Moderna Biotech Spain S.L.
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Spain

23 December 2021

Direct Healthcare Professional Communication

Spikevax▼ (also known as COVID-19 Vaccine Moderna): extension of shelf life from 7 months to 9 months; including retrospective updates for manufactured batches

Dear Healthcare Professional,

Moderna Biotech Spain, S.L. in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

- From 23 December 2021, a **new shelf life of 9 months** has been approved in the UK for Spikevax (extended from 7 months).
- The Product Information will be updated and the extended shelf life included on the labels for vials manufactured from February 2022 onwards (those with an expiry date of November 2022 onwards).
- **This 2-month extension should be applied retroactively to vials manufactured before December 2021 and during the implementation period (any batches with a listed expiration up to August 2022) -** see table on page 2 for updated expiration dates.
- The storage conditions remain unchanged (–25 °C to –15 °C).
- The statement on storage on dry ice has been removed to allow storage, including during transport of the product, as low as at –50°C. The section has been amended to remove the reference to dry ice and states “Do not store below –50°C”.
- Within the 9-month shelf life, unopened vials may be stored refrigerated at 2°C to 8°C, protected from light, for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation. Once thawed, the vaccine should not be re-frozen.

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This extension of the shelf life by 2 months applies to all vials manufactured with an expiry date printed on the label as of 23 December 2021 onwards, as long as approved storage conditions between –25ºC and –15ºC have been maintained and the applied shelf life was 7 months.

Batches of Spikevax vaccine already distributed in the UK and those to be produced and distributed in UK in December 2021 and in January 2022 will continue to be labelled with a 7 months shelf life, as the implementation of the change is ongoing. The extension of expiry dates will therefore apply to vials on the market as described in the table below:

Printed expiry date	Updated expiry date
December 2021	February 2022
January 2022	March 2022
February 2022	April 2022
March 2022	May 2022
April 2022	June 2022
May 2022	July 2022
June 2022	August 2022
July 2022	September 2022
August 2022	October 2022

The new printed label indicating 9 months shelf life will be implemented for all new vials manufactured **as of February 2022. Therefore, the last vials to be subjected to retroactive shelf life extension are vials with printed expiry date Aug 2022 (manufactured in Jan 2022).**

All vials with an expiry date from **November 2022 onwards** (manufactured in Feb 2022) will already have a 9-month shelf life printed on the label.

Please note that all the supplementary information on Spikevax impacted by this change is being updated accordingly.

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

Spikevax has been approved in the UK under conditional marketing authorisation for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. It was previously available as COVID-19 Vaccine Moderna, following approval by the MHRA on 8 January 2021.

Call for reporting

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 Yellow Card App.

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 to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.

Suspected side effect can also be reported by calling 0800 731 6789 for free.

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