Question for written answer E-003922/2018
to the Commission
Rule 130
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Subject: The need for updated legislative provisions regarding advanced therapeutic medicinal products (ATMPs)

Over the past 50 years, rare disease patients, such as those with haemophilia, have greatly benefited from advances achieved in science, many of which have significantly improved the lives of patients and their families. These scientific advances, in the form of breakthrough treatments, have often been the catalyst for legislative change (e.g. the 2000 Orphan Medicinal Products Regulation and the 2007 Advanced Therapeutic Medicinal Products (ATMPs) Regulation). However, as Commissioner Andriukaitis has stated, 'scientific developments with potential for application in healthcare are occurring at an unprecedented pace'[1].

Novel therapies are currently in development for many rare diseases. Yet, the latest joint European Commission and EMA action plan[2] on ATMPs does not foresee changes to the present legal framework, despite the Commission's own report from 2014 on the ATMPs Regulation concluding that 'too burdensome requirements could have detrimental consequences for public health as it could prevent the appearance of valid treatments for unmet medical needs'[3].

To this end, could the Commission clarify the reasoning behind the decision not to establish new/updated legislative provisions for ATMPs?

1 http://europa.eu/rapid/press-release_SPEECH-17-3546_en.htm
2 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/10/WC500237029.pdf
3 http://ec.europa.eu/transparency/regdoc/rep/1/2014/EN/1-2014-188-EN-F1-1.Pdf