European Alliance for Transformative Therapies

European Alliance for Transformative Therapies (TRANSFORM)

Aligning4ATMPs: Paving the road ahead of a critical year

Event Report

22 April 2026

Executive Summary

On 22 April 2026, the Co-Chairs of the MEP Group for Transformative Therapies, MEPs Stine Bosse (Renew, Denmark), Billy Kelleher (Renew, Ireland), and Tomislav Sokol (EPP, Croatia), co-hosted a roundtable with the TRANSFORM Alliance. The discussion focused on the Biotech Act I and its implications for Advanced Therapy Medicinal Products (ATMPs).

The meeting was structured around three breakout tables addressing different aspects of the Biotech Act I, and brought together key representatives from the European Institutions, alongside stakeholders from the industry, academia, healthcare professionals and patient organisations. The meeting aimed to foster cross-sector dialogue on key aspects of the legislation, with the objective to define priority axes and actionable recommendations.

Through the different perspectives shared, a clear and cross-cutting message emerged: the EU's main challenge will be to ensure the effective implementation of EU frameworks on the ground. This requires enhanced coordination and cooperation between the 27 Member States, as well as a stronger EU support to strengthen Member States capacity to invest, innovate, and build a truly competitive and equitable health ecosystem capable of delivering safe, high-quality, and tailored treatments to patients in Europe.

Opening Remarks

Opening the discussion, MEP Stine Bosse presented the Biotech Act I as a major strategic opportunity to position Europe as a global leader in ATMPs. She described the Act as a "historic, bold and far-reaching initiative" to streamline clinical trials, build industrial capacity, and strengthen biosafety frameworks. In particular, she emphasised the importance of working alongside stakeholders across the health value chain and genuinely integrating their perspectives, including through collaborative platforms such as the roundtable organised by TRANSFORM. In this context, she also highlighted the importance of exploring and implementing structural solutions to reduce fragmentation in the European regulatory landscape, including the potential development of the 28th Regime. Finally, she cautioned against relying solely on

legislative changes to accelerate clinical trials, noting that current delays are often linked to uneven implementation of existing rules across and by EU Member States.

> *"We need to build a 28th Regime in the context of the EU Biotech Act, not only to centralise decision-making at the European level, but to incentivise Member States to work better and faster."*
>
> - **Member of the European Parliament Stine Bosse (Renew Europe, Denmark), Co-Chair of the MEP Group on Transformative Therapies**

Building on these opening remarks, MEP Tomislav Sokol highlighted the role of ATMPs as a key driver of competitiveness and strategic autonomy for the EU at a particularly opportune time. He stressed their potential to address current unmet medical needs, thereby strengthening Europe's position in the global innovation landscape. MEP Sokol also underlined the synergies with the European Health Data Space and the Critical Medicine Act.

Moderated discussions

Participants all agree on the following premise:

Europe currently benefits from a strong scientific base and a robust innovation pipeline, particularly in the field of ATMPs. It must therefore capitalise on this advantage and use the Biotech Act I as an opportunity to strengthen its competitiveness in the global biotechnology landscape, notably in relation to the United States and China. European companies risk relocating outside the EU in response to procedures - both at European and national levels - that are overly complex, lengthy, and costly, and which remain heterogeneous across Member States. Such fragmentation continues to act as a barrier to innovation and research within the EU. Achieving this objective requires enhanced coordination and cooperation between EU Member States, both at operational and structural levels. And to be effective, this coordination must be supported and driven at the European level.

1) Building a truly operational and coherent innovation health ecosystem

Participants emphasised that the EU's capacity to develop and deploy ATMPs remains hindered by persistent fragmentation between EU Member States. This reflects insufficient harmonisation, coordination, and collaboration across regulatory frameworks, infrastructure, data sharing, and human capacity. Several participants noted that these shortcomings (also caused by uneven will at the level of national authorities) limit the effectiveness of European reforms and constitute a major obstacle to accelerating clinical trials and approval procedures.

In this context, key priorities include strengthening coordination between Member States through greater harmonisation of practices, improved interoperability of infrastructure, and enhanced data access and sharing, particularly within the framework of the European Health Data Space (EHDS), as well as better performance monitoring at both national and national-European levels.

Participants also highlighted the need to invest in technical and human capacity, including training and skills development. These efforts should be supported through strengthened European funding mechanisms, with active involvement of Member States in their implementation, and targeted support for startups and Small and Medium-sized Entreprises (SMEs).

2) Strengthening Europe's attractiveness and competitiveness

Participants underlined that EU is often perceived as a complex, slow, and insufficiently predictable environment for industrial stakeholders, which undermines its capacity to attract investment and retain research and production activities within the EU.

To address these challenges, participants suggested simplifying and accelerating procedures through "fast-track" mechanisms, including easing the requirements of Environmental Risk Assessments (ERA), for instance for GMO-containing products, while maintaining safety standards. They also stressed the need to confirm and maintain facilitative measures, such as the GMO exemption for clinical-stage ATMPs, as well as improve coordination between regulatory frameworks such as the Critical Trials Regulation (CTR), EU Health Technology Assessment Regulation (HTAR), Genetically Modified Organisms (GMO) Regulations, In Vitro Diagnostic Regulation (IVDR) and EU Substances of Human Origins (SoHO) Regulation. Participants also supported strengthening support for industrial stakeholders (particularly SMEs) through direct funding mechanisms to counter declining private investment at national level.

Participants put the spotlight on the need to connect the EU Centres of Excellence for ATMPs proposed in the Biotech Act I to existing networks (such as European Reference Networks (ERNs) and initiatives like Joint Action on Integration of ERNs into National Healthcare Systems (JARDIN), while avoiding excessive geographical concentration.

3) Ensuring equitable and sustainable access for patients

Discussions highlighted a persistent gap between innovation and effective patient access to ATMPs in Europe, which are largely driven by administrative, financial, and logistical barriers, as well as uneven implementation of existing frameworks across the 27 EU Member States, including of the Cross-Border Healthcare Directive.

Notably, patients face significant challenges in accessing and participating in clinical trials due to complex administrative procedures and delays, which not only slows down the development of innovative treatments but also negatively impacts the quality of care and patient outcomes.

To address these issues, participants emphasised the need to strengthen patient involvement at all stages of the ATMPs lifecycle, including clinical research, evaluation, and reimbursement decisions. This also requires improved implementation of the Cross-Border Healthcare Directive across EU Member States, particularly regarding reimbursement and the specific care pathways associated with ATMPs (e.g. multiple visits and long-term follow-up). Notably, participants

highlighted the need to improve reimbursement mechanisms for ATMPs and to support the development of adaptive pricing models. This could be facilitated by improving the alignment and predictability of clinical value assessments through Joint Clinical Assessments (JCAs). Ensuring long-term patient follow-up to better document the efficacy and safety of ATMPs will be crucial.

Conclusion

MEP Kelleher concluded the meeting by emphasising the value of contributions from patients and stakeholders across the healthcare ecosystem in shaping the Biotech Act, as well as in its future implementation on the ground, to ensure that research and the innovations arising from it translate into treatments that are truly tailored, safe, and equitably accessible in Europe. Notably, He stressed the importance of ensuring that patients are meaningfully involved in governance and decision-making processes, recognising their essential role in shaping the future of healthcare innovation.

While welcoming several of the new structures proposed under the Biotech Act I, including the Biotechnology Support Network and ATMP Centres of Excellence, he stressed that their success would depend on being built around genuine multistakeholder collaboration, meaningful patient involvement, and open, transparent engagement to strengthen expertise and build scientific trust. Looking ahead to the upcoming negotiations, he urged policymakers to consider carefully how these governance structures will be implemented in practice.

He encouraged participants to build on the relationships formed and the ideas developed during the event, while underlining that the MEP Interest Group on Transformative Therapies will remain closely engaged throughout the legislative process, with the future of ATMPs serving as one of the key indicators of the Biotech Act's success.