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Answer given by Ms Kyriakides
on behalf of the European Commission
(23.11.2020)

On 28 August 2020, the Commission signed an agreement with AstraZeneca to purchase COVID-19 vaccines for all EU Member States with a possibility to donate to lower and middle income countries or to re-direct to other European countries. All Member States will be able to purchase 300 million doses of the AstraZeneca vaccine, with an option for further 100 million doses, to be distributed on a population-based pro-rata basis.

The Commission ensured that the agreement with AstraZeneca is fully compliant with EU law and in particular fully respects and protects citizens' rights, in line with the Product Liability Directive[1]. In accordance with the Directive, liability remains with the manufacturer. However, in order to compensate for potential risks taken by manufacturers due to the unusually shorter timespan for vaccines development, the agreement provides for Member States to indemnify the manufacturer for possible liabilities incurred only under specific conditions set out in the agreement.

The Commission has made clear throughout the implementation of the Vaccines strategy[2] that it is not prepared to make compromises on the application of the existing rules that apply to bringing a pharmaceutical product into the market. These principles are equally valid for any indemnification clause the Commission negotiates.

Thus, the provisions on liability and indemnification do not alter in any way the regulatory burden of proof borne by the companies to demonstrate the safety and efficacy of their products. Any vaccine put on the market will have to meet the necessary safety requirements and undergo the independent scientific assessment by the European Medicines Agency as part of the EU market authorisation procedure.

[1] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985, p. 29–33.
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0245&from=EN