Quarantine, Product Recall and Disposal of Vaccines, Vaccination Centres and Pharmacy Stores

Standard Operating Procedure.

Document Reference No:	PTHB / MMP 443	
Version No:	2	
Issue Date:	April 2024	
Review Date:	April 2027	
Author:	Senior Pharmacy Technician	
Document Owner:	Chief Pharmacist	
Accountable Executive:	Medical Director	
Approved By:	Vaccination and Immunisation Operational Development Group	
Approval Date:	08/04/2024	
Document Type:	Standard Operating Procedure	Non-clinical
Scope:	PTHB	

The latest approved version of this document is online.
If the review date has passed, please contact the Author for advice.

Version Control:

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	11/01/2021
2	SOP moved from MMT SOP template to PTHB SOP template. Updated: Greater clarity around processes and paperwork updated.	08/04/2024

Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Nikki Mathers, Senior Pharmacy Technician, Immunisation/Vaccination, Therapies & Pharmacy Stores

Circulated to the following for Consultation

Date	Role / Designation
06/03/2024	Chief Pharmacist
	Senior Clinical Lead Nurse, Immunisation & Vaccination
	Head of Service: Public Health Programmes & Projects
	Lead Nurse, Clinical Supervisor & Vaccination Centre Manager, Immunisation & Vaccination
	Lead Nurse, Vaccination Centre

1 Introduction

Powys Teaching Health Board (PTHB) is committed to maintaining the safety and efficacy of medicines and vaccines to protect patients and staff.

Medicines/vaccines stored in the pharmacy store (PS) and in vaccination sites (VC) in PTHB are managed according to Standard Operating Procedures (SOPs) in line with pharmaceutical guidelines, legislation, and safe practice guidelines.

On rare occasions there may be instances when a product will require quarantining. The need to quarantine a product may come from several sources, for example:

- The manufacturer or regulator, as a drug recall.
- The pharmacy/vaccination team following a temperature excursion or transport temperature deviation.
- Any staff member on noticing a problem with the product.

The most common (but rare) reason for quarantining vaccine in VCs, outreach clinics and PS is due to a breach in the cold chain. Correct cold chain management will prevent temperature excursions, however, there may be occasions where breaches to the cold chain are unavoidable i.e. during a disruption to the power supply outside of normal working hours.

It is mandatory for all staff members involved in the management of medicines and vaccines to always follow this standard operating procedure.

2. Objective

- To clearly describe the process for placing medicines/vaccines under quarantine
- To describe the process for dealing with product recalls.
- To describe the process for safe disposal of vaccine

3. Definitions

- **PTHB** – Powys Teaching Health Board

- **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.

- **Medicine** – a substance used for treating, preventing or diagnosing disease, for contraception, inducing anaesthesia or modifying normal physiological function.

- **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.

- **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.

4. Role / Responsibilities

4.1 Service Lead

The Service Lead must:

- Ensure all staff read and understand this procedure.

4.2 Clinical Lead / Senior Nurse

- The senior nurse is responsible for ensuring that all appropriate staff for whom they have responsibility (i.e., anyone who has any involvement with vaccine stock management have read, understood, and adhere to the standards in this SOP. They are also responsible for managing any temperature excursion that may occur.
- The clinical lead / senior nurse is responsible for ensuring that staff are trained and competent to perform the duties

required of them in accordance with the requirements of the General Pharmaceutical Council (GPhC).

4.3 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores

- The senior pharmacy technician is responsible for arranging regular review to monitor compliance with this procedure and to provide advice and support on the correct procedures to follow should vaccine require quarantining, are recalled, or need to be disposed of safely. They are also responsible for providing advice on suitability of medicine/vaccine use following temperature excursions.
- The senior pharmacy technician is responsible for ensuring that VC pharmacy support staff are trained and competent to perform the duties required of them and that training meets the requirements of the General Pharmaceutical Council (GPhC).

4.4 Other Staff

- Unregistered staff supporting the pharmacy role must undertake education and training to meet GPhC standards.
- All staff employed by Powys Teaching Health Board (PTHB) who are involved in the management of vaccine stock are responsible for undertaking cold chain training, Good Distribution Practice (GDP) training, adhering to this SOP, maintaining competencies, and reporting and reacting to temperature excursions.

5. Quarantine of Vaccine – Vaccination Centres

The decision to quarantine the product should be made in conjunction with the senior technician for immunisation/vaccination.

If it is necessary to quarantine a product:

- Do not dispose of any vaccines or storage equipment.
- Segregate all quarantined products in clear plastic bags and label the bags appropriately to indicate clearly that the items are quarantined and should not be used (see appendix A).

Labels should read:

QUARANTINED STOCK. CASE No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

- Place quarantined products in the designated 'Quarantine Area' according to type of product i.e., vaccines will need to be stored in the fridge.
- Quarantined vaccines must be maintained between +2°C to +8°C and moved to an alternative monitored environment, if necessary, that is able to maintain the recommended +2°C to +8°C temperature range.
- The quarantine area should be clearly marked. Fridge items should be placed on a separate shelf of the fridge marked 'quarantine'.

5.1 Reporting & Quarantining a Product – Vaccination Centre.

- Contact the senior technician for immunisation/vaccination or other member of the pharmacy stores team to discuss if a product needs to be quarantined i.e. following a fridge excursion.

- If quarantine is necessary, complete the 'Under Quarantine' paperwork (Appendix B) and the 'Quarantine File Log VC' (Appendix D/E).

- Segregate the quarantined stock in the dedicated 'quarantine area/shelf' and email a copy of the 'Under Quarantine' paperwork (Appendix B) to the senior technician for immunisation/vaccination or other member of the pharmacy stores team: info.medicinesmanagement.powys@wales.nhs.uk and nikki.mathers@wales.nhs.uk Remember to add the quarantine case number to the quarantine labels. Place the paperwork in the VC quarantine folder.

- Stock must remain in quarantine until further investigation has been undertaken by the pharmacy stores team.

- For fridge temperature excursions, also complete a disruption of cold chain form FULLY and email to info.medicinesmanagement.powys@wales.nhs.uk and nikki.mathers@wales.nhs.uk along with a copy of the 'Under Quarantine' paperwork (see MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines for information on managing fridge temperature excursions) Medicines Management - SOPs - All Documents (sharepoint.com)

- The pharmacy stores team will investigate the incident and report the fate of the product and instructions back to the vaccination centre.

5.2 Returning a Product to Stock – Vaccination Centre

- If product has been assured for re-use, the pharmacy stores team will forward the 'Under Quarantine' (appendix B) paperwork back to the VC. The paperwork will contain details of the fate of the product.
- Ensure that the quarantined product case number and batch numbers reported back to the vaccination site from the pharmacy stores team, match the case number and batch numbers on the quarantine label on the quarantined stock in the fridge. Also check that the batch number matches the product inside the quarantine bag.
- If the quarantined products have been authorised for use, place them back into stock on the appropriate shelf in the storage area/fridge. Ensure any new expiry dates and times (if required) are clearly indicated on the product. Rotate stock where necessary i.e. products with the shortest expiry date at the front, to be used first.
- Ensure products are marked as advised by the MMT e.g., 'fridge excursion xx/xx/20xx'.

Products unsuitable for re-use must be disposed of appropriately and local stock management systems amended to reflect active stock numbers, including updates to the WIS system/Immform (where required). See section 9.

6. Quarantine of Vaccine – Pharmacy Stores

Segregate all quarantined products in clear plastic bags and label the bags appropriately to indicate clearly that the items are quarantined and should not be used (see appendix A).

Labels should read:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

- Segregate the product in the dedicated 'quarantine area/shelf' and complete the 'Under Quarantine' paperwork (Appendix B) and quarantine file log for pharmacy stores (Appendix C),
- Scan and save a copy in the relevant folder of the local stock management system.
- For fridge temperature excursions, also complete the relevant fridge excursion paperwork FULLY (see MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines) Medicines Management - SOPs - All Documents (sharepoint.com)
- A nominated member of the pharmacy stores team or other MMT member of staff will investigate the incident and determine actions required.

6.1 Returning a Product to Stock – Pharmacy Stores

- If product has been assured for re-use, ensure quarantined product case number and batch numbers match the case number and batch numbers on the quarantine shelf/area.
- Remove the authorised product/batches from quarantine and place on the appropriate shelf in the storage room/fridge. Ensure any new expiry dates and times (if required) are clearly indicated on the product.
- Ensure products are placed in the storage area/fridge in accordance with their expiry date/time with the products with the shortest expiry date/time at the front, to be used first.
- Ensure products are marked as otherwise necessary e.g., following a fridge excursion.

7. Investigating the fate of a quarantined products

7.1 Temperature Deviations

- In the event of a temperature deviation, confirmation of suitability for re-use or reduced expiry etc. must be sought from the manufacturer, Fridge Database (www.SPS.nhs.uk) or Public Health Wales. A 'Disruption of Cold Chain' form and 'DATIX' report must also be completed (See 'Incident Reporting' SOP for full details of process). Access to complete a 'DATIX' report can be found on PTHB home page http://nww.powysthb.wales.nhs.uk/page/67837
- Authorisation for releasing the product from quarantine must be provided in writing i.e., email from the manufacturer, PHW or screenshot of the Fridge Database. The authorisation must be printed and filed alongside the quarantine form (Appendix B 'Under Quarantine').
- Forward confirmation of release of product to Vaccination Site (if necessary) (i.e., Completed 'Under Quarantine' paperwork and fridge reporting log (See SOP 'Vaccine Fridge Monitoring and Excursions')
- If the product is not authorised for re-use, attach a copy of communication to the completed quarantine form (Appendix B 'Under Quarantine') and forward to VC.
- Where appropriate, inform VC that products unsuitable for re-use must be disposed of appropriately and vaccine stock logs amended to reflect active stock numbers, including updates to the WIS system/Immform (where required) – see SOP 107 - Safe & Secure Stock Management and Handling of COVID Vaccines within Powys Teaching Health Board Vaccination Sites
- PTHB Pharmacy Stores products unsuitable for re-use must be disposed of appropriately and vaccine stock logs amended to reflect active stock numbers, including updates to the WIS system/Immform (where required).

7.2 Any Other Quarantined Stock

- PTHB Pharmacy Stores team to contact the manufacturer/PHW/SPS or other specialist advice to discuss fate of quarantined stock.
- Report outcome to VC (if necessary) with clear instructions of product fate via completed 'Quarantine Form' (Appendix B). Where appropriate, drug accountability logs must be amended to reflect active stock numbers.
- The Pharmacy Stores product outcome should be documented on the 'Quarantine Form' (Appendix B) and dealt with accordingly i.e. disposed of or returned to stock.

8. Product Recall

- Product recall notifications will be communicated to PTHB Chief Pharmacist.
- https://www.gov.uk/drug-device-alerts also provides information of current recalls.
- The recall notice will advise on action to be undertaken. If quarantine is advised – follow above process. Otherwise, action as advised by the notice.
- Input details of recall notification onto the 'Alerts' spreadsheet in the shared drive.
- PTHB pharmacy store team must complete the product recall log (See Appendix F) and inform vaccination sites where recalled products may be in stock and request that they are quarantined until further notice, or other action taken as advised in the recall notice. A copy of the product re-call log should be forwarded to the vaccination site (See Appendix F). Vaccination site to file and keep in a dedicated folder on site.
- PTHB Pharmacy Stores team/MMT will instruct vaccination site on the course of action of recalled products (i.e. how to return)

9. Disposal of Vaccines

- Disposal of vaccines must comply with current waste regulations. Vaccines are classed as clinical waste.
- Vaccines should only be disposed of by incineration at a suitably authorised site.
- Equipment used for vaccination, including used vials, ampoules, syringes, or partially discharged vaccines should be disposed of at the end of a session by placing in a proper, puncture-resistant Yellow Lidded 'sharps' box according to local authority regulations and national guidance.
- The 'sharps' container should be sealed and replaced once it is two-thirds full, or the level indicated on the box by the manufacturer. The container should not be accessible to any unauthorised individual and disposed of as per local contractual procedures.
- If the vaccine for destruction is classed as 'live' then it should be disposed of in in a 'sharps' container marked "contains live vaccine".

10. Monitoring Compliance / Audit / Review

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

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

11. References

PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines Medicines Management - SOPs - All Documents (sharepoint.com)

Appendix A

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

QUARANTINED STOCK. Case No:
Product name:

Batch No.:

Expiry:

Manufacturer:
Date & Time Quarantined:
Sign:

Appendix B

UNDER QUARANTINE Reporting Form

Location: **Case Number**

Vaccination Centres must send this form electronically to the Pharmacy Stores Team

Name of Vaccine:	
Batch No & Expiry	Batch No. Expiry:
FOR QUARANTINE. Date & Time Quarantine Started **No. of vials/syringes: .....**	Date: Time: ***For Quarantine – a copy of this form must be sent to MMT***
FOR VACCINE WASTAGE – NON-COVID VACCINE ONLY. **Date and Time Vaccine Wasted:** **.....** **No. of doses: .....**	Date: Time: ***For non-Covid Vaccine Waste - this form does not need to be forwarded to MMT but must be filed at VC in 'QUARANTINE FOLDER.'***
Reason for quarantine: *e.g., temperature deviation, wasted dose*	
Action Taken: (MMT USE ONLY) *(e.g. Contacted manufacturer/SPS/Expert/PHW)*	
Product Suitable for Use: (attach communication)	YES
Following Quarantine ONLY - Date Product Returned to Shelf: **TO BE COMPLETED BY VC PHARMACY STAFF FOLLOWING MMT ADVICE**	Date:
Date Product Placed for Destruction: **TO BE COMPLETED BY VC PHARMACY STAFF** (enter details on WIS, where applicable)	Date:

Vaccination Centres must send this form electronically to the Pharmacy Stores Team info.medicinesmanagement.powys@wales.nhs.uk and copy in nikki.mathers@wales.nhs.uk

Place this form in the quarantine folder.

Place quarantined stock in a plastic bag and attach a quarantine label to the bag.

Once the quarantine cycle is completed, file any communication from Pharmacy Stores team/MMT regarding fate of the stock under the 'completed' section of the quarantine file, attached to this sheet.

Non-Covid vaccine waste - File this sheet in 'completed' section of quarantine file, do not send to Pharmacy Stores team/MMT.

Covid vaccine waste to be recorded directly on WIS.

Appendix C

QUARANTINE FILE LOG Pharmacy Stores

Case No.	Drug/Vaccine	Batch No.	Expiry (date & time)	Manufacturer	Date & Time Quarantine Started	Date & Time Quarantine Ended
CS01						
CS02						
CS03						
CS04						
CS05						
CS06						
CS07						
CS08						
CS09						
CS10						
CS11						
CS12						
CS13						
CS14						
CS15						
CS16						

Appendix D

QUARANTINE FILE LOG – Vaccination Centre

Location of Vaccination Centre: Concert Hall

Case No.	Drug/Vaccine	Batch No.	Expiry (date & time)	Manufacturer	Date & Time Quarantine Started	Date & Time Quarantine Ended
QCH01						
QCH02						
QCH03						
QCH04						
QCH05						
QCH06						
QCH07						
QCH08						
QCH09						
QCH10						
QCH11						
QCH12						
QCH13						
QCH14						
QCH15						
QCH16						

Appendix E

QUARANTINE LOG – Vaccination Centre

Location of Vaccination Centre: Newtown

Case No.	Drug/Vaccine	Batch No.	Expiry (date & time)	Manufacturer	Date & Time Quarantine Started	Date & Time Quarantine Ended
QNT01						
QNT02						
QNT03						
QNT04						
QNT05						
QNT06						
QNT07						
QNT08						
QNT09						
QNT10						
QNT11						
QNT12						
QNT13						
QNT14						
QNT15						
QNT16						

Appendix F

LOG OF VACCINE / MEDICAL DEVICE ALERTS AND RECALLS

Date of Alert	Type of Alert	Name of Product	Batch No.	Expiry Date	Any Patients Affected?	Document Action Taken	Print, Sign Name and Date