Question for written answer E-000977/2021
to the Commission
Rule 138
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Subject: Rights and obligations under conditional marketing authorisations

On 21 December 2020, the Commission granted the BNT162b2 vaccine a conditional authorisation for the EU market, although other countries have approved it for emergency use only. The Commission's website[1] states that conditional marketing authorisations are valid for one year. They impose the same liability on holders as standard marketing authorisations, but also come with specific obligations, for example to carry out new studies within a certain time frame in order to confirm that the benefits still outweigh the risks.

1. What specific obligations were set in the conditional marketing authorisations for the COVID-19 vaccines?

2. What is the time frame for meeting these obligations?

3. If anyone were to suffer long-term side-effects as a result of the vaccine, how would they claim compensation under a conditional marketing authorisation?

[1] https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_2390