europe can take a leading role in this area if exploit the partnership public-private and patients;
- ATMPs can be a workable model for fit-for-purpose innovation in healthcare, paving to exploitation of research achievements and personalized medicine.
- A governance effort is required to support increased scientific activities and make these achievements available to all European citizens;
- hence, **the active role of patients and patients' associations is pivotal for patient centred innovation.**
- Most important besides the reinforcements of patient rights, it's crucial to ensure to ensure patients active participation to all steps from research and development to design process clinical trials, access rules, including the exploitation of **citizen science initiatives**.