

To:

- ICS leads
- PCN-led local vaccination services
- Community pharmacy-led local vaccination services
- Vaccination centres
- Hospital Hubs and Hospital Hubs+
- CCG accountable officers
- All GP practices
- NHS trust and foundation trust:
 - chief executives
 - medical directors
 - chief pharmacists

Dr Emily Lawson DBE, Dr Jonathan Leach OBE and David Webb
NHS England and NHS Improvement
Skipton House
80 London Road
London
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cc.

- NHS regional directors
- NHS regional directors of commissioning
- Directors of public health
- All local government chief executives

1 February 2022

Dear Colleagues

Extending the post-thaw expiry date of specific batches of Spikevax® (also known as COVID-19 vaccine Moderna) for adults

We are writing to notify you that after discussions with Moderna Biotech Spain, S.L. (Moderna) and the Medicines and Healthcare products Regulatory Agency (MHRA), certain post-thaw expiry dates of unpunctured and undamaged Spikevax® vials as detailed in this letter may be extended from 30 days to 60 days.

For vials produced within the batches listed in Appendix 1 to this letter only, Moderna has assessed available data and can confirm that their stability assessments indicate no impact to product quality through extending the post-thaw expiry period of thawed product from 30 days to 60 days, when stored at 2-8°C, independent of the shelf life printed on the vial.

The MHRA is reassured therefore that there is no detrimental impact on the safety, quality or efficacy of the specified batches of vaccine and has no objection to the proposal of using these identified stocks of Spikevax® beyond their authorised expiry dates up to and including a maximum of 60 days when stored at 2-8°C.

We are asking those clinical colleagues responsible for the safe storage and handling of Spikevax® vaccines in their possession, to amend the post-thaw expiry dates accordingly for the batches identified in this letter. This extended shelf life will enable more patients to access these critical and life-saving vaccines over the coming days.

The NHS Specialist Pharmacy Service has developed a Standard Operating Procedure (SOP) which accompanies this letter and which NHS vaccine administration sites are expected to follow. Updates to this SOP will be made available [here](#) (for Hospital Hubs and Vaccination Centres) and [here](#) (for PCN designated sites).

The UK Health Security Agency (UKHSA), the Department of Health and Social Care (DHSC) and NHS England and Improvement have reviewed the Patient Group Direction and National Protocol supporting administration of the Spikevax® vaccine. They have jointly agreed that use of the batches identified in this letter, following formal notification of post-thaw expiry extension based on company data, would be reasonable and is therefore within the National Protocol and the Patient Group Direction.

As per normal clinical practice, please prioritise stocks which are nearing expiry.

Yours sincerely,



Dr Emily Lawson DBE
SRO, COVID-19 Vaccination
Deployment Programme, NHS
England and Improvement



Dr Jonathan Leach OBE
Medical Director, Vaccination
Deployment Programme, NHS
England and Improvement



David Webb
Chief Pharmaceutical Officer
for England, NHS England and
Improvement

Appendix 1

Spikevax® batches in scope

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