



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Director

Brussels,
 SANTE/B5/FS/sgr/ares(2016)3460619

Dear Petitioner,

Subject: Review of the Paediatric Regulation

Commissioner Andriukaitis asked me to thank you for your letter of 23 April 2016 and to reply on his behalf. You may have seen his twitter message that he read through the warm letters from children and parents affected by cancer with great understanding.

You are concerned about the impact the Paediatric Regulation¹ had so far on the development of medicines for children with cancer. You are therefore calling for changes to the Regulation in order to ensure that more of the new medicinal products for adults that are currently in the pipeline are subject to mandatory paediatric research.

The Paediatric Regulation is a unique tool in the current body of pharmaceutical law, as it is the only instrument, which compels companies to conduct age-specific research in a sector where development is usually company driven. This empowerment of directly influencing the research programmes of private undertakings comes however with certain limitations in order to remain balanced.

I am aware that there have been unfortunately some missed opportunities in the past with regard to oncology products, where companies rather relied on some of the derogations provided by the law than engaging in paediatric research on their own motion.

We are currently having a closer look at the impact the Paediatric Regulation had over the last ten years, on patients, research and undertakings. The results will be published next year in a report to the EU legislature, the Council and the Parliament. Before finalising its analysis, the Commission will invite the public to share its experience. This will be done through a public consultation, which will be launched in autumn this year.

Your comments come therefore at a timely moment and I would invite you to consider expressing your views during this consultation.

I much appreciate your concern for children with cancer. Like every other patient suffering from life-threatening diseases our children should receive a state-of-the-art therapy. The Commission supports the fight against cancer with many actions and I therefore thank you for bringing this matter to our attention.

Yours sincerely,

Tapani Piha
 pp Andrzej Rys

¹ Regulation (EC) No 1901/2006 concerning medicinal products for paediatric use, OJ L 378, 12.12.2006, p. 1.