



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

MEP Billy Kelleher
Renew Europe, Ireland



Moderated by Jacki Davis

#MEPsforATMPs

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 <i>Side interviews with media and TRANSFORM content creators</i>
10:00-10:10	Keynote address from MEP host <ul style="list-style-type: none"> MEP Billy Kelleher, First Vice-President Renew Europe Group & Co-Chair TRANSFORM MEP Interest Group (Confirmed)
10:10-10:15	Welcome remarks from the TRANSFORM Alliance <ul style="list-style-type: none"> Martine Pergent (Confirmed)
10:15-10:20	Patient testimonial: The potential of gene therapies for people living with a rare disease Video clip testimonial on the significance of gene therapies for patients <ul style="list-style-type: none"> Pre-recorded video with Armand Bagaïni (IPOPI)
10:20-11:10	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 <ul style="list-style-type: none"> MEP Tomislav Sokol (EPP, Croatia) (Confirmed) Paul de Boissieu, Chair, HTA subgroup on JCA (Confirmed) Adam Parnaby, Bristol Myers Squibb (Confirmed) Iva Galovic, European Federation of Neurological Associations (Confirmed) <p>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</p>
11:10-11:15	Clinician testimonial: The complexities of delivering cell therapies to [chronic condition/cancer] patients Video clip testimonial the role of clinicians in delivery of cell therapies to patients <ul style="list-style-type: none"> Pre-recorded video
11:15-12:15	Panel II: Shaping the future environment for the development and delivery of ATMPs From bench to bedside, how can the EU support a strong ecosystem for the development and delivery of advanced therapies? Presentation on the Commission's priorities for the Strategy for European Life Sciences, and its implications for ATMPs (10') <ul style="list-style-type: none"> Representative from Unit D.2 "Health Innovations & Ecosystems", DG RTD (Confirmed) MEP Stine Bosse (Renew Europe, Denmark), Co-Chair TRANSFORM MEP Interest Group (Confirmed) Matt Bolz-Johnson, Mental Health Lead and Healthcare Advisor, EURORDIS (Confirmed) Francis Pang, Orchard Therapeutics (Confirmed) <p>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 and Life Sciences Strategy.</p>
12:15-12:20	Closing remarks from the TRANSFORM Alliance <ul style="list-style-type: none"> Dr Alexander Natz, EUCOPE (Confirmed)
12:20-12:30	Conclusions and next steps for the TRANSFORM MEP Interest Group <ul style="list-style-type: none"> MEP Vytenis Andriukaitis (S&D, Lithuania) – (invited)
12:30-13:30	Meeting close and networking reception <i>Side interviews with media and TRANSFORM content creators</i>