European Alliance for Transformative Therapies

EUROPEAN ALLIANCE FOR TRANSFORMATIVE THERAPIES (TRANSFORM)

TRANSFORM MEP Interest Group Conference 2024

Relaunch of the MEP Interest Group: EU policy to secure safe and timely access to advanced therapies for patients

21 November 2024 | 10:00-12:30 CET | European Parliament, Brussels, Spinelli 5G1

Hosted by

#MEPsforATMPs

MEP Billy Kelleher
Renew Europe, Ireland

Moderated by Jacki Davis

BACKGROUND

With the recent European Commission communication on boosting the biomanufacturing and biotechnology sector, and Mario Draghi's report on the EU's competitiveness, innovative health technologies are set to become one of the EU's key tools for driving Europe's competitive edge forward.

The EU's competitive goals can only be achieved through a cohesive and comprehensive approach to the proposed Pharmaceutical Package and other legislative tools set to influence development of, and patient access to, Advanced Therapy Medicinal Products (ATMPs) in the years to come. The proposed changes to the EMA's structure and responsibilities will help promote patient-centric decision-making and a streamlined regulatory process for ATMPs; more clarity on cross-border access pathways, hospital exemption, (high) unmet medical need and the collection and use of real-world evidence would go even further in ensuring timely access. The EU HTA Regulation – with ATMPs undergoing joint assessment in 2025 – is another key legislation that will soon impact advanced therapies in the EU.

EVENT OBJECTIVES

The TRANSFORM Alliance believes that safe and timely access to innovative medicines for EU citizens can be realised through multi-stakeholder engagement with patients, clinicians, academics, developers and decision-makers at all levels. The relaunch of the TRANSFORM MEP Interest Group for the 10th mandate of the European Parliament is an opportunity to reiterate our shared commitment to fostering a patient-centric innovation ecosystem for ATMPs in Europe.

Key topics and questions on the agenda

1. **Priorities for the new mandate**
   How can regulatory and market support for cell and gene therapies further the European Commission's ambitions to improve industrial competitiveness and advance public health goals?
2. **Taking stock of the European Parliament's position on the Pharmaceutical Package, and the progress made during Council negotiations**
   How have different perspectives on regulatory sandboxes, unmet medical need and ATMP manufacturing and delivery affected the extent to which the proposed regulatory tools support the development and availability of ATMPs?
3. **Improving access to advanced therapies through EU-level action**
   How can the EU HTA Regulation support timely patient access at national level?

AGENDA

09:30-10:00	**Welcome coffee** *Side interviews with media and TRANSFORM content creators*
10:00-10:10	**Keynote address from MEP host** • MEP Billy Kelleher (Renew, Ireland), First Vice-President Renew Europe Group & Co-Chair TRANSFORM MEP Interest Group
10:10-10:15	**Welcome remarks from the TRANSFORM Alliance** • Martine Pergent, TRANSFORM Steering Group Member
10:15-10:20	Patient testimonial: **The potential of gene therapies for people living with a rare disease**
10:20-11:20	Panel I: Taking stock of the current legislative and regulatory landscape for ATMPs **The potential of the Pharmaceutical Package and the forthcoming EU HTA Regulation** • Adam Parnaby, Bristol Myers Squibb • Iva Galovic, European Federation of Neurological Associations **To cover:** Key issues for ATMPs in the Pharmaceutical Package, preparation for HTA Regulation implementation in January 2025, EU support for Member States coordination and best practice sharing on assessment of innovative therapies
11:20-11:25	Clinician testimonial: **The complexities of delivering cell therapies to patients**
11:25-12:15	Panel II: Shaping the future environment for the development and delivery of ATMPs **Advanced therapies in the biotechnology and biomanufacturing strategy and proposed Biotech Act** • MEP Stine Bosse (Renew, Denmark), Co-Chair TRANSFORM MEP Interest Group • Matt Bolz-Johnson, EURORDIS • Francis Pang, Orchard Therapeutics **To cover:** Barriers to ATMPs development in the EU and the recommendations in Draghi's report on competitiveness; Member State collaboration and best practice sharing to increase patient access to ATMPs; infrastructure and workforce training for ATMPs; interaction between the Biotech Act, Life Sciences Strategy and the Pharmaceutical Package.
12:15-12:20	**Closing remarks from the TRANSFORM Alliance**
12:20-12:30	**Conclusions and next steps for the TRANSFORM MEP Interest Group** • MEP Tomislav Sokol (EPP, Croatia)
12:30-13:30	**Meeting close and networking reception** *Side interviews with media and TRANSFORM content creators*