Question for written answer E-002940/2021
to the Commission
Rule 138
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Subject: Revision of the EU's cross-border healthcare framework

The EU's cross-border healthcare framework (Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and Regulation (EC) 883/2004 on the coordination of social security systems) is critical to enable patient access to gene therapies and other advanced therapy medicinal products (ATMPs) for severe and rare genetic diseases.

Unfortunately, the current framework does not work for patients in practice. As the Directive places the burden of upfront payments on patients, the Regulation is currently the only viable route for cross-border ATMP treatment. It is not without its own shortcomings, however, and marked by a complex and often opaque approval process and varying approval timelines across the EU that can delay or block access to potentially curative treatment.

While the evaluation of the Directive is under way, it is therefore critical that the Commission examines the current and future needs of patients with both pathways in mind.

1. Will the Commission consider taking steps to improve the use of the Regulation, notably by tackling disparities in approval timelines and approval processes, in the short term, for example via new guidelines or guidance documents to support Member States' decision-making?

2. Will the Commission commit to an overhaul of the Directive's reimbursement procedures, to remove financial barriers preventing people living with rare diseases from accessing treatment?