Moderna Biotech UK Ltd.
54 Portland Place, London, W1B 1DY

4th November 2022

Direct Healthcare Professional Communication

Spikevax▼ bivalent Original / Omicron BA.1 (50 micrograms/50 micrograms) dispersion for injection (elasomeran / imelasomeran): Temporary supply of product with different carton and multidose vial labels - GB Marketing Authorisation number PLGB 53720/0004

Dear Healthcare Professional,

Moderna Biotech UK Ltd (Moderna) in agreement with the Medicines Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary:

- The **initial supply** of "Spikevax bivalent Original / Omicron" will have a different tradename (in particular the word "Bivalent" is not included), and different carton and vial labels to the licensed product, and will consist of:
    - Batches of vials containing **2.5 mL (5 doses) entering the supply chain from mid/end August onwards**
    - A batch of vials containing **5 mL (10 doses) entering the supply chain from end of August**
    - **Both 2.5 mL and 5 mL vials may be circulating in the supply chain at the same time, but these batches will only differ in fill volume/number of doses per vial**
- To ensure continuity in supply, the MHRA has agreed for these batches to be supplied to market initially via Batch Specific Variations and later under Regulation 266 of the Human Medicines Regulations (HMR) 2012, and therefore they are approved to be used as licensed product.
- An exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, exempts the Marketing Authorisation Holder (MAH) from the obligation that certain particulars should appear on the outer and immediate packaging of Spikevax bivalent Original / Omicron and that the information must be given in English.
- The leaflet supplied with the batches is approved, therefore please ensure that this Spikevax bivalent Patient Information Leaflet (PIL) is provided to vaccine recipients. Copies of the PIL and Summary of Product Characteristics (SmPC) are also available by scanning the QR code on the carton or on the following website at https://modernacovid19global.com/en-GB
- Where necessary, reassure vaccine recipients that they are receiving the correct vaccine and that it is the same vaccine approved by the MHRA.

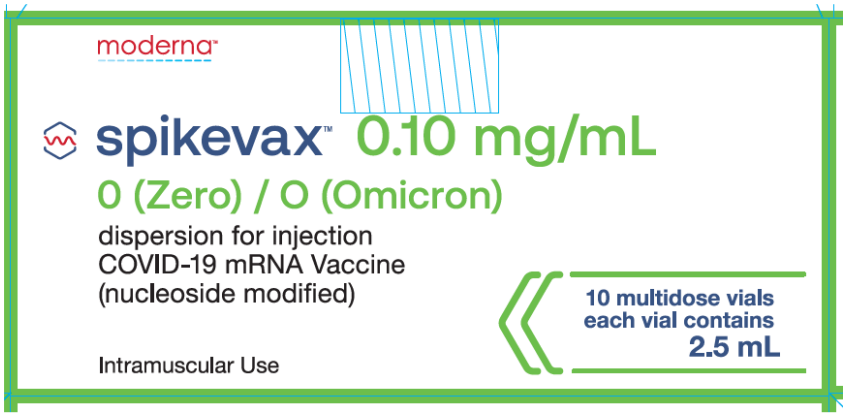
Moderna Biotech UK Ltd.
54 Portland Place, London, W1B 1DY

Background

Spikevax▼ bivalent Original / Omicron BA.1 (50 micrograms/50 micrograms) dispersion for injection (elasomeran / imelasomeran) has been approved in Great Britain under a conditional marketing authorisation, and is is indicated as a booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

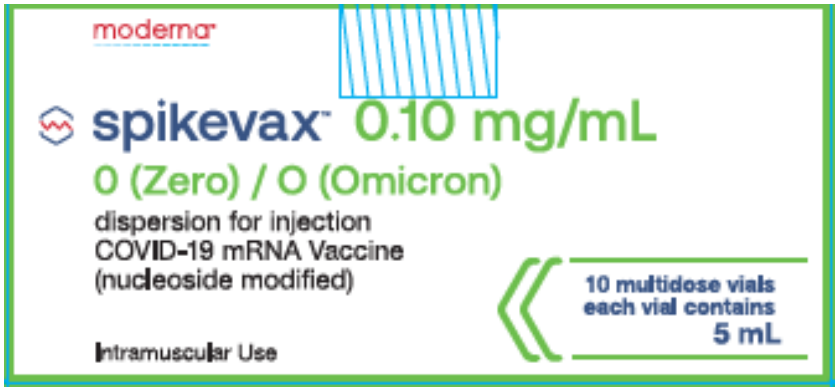
This was granted in the interest of public health because the medicine addresses an unmet medical need, and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required. The use of this vaccine should be in accordance with official recommendations.

Example of 2.5 mL Carton and Vial Label for Initial Launch:

2.5 mL Carton Label 	Trade name as **spikevax 0 (Zero) / O (Omicron)** Concentration as **0.10 mg/mL** Uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified) **Vial size is 2.5 mL** The PLGB number will not appear on the carton
2.5 mL Multidose Vial Label 	Uses abbreviated version of name as **spikevax 0 / O** Concentration as **0.10 mg/mL** Uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified) **Vial size is 2.5 mL**

Moderna Biotech UK Ltd.
54 Portland Place, London, W1B 1DY

Example of 5 mL Carton and Vial Label for Initial Launch:

5 mL Carton Label 	Trade name as **spikevax 0 (Zero) / O (Omicron)** Concentration as **0.10 mg/mL** Uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified)" **Vial size is 5 mL** The PLGB number will not appear on the carton
5 mL Multidose Vial Label 	Uses abbreviated version of **spikevax 0 / O** Concentration as **0.10mg/mL** Uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified)" **Vial size is 5mL**

Moderna Biotech UK Ltd.
54 Portland Place, London, W1B 1DY

Call for reporting

Spikevax▼ bivalent Original / Omicron BA.1 (50 micrograms/50 micrograms) dispersion for injection (elasomeran / imelasomeran) is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and patients are asked to report any suspected adverse reactions associated with the use of COVID-19 vaccines to the Coronavirus Yellow Card reporting site at https://coronavirus-yellowcard.mhra.gov.uk/ or via the free Yellow Card App (available from the Apple App Store or Google Play Store).

When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

Other suspected adverse drug reactions (ADRs) should be reported via the Yellow Card scheme. Report via the website https://www.gov.uk/yellowcard, the Yellow Card app, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.

Adverse events can also be reported to Moderna on 0800 0857562 or Email: EMEAMedinfo@modernatx.com

If you have any questions, please refer to the current approved Product Information for Spikevax bivalent at https://modernacovid19global.com/en-GB

Detailed information on this medicine is available on the MHRA website at https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

Sincerely,

Dr Philip Cruz
Medical Director
Moderna Biotech UK Ltd

Acting on behalf of
MARKETING AUTHORISATION HOLDER
MODERNA BIOTECH SPAIN, S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain