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

27th September 2022

Direct Healthcare Professional Communication

**Spikevax▼ COVID-19 mRNA Vaccine (nucleoside modified) – important shelf-life update when stored at ultra-low-temperature conditions**

**European Marketing Authorisation Numbers**
**EU/1/20/1507/001**
**EU/1/20/1507/002**
**EU/1/20/1507/003**

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:**

- On 07 September 2022, a new shelf-life at ultra-low-temperature storage conditions (–50ºC to –15ºC) was approved by the European Medicines Agency (EMA) for Spikevax dispersion for injection 0.2 mg/mL
- Alternative storage conditions have been added to the Summary of Product Characteristics (SmPC), allowing extension of the shelf-life from 9 months to 12 months in certain circumstances
- Extension of the labelled 9-month shelf-life by a further 3 months (to 12 months) is possible when the product has been stored at **–50ºC to –15ºC** without interruption for 9 months. However, this change results in a reduction of the time allowed for use under the short-term 2°C to 8°C storage conditions (from 30 days to **14 days**
- As such, settings in possession of product stored within these ultra-low-temperature conditions can use it for **up to 3 additional months beyond the printed expiry date** (for a total of 12 months), provided that once thawed and placed at 2°C to 8°C, the unopened vial will be used up within a **maximum of 14 days**

**Background**
Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older. The use of this vaccine should be in accordance with official recommendations.

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Chemical and physical stability has also been demonstrated for unopened vaccine vials when stored for 12 months at –50°C to –15°C provided that once thawed and stored at 2°C to 8°C, protected from light, the unopened vial will be used up within a **maximum of 14 days** (instead of 30 days, when stored at –50ºC to –15ºC for 9 months).

**Please note that carton box expiry date will reflect the 9-month shelf-life.**

If in doubt regarding the shelf-life of a specific batch, kindly contact: globalproductinquiries@modernatx.com

Batches held in UK/Northern Ireland to which this change applies:

| Batch Number | Printed Expiry Date | Updated Expiry Date |
|---|---|---|
| 000393A | 09/12/2022 | 09/03/2023 |
| 000401A | 10/12/2022 | 10/03/2023 |
| 000464A | 05/01/2023 | 05/04/2023 |
| 000470A | 09/01/2023 | 09/04/2023 |
| 000479A | 21/01/2023 | 21/04/2023 |
| 000475A | 20/01/2023 | 20/04/2023 |

The other special precautions for storage remain unchanged:

- Within the 9-month shelf-life, unopened vials may be stored refrigerated at 2°C to 8°C, protected from light, for maximum 30 days.
- Within this period of storage at 2°C to 8°C after thawing, up to 12 hours may be used for transportation at 2°C to 8°C.
- Once thawed, the vaccine should not be re-frozen.
- The unopened vaccine may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.

For product information please refer to https://modernacovid19global.com/

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**Call for reporting**

**Spikevax▼ 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).

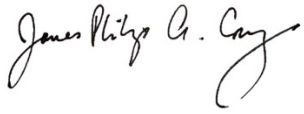
When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

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

Detailed information on this medicine is available on the European Medicines Agency website at http://www.ema.europa.eu.

Sincerely,



**Dr Philip Cruz**
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Acting on behalf of
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