Since mid-July 2022, the European Medicines Agency (EMA) has been evaluating initial data of the following mRNA vaccines: the bivalent version of Spikevax combining original Wuhan strain with the Omicron variant BA.1, the monovalent version of Comirnaty BA.1 and the bivalent version of Comirnaty combining Wuhan strain with BA.1. The Commission is also aware that companies are working on a candidate version of the vaccine including BA4/5.

The Commission is not in a position to comment on the US Food and Drug Administration (FDA) strategy. The European experts will closely assess the evolving epidemiological situation and will decide on the best way forward for Europe. It should be noted that EMA is closely collaborating with global regulators (including FDA) on the key principles on adapting vaccines to tackle virus variants\(^1\). Based on the data currently available, adapted vaccines that target an Omicron strain offer increased protection. Bivalent adapted vaccines, which combine a Wuhan and an Omicron strain, offer an even wider immune response.

The Commission relies on the independent scientific advice of EMA to authorise new medicines. The EU’s vaccines contracts give Member States access to adapted vaccines as soon as they are authorised in the EU and made available by manufacturers. It is for Member States to make decisions about which of these vaccines they choose to deploy. The Commission will support Member States in this and continue to provide coordination via the Vaccines Steering Board.

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