

To:

NHS England and NHS Improvement
Skipton House
80 London Road
London
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- 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

cc.

- Regional directors
- Regional directors of commissioning
- Regional medical directors
- Regional chief pharmacists
- Directors of public health
- All local government chief executives

17 January 2022

Dear Colleagues

Extending the post-thaw expiry date of specific batches of Comirnaty® (30 microgram/dose) for Adults and Adolescents

We are writing to notify you that after discussions with Pfizer Inc. and the Medicines and Healthcare products Regulatory Agency (MHRA), certain post-thaw expiry dates of unpunctured and undamaged Comirnaty® (30microgram/dose) vials as detailed in this letter may be extended from 31 days to 45 days.

For vials produced within the batches outlined in Appendix 1 only, Pfizer Inc. has assessed available data and confirmed that their stability assessments indicate no impact to product quality through extending the post-thaw expiry date of thawed vaccines from 31 days to 45 days.

The MHRA are reassured therefore that there is no detrimental impact on the safety, quality or efficacy of the identified vaccine and have no objection to the proposal of using these identified stocks of Comirnaty® beyond their authorised post-thaw expiry dates up to and including a maximum of 45 days from the date of removal from ULT storage.

We are asking those clinical colleagues responsible for the safe storage and handling of Comirnaty® 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.

As per normal practice, stocks nearing expiry should be the priority.

The NHS Specialist Pharmacy Service has developed a Standard Operating Procedure (SOP) which accompanies this letter and we would ask that this SOP is followed. Updates to this SOP will be made available [here](#).

Yours sincerely



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



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

Appendix 1

Comirnaty® batches in scope

Batch Ref	
FN5254	FK9712
FL9994	FM3802
FN3543	FK0112
FK9706	FH3220
FM3092	FH4751
FN1664	FF8288
FK9707	FK0596
FG3712	FK9413
FN4817	FH0114
FF3319	FL1939