

12th September 2022

Direct Healthcare Professional Communication

Spikevax ▼ bivalent Original / Omicron (elasomeron / imelasomeron): Temporary supply of product with different carton and multidose vial labels - GB Marketing Authorisation number PLGB 53720/0004

Four extra batches added from previous letter dated 9th September 2022

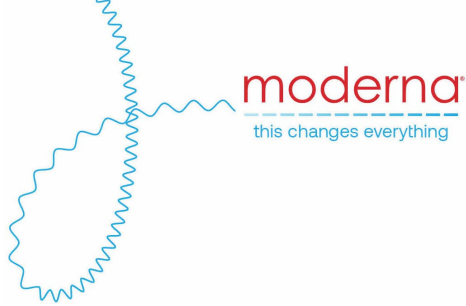
(Direct Healthcare Professional Communication)

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 licenced product, and will consist of:
 - 29 batches of vials containing **2.5 mL (5 doses) entering the supply chain from mid/end August**
 - 1 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 via a Batch Specific Variation 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) 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.
- 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

Spikevax bivalent Original / Omicron (elasomeran / imelasomeran) has been approved in Great Britain under a conditional marketing authorisation. Spikevax bivalent Original / Omicron 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.

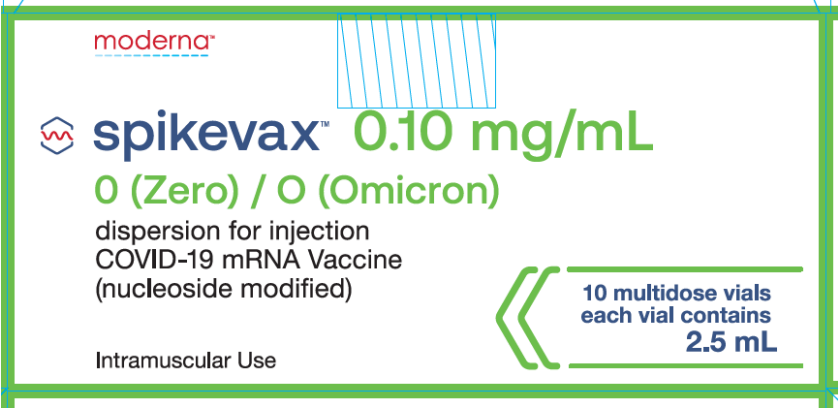

This was granted in the interest of public health because the medicine addresses an unmet medical need, and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required. The use of this vaccine should be in accordance with official recommendations.

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
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
200028A	7010722092	5	2.5 mL	21-May-23

Manufacturer Batch Number	Moderna Batch Number	Doses per vial	Vial volume	Expiry Date
200080A	7010722104	5	2.5 mL	17-May-23
200083A	7010722107	5	2.5 mL	18-May-23
200084A	7010722108	5	2.5 mL	19-May-23

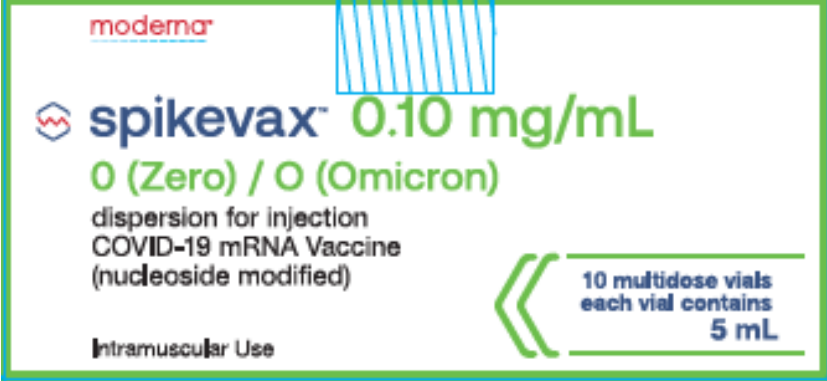

Details on the differences:

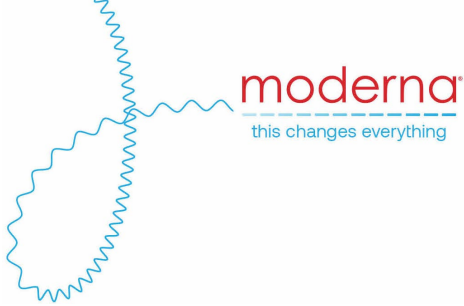
<p style="text-align: center;">2.5 mL Carton Label</p> 	<p>Trade name as spikevax 0 (Zero) / 0 (Omicron)</p> <p>Concentration as 0.10 mg/mL</p> <p>Uses the descriptor “COVID-19 mRNA Vaccine (nucleoside modified)”</p> <p>Vial size is 2.5 mL</p> <p>The PLGB number will not appear on the carton</p>
<p style="text-align: center;">2.5 mL Multidose Vial Label</p> 	<p>Uses abbreviated version of name as spikevax 0 / 0</p> <p>Concentration as 0.10 mg/mL</p> <p>Uses the descriptor “COVID-19 mRNA Vaccine (nucleoside modified)”</p> <p>Vial size is 2.5 mL</p>

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:

<p style="text-align: center;">5 mL Carton Label</p> 	<p>Trade name as spikevax 0 (Zero) / 0 (Omicron)</p> <p>Concentration as 0.10 mg/mL</p> <p>Uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified)"</p> <p>Vial size is 5 mL</p> <p>The PLGB number will not appear on the carton</p>
<p style="text-align: center;">5 mL Multidose Vial Label</p> 	<p>Uses abbreviated version of spikevax 0 / 0</p> <p>Concentration as 0.10mg/mL</p> <p>Uses the descriptor "COVID-19 mRNA Vaccine (nucleoside modified)"</p> <p>Vial size is 5mL</p>



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

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.

Call for reporting

Spikevax ▼ bivalent Original / Omicron (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).

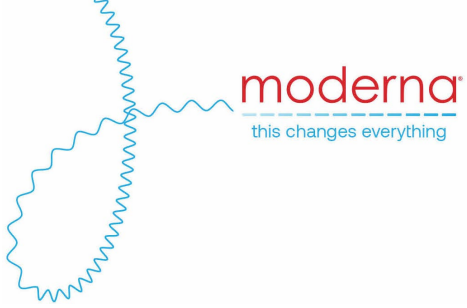
When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

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, SystemOne, 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>



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

Sincerely,

A handwritten signature in black ink, appearing to read "James Philip A. Cruz".

Dr Philip Cruz
Medical Director
Moderna Biotech UK Ltd

Acting on behalf of
MARKETING AUTHORISATION HOLDER
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