Question for written answer E-010587/2015
to the Commission
Rule 130
Jana Žitňanská (ECR)

Subject: Regulation No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use

The main objective of Regulation No 1901/2006 on medicinal products for paediatric use is to facilitate the development and accessibility of medicines for children without subjecting children to excessive clinical tests and without delaying authorisation of medicines for other age groups. However, many professionals, pharmaceutical company representatives and even parents of children suffering from various illnesses claim that this regulation has not brought any fundamental changes and that children still have to undergo drastic treatments with serious side effects, travel out of the EU for treatment, or even rely on the practice of 'off-label' treatment, i.e. using medicines for unapproved purposes.

Given that 21 % of the EU population is under 18 and that thousands of them become seriously ill each year,

what specific steps, besides the planned revision of the regulation in 2017, does the Commission plan to take in order to improve the situation with regard to paediatric medicines?