Question for oral answer O-000135/2016
to the Commission
Rule 128
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on behalf of the Committee on the Environment, Public Health and Food Safety

Subject: Review of the regulation on paediatric medicines

Children constitute a vulnerable population group with developmental, physiological and psychological differences from adults. Age-related and developmental-related research, as well as the availability of suitable medicinal products, are of particular importance. The Paediatric Regulation was adopted ten years ago to ensure high-quality research into the development of medicines for children and appropriate authorisation of medicines used by them. This regulation has delivered on many of its goals, but several shortcomings were identified in 2013 in the progress report adopted by the Commission, particularly as regards paediatric investigation plans and paediatric oncology.

What will be the focus of the public consultation to be launched during the autumn?

How does the public consultation fit in with the report provided for in Article 50 of the regulation which the Commission had to adopt before the end of January 2017?

Beyond those two elements, does the Commission intend to revise the regulation?

How does the Commission intend to ensure that all therapeutic areas are covered equally, and how will it improve the impact of the regulation in areas of particular paediatric need, such as paediatric oncology?

How does the Commission plan to address the shortcomings of the Paediatric Regulation, including:

– the fact that so few paediatric investigation plans have been completed,

– the near-systematic deferral of paediatric studies, and

– the extremely low number of paediatric use marketing authorisations (PUMAs)?

Tabled: 9.11.2016
Forwarded: 11.11.2016
Deadline for reply: 18.11.2016