1. **Purpose**

This SOP describes the process of receipt and thawing of all Spikevax COVID-19 vaccines received frozen at -25°C to -15°C including:

* transferring vaccines into a refrigerator to thaw
* assigning a post-thaw expiry date
* recording data attributes needed to provide data for the national vaccination programme.

1. **Scope**

This SOP is applicable to the receipt and **immediate thawing** in a refrigerator of all Spikevax vaccines received frozen at -25°C to -15°C.

For receipt and storage of all COVID-19 vaccines received at 2°C to 8°C refer to SOP HCV 1.

For receipt of frozen Comirnaty vaccines refer to SOPs HCV 3 and HCV 4.

1. **Responsibility**

Only staff suitably trained and competent the allocation of post-thaw expiry dates may perform this activity.

1. **Health and Safety**

The handling of frozen vaccines does not usually require the wearing of protective gloves, however some individual staff may not be able to tolerate cold temperatures and may need to wear lightweight gloves for comfort.

1. **Procedure**
   1. **Accepting the delivery**
      1. Check:
   * the number of shippers matches the number listed on the delivery note, carrier’s receipt or proof-of-delivery device
   * all shippers are in good condition and no damage is evident
   * all shippers are addressed correctly
   * the shippers have not expired
     1. If any part of the delivery is damaged, already opened, missing or otherwise not as expected report without delay to [insert senior staff job title].

If the delivery appears to be in order, accept the shipment according to the established acceptance-of-delivery process.

* 1. **Unpacking the delivery and amending the expiry date**
     1. Check the refrigerator is within the range 2°C to 8°C and that no alarms are displayed. If out of range or is showing an alarm, do not proceed and report to [insert details here].
     2. Remove the cartons from the shipper and place them onto the trolley or a bench immediately adjacent to the fridge. If there is any distance to travel between the shipper and the freezer use a trolley instead of carrying the cartons.
     3. Check:
        + the tamper evident seals are intact
        + there is no evidence of any damage
        + the identity, batch number, expiry date and quantities against the delivery note.

and endorse the delivery note to confirm.

* + 1. If there is any damage or discrepancy,
       - quarantine the stock in refrigerator, clearly identifying them e.g. in a separate bag
       - report without delay to [insert senior staff job title].

N.B. If any vials are broken, deal with the spillage following SOP HCV 7. No special spillage procedures are required for thawed Spikevax COVID-19 vaccines.

* + 1. Complete one thaw label (see Appendix 1) for each carton detailing
       - Time and date removed from the shipper
       - Time and date of expiry i.e. 30 days from removal from the shipper.
       - Batch number
       - Signature of person completing the label

N.B. the expiry is calculated to the nearest day. There is no need to record expiry time. The expiry will be at midnight at the end of the calculated day of expiry.

* + 1. Obtain a check from another suitably trained and competent person:
       - check the thawed expiry date and time calculation
       - check the batch number
       - check that there are exactly the same number of completed thaw labels as there are cartons
       - sign the labels to confirm the check is complete.
    2. Cross through the original expiry on the carton.
    3. Attach one thaw label to each of the cartons, ensuring that the original batch number is not covered.
    4. Transfer the cartons into the fridge to thaw. This may take up to 24 hours.
  1. **Logging receipts on the stock control system**
     1. For each purchase order, receive the goods on to the stock control system (Foundry and pharmacy stock management system).
     2. Forward completed delivery documentation to [insert job title].
     3. Receipt of vaccine on to the pharmacy stock management system must capture the following product details:
  + Date and time received into system
  + Supplier
  + Purchase order number
  + dm+d medicine name (AMP/P) This must be the ‘branded’ level description
  + dm+d ID code
  + Pack size and number of vials received
  + Batch number (This cannot be scanned and **must** be checked by a second person to ensure the correct information is recorded)
  + Expiry of vials

1. **Document history**

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| --- | --- | --- | --- |
| **Date** | **Version** | **Section** | **Details** |
| 18/08/2022 | 1.0 | All | This is the first version published. Supersedes MDH3. |

1. **Associated documents**

SOP HCV 1: Receipt and storage of COVID-19 Vaccines at 2-8C

SOP HCV 3: Receipt of ULT frozen Comirnaty, thawing, and assigning a post-thaw expiry date

SOP HCV 4: Receipt of ULT frozen Comirnaty and storage in ULT freezer

**Appendix 1**

Example completed thaw label. If blank thaw labels are not available the template below may be used as an example for locally printed labels.

