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To:

- ICS and STP leads
- All CCG Accountable Officers
- All NHS Foundation Trust and Trust Chief Executives
- All COVID-19 vaccination sites
- CCG Chief Pharmacists/Heads of Medicines Optimisation
- Hospital Chief Pharmacists
- All PCNs and all GP practices
- All Community Pharmacy
- All Local Authority Chief Executives

Copy to:

- Chairs of ICS and STPs
- All CCG Chairs
- Chairs of NHS trusts and foundation trusts
- NHS Regional Directors
- NHS Regional Directors of Commissioning
- Regional Chief Pharmacists
- NHS Community Trust Chief Pharmacists
- Superintendents of Community Pharmacies providing COVID-19 vaccinations

20 May 2021

Dear Colleague

***COVID-19 Vaccine Pfizer-BioNTech: change to shelf life when stored in refrigerators at 2-8C***

Earlier today, and following an assessment of additional data supplied by Pfizer/BioNTech, the Medicines and Healthcare products Regulatory Agency (MHRA) has amended the Conditions of Authorisation of the COVID-19 mRNA Vaccine BNT162b2 (commonly known as “COVID-19 Vaccine Pfizer-BioNTech”) under Regulation 174 of the Human Medicines Regulation 2012.

This change extends the approved storage period of the unopened, thawed vial at 2-8°C (i.e. cold chain conditions) from five days to **one month** (31 days). The full details of the revised Conditions of Authorisation can be found [here](#).

This is a welcome move which brings additional flexibility to our vaccination programme. Vaccination administration sites will now have a longer period of time over which to use this vaccine, supporting efforts to open up booking slots, minimise waste and ensure that cohort penetration is achieved. It will become easier to align vaccine clinics with the delivery and availability of this vaccine. Planning for ‘roving’ or ‘pop-up’ vaccination

services will also be made easier by this amendment. In turn, we expect that the need for administration sites to engage in 'Mutual Aid' will significantly diminish.

Nevertheless, it is important to be fully aware that no other Conditions of Authorisation for COVID-19 Vaccine Pfizer-BioNTech relevant to the handling of the vaccine itself have changed and that this vaccine remains inherently fragile. It must be treated with care and in particular, it is important that any transportation and preparation of the vaccine always takes place within the permitted parameters and in accordance with the [Standard Operating Procedures](#) developed by the NHS Specialist Pharmacy Service. These Standard Operating Procedures are in the process of being updated with the amendment to the storage condition and this update will be completed shortly.

Operationally, the responsible NHS Hospital Chief Pharmacist, CCG Lead Pharmacist or Superintendent Pharmacist (as applicable), should engage with healthcare professionals operating on site now to make them aware of this development and to ensure that the implications for vaccine supplies already in their possession are carefully understood. Local procedures should be updated in line with the latest NHS Specialist Pharmacy Service guidance as soon as possible.

It remains important that vaccination administration sites continue to vaccinate all patients within eligible cohorts at pace, ensuring that residual on-site stock holdings remain low at all times.

Yours sincerely



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NHS England and NHS Improvement