1. **Purpose**

This SOP describes:

* Unpacking of frozen **Jynneos** vaccine from a shipper
* Transferring to a refrigerator to thaw, including application of a post thaw expiry label

1. **Scope**

**Jynneos** vaccine delivered frozen from the UK Health Security Agency (UKHSA) in -20°C shippers.

This SOP must not be used for Imvanex. See SOP IMH1.

1. **Responsibility**

Staff performing this procedure must be suitably trained and competent in handling frozen products and the use of pharmacy refrigerators.

Sites are responsible for preparing their own thaw labels. A suggested template thaw label is provided in appendix 1. Sites must test labels prior to use, to ensure they effectively adhere to the frozen vaccine carton surface.

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. **Supporting information**

Jynneos is shipped at -20°C and the -20°C expiry of the vaccine is printed on the outer carton

For further information see the[direct healthcare professional communication (DHPC) letter avalible at](file:///\\rlbuht.lan\groups\PPU\QA%20Services\COVID%2019\Vaccines\Vaccine%20SOPs%20project\Monkeypox\ direct%20healthcare%20professional%20communication%20(DHPC)%20letter%20avalible%20at) <https://www.sps.nhs.uk/wp-content/uploads/2022/08/Jynneos_UK_HCP_letter.docx-1.pdf>

1. **Procedure**
   1. Check the temperature display on the fridge to ensure it is between 2 and 8°C. If it is not, do not proceed and follow local SOP for fridge temperature excursions.
   2. Unpack the shipper as soon as possible, and before the expiry date on the shipper.
   3. 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 fridge use the trolley instead of carrying the cartons to reduce the risk of dropping.
   4. Perform receipt checks according to local SOPs for the receipt of medicines.
   5. Check the -20°C expiry date printed on the carton has not been exceeded.
   6. Calculate the refrigerated use by date of the product based on storage at 2 to 8°C. This is 8 weeks from the point thawing starts. Ensure the refrigerated use by date is within the -20°C expiry date.
   7. Complete one thaw label for each carton detailing:
   * Date removed from the shipper and placed into a refrigerator
   * Use by date (see point 6.6)
   * Batch number
   * Signature of person completing the label
   1. Cross through the original expiry on the carton.
   2. Obtain a check from another suitably trained and competent person:

* check the post thaw use by date on the label(s) (see point 6.6)
* check the new post thaw use by does not exceed the -20°C expiry date printed on the carton
* check the batch number matches the carton
* 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.
  1. Attach one thaw label to each of the cartons, ensuring that the original batch number is not covered.
  2. Transfer the cartons into the fridge to thaw. Vaccines must be placed on an empty shelf within the fridge whilst thawing, this is to ensure they are well spaced from other medicines stored in the fridge.

NB. Thawing in a refrigerator may take between 4 to 24 hours depending on the temperature of your refrigerator and how much vaccine is being thawed.

* 1. Check the temperature display on the fridge to ensure it returns to between 2 and 8OC. If it does not, follow local SOP for fridge temperature excursions.

1. **Document history**

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| **Date** | **Version** | **Section** | **Details** |
| 11/08/2022 | 1.0 |  | New procedure to reflect Jynneos brand only which does not require calculation of -20C expiry as it is printed o the carton |

**Appendix 1**  Suggested Jynneos thaw label template

JYNNEOS Vaccine thaw label

Once removed from the freezer/ shipper, the vaccine can be stored for up to 8 weeks at 2 to 8°C

Batch Number:

Date thaw at 2 to 8°C started:

Post thaw use by date:

Signed:\_\_\_\_\_\_\_ Checked:\_\_\_\_\_\_\_\_\_

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8 WEEKS