

Extending the post thaw expiry of Moderna COVID-19 Vaccine (Spikevax)

Version: 1.0 01.02.22

Supersedes:

NA

Date effective:

Date for review:

1. Purpose

This SOP describes the process for extending the post thaw expiry of Moderna COVID-19 Vaccine (Spikevax) by 30 days in accordance with advice issued by Moderna and the MHRA on 14 January 2022.

2. Scope

This SOP applies only to Moderna COVID-19 Vaccine (Spikevax) vials that have been stored in accordance with the manufacturer's conditions as stated in the SPC (sections 6.3 and 6.4), and from the following batches:

Batch Refs	Batch Refs
3004732	000014A
3004737	000022A
3005237	000029A
3005287	000040A
3005686	000050A
3005688	000059A
3005889	000071A
3006325	000074A
	000084A
	000089A
	000123A
	000124A

It does not apply to:

- any vaccines that have been subject to a temperature excursion; vaccines previously subjected to a temperature excursion must not have their expiry dates extended.
- vials that have been stored outside of the manufacturer's storage conditions as stated in the SPC

3. Responsibility

All stages of this procedure must be undertaken by or under the supervision of a pharmacist.

4. Procedure

4.1. Obtain a printed copy of the Post Thaw Expiry Extension Record Form (see appendix 1) to record relevant product details, calculations and checks.

4.2. Identify all the cartons of Moderna COVID-19 Vaccine (Spikevax) which require their post thaw expiry extending. Only one carton at a time must be removed from the refrigerator for expiry amendment, this is to avoid mistakes and to maintain the cold chain.

- Check that the batch number matches one of the batch numbers in the scope of this document above. **If it does not, do not proceed.**
- Enter today's date, the number of vials in the carton and the manufacturer's batch number in columns A, B and C.

Written by:

Sig.

Date:

Approved by:

Sig.

Date:

Authorised by:

Sig.

Date:

The NWPQA Service is part of:



Extending the post thaw expiry of Moderna COVID-19 Vaccine (Spikevax)

Version: 1.0 01.02.22

Supersedes:

NA

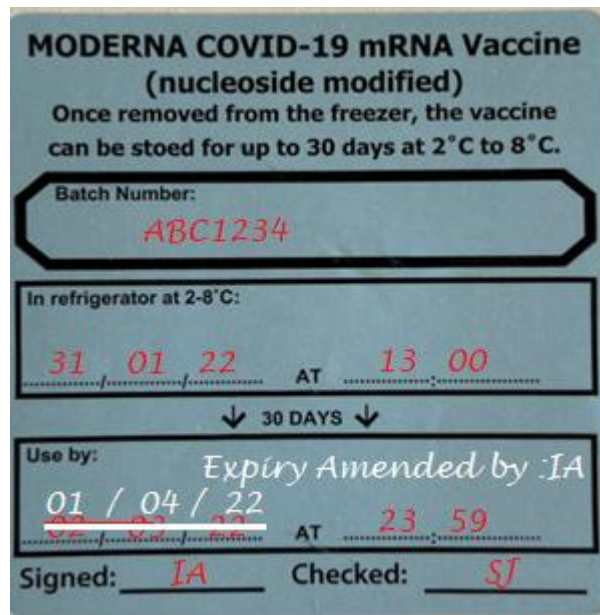
Date effective:

Date for review:

- Enter the expiry date at 2-8°C in column D.
- Confirm whether the carton is known to have been subject to a previous temperature excursion and enter yes/no in column E. **If yes, do not proceed.**
- Calculate the new extended expiry by adding 30 days to the existing post thaw expiry date at 2-8°C handwritten on the carton. Write this in column F.

4.3. Obtain an independent check of all steps in 4.2 above (independent checker signs in Column G).

4.4. Amend the expiry date at 2-8°C by crossing through the original post thaw expiry on the carton and writing the new post thaw expiry on the carton, with your signature. See example image below:



MODERNA COVID-19 mRNA Vaccine (nucleoside modified)
Once removed from the freezer, the vaccine can be stored for up to 30 days at 2°C to 8°C.

Batch Number: ABC1234

In refrigerator at 2-8°C:
~~31 01 22~~ AT ~~13 00~~

↓ 30 DAYS ↓

Use by: 01 / 04 / 22 *Expiry Amended by IA*
~~31 01 22~~ AT ~~13 00~~

Signed: IA Checked: SJ

Record your name in column H.

4.5. Obtain an independent check of transcription of the calculated details onto the carton (independent checker signs column I).

Document history

- V1.0 – First Version Issued

6. Associated documents

- Appendix 1: Post Thaw Expiry Extension Record Form

Written by:

Sig.

Date:

Approved by:

Sig.

Date:

Authorised by:

Sig.

Date:

The NWPQA Service is part of:



Extending the post thaw expiry of Moderna COVID-19 Vaccine (Spikevax)

Version: 1.0 01.02.22

Supersedes: NA

Date effective:

Date for review:

Post Thaw Expiry Extension Record Form								
Site Name			Foundry Code					
A	B	C	D	E	F	G	H	I
Date	Number of vials in carton	Batch number of carton	Original expiry 2-8°C	Has there been any previous temperature excursion? (yes/no)	New expiry at 2-8 °C (original expiry at 2-8 °C + 30 days)	Independent check of new expiry at 2-8 °C by:	Expiry on carton amended by:	Carton amendment independently checked by:

Written by:

Sig.

Date:

Approved by:

Sig.

Date:

Authorised by:

Sig.

Date: