



European Alliance
for Transformative
Therapies

European Alliance for Transformative Therapies (TRANSFORM) MEP Interest Group discussion

The EU Pharmaceutical Package:
A once-in-a-generation opportunity to deliver the promise of transformative therapies to all European patients

1 JUNE 2023 | 15:00 – 17:15 CEST | Online

Event hosted by the **MEP Interest Group on Transformative Therapies**

Moderated by Jacki Davis

#MEPsforATMPs

15:00 *Opening keynote address from Chair of MEP Interest Group
Launch of TRANSFORM's Position Paper on the Pharmaceutical Package: What does the legislative review mean for the European ATMP ecosystem?*

MEP Ondřej Knotek (Renew Europe, Czechia) - confirmed

15:05 *In conversation with TRANSFORM members: TRANSFORM's ambition for safe and timely access to ATMPs in the EU*

Exchange between **Simone Boselli (Public Affairs Director, EURORDIS)** and **Alexander Natz (Secretary General, EUCOPE)** - confirmed

15:15 *Deep dive on TRANSFORM's positions:*
From research to clinical development: a dynamic European environment that responds to patients' needs

- **Tomislav Sokol**, Member of the European Parliament (EPP, Croatia) - confirmed
- **Giovanni Migliaccio**, Board of Directors, European Paediatric Translational Research Infrastructure (EPTRI) - confirmed
- **Dimitrios Athanasiou**, PDCO Member European Medicines Agency (EMA), Board Member, World Duchenne Organization (WDO) – confirmed
- **Jack Brownrigg**, Early Clinical Development Team Lead (BioMarin) – confirmed

Q&A

Topics covered: incentives to innovative research, academic development and translational research, GMO exemption, clinical trials, early dialogues

16:05	<p><i>Deep dive on TRANSFORM's positions:</i></p> <p><i>From marketing authorisation to access: a future-proof regulatory framework for innovative therapies in the Pharmaceutical Package</i></p>
	<ul style="list-style-type: none"> • Ondřej Knotek, Member of the European Parliament (Renew, Czechia) - <i>confirmed</i> • Laura Savini, Policy Officer, European Haemophilia Consortium (EHC) - <i>confirmed</i> • Ana Hidalgo-Simón, reNEW Translational Ambassador, Leiden University Medical Center - <i>confirmed</i> • Paschalia Koufokotsiou, Policy Officer, Pharmaceutical and Health Policy, DG SANTE - <i>confirmed</i> • Caroline Pothet, Deputy Head of Advanced Therapies, European Medicines Agency - <i>confirmed</i> • Caroline Mougin, Market Access Director for Cell and Gene Therapies, Novo Nordisk - <i>confirmed</i> <p>Q&A</p> <p><i>Topics covered: regulatory sandboxes, EMA restructuring, HE, RWE, access pathways, early dialogues</i></p>
17:00	<p><i>Reflections from the panel discussions: The view from a Member State</i></p> <p>Member state representative (tbc)</p>
17:10	<p><i>Closing keynote address: the role of TRANSFORM in the upcoming negotiation of the Pharmaceutical Package</i></p> <p>Stelios Kypouropoulos, Member of the European Parliament (EPP, Greece) - <i>confirmed</i></p>
17:15	<p><i>Meeting close</i></p>



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