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

12th 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)

- **End of UK Regulation 174 authorisation for Northern Ireland and reverting to supply under EU Marketing Authorisation**
- **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). Upon EU authorisation, the UK Regulation 174 authorisation for temporary supply to Northern Ireland was rescinded, and Northern Ireland will now revert to supply under the terms and conditions of the EU Marketing Authorisation.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. It will consist of:
  - 25 batches of vials containing **2.5 mL (5 doses) entering the supply chain <u>from mid/end August</u>**
  - 1 batch of vials containing **5 mL (10 doses) entering the supply chain <u>from end of August</u>**
  - **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 EMA has granted an exemption for these batches to be supplied to market 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

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- 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.

Background

To prepare for the manufacturing of this vaccine months ahead of regulatory approval, Moderna used the naming guidance in effect at that time, according to World Health Organization (WHO), for the labeling of the packaging. Consulting with the EMA, Moderna proceeded with the name **"Spikevax 0.10 mg/mL 0 (Zero) / O (Omicron) dispersion for injection."**

- *Therefore, the initial vial labels and cartons that have been manufactured and used for launch are included below for reference, along with a current list of batches which may appear for use in Northern Ireland.*
- These cartons refer to the trade name as "Spikevax 0 (Zero) / O (Omicron)" and the vial labels use the abbreviated version of "Spikevax 0 / O". This labelling also includes the concentration as "0.10 mg/mL" and uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified)."

Supply from Mid/End August Onwards

Manufacturer Batch Number	Moderna Batch Number	Doses per vial	Vial volume	Expiry Date
200005A	7010722011	5	**2.5 mL**	14-Mar-23
200006A	7010722012	5	**2.5 mL**	15-Mar-23
200007A	7010722021	5	**2.5 mL**	16-Mar-23
200008A	7010722022	5	**2.5 mL**	19-Mar-23
200009A	7010722023	5	**2.5 mL**	20-Mar-23
200010A	7010722024	5	**2.5 mL**	21-Mar-23
200011A	7010722025	5	**2.5 mL**	22-Mar-23
200001A	7010722007	5	**2.5 mL**	03-Mar-23
000477A	7010722070	5	**2.5 mL**	25-Apr-23
200012A	7010722060	5	**2.5 mL**	19-Apr-23
200002A	7010722008	5	**2.5 mL**	10-Mar-23
200003A	7010722009	5	**2.5 mL**	11-Mar-23
200004A	7010722010	5	**2.5 mL**	12-Mar-23
200014A	7010722062	5	**2.5 mL**	16-Apr-23
200015A	7010722063	5	**2.5 mL**	18-Apr-23
200016A	7010722064	5	**2.5 mL**	20-Apr-23
200017A	7010722065	5	**2.5 mL**	28-Apr-23

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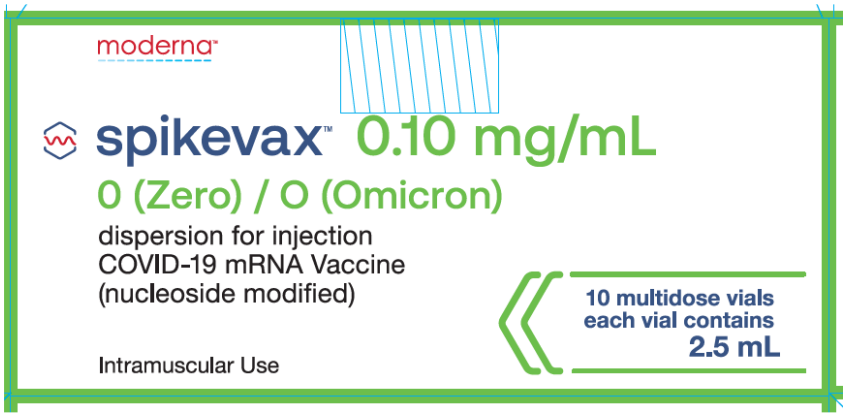
200018A	7010722066	5	**2.5 mL**	30-Apr-23
200019A	7010722067	5	**2.5 mL**	29-Apr-23
200020A	7010722068	5	**2.5 mL**	30-Apr-23
200013A	7010722061	5	**2.5 mL**	25-Apr-23
200037A	7010722101	5	**2.5 mL**	12-May-23
200036A	7010722100	5	**2.5 mL**	13-May-23
200038A	7010722102	5	**2.5 mL**	14-May-23
200039A	7010722103	5	**2.5 mL**	13-May-23

Details on the differences:

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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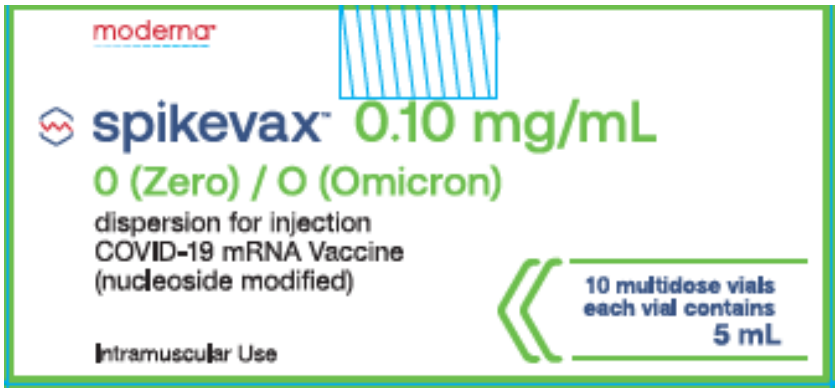
Supply from End August onwards

Manufacturer Batch Number	Moderna Batch Number	Doses per vial	Vial volume	Expiry Date
000460A	7013222006	10	**5 mL**	27-Apr-23

Details on the differences:

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 EU Marketing Authorisation 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**

Further batch specific information regarding labelling will be supplied on a regular basis, and a further Dear Healthcare Professional Letter will be issued as the new artwork enters the supply chain.

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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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