Question for written answer E-003626/2020
to the Commission
Rule 138
Marc Botenga (GUE/NGL)

Subject: Data and market exclusivity derogation Covid-19

Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems contains a derogation from data and market exclusivity periods applicable in the European Union. EU legislation does not currently contain a similar derogation for compulsory licences granted for the marketing of medicinal products within the EU.

1. Does the absence of such a derogation with regard to marketing within the EU limit the effect of compulsory licences granted by Member States, in accordance with TRIPS flexibilities, considering that EU rules on data and marketing exclusivity periods could effectively block the marketing of generic medicinal products for a period of up to 10 years?

2. What other current EU legislation does the Commission identify as potentially weakening the effect of the use of TRIPS flexibilities by Member States?

3. In the context of a future vaccine for SARS-CoV-2 or treatment of Covid-19, does the Commission plan to propose any derogation from data and market exclusivity for compulsory licences granted for the marketing of medicinal products within the European Union?