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

29th September 2022

Direct Healthcare Professional Communication

Spikevax▼ bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)
(elasomeran/imelasomeran)

- **Temporary supply of product with different product name, carton and multidose vial labels**

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:

On 1st September 2022, "Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection" was authorised for use in the EU (numbers EU/1/20/1507/004 and EU/1/20/1507/005). Supply to Northern Ireland will now revert to supply under the terms and conditions of the EU Marketing Authorisation.

Summary:

- The **initial supply** of "Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection" will have a different tradename (in particular the word "bivalent" is not included), and different carton and vial labels to the licensed product. This initial supply will be **entering the supply chain from mid/end August onwards**.
- To ensure continuity in supply, the EMA has granted an exemption for these batches to be supplied to market until **31st October 2022**, and therefore they are approved to be used as licensed product.
- 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) for Northern Ireland 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 European Medicines Agency (EMA).
- New artwork will be introduced from quarter 4 (Q4) 2022/2023 onwards and will be subject to a further Direct Healthcare Professional Communication letter.

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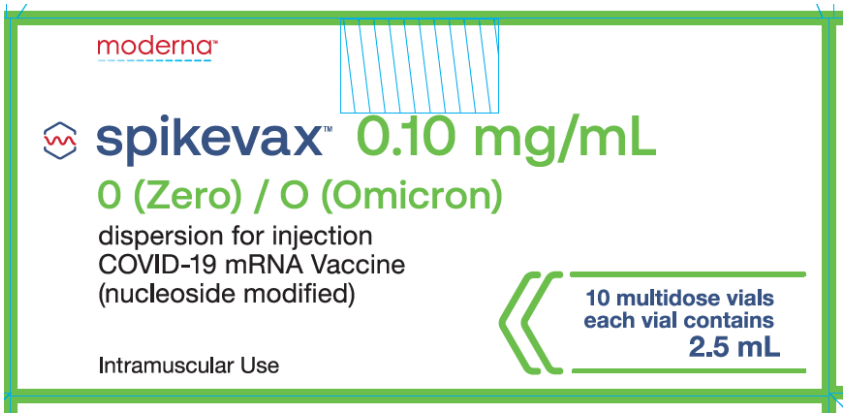
Background

"Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection" (elasomeran / imelasomeran) has been approved in Northern Ireland under a conditional marketing authorisation. Spikevax bivalent Original/Omicron BA.1 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 a primary vaccination course against COVID-19.

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 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 EU Marketing Authorisation Number will not appear on the carton
2.5 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 2.5mL**

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Call for reporting

Spikevax▼ bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) (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 EMA website at https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax

Sincerely,

Dr Philip Cruz
Medical Director
Moderna Biotech UK Ltd

Acting on behalf of
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