Question for written answer E-002202/2020
to the Commission
Rule 138
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Subject: EU orphan drugs

According to the European Medicines Agency's 2019 annual report on the use of the special contribution for orphan medicinal products, 169 orphan drugs have been approved in the EU since 2000.

Twenty years after the adoption of Regulation (EC) No 141/2000 (the Orphan Regulation), we see that this legislation is fulfilling its aim to stimulate the costly research and development of orphan medicinal products. Another finding of this report is that only five new orphan medicines were approved in 2019. In addition, the number of applications submitted for orphan medicine designation stayed the same as in 2018. Considering that the Commission is evaluating the functioning of the Orphan Regulation:

1. Does it believe that this concerning trend in new orphan medicines is related to the incentives for finding treatments for rare diseases that have been available to developers and researchers in the last few years?

2. What steps will it take to help the EU's pharmaceutical and biotech industry to remain an innovator and world leader, as per the mission letter?