Priority question for written answer P-002494/2022
to the Commission
Rule 138
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Subject: Provenance of strains of the updated COVID-19 vaccine

In the past two weeks the reproduction number for the SARS-CoV-2 virus has exceeded 1 in many countries. At present, only a few months before autumn, there is still no formal decision on the composition of the updated COVID-19 vaccine or a clear research direction.

On 15 and 17 June this year, the European Medicines Agency (EMA) launched a review of the preclinical data for the bivalent vaccines of BioNTech/Pfizer and Moderna.

And on 30 June the US Food and Drug Administration informed manufacturers wishing to update their COVID-19 vaccines that they should develop a modification that would add the spike protein component Omicron BA.4/5 to the current vaccine formulation to create a bivalent booster vaccine. Given the above, and in view of the information made available:

1. When the EMA begins its work to review the preclinical data of the updated Comirnaty and Spikevax vaccines, which strain (Omicron, BA.1, BA.4/5, Wuhan strain) will be concerned?

2. Is there a possibility that, following the review of the research in the coming autumn, the updated COVID-19 vaccines of the EU and US will target different strains?

3. What action strategy does the Commission intend to adopt in a hypothetical situation where the World Health Organisation, regulatory bodies such as the EMA, FDA, etc. and other bodies of the International Coalition of Medicines Regulatory Authorities adopt different recommendations on the modified composition of adapted COVID-19 vaccines?