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To: CCG Chief Pharmacists/Heads of medicines optimisation

Cc: Hospital Chief Pharmacists

CCG Chief Officers

NHS Community Trust Chief Pharmacists

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Dear Colleague

**COVID-19 vaccination: Governance, handling, and preparation of vaccines by GP led Local Vaccination Centres (PCN designated sites)**

The purpose of this letter is to set out the principles and expectations necessary to maintain integrity, and therefore safety, quality and effectiveness, of the COVID-19 vaccines. The novel characteristics of the first vaccine (Pfizer/BioNTech *Covid-19 mRNA Vaccine BNT 162b2*) which is authorised for supply by the Medicines and Healthcare products Regulatory Agency (MHRA), 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.

**Legal basis and expectations of HMR regulation 174 (temporary) 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 licensing authority (the UK and NI Health Ministers) 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 (HMR) 2012, as amended. Regulation 174A

provides for conditions to be attached to the temporary authorisation, which will generally be done in order to assure the safety, quality and efficacy of the specific medicine. Ministers would consider doing so after taking advice of the independent expert advisory committee for medicines, the Commission on Human Medicines. Supply and administration of the medicine (COVID-19 vaccine in this case) must comply with the conditions. These conditions will be in addition to the normal regulatory requirements for control of manufacture, distribution, compliance with appropriate good practices, monitoring and reporting of adverse reactions etc.

Healthcare organisations and healthcare professionals are also subject to legislation and good governance requirements. The relevant exemptions that exist for healthcare professionals at the final stages of supply are in Regulation 3 of the HMRs (for doctors, dentists, nurses and midwives) and section 10 of the Medicines Act 1968 (for pharmacists in certain health care settings).

Regulation 3 of HMR provides that:

- A medicinal product can be manufactured or assembled by a doctor without the need for a manufacturer's licence or marketing authorisation provided that the medicinal product is supplied to a patient of that doctor in the course of the treatment of that patient or to a patient of another doctor who is a member of the same medical practice and is not manufactured or, as the case may be, assembled on a large scale by an industrial process; and
- A medicinal product can be assembled by a registered nurse or a registered midwife without a manufacturer's licence if the nurse or midwife is acting in the course of his or her profession and is not assembled on a large scale by an industrial process.

For the purposes of the national vaccination programme against COVID-19, there may be a number of different settings in which doctors and nurses will be undertaking the final dilution and drawing up of the vaccine, or will be responsible for another health care professional undertaking the final dilution and drawing up of the vaccine in their name, for administration to patients who are only temporarily their patients and under their care. Where what is being done is professionally appropriate, both for the person doing the final preparation and, if different, the person in whose name the final preparation is being done, this will be treated as compliant with regulation 3.

Section 10 of the 1968 Medicines Act provides that the restrictions imposed by regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of HMR do not apply to anything which is done in a registered pharmacy, a hospital, a care home service or a health centre and is done there by or under the supervision of a pharmacist and includes both assembly and the activity of preparing or dispensing a medicinal product in accordance with a prescription given by an appropriate practitioner. Because of the premises related restrictions in section 10, it is unlikely that it will be relevant to PCN led local vaccination centres administering the first vaccine (Covid-19 mRNA vaccine BNT 162b2) in England because in effect it would only be relevant where the local vaccination centre was a registered pharmacy.

**In practice, the professional expectations are as follows:**

**GP led local vaccination services**: Regulatory compliance by the doctor/GP under reg.3 of the Human Medicines Regulations 2012 means they have to understand the process being done in their name and be accountable for it. However, it is not essential that the final dilution done at PCN hubs or NHS community trusts is done by GP or pharmacy professionals. What is essential is that it is being done by doctors acting within their professional competence or by someone acting on the doctor's behalf who is acting within their professional competence. Ordinarily the skills in question would be the skills one would expect to find amongst pharmacy professionals, but there will for example be nurses who have the right qualifications, skills and experience.

**Supporting GPs in delivering this important role**

It is fully recognised that some GPs may not be used to dealing with "fragile" medicines of this nature, such as this first vaccine (Pfizer/BioNTech COVID-19 mRNA Vaccine BNT162b2). GPs will be accountable for their safe and effective use in their patients, so a series of measures are being put in place to support GPs.

**Local Covid-19 vaccines policy**

Corporate and professional governance for use of the vaccines should be based on normal NHS medicines governance arrangements. A model *NHS COVID-19 Vaccine handling and management policy 2020-21* is set out at Annex A, and this should be finalised and adopted as soon as possible by the appropriate Prescribing Committee, authorised by the committee chair and the relevant PCN Clinical Director together with the Primary Care Lead Pharmacist, and shared with a Named clinical lead on behalf of each of the PCN sites from which vaccine will be delivered by participating practices.

**Technical Standard Operating Procedures (SOP)**

To mitigate risks of inadvertently inactivating the vaccine a suite of technical SOPs has been developed. These will be available at SPS Guidance for CCG Chief Pharmacists (please note that you will need to be a registered Specialist Pharmacy Service (SPS) user and signed in to access this website). 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 Medicines and Healthcare products Regulatory Agency (MHRA) are available here: Conditions of Authorisation

Further technical SOPs, if required, will be provided as additional vaccines become available.

**Oversight and support of vaccine processes by senior pharmacists**

Given the novel nature of the vaccines, pharmaceutical expertise and oversight will be provided to ensure integrity of the vaccines. CCG Chief Pharmacists will support GPs by ensuring the safe handling and use of the vaccines at PCN designated sites for vaccine delivery. The name of the Lead Responsible CCG Chief Pharmacist for each Local Vaccination Centre must be identified to your NHS England and NHS Improvement Regional Chief Pharmacist. CCGs will be confirming before vaccine is

delivered that full clinical assurance has been carried out for each PCN designated site. The Lead Responsible CCG Chief Pharmacist should be intimately involved in providing clinical assurance and, working with NHS hospital chief pharmacists, should identify senior pharmacy team members with significant experience of the delivery of, and training related to, aseptic preparation or a senior nurse with experience in aseptic non-touch technique training in order to ensure compliance with the technical SOPs. CCG Chief Pharmacists may also want to take the opportunity of vaccine deployment happening in hospitals first to spend some time observing hospital staff how they go about dealing with the vaccine. Community services chief pharmacists will also be a source of general advice on vaccine management. Through the Regional Chief Pharmacists, the NHS Specialist Pharmacy Service, which has led the development of the technical SOPs, will allocate expert pharmacy quality assurance staff to each Lead Responsible CCG Chief Pharmacist to help familiarise themselves with the technical SOPs, and will also be on hand to answer any queries as they arise.

Yours sincerely

Dr Keith Ridge CBE

Chief Pharmaceutical Officer for England

**Annex A: Model NHS COVID-19 Primary Care Vaccine handling and management policy 2020-21**

**Document definition:**
**This is a model policy document to enable Primary Care Networks to implement good governance in the context of the safe and secure handling and management of COVID-19 vaccines.**

Throughout the document the term 'Primary Care Lead Pharmacist' is used; this refers to the pharmacist lead for a locality in primary care, as agreed by the Regional Chief Pharmacist and often being the CCG lead pharmacist, who is responsible for supporting the PCN Clinical Director to deliver the governance requirements specified in this policy.

## Target Audience: Who Should Read This Policy?

All staff responsible for planning and managing the primary care COVID-19 vaccination programme in 2020/21, and all Pharmacy staff engaged in supporting and delivering the COVID-19 vaccination programme in 2020/21.

## Introduction

The COVID-19 vaccination programme is of the highest priority for the NHS. In order to deliver this programme both safely and effectively, good practice in the handling and management of vaccine is paramount. It is anticipated that a number of COVID-19 vaccines will be introduced during 2020 and 2021, so good governance is essential. Clarity of both the overarching principles and the detailed 'standard operating procedures' are required to enable safe, effective implementation and delivery of the vaccination programme. This document is to be read alongside the Standard Operating Procedure documentation developed for all COVID-19 vaccines and all environments in which they are handled.

## Purpose

This policy document enables corporate and professional governance for use of the COVID-19 vaccines, with the expectation that all areas detailed are addressed locally and that standard NHS medicines governance arrangements are in place. It is anticipated that the appropriate Prescribing Committee agrees this policy, and that it is authorised as soon as possible by the committee chair and the relevant PCN Clinical Director, together with the Primary Care Lead Pharmacist.

The document is intended to provide the overarching principles for robust governance of the safe and secure handling and management of COVID-19 vaccines in the end-to-end supply chain for the vaccination programme.

## Objectives

- To ensure that all staff involved in delivery of the vaccination programme are aware of, and adhere to, the correct procedures for the ordering, receipt, storage, supply and administration of the product.
- To ensure that the physical and biochemical integrity and sterility of all vaccines and related medicines is maintained.

- To ensure that all staff involved in delivery of the vaccination programme are aware of the relevant characteristics of COVID-19 vaccines and the implications this has for vaccine efficacy and patient safety.
- To provide assurance that vaccine safety, sterility, quality and efficacy is protected.
- To define key roles and responsibilities needed to deliver this assurance.
- To ensure that all staff understand their critical roles and responsibilities in delivering these objectives.

**COVID-19 Vaccines**

There are a number of COVID-19 vaccines under development and it is anticipated that a range will be utilised in the vaccination programme. None will be authorised at the start of the programme so initially they will be unlicensed products temporarily authorised for supply under Regulation 174 of the Human Regulations 2012. This regulation enables the Medicines and Healthcare products Regulatory Agency (MHRA) to authorise use of a product on a temporary basis in response to the spread of pathogenic agents.

The characteristics of the different vaccines may vary considerably and will increase in clarity over time. Prior to licensing the product characteristics are available in the relevant 'Healthcare Professional Factsheet' and patient information in the 'Consumer Factsheet'. Following award of the Marketing Authorisation this information is available in the Summary of Product Characteristics and Patient Information leaflet respectively. The first requires transport and storage under ULT conditions (-70 +/- 10 C). This may not be the case for those that follow, but cold chain will be critical for all. Use of vaccines that have deviated from recommended storage or transportation conditions risks compromising vaccine efficacy and patient safety. Vaccines that have not been transported or stored correctly may be ineffective or harmful; they would therefore no longer be within the terms of their product authorisation or temporary regulation 174 authorisation and must not be used. Means of detecting when a temperature excursion has occurred are required. The focus on avoidance of waste should also be of high priority.

Further information concerning COVID-19 vaccines is available in the Public Health England publication 'COVID-19 vaccination programme Information for healthcare practitioners', available on https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

**Legal framework and practice standards.**

All activity is to be undertaken in accordance with the Human Medicines Regulations 2012, as amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

Adherence to national standards of good practice is required including those set by the Care Quality Commission, the National Institute for Health and Care Excellence, Public Health England and the Royal Pharmaceutical Society of Great Britain, as detailed in the appendix 1 below.

## Roles and responsibilities under this policy

The legal entity responsible for operating the vaccination site is to assign responsibility for clinical and operational oversight. The PCN Clinical Director is responsible for service provision, aided by the relevant Primary Care Lead Pharmacist to ensure safe and secure handling and management of the COVID-19 vaccine and related medicines.

## Accountability and responsibility for vaccines, associated medicines and their supply chain

- The PCN Clinical Director is accountable for the safe and secure handling and management of medicines on all vaccination sites operating within or under the jurisdiction of their employing legal entity. This includes oversight of those elements of practice within designated vaccination sites that may impact upon product integrity, from receipt of product to vaccine administration. The PCN Clinical Director will be aided by the relevant Primary Care Lead Pharmacist.

- The appropriate Prescribing Committee is to document the above named individuals.

- The PCN Clinical Director may delegate operational responsibility for oversight of ordering, receipt, storage and safe handling of vaccines and medicines, to a named and suitably trained member of staff on each vaccination site, aided by the relevant Primary Care Lead Pharmacist.

- This responsibility extends to oversight of issue of vaccines and medicines to roving vaccinators and for administration of vaccines by PCN staff within care homes.

- The Specialist Pharmacy Services Regional Quality Assurance Specialists will work with the Primary Care Lead Pharmacist to provide specialist pharmaceutical expertise in the development of systems and processes of work to ensure the safe and secure handling of the vaccine.

## Handling and management of vaccine and medicines in vaccination sites

The PCN Clinical Director must ensure that all activities are carried out in accordance with:

- This policy document
- The relevant nationally authored documents and Standard Operating Procedures (SOPs)
- Relevant local organisational medicines policies
- Standard good practice guidance including aseptic technique
- Relevant Health and Safety guidance
- National Standards including those detailed in appendix 1

## Local amendments to this policy

Any amendments to this policy or relevant SOPs must be ratified by the appropriate Prescribing Committee responsible for medicines governance for the area in which the vaccination site is situated.

## Staff authorisation to be supplied with and administer COVID-19 Vaccines

The Primary Care Lead Pharmacist must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction, protocol or written instruction, and that the staff groups who are supplied with, prepare, and administer the COVID-19 vaccine are those defined as eligible to do so.

## Safety and security of vaccines and related medicines

The Primary Care Lead Pharmacist must ensure that that safe and secure handling and storage of vaccine and medicines are in place in accordance with principles and guidance encompassed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)', available on https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines.

## Storage and transportation of vaccines

The 'cold chain' is a term used to describe the cold temperature conditions in which certain products need to be kept during storage and distribution. Maintaining the cold chain ensures that vaccines are transported and stored according to the manufacturer's recommended temperature range until the point of administration. Vaccines must be stored at the correct temperature and transported only in approved and validated packaging, and the temperature of the vaccine carrier and contents monitored and reviewed before use.

The Primary Care Lead Pharmacist must ensure that storage and transportation are undertaken in accordance with the relevant SOPs, that cold chain temperatures are monitored correctly and that any 'out of specification' recordings are addressed promptly and appropriately, and that a full audit trail is maintained. Further details are included in the relevant SOPs and in manufacturers' information.

## Workforce and training

All staff undertaking duties at the vaccination site must meet the necessary training standards and competencies in line with the SOPs and standard organisational processes.  A training needs assessment is required for the roles within the vaccination services, with corresponding training materials and assessment process, to enable timely and focussed workforce development.

As detailed in 'Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)' (see appendix 1) 'the

named individual ensures that accountable individuals are competent and supported in their role as it relates to the safe and secure handling of medicines'.

The roles assigned to support the rollout of COVID-19 vaccination need to be in accordance with legislation including that detailed in the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

**Precautions**

Anaphylaxis kits including injections of intramuscular adrenaline 1:1,000 must be in date and readily available at all locations undertaking vaccination.
Any needlestick or other injuries must be addressed in accordance with the policies of the relevant employing legal entity.

**Maintenance of records**

All records must be maintained in accordance with relevant SOPs. These include the ordering, receipt and issue of vaccines, tracking of product, plus patient focused records including consent and administration.

Any serious adverse reactions are to be escalated for immediate senior clinical input; such situations are to be fully documented following the event and a record kept of relevant product batch numbers. A record of all serious adverse events is to be provided to the Primary Care Lead Pharmacist.

**Data Protection**

All staff have a responsibility to ensure that they do not disclose information about the service, service users, staff members and corporate documentation to unauthorised individuals.

**Disposal of vaccines and other waste**

Disposal of waste vaccines and any sharps must be undertaken in a safe and secure manner in accordance with relevant SOPs.
If any packaging includes dry ice this must also be disposed of in a safe and secure manner using appropriate personal protective equipment.

**Business Continuity Planning**

The Primary Care Lead Pharmacist will be responsible for establishing an agreed business continuity plan in relation to safe and secure handling of vaccines, and for testing this plan in line with the organisational emergency preparedness processes and NHS Core Standards for Emergency Preparedness, Resilience and Response (https://www.england.nhs.uk/ourwork/eprr/gf/). The business continuity plan should detail how the relevant aspects of the service will respond, recover and manage during disruption relating to people, information, security, premises including utilities, facilities particularly refrigerator (and if relevant ULT) failure, supplier, IT and data.

**Go-live checklist**

A proposed COVID-19 Vaccination – Primary Care Site: Pharmacy Go-Live Checklist is provided in Appendix 2.

Document prepared by team of the NHSE/I Chief Pharmaceutical Officer; 7.12.20

**Appendix 1: Links to relevant National Standards**

CQC Regulation 12: Safe Care and Treatment
https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment
'The intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Providers must assess the risks to people's health and safety during any care or treatment and make sure that staffs have the qualifications, competence, skills and experience to keep people safe.
• Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities. Medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe.
• Providers must prevent and control the spread of infection. Where the responsibility for care and treatment is shared, care planning must be timely to maintain people's health, safety and welfare.
The CQC understands that there may be inherent risks in carrying out care and treatment, and we will not consider it to be unsafe if providers can demonstrate that they have taken all reasonable steps to ensure the health and safety of people using their services and to manage risks that may arise during care and treatment'

NICE Clinical Guideline QS61: Infection Prevention and Control
https://www.nice.org.uk/guidance/qs61
This quality standard covers preventing and controlling infection in adults, young people and children receiving healthcare in primary, community and secondary care settings.

The Green Book - Immunisation against infectious disease (Public Health England)
https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book
The latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. The COVID-19 vaccine chapter is available on: https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

Professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society of Great Britain)
Adhere to the documented governance principles and relevant guidance. Available on https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

## Appendix 2: 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

- ☐ Approval of local policy to assure safe and secure handling of the vaccine from receipt to administration (via appropriate Prescribing Committee)
- ☐ GP oversight identified by PCN Clinical Director
- ☐ Lead identified for oversight of training for vaccine preparation
- ☐ Primary Care Lead Pharmacist identified
- ☐ SPS RQA approval of plan and that relevant MHRA Good Distribution Practice obligations are in place

### 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

### 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
- ☐ Primary Care Lead Pharmacist agreement to vaccination site layout and preparation areas

### Sign off

- ☐ PCN Clinical Director
- ☐ Primary Care Lead Pharmacist
- ☐ Regional Chief Pharmacist