Question for written answer E-010157/2014
to the Commission
Rule 130
Glenis Willmott (S&D)

Subject: EU Paediatric Regulation

The EU Paediatric Regulation was a huge step forward in ensuring that medicines are developed specifically for children, which has too often been overlooked in the past. When it comes to childhood cancers, there are sometimes no treatments available, and clinical trials using new medicines might be a child's only hope of survival.

The current rules mean that drugs may be exempted from obligations to carry out research in children if they are licensed for diseases that do not occur in children. However, this means that some cancer treatments are granted a waiver from the obligations of the Paediatric Regulation, despite the fact that the medicines have mechanisms of action which could be effective against childhood cancers.

The Commission recently published updated guidelines on the Paediatric Regulation, and in the public consultation many stakeholders raised the problem concerning waivers, including the Institute of Cancer Research, the German Society of Pediatrics and Adolescent Medicine, the Netherlands' Medicines Evaluation Board and the UK's Teenage Cancer Trust.

Unfortunately, the guidelines have not fully addressed the problem, and it seems that the only solution will be to revise the legislation itself.

Given the urgency of the problem, and the feedback the Commission has already received, will the Commission revise the Paediatric Regulation before the previously stated date of 2017?