Question for written answer E-001980/2017 to the Commission Rule 130 Mireille D'Ornano (ENF)

Subject: Vaccination against rotavirus infections

In 2006, the vaccines RotaTeq and Rotarix were granted two marketing authorisations in the European Union. Rotavirus vaccination is effective in 84 % to 91 % of cases.

The World Health Organization recommends vaccination for young infants and has issued a statement on the risks and benefits of rotavirus vaccination (May 2015). However in France, the 'Haut Conseil de la santé publique' [High Council for Public Health] issued a negative opinion on 21 April 2015 in light of the risk of serious side effects and in particular acute intussusception. There were, in fact, 47 cases of acute intussusception reported in France between 2006 and 2015, which corresponds to an incidence of between one and six cases per 100 000 young infants vaccinated. Worldwide the notification rate for adverse side effects stands at 38.4 cases per 100 000 young infants.

In September 2016, the European Centre for Disease Prevention and Control issued its preliminary scientific advice on rotavirus vaccination.

Will the Commission be monitoring instances of side effects and in particular, acute intussusception?

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