Responding to Vaccine Pharmaceutical Incidents (non-clinical)

Standard Operating Procedure.

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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 MMT SOP 0125	14/01/2021
1.1	Wording updated for more clarity	05/09/2022
1.2	Updated to indicate that this SOP does not include reporting clinical vaccine incidents	19/03/2023
4	MMT SOP 0125 moved to PTHB SOP template	20/05/2024
5	Updated to include section on 'off-label' use of vaccines (section 5 (5.2))	18/09/2025

Engagement & Consultation

Key Individuals/Groups Involved in <u>Developing</u> this Document

Role / Designation
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Circulated to the following for Consultation

Date	Role / Designation
11/03/2024	Vaccination Centres Clinical Lead Nurse
11/03/2024	Vaccination Centre Lead Nurse
02/09/2025	Senior Pharmacist, Community Services Pharmacy Team
18/09/2025	Operational Development Group, Vaccination Service

1 Introduction

It is essential that staff are aware of how they should respond to pharmaceutical incidents in order for them to be investigated, documented and reported accurately and consistently.

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

2. Objective

To clearly establish any actions which must be taken when responding to pharmaceutical incidents involving vaccines, including how to report an Adverse Drug Reaction (ADR). Note, this SOP does not cover responding to clinical incidents.

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 428 Use of Labcold™ Portable Vaccine Carriers
- MMP 429 Safe and Secure Stock Management and Handling of Vaccine in Vaccination Centres and Community Settings
- MMP 430 Cleaning / Defrosting PTHB Medicines / Vaccine Refrigerators
- MMP 432 Use and Management of Helapet Vaccine Porters
- MMP 439 Roles, Responsibilities and Training – Vaccine Management in Vaccination Centres and in Community Settings
- MMP 443 Quarantine, Product Recall and Disposal of Vaccines
- MMP 447 Vaccination Team/Pharmacy Store Team Stock Management – Record Keeping

All SOPs can be accessed via the vaccine management SOP folder located in each vaccination centre and via the Medicines Management website Policies, Procedures, Protocols, SOPs and Guidelines - Powys Teaching Health Board

3. Definitions

- **ADR** – Adverse Drug Reaction is a response to a medicinal product which is noxious or unintended.
- **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.

- **GPhC** – The General Pharmaceutical Council is the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.

- **GDP** – Good Distribution Practice requires that medicines are obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions, as required by the product specification.

- **PTHB** – Powys Teaching Health Board

- **SmPC** – Summary of Product Characteristics

- **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.

- **WIS** – Welsh Immunisation System

4. Role / Responsibilities

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

The senior pharmacy technician for is responsible for:

- Ensuring that Vaccination Centre (VC) staff are trained and competent to perform the duties required of them in accordance with GPhC standards Standards | General Pharmaceutical Council (pharmacyregulation.org)
- Arranging regular review to monitor compliance with this procedure.
- Providing advice and support on how to respond to pharmaceutical incidents.
- Providing advice and support on the documentation process when responding to pharmaceutical incidents.
- Informing staff of the outcome of investigations into pharmaceutical incidents.

4.2 Senior Clinical Lead Nurse / VC Lead Nurses

The senior clinical nurse / VC lead nurses (in collaboration with the senior pharmacy technician) are responsible for:

- Ensuring that staff for whom they have responsibility within the VCs are trained and competent in vaccine management in accordance with GPhC standards Standards | General Pharmaceutical Council (pharmacyregulation.org).
- Ensuring that they understand how to respond to pharmaceutical incidents e.g. that they are documented and reported immediately to the senior pharmacy technician via Info.MedicinesManagement.Powys@wales.nhs.uk and where appropriate reported via DATIX.

4.4 Other Staff

- All VC staff (registered and Health Care Support Workers (HCSW) Immunisers) are responsible for undertaking cold chain training, vaccine storage training, Good Distribution Practice (GDP) training, adhering to this SOP, maintaining competence, and appropriately reporting and reacting to pharmaceutical incidents.

5. Process for Reporting Vaccine Pharmaceutical Incidents

5.1 Cold Chain – Temperature Deviation / Excursion

If there is a disruption of the cold chain (e.g. outside of +2 ^{o}C to +8^{o}C), immediate action must be taken (e.g. reporting to the senior pharmacy technician and/or pharmacy store pharmacy technician. The incident must be recorded on the disruption of cold chain form and reported via DATIX). The affected vaccine must be quarantined until further notice from the pharmacy store team. These tasks may be delegated to appropriately trained individuals to ensure a swift response to the temperature excursion but overall management to the response to the disruption of the cold chain is jointly held between the lead nurse on site and the senior pharmacy technician.

Please see MMP 427 - Safe and Secure Management of Refrigerated Medicines and Vaccines for detailed instruction of responding to cold chain incidents and MMP 443 Quarantine, Product Recall and Disposal of Vaccine.

5.2 Use of 'off-label' vaccine

Off-label (or off-licence) use of vaccines involves administering a licensed vaccine in a way not specified by its product license, such as for a different age group, schedule, or due to a temporary storage deviation.

Off-label use is based on evidence that it provides clear benefits and that the vaccine remains safe and effective for its new application.

Medicines/vaccines should be stored according to the conditions detailed in the Summary of Product Characteristics (SmPC) Home - electronic medicines compendium (emc). However, in the event of an inadvertent or unavoidable deviation of these conditions, the pharmacy store team or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy store team/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use, this would constitute off-label administration under the PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a decision has been taken to continue to use vaccines that have been stored outside the manufacturer's recommended temperature range, the administering practitioner or provider assumes responsibility for using the vaccine. The pharmacy store/Medicines Management Team will document the advice sought, the risk assessment and its conclusions, to support practitioners in practice and as part of a good clinical governance process[1].
In Vaccination Centres the cause of off-label use of vaccines is likely to be due to a temporary storage deviation e.g. a disruption to the cold chain. In this instance, follow the instructions in section 5.1 above and report to the pharmacy store team. The pharmacy store team will investigate the temperature excursion and will provide assurance as to whether the vaccine can be used as normal (e.g. within its licence), can be used off-label or must be disposed of.

Where vaccines have been approved for off-label use due to an inadvertent temperature excursion, then this must be indicated on the vaccine outer packaging. This will alert vaccination colleagues that the vaccine has been stored in a way other than that described in its licence and that the vaccinee must be informed of this before the vaccine is administered.

[1] Vaccine incident guidance: Responding to errors in vaccine storage, handling and administration

When an off-label vaccine is offered, individuals, parents or carers should be informed that the use is outside the product's official license but can given according to known information provided by the vaccine manufacturer who will advise on whether the vaccine can still be used (based on special stability studies).

Individuals should be assured that the decision to allow the vaccine to be used 'off-label' will only be taken if the vaccine is still considered to be safe and effective and that where small temporary changes in storage temperature have occurred that this won't affect the safety of the vaccine, nor the way in which it works.

Individuals, parents or carers should be provided with a leaflet explaining the reasons why some vaccines that have been temporarily stored outside the recommended temperature range, can still be used safely[2].

5.3 Reporting Vaccine Waste

Any vaccine waste e.g., expired stock, vaccine spillage, unused doses of covid vaccine etc. must be recorded via the Welsh Immunisation System (WIS). Where WIS does not support vaccine waste recording e.g., MMR vaccine then this waste must be recorded on the relevant stock management Excel spreadsheet. NB Any unusual levels of waste e.g. large quantities of vaccine must be reported immediately to the senior pharmacy technician.
The senior pharmacy technician will report waste via ImmForm where applicable and will inform the Vaccination Programme Wales (VPW) of unexpected large volumes of waste.

Please see MMP 429 Safe and Secure Management and Handling of Vaccine in Vaccination Centres and Community Settings for reporting vaccine waste.

5.4 Vaccine Spillage

Spillages on skin/eyes

- Staff must be aware of the location of handwashing facilities and eyewash kits.
- Spillages on skin should be washed with soap and water.

[2] The use of vaccines that have been temporarily stored outside the recommended temperature range - A brief guide for parents, carers and patients

- If a vaccine is splashed in the eyes, a sterile 0.9% sodium chloride solution must be used to irrigate the eyes and medical advice should be sought.

Spillages on surfaces

- Warn others that there has been a spill.
- Assess the spillage: if this procedure cannot be followed or there are any other concerns about safety, escalate to the lead nurse on site.
- Put on a pair of disposable gloves.
- Carefully absorb the spill onto paper towels or wipes, taking care with broken glass.
- Scoop up the spillage and place everything, including the disposable gloves, into an appropriate waste container.

Clean down the area:

- with any available detergent and water
- Wash hands after clean down.

Reporting

- Report the spill to lead nurse on site.
- Where the spill is to skin/eyes the individual must be monitored and any adverse effects reported.
- Record the number of broken or contaminated doses as discarded stock on WIS, or report to pharmacy stores team for stock requiring recording on ImmForm.
- When the above procedure cannot be followed or there are any concerns about the safety of personnel this must be escalated to the lead nurse on site. In turn they should inform senior pharmacy technician or PTHB Chief Pharmacist.

5.5 Adverse Drug Reactions (ADRs)

Any Suspected ADRs should be reported via the 'Yellow Card Scheme'.

Covid vaccine ADRs can be reported either online via the specific Coronovirus Yellow Card Website: https://coronavirus-yellowcard.mhra.gov.uk or via the paper form available in the back of the BNF.

Only serious ADRs should be reported for established vaccines, however all ADRs should be reported for new vaccines (BNF black triangle).

All ADRs in children should be reported.

6. Monitoring Compliance / Audit / Review

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

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

7. References

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

SOP-HCV-7-Dealing-with-spillages-of-COVID-19-vaccines-V1.1-27.03.23.docx (live.com) accessed 11/03/2024