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

Dear Healthcare professional,

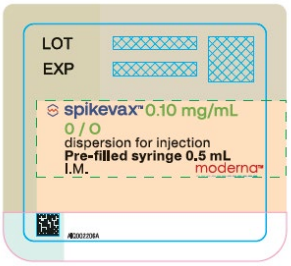
MODERNA BIOTECH SPAIN, S.L. (Moderna) in agreement with the European Medicines Agency (EMA) and the <Local Authority> would like to inform you of the following:

Summary

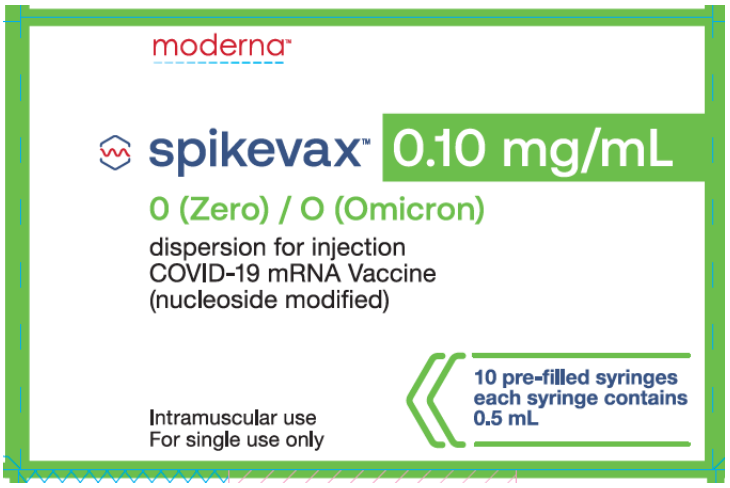
- **Pre-filled syringes of 'Spikevax bivalent Original/Omicron BA.1 25 micrograms/25 micrograms dispersion for injection in pre-filled syringe' incorrectly labelled as 'Spikevax 0 (Zero) / O (Omicron) 0.10 mg/mL' have been distributed in the <Member State> market.**
- **Furthermore, the syringe label 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: xxx.**
- **Batches allocated but not supplied are xxx and xxx.**

Background

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



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 *<National Competent Authority Website, to be completed nationally>*.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the national spontaneous reporting system *<include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>*, including batch/Lot number if available.

Company contact point

Adverse events can also be reported to Moderna on <local Phone number> or e-mail:
EMEAMedinfo@modernatx.com

Sincerely,

Moderna Biotech Spain, S.L.

Communication plan for Direct healthcare professional communication

COMMUNICATION PLAN	
Medicinal products/active substances	**Spikevax bivalent Original/Omicron BA.1, pre-filled syringe**
Marketing authorisation holders	Moderna Biotech Spain, S.L.
Safety concern and purpose of the communication	Incorrect syringe label and outer carton
Communication recipients	To be defined with the impacted member states
Member States where the communication will be distributed	Austria, Belgium, Malta, Luxemburg and Denmark

Timetable	Date
Communication and communication plan (in English) agreed by PRAC and CHMP	15/12/2022
Submission of translated Communication to the national competent authorities for review	+ 5 Working days
Agreement of translations by national competent authorities	+ 5 Working days
Dissemination of communication (electronically), as agreed with the individual national competent authorities (see above)	To be decided at national level