

European Alliance for Transformative Therapies (TRANSFORM)

MEP Interest Group 2023 Conference

COUNTDOWN TO EU ELECTIONS

HOW CAN POLICYMAKERS SECURE THE PROMISE OF ADVANCED THERAPIES FOR PATIENTS OVER THE NEXT 6 MONTHS?

12 October 2023 | 10:00 – 12:15 CET

European Parliament, Brussels, Room Spaak 5B1



Event co-hosted by:

MEP Ondrej Knotek (RE, Czechia), Chair of the TRANSFORM MEP Interest Group



MEP Susana Solís-Pérez (RE, Spain), Member of the TRANSFORM MEP Interest Group

BACKGROUND

The current mandate of the European Parliament is ending, with elections in June 2024. This gives MEPs little more than six months to work on outstanding files.

The Parliament is currently reviewing several health legislative proposals that will impact the ATMP ecosystem, including: the Regulation on Substances of Human Origin (SoHO), crucial for products derived from human substances; the European Health Data Space (EHDS), a cornerstone of a new era of digital health, interoperability and innovation; and the proposed Pharmaceutical Package, which contains rules that impact

every stage of product development, from R&D to access. Together, they present an opportunity to future-proof healthcare systems and strengthen patients' access to care by ensuring the EU is attractive for R&D and, therefore, new therapies.

The TRANSFORM MEP Interest Group is pleased to host this timely event, together with the TRANSFORM multi-stakeholder Alliance, to explore how policymakers can ensure innovative therapies are a cornerstone of EU healthcare for the future.

KEY QUESTIONS TO BE ADDRESSED

1. Have the current EU healthcare legislative proposals sufficiently acknowledged the specificities of highly specialised, advanced therapies (ATMPs)?
2. How can EU-level action support healthcare systems to integrate innovation and ensure access for patients to advanced therapies?
3. Beyond legislation, what action(s) is needed to ensure safe and timely access to potentially transformative treatments across the EU?



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for Transformative
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Agenda

10:00	<p>Opening keynote address from Chair of MEP Interest Group Overview of Parliament's activities since 2019: key achievements for the ATMP ecosystem during this mandate</p> <p>MEP Ondřej Knotek (Renew Europe, Czechia)</p>
10:10	<p>Welcome from TRANSFORM Steering Group representatives The importance of a multi-stakeholder dialogue for ATMPs</p> <p>Alexander Natz (Secretary General, EUCOPE) Martine Pergent (President, IPOPI)</p>
10:20	<p>TRANSFORM Alliance presentations & discussion Is forthcoming EU policy fit for ATMPs? The case for why cell and gene therapies are unique</p> <p>Presentations from TRANSFORM Alliance members on TRANSFORM's positions and the specificities of ATMPs: ATMPs through the lens of patients: Eleni Antoniou, Thalassaemia International Federation ATMPs through the lens of clinicians: Claire Booth, European Society of Gene and Cell Therapies ATMPs through the lens of researchers: Giovanni Migliaccio, European Paediatric Translational Research Infrastructure ATMPs through the lens of industry: Anne Kerber, Bristol Myers Squibb</p> <p>Concluding words from MEP Interest Group member: MEP Billy Kelleher (Renew Europe, Ireland)</p>
11:00	<p>Patient intervention The potential of ATMPs for the patient community - Living without Thalassaemia</p> <p>Testimonial from two former Thalassaemia patients: Giuseppe Selvarolo and Simona Annese</p> <p><i>Translation IT/EN available</i></p>
11:10	<p>Panel debate with audience Q&A Towards safe and timely access to ATMPs: what are the solutions for the EU's access challenge?</p> <p>MEP Susana Solís Pérez (Renew Europe, Spain) Martine Pergent, IPOPI Ana Hidalgo-Simon, reNEW Consortium Thomas Bols, PTC Therapeutics</p>
12:00	<p>Closing remarks What to expect from the European Parliament over the next 6 months? Quo vadis after 2024?</p> <p>MEP Tomislav Sokol (EPP, Croatia)</p>
12:15	<p>Meeting close <i>Followed by networking reception (60 minutes)</i></p>