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To:

Community Pharmacy Owners, and the Superintendent and Responsible Pharmacists of designated community pharmacies

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Cc:

Hospital Chief Pharmacists
CCG Chief Pharmacists

Dear colleague

COVID-19 vaccination: Governance, handling, and preparation of vaccines by designated community pharmacies

The purpose of this letter is to set out the principles and expectations necessary to maintain the integrity, and therefore safety, quality and effectiveness, of COVID-19 vaccines. If you receive this as a pharmacy owner or the superintendent of a pharmacy business, please disseminate this appropriately in your business. This letter complements the General Pharmaceutical Council's Standards for Registered Pharmacies and Standards for Pharmacy Professionals, which must be complied with at all times.

Pfizer/BioNTech COVID-19 mRNA Vaccine BNT 162b2

The novel characteristics of this first vaccine, which was initially temporarily authorised for supply by the Medicines and Healthcare products Regulatory Agency (MHRA) but has now has a conditional marketing authorisation from the European Medicines Agency, make it essential that very careful attention is given to its receipt, storage, movement/transportation and preparation.

This vaccine is inherently "fragile" in nature and so must be handled carefully. The key component is mRNA (messenger Ribonucleic Acid) which is a delicate substance. The mRNA is encased in microscopic lipid nanoparticles both to protect it and to help it get into cells. Once inside the cell, the mRNA instructs the cell to produce particular coronavirus proteins, and it is this that leads to the immune response that protects us. But the nanoparticles are delicate and this is why the vaccine is frozen so that the nanoparticles do not degrade, including when being transported. Similarly, if the thawed vial is shaken rather than gently inverted during preparation, the lipid nanoparticles may again degrade, or release the mRNA which is destroyed. Once the vaccine is diluted, it is not yet clear how much movement the vaccine can withstand and so that is why the vaccine must not be transported after dilution.

Other COVID-19 vaccinations

As other vaccines become available it is likely they will also be temporarily authorised by the MHRA or be given conditional marketing authorisations. These vaccines are also likely to be subject to conditions of use and pharmacists should ensure adequate skills and competence of staff receiving, handling and administering the vaccine as it will be crucial for efficacy of these vaccines that they are stored and handled completely in line with the manufacturer's instructions and MHRA conditions.

Legal basis and expectations of the different routes to authorisation for supply of the vaccine products

It is important that all registered healthcare professionals dealing with the vaccines are familiar with the law underpinning any regulatory authorisation of the vaccines and the consequential expectations of professional accountability and practice.

The UK medicines regulatory framework empowers the MHRA to temporarily authorise the supply or distribution of unlicensed medicinal products in response to certain public health events, for example a pandemic. The specific legislation is set out in regulation 174 and 174A of the Human Medicines Regulations 2012 ("HMRs"), as amended. The initial batches of the Pfizer/BioNTech vaccine approved for distribution in the UK were authorised under this process, and supply and distribution of these vaccines must comply with the conditions attached to the temporary authorisation. These conditions are in addition to the normal regulatory requirements for control of manufacture, distribution, compliance with appropriate good practices, monitoring and reporting of adverse reactions etc. The EU has also now granted a conditional marketing authorisation for the Pfizer/BioNTech vaccine, and this conditional marketing authorisation will apply automatically in the UK. From January 2020, the regulatory position becomes more mixed, as at that point MHRA will also be empowered to issue conditional marketing authorisations. I will write again about the specific implications of the different routes to authorisation in the New Year. However, the issues around the handling the vaccines and preparing them for final administration, and who may administer them, are common to all the methods of approval.

Healthcare organisations and healthcare professionals are also subject to legislation and good governance requirements with respect to medicines. However, Regulations 3, 3A and 4 of the HMRs, read with section 10 of the Medicines Act 1968, contain exemptions for doctors, nurses and pharmacists, subject to certain conditions, from holding a manufacturer's licence and a marketing authorisation, to allow them to undertake final processes at the end of the medicines supply chain. For example, section 10 allows both assembly and the activity of preparing or dispensing a medicinal product in accordance with a prescription under the supervision of a pharmacist in a registered pharmacy. New regulation 3A of the HMRs ensures that all professionally justified acts of preparation and assembly of a COVID-19 vaccine may be undertaken by or under the supervision of a doctor, nurse or pharmacist, at any location, without precipitating the need for a manufacturer's licence or marketing authorisation – provided those acts are done under NHS arrangements. It should be noted that this new regulation is a temporary measure to help support COVID-19 vaccination - regulation 3A of the HMRs ceases to have effect on 1st April 2022.

In practice, the professional expectations are as follows for designated community pharmacy Local Vaccination Services:

Regulatory compliance by the pharmacist under section 10 of the 1968 Medicines Act and new regulation 3A of the HMRs mean they have to understand the process being done by them or under their supervision and be accountable for it.

In the case of Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2, which needs to be diluted, it is not essential that the final dilution is done by a registered pharmacist. What is essential is that it is being done either by pharmacists acting within their professional competence or by someone acting under the supervision of a pharmacist. This is applicable for preparation of the vaccine for administration for an individual whether in accordance with the National Immunisation Protocol or the Patient Group Direction.

Supporting pharmacy staff in delivering this important role

It is fully recognised that some pharmacy staff may not be used to dealing with "fragile" medicines such as Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2. Pharmacists will be accountable for the safe and effective use of the vaccine, so a series of support measures are being put in place. Detailed information is available on the Specialist Pharmacy Service (SPS) website and Regional Chief Pharmacists and regional Quality Assurance Pharmacists are supporting their Regional Vaccination Operations Centres (RVOCs) to answer questions from all Local Vaccination Services.

The General Pharmaceutical Council has produced guidance for community pharmacies providing COVID-19 vaccination which is available here. Pharmacy owners, Superintendent Pharmacists, Responsible Pharmacists, clinical leads, clinical supervisors and pharmacists working under the terms of the Patient Group Direction or the National Immunisation Protocol should be familiar with this guidance.

Accountability for community pharmacy-led COVID-19 local vaccination services.

Corporate and professional governance for use of the vaccines should be based on normal pharmacy governance arrangements. Appropriate risk assessments, controls and continuing assurance must be in place.

The Pharmacy Owner/Superintendent Pharmacist must be satisfied that overall governance, systems and processes for handling COVID-19 vaccines are appropriate and robust, including adherence to the nationally developed standard operating procedures (SOPs) (see below). The Superintendent Pharmacist should be available to the Responsible Pharmacist, where applicable, to offer support and advice in a timely way. A community pharmacy checklist is provided at Appendix 1 to help the Superintendent Pharmacist/Pharmacist Owner to assure themselves that designated pharmacies are ready.

Role of the Responsible Pharmacist

The Responsible Pharmacist's role is to secure the safe and effective running of the pharmacy and all pharmaceutical services provided at or from the pharmacy. The Responsible Pharmacist will be accountable for ensuring that the individual registered premises or associated premises are fit to receive, store and use vaccine, that they and all involved staff are working to the SOPs (see below), and that staff involved are competent.

The General Pharmaceutical Council's provisional registration scheme does not allow provisionally registered pharmacists to act as Responsible Pharmacist with responsibility for a Covid vaccination service delivered at or from a registered pharmacy (including in 'associated premises') or to be the pharmacist in charge of a vaccination service being provided in 'associated premises'.

Supervising Pharmacist

Any pharmacist supervising administration of COVID-19 vaccination under the terms of a National Immunisation Protocol or administering vaccinations under the terms of a Patient Group Direction must be trained and fully competent to do so.

An appropriate governance framework should be in place between any pharmacist supervising administration or administering COVID-19 vaccine, the Responsible Pharmacist of the pharmacy from which the service is provided and the Superintendent Pharmacist/Pharmacist Owner. This framework must detail the respective professional and legal accountabilities of the pharmacy professionals involved in governing and delivering the service. In particular, the framework must detail the risks to patient safety, the steps and measures in place to mitigate those risks, and the names of the individuals who are accountable for putting those steps and measures in place, for operating them, and for providing assurance that they are operating as intended, and for scrutinising that assurance and reporting accordingly. It is important that all members of the pharmacy team are clear who to raise issues with that may impact on patient safety, and feel enabled to do so.

Technical Standard Operating Procedures (SOP)

To mitigate risks of inadvertently inactivating the Pfizer/BioNTech vaccine, a suite of technical SOPs has been developed. These are available at SPS Guidance for CCG Chief Pharmacists (please note that you will need to be a registered (SPS) user and signed in to access this website using an NHS mail address). Information for Healthcare Professionals has also been published by the MHRA and is available here: HCP Information. The Conditions of Authorisation for Vaccine BNT162b2 as outlined by the MHRA are available here: Conditions of Authorisation

As future vaccines become available, similar information will be developed for these and provided on the SPS website.

Advice and support of vaccine processes by senior NHS pharmacists

Given the novel nature of the vaccines, pharmaceutical expertise and oversight will be necessary to ensure integrity of the vaccines. In the first instance, this should be the Superintendent Pharmacist/Pharmacy Owner consulting published information. NHS England and NHS Improvement (NHSEI) Regional Chief Pharmacists and SPS Regional Quality Assurance Specialists will be available to support Superintendent Pharmacists/Pharmacist Owners where necessary. A request should be submitted via the RVOC.

Yours sincerely

Dr Keith Ridge CBE

Chief Pharmaceutical Officer for England

Appendix 1: COVID-19 Vaccination – Primary Care Site: Pharmacy Go-Live Checklist

The following list provides an indication of the specific items for consideration in providing assurance that the pharmacy and medicines handling requirements for the vaccination programme have been met. It is by no means definitive and is subject to change.

Governance and leadership

- ☐ Risk assessment for service and clear mitigation
- ☐ SOP on safe and secure handling of the vaccine from receipt to administration
- ☐ Responsible Pharmacist to ensure controls are in place with clearly defined accountability
- ☐ Pharmacist supervising administration or administering vaccine to ensure continuing assurance
- ☐ Lead identified for oversight of training for vaccine preparation

Standard Operating Procedures (SOPs)

- ☐ SOPs for receipt, storage, stock control, temperature excursions, record keeping and security in place
- ☐ SOPs for preparation of individual doses of vaccine in place
- ☐ SOPs for administration of individual doses of vaccine in place
- ☐ SOPs for waste handling in place

Workforce and training

- ☐ Appropriately skilled workforce identified for service delivery
- ☐ Appropriately skilled pharmacy workforce identified for service delivery support
- ☐ Standard training material relating to SOPs and service delivery available
- ☐ Training delivery plan in place
- ☐ Competence assessment in place for appropriate elements such as Patient Group Direction or National Protocol.

Premises, equipment and supply

- ☐ Sufficient validated fridge and, where appropriate, freezer capacity available
- ☐ Fridge (and freezer if required) automatic temperature monitoring and logging system installed
- ☐ Fridge (and freezer if required) alarms installed and tested
- ☐ Supply of vaccine and non-vaccine consumables determined
- ☐ Superintendent pharmacist agreement to vaccination site layout and preparation areas

Sign off

- ☐ Superintendent Pharmacist/Pharmacist Owner

Appendix 2

Regional Vaccination Operation Centre (RVOC) contact details

1. North East & Yorkshire - england.ney-vacc-cell@nhs.net
2. North West Covid-19.MVNW@nhs.net
3. Midlands england.midscovid19voc@nhs.net
4. East of England england.eoe-vacprg@nhs.net
5. London england.london-covid19voc@nhs.net
6. South East RVOC england.servoc@nhs.net
7. South West england.swcovid19-voc@nhs.net