

Roles, Responsibilities and Training - Vaccine Management in Vaccination Centres and in Community Settings

Standard Operating Procedure.

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3	Transfer of MMT SOP 0147 ATO / Pharmacy Support Staff Duties v3.1 to PTHB template. Significant update with the introduction of sections for each duty, for clarity.	08/04/2024
4	Section 6.2 Supporting Vaccinators. Inclusion of vaccine specific instruction to ensure that Covid vaccine sits at room temperature for a defined length of time before administration.	18/06/2024
5	• Amendment to SOP title • Removal of reference to pharmacy folders – no longer in use. • Introduction – clarification around staff groups • Responsibilities – minor updates and rewording • Section 6 – Heading -Pharmacy Support Duties changed to Handling Vaccine • Section 6 – reference to pharmacy support removed, replaced with 'named person assigned to pharmacy area'. • Section 6: taking anaphylaxis kits into the community; addition of returning anaphylaxis kits to base • Section 6.3. Refrigerators/Cold Chain -Fridge data logger download- changed from 56 days to weekly. Removal of reference to SD cards. • Section 7 – Training. Clarification of responsibilities and training requirements for different staff groups	29/05/2025
6	• Removal of 'Immuniser' from HCSW title • Addition – further information on responsibilities and working within competencies • Inclusion of reference to individuals' responsibility to ensure training tracker is kept up to date • Removal of reference to coloured trays	19/08/2026

	• Addition of importance of effective communication between team members • Inclusion of the importance of ensuring a separate vaccine tray is issued to vaccinators for different vaccines in use • Reminder included to ensure that correct monitoring paperwork is provided with each Labcold™ and Helapet Vaccine porter • Reminder to not overload Labcold™ Portable Vaccine Carriers • Clear process to describe when to download data logger data and when to analyse. • Reference to use of 'Disruption of Cold Chain Form' • Reminder that the stock management spreadsheet must be maintained and should not contain blank cells • Addition of applying green stickers to boxes of unused vaccine returned from vaccination clinics • Clarity around identification of opened boxes of vaccines • Reminder added to not line Labcold™ Vaccine Carriers with cool packs • Removal of reference to oxygen cylinders and associated appendix	
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Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Senior Pharmacy Technician, Immunisation/Vaccination & Pharmacy Stores
Pharmacy Stores Pharmacy Technician
Vaccination Centre Health Care Support Workers

Circulated to the following for Consultation

Date	Role / Designation
26/02/2024	Chief Pharmacist
	Senior Clinical Lead Nurse, Immunisation & Vaccination
	Head of Service: Public Health Programmes & Projects
	Lead Nurse, Clinical Supervisor & Vaccination Centre Manager, Immunisation & Vaccination (South)
	Lead Nurse & Clinical Supervisor (North)
12/05/2025	Senior Clinical Lead Nurse, Immunisation & Vaccination Service
	Deputy Clinical Lead, Immunisation & Vaccination Service
	Lead Nurse & Clinical Supervisors: Immunisation & Vaccination.
	Head of Service, Community Pharmacy Service
29/05/2025	Vaccination Programme Operational Development Group for update approval
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1 Introduction

Powys Teaching Health Board (PTHB) is committed to the safe and secure handling of vaccines to protect patients and staff.

Staff (registered e.g. nurses and unregistered e.g. Health Care Support Workers (HCSWs) in Vaccination Centres (VCs) support this and are integral members of the vaccination team. Staff responsible for the day-to-day management of vaccine are defined as Healthcare Support Workers (HCSWs). Registrants also contribute to vaccine management and act as supervisors to their HCSWs colleagues. Both unregistered and registered staff provide a core vaccine management service in accordance with professional standards, medicines/vaccine standards and legislation.

VC staff ensure the safe use of vaccines through good vaccine management and governance of the cold chain, and support the provision of a safe, effective, and efficient vaccination service for the residents of Powys.

This SOP clearly outlines the specific duties and training requirements of VC staff working within VCs and other community settings to ensure the safe and secure management of vaccine and maintenance of the cold chain.

It is mandatory for all staff members to always follow this standard operating procedure.

It is mandatory that all staff members read the SOPs listed in the essential reading section of this SOP.

It is mandatory for all unregistered staff (HCSWs) undertaking vaccine management duties in VCs to be trained and signed off as competent in all aspects of vaccine management/cold chain maintenance and to undertake all other training required for the role e.g., level 2 stock management course (GPhC accredited) (see section 7, Training for details)

It is mandatory for all registered staff to have a general underpinning knowledge of basic medicines legislation and to be able to supervise their HCSW colleagues, where required, in safe management of vaccine (see section 7. Training for details)

This process follows compliance with current legislative requirements and good practice guidance.

2. Objective

- To clearly outline the duties and training required of VC staff in accordance with professional standards and medicines legislation to support PTHB vaccination programmes.

3. Essential Reading

For information to support the requirements of this SOP, the following **must** be read:

- MMP 427 Safe and Secure Management of Refrigerated Medicines / Vaccines
- MMP 429 Safe and Secure Stock Management, Handling & Preparation of Vaccines in PTHB Vaccination Centres and other Community Settings
- MMP 428 Use of Labcold™ Portable Vaccine Carriers
- MMP 432 Use and Management of Helapet Vaccine Porters
- MMP 430 Cleaning / Defrosting PTHB Medicines / Vaccine Refrigerators
- MMP 443 Quarantine, Product Recall and Destruction of Vaccines
- MMP 444 Responding to Pharmaceutical Incidents
- MMP 447 Vaccination Team/PS Team Stock Management - Record Keeping

All SOPs can be accessed via the Medicines Management website [Policies, Procedures, Protocols, SOPs and Guidelines - Powys Teaching Health Board](#) or via the Vaccination Centre Teams Channel. SOPs can also be located in the vaccine management SOP folder located in each vaccination centre, also see Section 7 - Training

4. Definitions

- **Cold chain** – is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient.
- **Data logger** – an electronic device which allows a detailed analysis of temperature. Data loggers can be used to provide assurance that the cold chain has been maintained and to provide information about the duration of temperature excursions. Data loggers are frequently placed in medicines refrigerators and in vaccine porters during transportation.

- **GPhC** – The General Pharmaceutical Council are the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.
- **HCSW** - Health Care Support Worker
- **PTHB** – Powys Teaching Health Board
- **Quarantine**-To separate/isolate affected stock from supply chain which must be clearly labelled with 'Quarantined – do not use' and dated.
- **Supply Chain**- Term used to describe the whole cold chain process from the point of receiving the medication into stock, transport, maintaining the medicines and the point of supplying medication.
- **Temperature deviation/excursion** – any incident where the recorded Labcold™ portable vaccine carrier temperature is outside of the recommended range of +2°C to +8°C.
- **Vaccine** – a suspension of attenuated or killed microorganisms (viruses, bacteria or rickettsia) or of antigenic proteins derived from them, administered for prevention, amelioration or treatment of infectious disease.

5. Roles / Responsibilities

5.1 Senior Clinical Lead Nurse / VC Lead Nurse

- The senior lead nurse / VC lead nurse, in collaboration with the senior pharmacy technician for immunisation / vaccination, and pharmacy stores, is responsible for ensuring that all appropriate staff for whom they have responsibility (e.g., anyone who handles vaccines in VCs / community settings) are trained and competent in vaccine management, have undertaken all other necessary training e.g., cold chain training and have read, understood, and adhere to the standards in this SOP.

5.2 Senior Pharmacy Technician, Vaccination/Immunisation, & Pharmacy Stores (Senior Pharmacy Technician)

- The senior pharmacy technician is responsible for ensuring that staff in VCs are provided with training opportunities in the duties required of them to ensure safe management of vaccine.
- The senior pharmacy technician is responsible for arranging regular review to monitor compliance with this SOP, providing vaccine management support and training, and for ensuring training records are up to date.
- The senior pharmacy technician is responsible for maintaining lines of communication with VC staff to provide support and updates.

5.3 Pharmacy Technician Immunisation / Vaccination & Pharmacy Stores

Under the supervision of the senior pharmacy technician the Pharmacy Store Technician is responsible for providing and coordinating training for both registrants and non-registrants involved in vaccine management activities. This includes ensuring staff are competent in basic pharmacy procedures, vaccine handling and storage requirements, cold chain maintenance, fridge monitoring processes, temperature recording, escalation of temperature excursions, and completion of all relevant documentation. The Pharmacy Store Technician is also responsible for maintaining training records, providing refresher training where required, and supporting ongoing compliance with local procedures, national guidance, and governance requirements.

5.4 Other Staff (Registrants and HCSWs)

All staff are responsible for their own actions and must maintain professional accountability for the tasks and duties they undertake. Staff should work within their scope of competence, follow approved policies, procedures and guidance, promptly report any errors, incidents or concerns, and take appropriate action to rectify issues where possible. Staff are expected to seek advice or support when required to ensure the safe and effective management of vaccines and related activities.

- With support from the senior pharmacy technician/pharmacy stores pharmacy technician, HCSWs must undertake education and training to

	meet GPhC standards to be able to safely manage vaccines. • All staff (registered and HCSWs) handling vaccine in VCs, and other community settings are responsible for undertaking cold chain / vaccine storage training, Good Distribution Practice (GDP) training, adhering to this SOP, maintaining competencies and updating any other training wherever required. • All staff are responsible for reading vaccine management related SOPs to support the duties outlined in this SOP and must date the SOP log attached to each SOP when read (see section 3). • All staff are responsible for keeping the VC training tracker up to date.
6. Managing Vaccine Staff who handle vaccine in VCs and any wider community settings must have received training and be competent in vaccine management activities (see section 7). They must: • Liaise with the pharmacy team in relation to all vaccine stock management operational duties and training requirements. 6.1 Vaccine Storage Area With support from the pharmacy team, a named person must be assigned to cover the following activities: • Maintaining the vaccine storage area e.g. keeping the area free from clutter and organizing all consumables/equipment neatly. • Regular sanitising of the vaccine storage area and equipment e.g. surfaces, high touch areas e.g. fridge handles, vaccine trays. • Managing the VC anaphylaxis kit e.g. ensuring that it is locked away in the medicine's cupboard when not in use, ensuring that it is kept in a safe location during vaccination sessions and that staff are aware of the location of the kit. • Performing regular expiry checks of the contents of all anaphylaxis kits and informing the pharmacy team in advance of items expiring. • Managing the small supply of VC anaphylaxis kits for use in community settings e.g. for outreach clinics and ensuring that these kits are not left unattended during vaccination sessions.	

- Ensuring that anaphylaxis kits taken from VCs into community settings are returned to base and locked in the medicine's cupboard at the end of the day.
- Ensuring that the correct Patient Information Leaflets (PILs) are available for VC administration staff to hand out to patients for the vaccine in use.
- Managing vaccine handout toward the end of the day in collaboration with the VC administration team and the lead nurse to avoid unnecessary waste.
- Where able, preparing vaccine trays in readiness for the next day (when vaccination sessions are planned on the main vaccination sites).
- Holding the pharmacy key throughout a shift (for fridge and medicines cupboard).
- Supporting training of new staff in vaccine management with support from the senior pharmacy technician and/or the pharmacy store pharmacy technician.
- Responding to pharmaceutical incidents e.g. product re-call, with support from the senior pharmacy technician and /or the pharmacy store pharmacy technician.
- Staff must always maintain clear and effective communication with colleagues, particularly when handing over responsibilities at the end of a shift or working day. Any outstanding tasks, issues, vaccine stock concerns, delivery updates, incidents, or actions requiring follow-up must be communicated clearly to the colleague assuming responsibility to ensure continuity of service and patient safety.

6.2 HCSWs: Supporting Vaccinators

The named person assigned to vaccine management is responsible for:

- Assembling vaccine trays for vaccinators, and that it contains the correct number of consumables.
- Ensuring that in instances where more than one vaccine product is being used at a vaccination session, a separate tray is used for each vaccine type when issuing vaccines to vaccinators. This is to minimise the risk of selection errors, ensure accurate vaccine identification, and support the safe administration of vaccines.
- Ensuring that vaccines are always handled carefully and kept upright (particularly fragile Covid vaccines).
- Ensuring that vaccine stock held in the fridge is protected from light (e.g., the vaccine box lid always remains closed).

- Inspecting Covid vaccine vials for particulates by carefully holding up to the light in an upright position, before handing out to vaccinators.
- Reminding vaccinators when vaccine/diluent (where applicable) batch numbers may change mid-session.
- Preparation/supply of vaccination cards where necessary

6.3 Refrigerators / Cold Chain

The named person assigned to vaccine management is responsible for:

- Monitoring fridge temperatures, re-setting and recording on the Welsh Immunisation System (WIS), twice daily.
- Ensuring that VC vaccine fridges are locked when not in use throughout the day e.g., during breaks or when the fridge area is vacated for any other reason.
- Ensuring that Labcold™ vaccine carriers / Helapet vaccine porters are not left unattended when in use at outreach clinics.
- The swift transfer of vaccine deliveries from +2°C - +8°C to the VC refrigerator to ensure maintenance of the cold chain.
- Ensuring that when fridges are in use, the fridge door/vaccine porter lid e.g. at outreach clinics, is opened for the absolute minimum amount of time.
- Ensuring that vaccine porter lids e.g. Helapet and Labcold vaccine carriers are closed securely after opening to ensure that the cold chain is maintained.
- Ensuring that the correct paperwork is provided to staff for outreach clinics e.g., for vaccine porter monitoring purposes.
- Ensuring that the fridges are not overloaded with stock, to allow air to circulate freely.
- Ensuring that Labcold™ portable vaccine carriers are not overloaded with stock for use at outreach clinics, so that the unit is able to function efficiently.
- Ensuring that Helapet vaccine porters are prepared correctly before loading with stock e.g., suitably cooled cool packs are used (e.g., cooled for 24 hours before use) and that the correct sized cool packs are used for the vaccine porter in use.
- Management of data loggers e.g., downloading data, analysing data and re-configuring the data logger after use. Data logger downloads must be suitably named saved in the relevant file in the Vaccination Team Teams Channel, for easy retrieval.
- Responding to and reporting temperature excursions immediately to the lead nurse, senior pharmacy technician and/or pharmacy stores pharmacy technician. If the senior technician / pharmacy stores pharmacy technician is

unavailable, contact the pharmacy team immediately, for advice PTHB.VaccPharmacyStoreOrders@wales.nhs.uk or call 01874 712641

- Following a temperature excursion, providing the pharmacy team with a completed 'disruption of cold chain' form, the relevant data logger downloads and any other information requested by the pharmacy team.
- Following the procedure for quarantining stock
- Ensuring that there are spare replacement batteries in the VC for refrigerators.
- Responding to fridge alarms quickly and efficiently.
- Checking that fridges and other equipment e.g. Labcold™ vaccine carriers, data loggers are being used within their calibration period.
- Informing the pharmacy team immediately if the fridge is not operating efficiently.
- Cleaning vaccine refrigerators (defrosting where necessary) every month and Labcold™ portable vaccine carriers/Helapet vaccine porters/cool packs after every use.
- Managing cool pack stock to ensure that suitably cooled cool packs (e.g., cooled for 24 hours prior to use) are readily available

6.4 Stock

With support from pharmacy staff, the named person assigned to vaccine management is responsible for:

- Monitoring stock levels and recording on WIS / stock management spreadsheet twice daily.
- Reporting stock levels, batch numbers and expiry dates to senior pharmacy technician once weekly.
- Receipting stock onto WIS / vaccine management spreadsheet.
- Ensuring stock is rotated so that shortest dated stock is at the front of the fridge to be used first.
- Monitoring vaccine expiry dates to ensure that waste is avoided.
- Where possible, segregating different vaccines on separate shelves in the fridge to avoid errors in choosing the wrong vaccine.
- Ensuring that fridges are not overstocked e.g. air is able to circulate freely and that the fan / probes are not obstructed.
- Preparation of vaccine for transfer to community settings and entering transfer details onto the stock management Excel spreadsheet.

- Ensuring that the stock management log is up to date, filled in correctly at all times (in accordance with pharmacy governance standards) and that there are no blank cells across the workbook (n/a where necessary). Full names, not first names, must be used across the workbook.
- Managing stock returned from community settings e.g., care homes/outreach, to ensure that the cold chain can be assured before returning to stock (e.g., analyse the data logger download and save in the relevant file on the VC Teams channel).
- Where vaccine is returned unused to the VC and where the cold chain can be assured, placing a green sticker on the vaccine box and placing in the front of the fridge to be used first at the next vaccination clinic.
- Marking opened vaccine boxes with a cross on the front of the box for easy identification.
- Managing quarantined stock e.g., completing quarantine forms, responding to recommended outcomes from pharmacy store staff following investigation into quarantined stock.
- Responding to pharmaceutical incidents with support from the pharmacy store team
- Entering vaccine stock wastage onto WIS.
- Using the stock management Excel spreadsheet for vaccines not supported by WIS e.g. MMR vaccine.
- Managing vaccine transfers for community settings e.g. for care homes, outreach. Raise a reference number and complete the VC Order Processing Spreadsheet located in the Pharmacy Teams channel.

6.5 Vaccine Porters – Helapet

With support from the pharmacy team, the named person assigned to vaccine management is responsible for:

- Managing VC Helapet vaccine porters and cool packs e.g., ensuring excess VC Helapet vaccine porters/cool packs are returned to pharmacy stores and that VC Helapet vaccine porters and cool packs are cleaned after each use.
- Ensuring that cool packs are cooled in the fridge 24 hours before re-use and the relevant paperwork is used to indicate when the cool packs will be next ready for re-use.
- Ensuring Helapet vaccine porters are loaded correctly e.g., the correct number and size of cool packs are chosen for the vaccine porter in use and that the vaccine porter is lined with bubble wrap prior to filling with vaccine.

- Ensuring a Helapet vaccine porter log is provided with each unit when used at outreach / walkabouts etc.
- Ensuring a data logger has been reconfigured and is placed in the Helapet vaccine porter with the vaccine before it leaves the VC.
- Ensuring data loggers are placed in any spare, empty Helapet vaccine carriers that may be transferred into community settings e.g., for emergency use.
- Management of data loggers e.g., downloading data and reconfiguring the data logger after use. Helapet vaccine porter data loggers must be downloaded after every use, analysed for cold chain assurance and the data downloaded and saved in the relevant file in the VC Teams channel
- Inform the VC lead nurse and pharmacy team immediately if any temperature excursions (for any length of time) are evident from the data download.

6.6 VC Helapet vaccine porters/cool packs stock levels

The named person assigned to vaccine management is responsible for:

- Maintaining 2 large vaccine porters and 24 large cool packs in the VC in case of emergencies (e.g., power failure). Each centre should also keep one medium vaccine porter and 28 small cool packs (for ad hoc use in the community) and one small vaccine porter and 12 small cool packs (for ad hoc use in the community). In total:
 - 2 large Helapet vaccine porters
 - 1 medium Helapet vaccine porter
 - 1 small Helapet vaccine porter
 - 24 large cool packs
 - 40 small cool packs

N.B. These quantities can be increased during busier periods or decreased during quieter periods.
- Do not stack cool packs more than 3 high in the refrigerator.

6.7 Vaccine Porters - Labcold™

The named person assigned to vaccine management is responsible for:

- Managing Labcold™ Portable Vaccine Carriers e.g., ensuring that they are plugged in, and that the temperature has stabilised between +2°C to +8°C before packing with vaccine.

- Ensuring a data logger has been reconfigured and is placed inside the Labcold™ Portable Vaccine Carrier with the vaccine before it leaves the VC.
- Ensuring that the Labcold vaccine porter is not lined with bubble wrap/cool packs or include any other material within the unit, as this may affect the efficiency of the unit, resulting in abnormal temperature readings.
- Ensuring that the member of staff transferring vaccine from the VC into a community setting are aware that the Labcold™ Portable Vaccine Carrier must be plugged into the vehicle AV socket and secured appropriately throughout the journey.
- Providing a temperature monitoring log for each Labcold™ Portable Vaccine Carrier in use and a monitoring log for each Helapet vaccine porter in use.
- Completing the Labcold™ temperature monitoring log when on duty at outreach clinics and taking appropriate action if the temperature display on the unit indicates that the temperature has breached e.g., outside of +2°C to 8°C
- Management of data loggers:
 - Checking the returned Labcold™ temperature monitoring log at the end of the day to ensure that there have been no temperature deviations (if a temperature excursion is evident, liaise with the member of staff that was on duty to ensure that appropriate actions were taken).
 - Downloading the data logger data. e.g., where the manual Labcold™ temp log indicates a temperature excursion has occurred, but no action has been taken. Data logger must be downloaded and analysed and actioned appropriately.
 - Downloading and analysing data loggers used with Helapet vaccine porters and taking appropriate action if a temperature excursion is identified.
 - Ensuring that all data loggers used with Labcold™ Portable Vaccine Carriers and Helapet vaccine porters are downloaded, named appropriately and saved in the relevant file for easy retrieval.
- Placing a green sticker on the vaccine carton when the cold chain can be assured for unused vaccine returned to the VC fridge from community settings. Inform the VC lead nurse and pharmacy team immediately if any temperature excursions (for any length of time) are evident from the data download and quarantine stock until further notice.
- Ensuring that Labcold™ Portable Vaccine Carriers are cleaned (with Clinell wipes) after use and are stored safely and securely to avoid damage to the unit.

7. Training

All authorised staff handling vaccine within VCs/Community Settings must be trained and competent to do so.

Non-Registrants (HCSWs)

HCSWs supporting vaccine management must undertake education and training to meet GPhC standards, e.g. Level 2 qualification in Stock Management.

HCSWs - The following training must be completed:

- New starters must work alongside a trained and competent member of the VC team for a period of time to familiarise themselves with the principles of vaccine management and associated practical duties, prior to competencies being signed off. This time may vary between individuals, according to experience.
- Following adequate training and where the individual feels confident and competent to undertake the practical duties associated with vaccine management with minimum supervision, competencies can be signed off; either by trained and competent VC pharmacy support staff e.g., GPhC accredited staff member (HCSW) or by a member of the pharmacy team.
- The signed competency sheet must be forwarded to the pharmacy team and the newly trained member of staff must keep the original copy in their training file.

Registrants

Registrants are responsible for identifying their own training needs and will be supported by the senior pharmacy technician / pharmacy stores pharmacy technician:

- Registrants are accountable for their own actions and must exercise professional judgement in vaccine management and administration in accordance with standards set by their professional body and in accordance with medicines legislation. Registrants must be able to supervise their HCSW Immuniser colleagues in safe management of vaccine. The senior pharmacy technician and/or the pharmacy store pharmacy technician can provide support on any vaccine management training needs identified by individual clinicians, on request.

- Registrants must be proficient in the practical elements necessary to ensure the safe and secure management of vaccine in VCs and in community settings:
 - Taking and recording fridge temperatures, re-setting the fridge temperature
 - Use data loggers e.g. reconfiguring, downloading, analysing, naming and saving in relevant VC Teams folder.
 - Use of WIS e.g. fridge/stock monitoring/recording waste
 - Use of vaccine porters including Labcold™ portable vaccine carriers. All new starters must sign the competency sheet once training in Labcold™ portable vaccine carrier use has been completed (access here: [Competency Checklists Vaccine Management](#))
 - Maintaining the vaccine stock management Excel spreadsheet
 - Good understanding of stock management e.g. how to store vaccine correctly, stock rotation/expiry date checking
 - Managing waste (e.g., minimising waste toward the end of a vaccination session)
- All non-registrants (HCSWs) and registered staff are responsible for ensuring that training records relating to vaccine management are up to date and that where appropriate the VC training tracker is updated.

All staff must also be up to date with cold chain and vaccine storage training which can be accessed via ESR:

[070 Cold Chain Training –The safe and secure management of refrigerated medicine](#) (annual)

[000 Vaccine Storage](#) (one off)

All staff handling vaccine in VCs and community settings must be familiar with Good Distribution Practice (GDP). GDP training is undertaken individually in the form of a PowerPoint presentation and is certificated 'in-house'. This training must be refreshed annually. For information on how to access GDP training contact the pharmacy team

All staff handling vaccine must be familiar with and have access to the VC vaccine Management folder. For access contact the Pharmacy team.

8. Monitoring Compliance / Audit / Review

Compliance with this SOP will be audited during annual pharmacy audits in vaccination centres.

This SOP will be reviewed every three years or earlier should changes to legislation or to practice indicate otherwise.

9. References

PTHB Vaccination Centre SOPs

[https://nhswales365.sharepoint.com/:f:/r/sites/POW MVCPharmacy Team/Shared%20Documents/General/Standard%20Operating%20Procedures%20from%20April%202023?csf=1&web=1&e=uiqGhE](https://nhswales365.sharepoint.com/:f:/r/sites/POW_MVCPharmacyTeam/Shared%20Documents/General/Standard%20Operating%20Procedures%20from%20April%202023?csf=1&web=1&e=uiqGhE)