MODERNA BIOTECH SPAIN, S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

22nd November 2022

Spikevax bivalent Original/Omicron BA.4-5
(50 micrograms/50 micrograms)/mL dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)
(elasomeran/davesomeran)

European Marketing Authorisation number EU/1/20/1507/006

Dear Healthcare Professional,

MODERNA BIOTECH SPAIN, S.L. (Moderna) in agreement with the European Medicines Agency (EMA) and the HPRA would like to inform you of the following:

- As of 20 October 2022, an updated bivalent vaccine, **"Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection"** has been authorised for use as a **0.5 mL booster** dose in individuals 12 years of age and older in addition to the BA.1 bivalent vaccine authorised for use on 1 September 2022.

- Moderna would like to draw your attention to the difference in formulation and packaging compared to "Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection" that was authorised for use on 1 September 2022.

The use of this vaccine should be in accordance with official recommendations. Consult with your local health authority for more information.

Background on updated vaccine

In the approved SmPC and Patient Leaflet, the medicinal product is identified as "Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection." The vaccine dose is 0.5 mL and is to be administered intramuscularly.

The cartons and vial labels for this product refer to the trade name as "Spikevax bivalent Original / Omicron BA.4/BA.5 dispersion for injection."

- The trade name on the carton and vial label differs slightly from the final approved trade name in the SmPC/Patient Leaflet.

- The **booster dose of 0.5 mL** does not appear on the vial label or carton.

- The **booster dose of 0.5 mL** with Spikevax bivalent Original/Omicron BA.4-5 has a different concentration than the original booster dose (Spikevax 0.2 mg/mL dispersion for injection or Spikevax 0.1 mg/mL dispersion for injection at a 0.25 mL dose).

- Neither the vial label nor carton for Spikevax bivalent Original/Omicron BA.4-5 specifies that the product is a **booster dose**.

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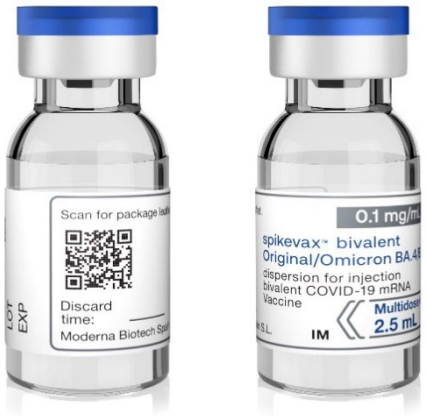
Healthcare professionals are asked to take the following actions prior to administration of the Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL vaccine to a recipient:

1. Ensure that the correct Spikevax bivalent vaccine is selected for use. For comparison purposes:

Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection was labeled as **"Spikevax 0.10 mg/mL 0 (Zero) / O (Omicron) dispersion for injection."** 	**Bivalent BA.1 Booster** **Blue cap** **Green border label** 
Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection 	**Bivalent BA.4-5 Booster** **Blue cap** **Grey border label** 

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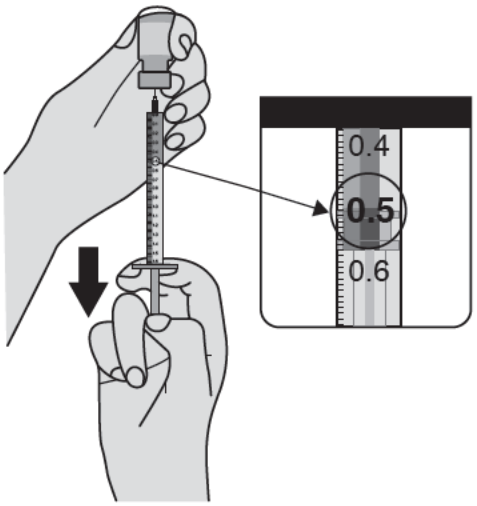
2. Ensure that each eligible recipient **12 years of age and older** receives a **0.5 mL dose** of Spikevax bivalent Original / Omicron BA.4-5 dispersion for injection. There should be an **interval of at least 3 months** between administration of Spikevax bivalent Original/Omicron BA.4-5 and the last prior dose of a COVID-19 vaccine. **Vaccine Indication:** Spikevax bivalent Original/Omicron BA.4-5 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older who have previously received at least primary vaccination against COVID-19.	**bivalent Spikevax booster**  **≥12 years: 0.5 mL dose**
3. The appropriate Spikevax bivalent vaccine prescribing information and patient information leaflet can be found via the QR code on the vial label and carton. https://www.ModernaCovid19Global.com	https://www.ModernaCovid19Global.com

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu and of the Health Products Regulatory Authority www.hpra.ie.

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions via the HPRA Pharmacovigilance website; www.hpra.ie including the vaccine brand and batch/Lot number if available.

Company contact points:

Telephone: 1800 800 354

Email: EMEAMedinfo@modernatx.com

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Sincerely,

Cesar Sanz Rodriguez
Vice President, Medical Affairs EMEA (Europe, Middle East & Africa)