

# Realising the Potential of Transformative Therapies: 5 Policy Asks to Optimize Cross-border Patient Access to Advanced Therapies

By the **MEP Interest Group on Transformative Therapies**

#MEPsforATMPs

**A well-developed and highly functioning cross-border healthcare framework at the EU level is essential** to provide patients with access to needed life-saving and life-transforming therapies.

Building on the [TRANSFORM Recommendations](#), the TRANSFORM MEP Interest Group calls for **legislative simplification**, the right for citizens to **access information about their disease and treatment of their disease** and **EU funding to enable cross-border patient access to ATMPs**.

- 1. Calls upon the Commission to review both the Cross-Border Health Services Directive (Directive 2011/24) and the Social Security Regulation (Regulation 883/2004) - merging the authorization and reimbursement rules of both under the Social Security Regulation 883/2004**

It is clear that the current system for the cross-border access to healthcare works only in certain well-defined cases, essentially covering smaller, healthcare interventions (e.g. hip replacements, knee operations, etc) or more sophisticated treatments (e.g. radiology treatment for certain cancers), which are well covered and reimbursed in all EU Member States. It does not work for rare disease patients who need highly specialised care, only available in certain Member States. In order to address this, the European Commission needs to:

- Simplify the system and make it more transparent to patients by merging the two different sets of authorization and reimbursement rules (Directive 2011/24 and Regulation 883/2004) under Regulation 883/2004 which is directly applicable.
- Health services should be paid directly as if the patient is insured by the social security system of that country and the treatment should be approved in the country of treatment basket of care.
- Develop guidelines setting acceptable and harmonised review and approval timelines to expedite time-to-treatment in the EU.

## **2. Extend the role of the European Reference Networks (ERNs) to assess whether cross-border treatment is clinically justified**

- ERNs should be involved in the confirmation of the therapeutic option as well as the knowledge sharing/diagnosis to facilitate the national approval process for cross-border funding.

## **3. Upscale the role of National Contact Points (NCPs) to support the provision of information on cross-border treatment and act as an interface between cross-border patients, ERNs and their national social security systems**

- Provide training to NCPs on the specificity of some ATMPs and the need for highly specialised and multi-disciplinary teams for their administration, so that they can proactively inform their citizens about the rights they have to cross-border access when they need it and the process to follow.
- Encourage NCPs to provide information on the funding paths and approval steps, taking into account their country's specificities and language. Provide clear information on which centres in the EU are administering ATMPs. This information could be centralized on the European Commission's website. The NCPs could become the interface between cross-border patients, treatment centres/ERNs and national security systems to assist a patient with the application for cross-border treatment and the actual treatment pathway.

## **4. Operationalise a pan-European infrastructure for the long-term follow-up of patients treated with ATMPs**

- For ATMPs that require administration in specialist centres, encourage multi-stakeholder discussions to designate suitable centres and develop adequate delivery and follow-up care protocols that support and follow the patient long after the delivery of the therapy.

## **5. Provide EU cross-border funding to minimize the burden on families, e.g. by covering travel and costs of stay**

- Allocate funding from EU4Health to the patient and the family to travel to the center of treatment and undergo the treatment, and to allow them to stay in the host country for the required period.

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