Question for written answer E-001884/2017
to the Commission
Rule 130
Enrico Gasbarra (S&D)

Subject: Paediatric medicines

20% of the EU population is under the age of 18. The off-label use of drugs in children and adolescents is extremely widespread, as 50-90% of drugs have no paediatric indications because no studies have been carried out on that age group.

New EU legislation (Regulation No 1902/2006) was introduced with the aim of improving children's health by enhancing the quality of research and the protection of ethical safeguards.

Since the Paediatric Medicines Regulation came into force, only two innovative targeted anti-cancer drugs have been authorised for a paediatric malignancy based on an agreed paediatric investigation plan (PIP).

That said, what action is the Commission taking to submit, in due course, the report referred to in Article 50 of the Paediatric Medicines Regulation and to remove the current obstacles to innovation in the paediatric medicines sector?

How does it intend to renew, in Horizon 2020, the funding provisions developed to support high-quality paediatric clinical research, following a critical review of the projects currently being funded?