Question for written answer E-005306/2020
to the Commission
Rule 138
Tomislav Sokol (PPE)

Subject: Environmental impact assessment

The first major study that pointed to the presence of medicines in the environment was published as far back as 1970. It is recognised that most medicines end up in soil and water. There are over 3 000 active pharmaceutical ingredients on the EU market, and environmental impact assessments have still not been carried out for some of them. Such an assessment was not a regulatory requirement for placing a medicinal product on the market until 2006. More precisely, the obligation to submit an environmental risk assessment for human medicinal products with an application for marketing authorisation was introduced by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 / EC on the Community code relating to medicinal products for human use, which the Member States were required to implement by 30 October 2005. In the light of this:

1. Exactly how many active pharmaceutical ingredients are on the European Union market for which no environmental impact assessment has been conducted?

2. According to the Commission, do such pharmaceutical ingredients pose a danger to the environment and/or to human health?

3. Does the Commission consider it necessary to make a legislative intervention by introducing an obligation to assess the environmental impact of those pharmaceutical ingredients that have been placed on the market without such an assessment having been conducted?