

STANDARD OPERATING PROCEDURE FOR THE ORDERING, RECEIPT, CHECKING, STORAGE, QUARANTINING & DELIVERY OF COLD CHAIN ITEMS

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VALIDITY – All local SOPs should be accessed via the Trust Intranet to ensure the current version is used

CHANGE RECORD

Version	Date	Change details
1.00	21/12/2020	New SOP
1.1	23/03/2022	Updated contact details Approved by DTG 31-Mar-22

Contents

1. INTRODUCTION	3
2. SCOPE	3
3. DUTIES AND RESPONSIBILITIES	3
4. PROCEDURES	3
4.1 Storage conditions.....	3
4.2 Ordering, Receipt and Checking.	4
4.3 Check of Delivery Consignment	4
4.4 Checking the cold chain Order	4
4.5 Quarantining Stock.....	4
4.6 Stock Management	5
4.7 Cold Chain Delivery.....	5
4.8 Cold Chain Equipment	6
4.9 Training	6
5. REFERENCES	6
Appendix 1 – Fridge item delivery note.....	7
Appendix 2 – MT28 Weight Record Chart	8
Appendix 3 – MC3 Weight Record Chart.....	9

1. INTRODUCTION

These procedures describe the standard operating procedures for the safe and secure handling of cold chain items; Ordering, Receipt, Storage, Stock Management, Distribution, Returns and Waste in accordance with the current Humber Teaching NHS Foundation Trust (HTFT) Safe and Secure Handling of Medicine Procedures (SSHMP) and the Department of Health, 'Green Book'.

The efficacy of refrigerated items depends on maintain the cold chain at all times. Inadequate temperature control can reduce the efficacy.

2. SCOPE

These procedures must be adhered to by all staff employed by HTFT, who are involved with ordering, receipt and delivery of cold chain items.

This is to ensure that all cold chain medicines can be stored and transported whilst maintaining the correct storage temperature range.

3. DUTIES AND RESPONSIBILITIES

The Principal Pharmacy Technician has overall responsibility for the effective implementation of these procedures.

All staff are responsible for completing any task delegated by the Principal Pharmacy Technician in accordance with the SOP.

Ward staff are responsible for monitoring the maximum and minimum temperatures of ward fridges.

The pharmacy team are responsible for monitoring the temperature of the cold store and any fridges in the possession of the department.

4. PROCEDURES

4.1 Storage conditions

For safe storage of pharmaceutical products the refrigerator must comply with the standards of performance laid down by The Buying Agency (recognised by the department of Health)

The refrigerator

- Must be dedicated to the storage of pharmaceutical products only
- Must be lockable or in a locked room
- Not sited next to a radiator
- Must be located so that there is enough space for air to circulate freely around the back of the refrigerator
- Must be serviced and calibrated yearly by a trust approved contractor.
 - The contractor (Airco at present) will ensure that a sticker stating the last date of service is visible on the fridge.
 - If the service sticker is not visible, please contact HTFT pharmacy department for advice.
- Plug must be secured to avoid disconnection

- Must have a maximum and minimum thermometer
- Contents must be evenly distributed within the fridge
- Must **not** be over filled.
- Temperature should be maintained between 2 and 8 degrees Celsius. If the temperature falls outside of the recommended range, advice should be sought from the pharmacy department.

4.2 Ordering, Receipt and Checking.

4.2.1 Order Process

The pharmacy team are responsible for ordering medicines via the selected wholesalers.

4.3 Check of Delivery Consignment

Please Note: This is an inspection of the outer carton only

Staff accepting the cold chain delivery consignment must check the following

- The consignment appears to be in good condition and all boxes are sealed.
- There are no signs of leakage on the packaging.
- Each box delivered is addressed to the appropriate ward/department accepting the consignment.
- If a consignment is not expected, damaged or the delivery driver has not got identification inform a member of the pharmacy team immediately.
- The consignment must be checked and transferred immediately into the refrigerator(s).

4.4 Checking the cold chain Order

All cold chain deliveries must be checked as follows:

- Open the consignment and remove any paperwork. The consignment must contain a delivery note.
- Check the supplier details and the receiver details on the delivery note.
- Check the delivery note to ensure the order received corresponds with the order placed.
- Remove the stock from the delivery box and check the products match the delivery note (ensure the accuracy of the item e.g. quantity, pack size, form, strength etc).
- Check stock is in good condition.
- Tick against each line on the delivery note as the items are checked.
- Sign and date the delivery note – Delivery notes must be kept for 2 years from the date of issue.

4.4.1 Discrepancies/Damaged stock

If there is a discrepancy with the order, stock is visibly damaged or the innermost container has been compromised the affected stock must be quarantined awaiting a decision from a member of the pharmacy team.

4.5 Quarantining Stock

- Contact the pharmacy team to alert them of the need to quarantine.
- Segregate the quarantined stock from current stock held in the refrigerator.

- Following assessment by the pharmacy team any quarantined stock that are deemed unsuitable to be returned to stock, will be disposed of in accordance with HTFT SSHMP.

4.6 Stock Management

Storage of received orders

- Checked stock must be stored in the designated pharmaceutical refrigerator(s)
- All items of the same type must be stored together.
- Items with the shortest expiry dates must be stored so they are selected first.

4.7 Cold Chain Delivery

4.7.1 Transport

Transportation of cold chain items from one destination to another must be kept within a maximum of 4 hours. The time begins when the items are removed from the controlled refrigerated area.

4.7.2 Vaccine Porter Preparation

- Prior to vaccine porter preparation ensure that each refrigerator EasyLog data logger has been downloaded and check all temperature readings have remained between 2-8°C.
- Any deviation outside of the recommended temperature range must be reported to the Principal Pharmacy Technician and the fridge quarantined.
- If the temperature readings have remained between 2 to 8°C, the vaccine porters can be prepared.
- Calculate the number of vaccine porters and gel packs required.
- Check each vaccine porter and gel pack for visible damage – damage should be reported to the Principal Pharmacy Technician.
- Ensure there is a cold chain delivery note for each item being delivered. (Appendix 1)

Vaccine Porters 9:

- Add one MT28 gel pack to the bottom of the porter, add one MT28 gel pack to each side of the porter (5 packs in total)
- Pack the vaccines in their original packaging into the porter as per manufacturer's instructions.
- Leave enough space at the top of the porter for one further MT28 gel pack (making a total of 6 gel packs in accordance with manufacturer's guidance) and the lid.
- Any voids must be filled with bubble wrap.
- Securely fit the lid.
- The outer casing must be fastened in place.
- Vaccine porter **must** not be stacked.

Vaccine Porter 24

- Add two MC3 gel packs to the bottom of the porter, add one MC3 gel pack to each side of the porter (6 packs in total)
- Pack the vaccines in their original packaging into the porter as per manufacturer's instructions.
- Leave enough space at the top of the porter for two further MC3 gel pack (making a total of 8 gel packs in accordance with manufacturer's guidance) and the lid.
- Any voids must be filled with bubble wrap.
- Securely fit the lid.

- The outer casing must be fastened in place. Vaccine porter **must** not be stacked. More information regarding packing Vaccine Porters can be found at:

[Vaccine Porter Carrier System - Medical and Cleanroom Disposables - Helapet](#)

4.8 Cold Chain Equipment

4.8.1 EasyLog Data Loggers

- EasyLog data loggers are to be replaced annually. Replacements can be ordered by emailing hnf-tr.pharmacyprocurement@nhs.net
- Data Logger batteries must be changed annually. A message will appear on screen when the battery is running low; the data logger will have an amber flashing light.
- Refer to the data logger user guide
- Data logger batteries are ordered via Oracle, catalogue number WPA181

4.8.2 MediTray Cool packs

- must be chilled for 24 hours before use
- must not be stored more than 3 gel packs high when normalising.
- must be stored flat
- must be weighed every 3 months and the information recorded on the MediTray Weight Record Chart. (Appendix 2 and 3)
- Must be replaced if they fall outside of the manufactures recommended weight limit and/or there are signs of damage.
- If dropped visually inspect the cool pack for damage

Note: MC3 should weigh 1100g +/-20g, MT28 should weigh 600g +/-20g.

4.9 Training

Training will be provided by HTFT Pharmacy Department.

5. REFERENCES

- Safe and Secure Handling of Medicines Procedures
<https://intranet.humber.nhs.uk/safe-and-secure-handling-of-medicines-procedures.htm>
- Immunisation Guidelines
<https://intranet.humber.nhs.uk/immunisation-guidelines.htm>
- Immunisation against infectious disease: The Green Book
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book-the-green-book>

Appendix 1 – Fridge item delivery note



Humber Teaching
NHS Foundation Trust

*Pharmacy Department
Trust Headquarters
Willerby Hill
Beverley Road
Willerby
HU10 6ED
Tel: 01482 389113*

Fridge item delivery note:

Pharmacist / Technician's name : (Block capitals)	
Signature:	
Date:	
Delivery person's name: (Block capitals)	
Signature:	
Delivery date:	
Time left pharmacy:	
Details of items to be delivered:	
Delivery address:	
Name of person's receiving fridge items: (Block capitals)	
Signature:	
Date of receipt:	
Time of receipt:	

Appendix 2 – MT28 Weight Record Chart

MT28 Weight Record Chart

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

NOTES:

All Meditrays must be weighed every 3 months

MT 28 Meditrays should weigh 600g +/-20g

Meditrays outside of the recommended weigh and/or showing damage should be replaced

Caring, Learning and Growing





Appendix 3 – MC3 Weight Record Chart

MC3 Weight Record Chart

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

Meditray Number:

Date	Weight Recorded	Sign and Print name	Comments

NOTES:

All Meditrays must be weighed every 3 months

MC3 Meditrays should weigh 1100g +/-20g

Meditrays outside of the recommended weigh and/or showing damage should be replaced

