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

3rd February 2023

Direct Healthcare Professional Communication

Spikevax bivalent Original/Omicron BA.1, pre-filled syringe Labelling deviation

Dear Healthcare professional,

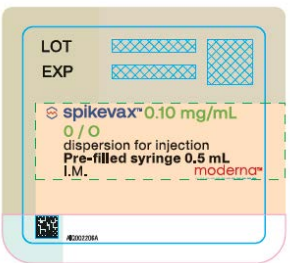
MODERNA BIOTECH SPAIN, S.L. (Moderna) in agreement with the European Medicines Agency (EMA) and the Malta Medicines Authority would like to inform you of the following:

Summary

- **Pre-filled syringes of 'Spikevax bivalent Original/Omicron BA.1 25 micrograms/25 micrograms dispersion for injection in pre-filled syringe' incorrectly labelled as 'Spikevax 0 (Zero) / O (Omicron) 0.10 mg/mL' have been distributed in the Maltese market.**
- **Furthermore, the syringe label and outer carton do not contain the final INNs (elasomeran / imelasomeran).**
- **Although the labelling is incorrect, the content of the pre-filled syringe is confirmed to be Spikevax bivalent Original/Omicron BA.1 25 micrograms/25 micrograms dispersion for injection.**
- **Healthcare professionals should ensure that the correct name of "Spikevax bivalent Original/Omicron BA.1 25 micrograms/25 micrograms dispersion for injection in pre-filled syringe" and INNs (elasomeran / imelasomeran) are recorded in the patient's vaccination record.**
- **The affected pre-filled syringes belong to batch numbers already supplied: 0000006.**

Background

Moderna has identified an incorrect labelling issue with the pre-filled syringe presentation for Spikevax bivalent Original/Omicron BA.1 distributed in Malta. The syringe label includes the incorrect trade name 'Spikevax 0 / O 0.10 mg/mL':



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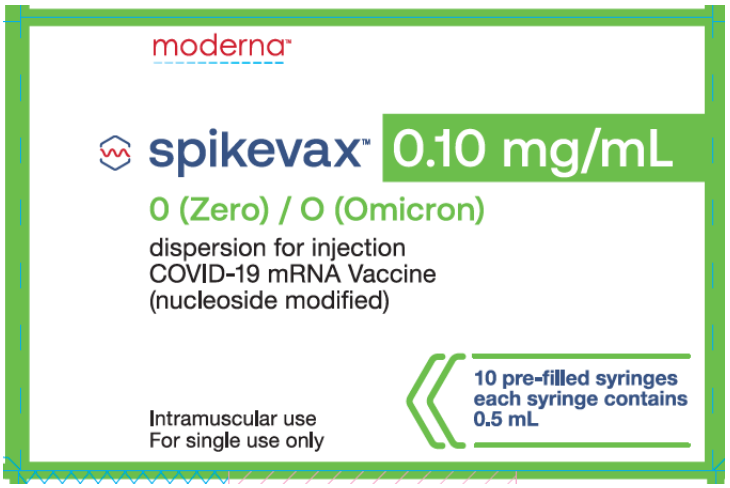
Additionally, the outer carton does not contain the final INNs (elasomeran/imelasomeran).



The pre-filled syringe labels and outer cartons were printed prior to agreement with EMA on the final name of the vaccine in order to ensure timely supply in Europe.

We herewith confirm that this is the same product as 'Spikevax bivalent Original/Omicron BA.1 25 micrograms/25 micrograms dispersion for injection in pre-filled syringe.'

Guidance

Ensure that this product is used for booster vaccine administration only.
The appropriate Spikevax bivalent vaccine Summary of Product Characteristics and package leaflet can be found via the QR code on the carton.
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 Medicines Authority of Malta https://medicinesauthority.gov.mt/home

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the national spontaneous reporting system. Submit electronically to the Medicines Authority https://medicinesauthority.gov.mt/adrportal, including batch/Lot number if available.

Company contact point

Adverse events can also be reported to Moderna on 8006 5066. or e-mail: EMEAMedinfo@modernatx.com

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Sincerely,

Moderna Biotech Spain, S.L.