GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Cwm Taf Morgannwg University Health Board	**Reference Number: TBC** **Version Number: 1**

COVID VACCINATION MEDICINES MANAGEMENT POLICY

Introduction

This policy provides the legislative framework for the management of COVID Vaccines within Cwm Taf Morgannwg University Health Board. It includes pharmacist supervision of the preparation of COVID vaccines, their use at mass vaccination centres, peer vaccination centres and the administration of vaccines within the community by CTMUHB staff.

Objectives

The aim of this document is to provide the overarching framework for the delivery of COVID vaccinations within CTMUHB. To ensure that the appropriate systems are in place providing the assurance that we are meeting regulatory and legislative requirements governing the use of vaccines.

Operational Date	**Expiry Date**
March 2021	**Formal** – three years **Informal** – one year

Scope

This policy applies to all staff on all locations across the UHB working within mass vaccination centres, providing peer vaccinator services and CTMUHB staff providing vaccinations within the community.

Equality Impact Assessment	An Equality Impact Assessment has been undertaken and no impact has been identified
Distribution	All staff via internet and team briefings.
To be read by	All staff involved in the COVID Vaccination Programme in CTMUHB
Documents to read alongside this Policy	SOPs for management of COVID Vaccination

Approved by	MMEC (Endorsed) Q&S approved
Lead Director (responsible for formal review every three years)	Suzanne Scott-Thomas, Clinical Director of Medicines Management
Author Lead (carries out informal review annually)	Kathryn Howard, Team Leader Medicines Governance and MMPU
Freedom of Information Status	Open (most will be open, seek advice from the Head of Corporate Services if unsure)

If the review date of this policy has passed, please ensure that the version you are using is the most up to date either by contacting the document author or the Corporate Services Department.

To avoid use of out of date policies please do not print and then store hard copy of this document.

Out of date policies cannot be relied upon.

Amendment Record

If a change has been made to the document, the changes must be noted and circulated to the appropriate colleagues.

Detail of change	Why change made?	Page number	Date of change	Version	Name of Policy Author

Contents

1. Purpose

The aim of this policy document is to ensure that there are appropriate systems and assurances in place to meet the required standards and legislation governing the use of COVID vaccines in all care settings where Cwm Taf Morgannwg University Health Board (CTMUHB) staff are employed to provide a service.

2. Scope

This policy covers the storage and security of COVID vaccines along with the pharmacist supervision of the preparation of COVID vaccines at community vaccination centres, peer vaccination centres and the use of vaccines within community settings within CTMUHB.

CTMUHB has a responsibility to ensure the standards are met when vaccines are delivered via commissioned services from independent contractors through contract monitoring and assurances required prior to the deployment of the vaccine.

3. Introduction

The first COVID vaccine BNT162b created by Pfizer was granted a regulation 174 authorisation by the Medicines and Healthcare Regulatory Authority (MHRA) on 2 December 2020. This vaccine poses significant storage and preparation challenges if it is to be used safely and effectively. The preparation of this vaccine comes under The Medicines Act 1968/Human Medicines Regulation 2012 Section 10 and requires pharmacist supervision.

The second COVID-19 vaccine (Oxford- Astra Zeneca) was granted a regulation 174 authorisation by the Medicines and Healthcare Regulatory Authority (MHRA) on December 31st 2020. This vaccine is a multi-dose vial which is ready diluted.

The third COVID-19 Vaccine (Moderna) was granted a regulation 174 authorisation by the Medicines and Healthcare Regulatory Authority (MHRA) on January 8th 2021. This vaccine is a multi-dose vial which is ready diluted. The vaccine is not currently in use within CTMUHB, but like the Pfizer vaccine, poses storage issues as it must remain frozen until ready for use.

Storage; preparation; and administration of the vaccine comes under individual organisations' single corporate and clinical governance frameworks. This extends to all hospital sites, Mass Vaccination Centres

(MVCs) and to administration by health board employees in community settings.

The professional and legal responsibility for safe and secure handling of the vaccine rests with the Chief Pharmacist of each NHS organisation in all settings. This is particularly important where Community vaccination Centres or community teams are supplied vaccine other than in the manufacturer's original packaging, and in the preparation of BNT162b vaccine in hospitals and CVCs.

4. Legislative and NHS Requirements

4.1 Pharmacist Supervision

The concept of pharmacist supervision comes from The Medicines Act 1968/Human Medicines Regulation 2012 Section 10, which is an exemption for the production of medicines without a licence.

In order to achieve an acceptable level of supervision it is necessary to describe the requirements at three levels:

- Organisational Level
- Day to day operational level
- Individual product level

The professional and legal responsibility for safe and secure handling of the vaccine will rest with the Chief Pharmacist in all settings.

There must be an approval pack for each site. The site packs must be kept up to date as changes occur, i.e. vaccinators and responsible people.

The approval of the processes and associated procedures will be via the CTMUHB medicines management governance framework.

4.2 Instructions to Administer

The vaccines are a prescription only medicine (POM) which cannot be administered or supplied to patients unless one of four types of instruction are in place:

a) a signed Patient Specific Direction (PSD) or 'prescription'
b) a Patient Group Direction (PGD)
c) a National Protocol (applies to influenza and COVID-19 vaccines only).
d) a Written Instruction

The type of instruction in place in each vaccination site will be selected to ensure the appropriate authority is granted to the health care professionals delivering the COVID vaccination programme. A combination of instructions

may be used at any one site to maximise utilisation of the available workforce.

All Registered Health Care Professionals and Non-registered Health Care Professionals must ensure they know which instruction they are acting under and must understand the framework that the instruction provides. See Appendix 1 for further detail.

The PGD for administration of a COVID Vaccine will be approved and implemented as per the CTMUHB Policy for the Supply and Administration of Medicines under a PGD. This will be updated regularly in line with amendments to the National PGD Template and any changes communicated to user groups.

There will be a CTMUHB procedure and appropriate training & records to ensure compliance with the National Protocol requirements.

4.3 Use of COVID 19 Vaccines in Community Settings

The vaccine will be packed-down under the exemption provided under section 10 of the 1968 Medicines Act.

The Act requires such packing down only takes place in a registered pharmacy, or a hospital.

All packing down for use of the vaccine within community settings will be carried out within a hospital pharmacy within CTMUHB.

Appropriate transport arrangements for delivery of the vaccines and associated consumables will be in place to support CTMUHB healthcare professionals in the administration of the vaccine within the community.

A procedure will be in place to support the appropriate management of the vaccines in community settings.

4.4 Use of COVID 19 Vaccines at Community Vaccination Centres

The supply of a vaccine can be made within the same legal entity both to patients and to staff by that legal entity's own appropriate healthcare professionals.

CVCs within CTMUHB are owned or leased by the health board, and such premises come within the organisation's single governance structure and are subject to inspection in the usual way.

As stated in section 4.1 above, the accountability for proper handling of medicines in MVCs will rest with the respective organisation's Chief Pharmacist.

Where these conditions are met, the MHRA agrees an MVC can be considered a "hospital" for the purposes of the section 10 exemption.

4.3 Day to Day Operational Level Requirements

There must be an approved responsible person on each site at all times who is named in the pack for that site, this must be a registered healthcare professional.

There will be an operational policy/procedure for the management of the CVC which will include the management of the vaccines.

Each day an approved registered professional must sign in as the Responsible Person for the day on the Responsible Person Register.

Pharmacy must provide contact details of appropriate pharmacy staff who can be contacted when required, these will be detailed in the site pack.

Any incidents regarding the receipt, storage and preparation of a COVID-19 vaccine must be reported to pharmacy for investigation and recorded via DATIX.

Any Adverse Drug Reactions must be reported to the dedicated Coronavirus Yellow Card Reporting Site https://coronavirus-yellowcard.mhra.gov.uk/ as well as via DATIX.

4.4 Individual Product Level Requirements

Each COVID-19 vaccine will have a specific preparation method sheet approved by Pharmacy.

The preparation method must be followed at all times for each COVID-19 vaccine prepared.

5. Training Implications

An appropriate training plan must be in place and all CTMUHB staff involved in the provision of vaccination services must receive the appropriate training before they handle or administer any COVID vaccination.

Training and competency records must be kept up to date and must be retained for the required time and available on request.

6. Review, Monitoring and Audit Arrangements

6.1 Summary of approval process

The policy will be endorsed by the COVID-19 Vaccine Project Board, The MMEC and ratified by the Quality, Safety and Risk Committee in line with the OP1 Policy.

6.2 Operational date

This policy will be operational following the approved Health Board process. This will be documented on the front of the document.

6.3 Review of policies and procedures

This policy and supporting SOPs will be continually monitored and will be subject to formal review at three yearly intervals. Informal annual review will be undertaken as per the Health Board Policy for the Management, Identification and Authorisation of Policies and Procedures.
An earlier review may be warranted if one or more of the following occurs:-

- Regulatory / statutory changes or developments;
- Due to the results / effects of critical incidents;
- For any other relevant or compelling reason.

Robust communications systems must be in place to ensure any changes to the policy or underpinning SOPs are communicated to the staff involved in the vaccination programme in a timely manner.

6.4 Audit

Audit of compliance against this policy will be undertaken periodically during the course of the COVID Vaccination programme.

7. Managerial Responsibilities

7.1 Chief Pharmacist Responsibilities

The Chief Pharmacist must ensure there are robust systems in place, which include:

- Training programmes for the preparation of COVID vaccines
- Competency assessment of staff undertaking the preparation of COVID vaccines

- Registration of staff preparing vaccines assessed.
- Standard Operating Procedures (SOP) and associated documents in place and approved by pharmacy:
  - Ordering and Receipt of vaccines
  - Storage and security of vaccines
  - Preparation of vaccines
  - Preparation method
  - Disposal of vaccine
  - Management of Spillages
  - Packing down of COVID Vaccines
  - Transport of COVID Vaccines
- Contact details for appropriate pharmacy staff are available.

The mass vaccination site and peer vaccination site must be assessed by The Chief Pharmacist as acceptable for the storage and preparation of COVID vaccines. Evidence of this approval must be recorded in the site pack.

7.2 Organisational Responsibilities

CTMUHB will be responsible for the approval and assurance of compliance of this policy.

The appropriate support and resources will be provided to implement and discharge the services covered by this policy.

8. Retention / Archiving

In cases of incidents, / complaints / claims and other legal processes it is often necessary to demonstrate the policy and procedures in place at the time of the investigation. Therefore this policy will be archived and stored in line with the Records Management Policy.

9. Non Conformance

There is a requirement on all relevant staff to comply with the provisions of this policy and, where requested, to demonstrate such compliance.

The Welsh Risk Pool will not indemnify participants against incidents arising from non-compliance.

10. Equality Impact Assessment Statement

This policy has been subject to a full equality assessment and no impact has been identified.

11. Privacy Impact Assessment Statement

This policy has been subject to a full privacy impact assessment and no impact has been identified.

12. Freedom of Information Statement

The FOI status of this document is open.

13. References

1. Personal Communication. Chief Pharmaceutical Officer for Wales Letter. 2/12/20.

2. Guild of Health Care Pharmacists. GHP statement in support of the COVID-19 vaccination programmes across the UK and the role of the Pharmacist. 10/12/20.

3. National Protocol for Pfizer BioNTech COVID-19 vaccine. (COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection). Ref: Pfizer BioNTech COVID-19 vaccine protocol, v1.0. Valid from: 18 December 2020, Review date: 30 November 2021, Expiry date: 01 December 2021.

14. Appendices

Appendix 1: Table summarising the Legislative Requirements Governing the Administration of Vaccines
Appendix 2: Site Approval Form
Appendix 3: Responsible Person Approval Record
Appendix 4: Responsible Person Register
Appendix 5: Pharmacy Contact Details

Appendix 1: Legislative Requirements Governing the Administration of Vaccines

Normally a vaccine will already have UK marketing authorisation or licence and specific detailed information about the product available is published in the form of a Summary of Product Characteristics (SmPC), but this is not yet available. The vaccine is a prescription only medicine (POM) which cannot be administered or supplied to patients unless one of four types of instruction are in place:

a) a signed Patient Specific Direction (PSD) or 'prescription'
b) a Patient Group Direction (PGD)
c) a National Protocol* (applies to influenza and COVID-19 vaccines only).
d) a Written Instruction

Legal Mechanism	Who?	Large Vaccination Centre	Community Vaccination Centre	Roving Model	NHS Organisation model for vaccinating staff	Things to consider
Patient Specific Directions (PSDs)	PRESCRIBERS ONLY: doctors, independent nurse or pharmacist prescribers. Non-registered and registered staff can administer under a PSD of prescriber agrees and takes full accountability.	No prescribers are available in the current model – will need adaption to include prescribers.	No prescribers are available in the current model – will need adaption to include prescribers. Can be used in General Practice where prescribers could be available, and teams are known to them.	Could be used for General Practice led models, but nor preferred.	Not preferred as requires a prescriber to review each member of staff.	1. Limited to **prescribers** only. 2. A PSD for the supply of medicines is classified as a prescription form. This form is a legal document and supply must comply with the legislation on the validity of prescriptions. 3. Difficult to sustain long term. 4. Staff need to have had appropriate training. 5. Useful in GP model if prescriber agrees to take responsibility for team work.

Patient Group Directions (PGDs)	**Registered Health Care Professionals as defined by law;** Non-registered staff are not able to administer under a PGD (and the task cannot be delegated to them)	Cannot be used in current model which uses an expanded workforce. Can only be used where healthcare professionals are carrying out all tasks.	Cannot be used in current model which uses an expanded workforce. Can be used where registered healthcare professionals are carrying out all of the tasks e.g. primary care administration by practice nurses, or community pharmacy.	Used by registered healthcare professionals in the roving model.	Can be used by a NHS body but not Independent Occupational Health Providers.	*1.* Limited to Registered Health Care Professionals listed in the legislation *(chiropodists and podiatrists, dental hygienists, dental therapists, dieticians, midwives, nurses, occupational therapists, optometrists, orthoptists, orthotists and prosthetists, paramedics, pharmacists, physiotherapists, radiographers and speech and language therapists)* 2. PGDs are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. 3. PGDs need to include the name of the authorised, registered health professional using them and the registered healthcare professional must be trained in the use of the PGD. 4. PGDs must be authorised by an appropriate authorising body in line with the Human Medicines Regulations. For NHS Services this must be a CCG, Local authority, Public Health England, NHS England and Improvement or Health Board. 5. PGDs can usually only be used for licensed medicines. The recent amendment to the regulations (October 2020) allows the registered healthcare workforce that already operates under PGDs to administer vaccinations to

						continue to do so in the case of an unlicensed or temporarily authorised COVID-19 vaccine. 6. The COVID-19 Vaccine PGD is currently being developed by Public Health England and will follow and expedited process for development and publication once the required vaccine characteristic details are published. 7. The administration cannot be delegated, i.e. the registered HCP must both prepare and administer the vaccine.
National Protocol	Two-step process that enables tasks to be split between: **Non-registered healthcare workers** (e.g. new recruits to NJS and HCW). **Registered healthcare professionals.**	Should be used under current structure which uses an expanded workforce.	Should be used under current structure which uses and expanded workforce. Could be used in primary care if non-registered staff are needed to administer the vaccine alongside registered healthcare professionals.	Non registered staff are not currently in the roving model due to the extra skills required for treated vulnerable patient in care homes.	Could be used by not specifically defined in law.	1. A National Protocol is new type of instruction that was introduced to support the expanded influenza and COVID-19 Vaccination Campaign. This is a new legal mechanism which has been out in place following amendment of the Medicines Regulations. 2. It will allow those who are registered healthcare professionals who cannot operate under a PGD, and those who are not registered healthcare professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine. 3. It also allows the process of administration to be split into its component parts i.e. clinical assessment and consent, preparation of the vaccine and administration of the vaccine. 4. All stages can be done by one competent person (the registered

						healthcare professional) but in the case of large vaccination centres these tasks can be split with each person trained and authorised to complete their specific task as defined in the protocol. The clinical assessment and consent process must be undertaken by a registered healthcare professional and the preparation of the vaccine must only be undertaken and overseen by those health care professionals trained in aseptic technique and have the skills for dilution and drawing up as required by the vaccine.
Written Instruction	**Registered Healthcare Professionals** only within an occupational health setting i.e. registered nurses, midwives, nursing associates, operating dept. practitioners, paramedics or physiotherapists and pharmacists	Cannot be used	Cannot be used	Cannot be used	Must be used by private Occupational Health Teams and NHS organisations providing OHS to other NHS organisations.	1. Administration of influenza or COVID-19 vaccine by an organisation to employees, including peer-to-peer vaccination, is provision of an occupational health service (OHS). Medicines can be supplied or administered in the course of an OHS by a registered nurse acting in accordance with the written and signed instruction of a doctor – this instruction is commonly called a **written instruction.** 2. OHS are not a regulated activity and so are not registered with the CQC, Care Inspectorate, Healthcare Improvement Scotland, Health Inspectorate Wales or RQIA. Therefore in accordance with the current legislation PGDs cannot be used by independent providers of OHS but

						can be used by NHS organisations to vaccinate their own staff. 3. The use of written instruction allows medicines to be provided under an exemption to the regulations which is applicable to OHS. Under the exemption registered nurses can be instructed to administer a medicine. In Oct 2020, the Regulations were amended to allow occupational health vaccinators (that is registered nurses, midwives, nursing associates, operating department practitioners, paramedics or physiotherapists and pharmacists) who are employed or engaged by a person operating an occupational health scheme to administer influenza or coronavirus vaccines as part of an NHS Body or Local Authority (LA) occupational health scheme in accordance with the written directions of a doctor. This amendment is time-limited to April 2021.

Table 1. Taken from the GHP statement in support of the COVID-19 vaccination programmes across the UK and the role of the Pharmacist. (Ref: CO923 legal mechanisms for administration of the COVID-19 vaccine(s) 2 December 2020) Published 10.12.20.

Appendix 2: Site Approval Form

Site location			
Site Assessment Completed by		**Date of Assessment**	

Potential Risks	YES	NO	NA	Comments
Vaccine site is part of CTMUHB?	☐	☐[2]	☐	
Are there appropriate security measures in place?	☐	☐[2]	☐	
Is there a staff sign-in process?	☐	☐[1]	☐	
Is the site clean and tidy?	☐	☐[1]	☐	
Is there an appropriate area for receipt?	☐	☐[1]	☐	
Pharmacy approved SOP for receipt?	☐	☐[1]	☐	
Is there appropriate storage space available?	☐	☐[2]	☐	
Have the fridges been mapped?	☐	☐[2]	☐	
Do the fridges have continuous monitoring?	☐	☐[2]	☐	
Can the vaccine be locked up and are the keys in a safe place?	☐	☐[2]	☐	
Are ambient items stored in a clean and dry area off the floor?	☐	☐[1]	☐	
Pharmacy approved SOP for storage?	☐	☐[1]	☐	
Is the preparation area segregated from other activities?	☐	☐[2]	☐	
Suitable space for preparation to ensure no mix up or cross-contamination?	☐	☐[2]	☐	
Wipes and PPE available for preparation?	☐	☐[2]	☐	
Appropriate bins available for disposal of vaccine waste & Pharmacy approved SOP?	☐	☐[2]	☐	
Pharmacy approved SOP for preparation?	☐	☐[1]	☐	
Pharmacy approved SOP for spillages?	☐	☐[1]	☐	
Preparation method sheet available?	☐	☐[2]	☐	
Evidence of preparation and administration training provided?	☐	☐[2]	☐	
Details of Responsible staff in charge evident?	☐	☐[2]	☐	
Final Risk Score (FRS)				=

FRS	Description	Actions required to control risk
20 – 32	Intolerable risk	Site should not be used, if no other option then go to the step below
12 – 19	Undesirable risk	Actions should be taken to reduce/prevent risk and justified
6 – 11	Tolerable risk	Justifications of risk required
0 - 5	Negligible risk	No additional requirements

Justification:

Actions:

Risk Assessment Declaration - Site is suitable for use		Yes	No
Sign		**Date**	

Appendix 3: Responsible Person Approval Record

Name	Registration	Trained	Approved by	Date
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
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		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		
		YES / NO		

Appendix 4: Responsible Person Register

Date	Name	Title	Registration	Signature