To:

- CCG Chief Pharmacists/Heads of Medicines Optimisation
- Hospital Chief Pharmacists

Cc:

- NHS Community Trust Chief Pharmacists
- Superintendents of Community Pharmacies providing COVID-19 vaccinations
- Regional Chief Pharmacists
- Regional Directors of Commissioning
- Regional Vaccination Operation Centres

NHS England and NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

26 August 2021

Dear colleague

Impact of granting a Conditional Marketing Authorisation for Pfizer-BioNTech COVID-19 vaccine (Comirnaty®)

In late December 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a temporary Authorisation under Regulation 174 (R174) of the Human Medicines Regulations 2012 to permit the supply of identified COVID-19 mRNA Vaccine BNT162b2 batches, based on the safety, quality and efficacy data submitted by Pfizer/BioNTech. This authorisation was not a marketing authorisation.

Pfizer-BioNTech has been granted a Conditional Marketing Authorisation (CMA) for their vaccine, now branded as Comirnaty®. The supply of branded product to Public Health England commenced at the beginning of August 2021 with supply of the current R174 product finishing by the end of August 2021. The new Summary of Product Characteristics (SmPC) for the Comirnaty® product is available here.

It is important to note that there are no quality, safety or efficacy implications from the change in licensing status of the new licensed stock.

This letter draws your attention to a number of operational implications for the management of the Pfizer-BioNTech vaccines and asks you to take appropriate steps to make relevant colleagues aware.

These operational implications are listed below in a table for ease of reference. The changes apply specifically to Comirnaty® branded stock.

Topic	Changes relating to transition to CMA for Pfizer-BioNTech Comirnaty®
Timescale – estimated first likely delivery to NHS frontline	Expected in early September 2021.
Training for vaccinators	Updated training is available on the PHE website here. Pfizer has launched a website to support use of Comirnaty®.
National Protocols and/or Patient Group Directions	New Patient Group Directions and/or National Protocol for Comirnaty® is available here.
Specialist Pharmacy Service Standard Operating Procedures (SOP)	SOPs have been updated and are available here.
Summary of Product Characteristics (SPC)/Patient Information Leaflet (PIL)	Minor text differences. New Comirnaty® Patient Information leaflet (PIL) supplied with vaccine and must be issued to patients given Comirnaty® vaccine.
Artwork on vaccine box	Vial and carton labels will change. There are images of the new artwork in Specialist Pharmacy Service SOPs.
Expiry of Comirnaty® after dilution	**R174 vial label requires recording of time of dilution; Comirnaty® label requires addition of date and time of expiry after dilution.**
Batch Numbers	Batch numbers will change between R174 and CMA products, however the format will remain consistent.
Thaw labels	Thaw labels will not be provided; 2-8C expiry date will be handwritten in space provided on Comirnaty® carton label.
Transport of undiluted Comirnaty®	SPC allows 12 hours max total with no limit on number of journeys within that period.
Transport of diluted Comirnaty®	Comirnaty® may be transported at 2-8C for up to 6 hours after dilution.
Storage conditions	Ambient temperature has been redefined from 8-25C to 8-30C. There is no change to the maximum allowable time at ambient temperature.
Temperature stability data	More information is available to inform advice on management of temperature excursions.

Separate communications summarising these changes and signposting to relevant SOPs will be issued to vaccination sites through the SPOC communications channel. Please note that while efforts are being made within the supply chain to separate out the deliveries of the R174 stock and Comirnaty®, some vaccination sites are likely to have both stocks in refrigerators for a short period of time. Where possible we would advise that sites maintain adequate separation of these products.

While MHRA is content that the two products are pharmaceutically and clinically identical it remains the case that the conditions under which they have been approved for use are not identical. During the period in which both products may be in use, please note that some slight operational differences will remain in relation to labelling and these will be highlighted in the SOPs. Please also note that corresponding PILs should be provided for each.

Finally, I want to take the opportunity to remind you that all vaccines remain inherently fragile molecules and of the importance of adhering at all times to the dispositions of the temporary authorisation to supply and of the Marketing Authorisation, and to the SPS Standard Operating Procedures for handling them, at all points in delivery of your vaccination services.

Yours sincerely

Dr Keith Ridge CBE
Chief Pharmaceutical Officer for England