How to manage storage and distribution of COVID-19 Vaccine Janssen delivered at -20°C and +2 to +8°C temperatures?

This job aid specifically details the additional steps to be taken for the distribution and handling of the US-labelled Janssen COVID-19 vaccine and the possibility that both -20°C and +2-8°C labelled vaccine supplies are available in country during the same time periods.

Key Points:

- Covid-19 Janssen vaccines is supplied through Covax through two different mechanisms: Regular Covax supply mechanisms or United States of America (USG) donations.
- The COVAX supplied vaccine will be delivered at -20°C while the USG donation at +2-8°C. These are the same vaccine but will have different expiration dates due to the storage conditions upon delivery (e.g. frozen vs. thawed).
- The expiration date is stamped on the label of COVAX supplied vaccine, while the expiration date of the USG donated vaccine will be accessible through the QR code and shipping document.
- Clear messaging and training for the national immunization programme – vaccine implementation teams, that regardless of the packaging and supply mechanism (e.g. COVAX allocation or donation), the vaccine product is the same. This is important to avoid misperception regarding the quality of vaccine product in case the two differently labelled products become available in the country at the same time.
- When receiving the USG donated vaccine, clear instructions should be available for validating expiration date through the QR code and manually marking the validated date on the vaccine carton or vial (including, making provisions ahead of time on printing stickers or availability of waterproof ink marker pens). If manually writing, ensure that the date is clearly legible and visible on the carton or vial.
- Instructions for storage, distribution and handling of the -20°C labelled vaccine product under WHO Emergency Use Listing (EUL) are already available on the WHO website:
  - Janssen Ad26.COV2-S [recombinant], COVID-19 vaccine (who.int)
  - Preparing and Storing the COVID-19 Vaccine Janssen (immunizationacademy.com)

1. Overview

The COVID-19 Vaccine Janssen has been recommended for use by WHO under Emergency Use Listing (EUL) on 12 March 2021. Since then, the COVAX Facility has been coordinating the allocation of this vaccine to Advance Market Commitment (AMC) participating countries. In addition, to support the roll out of this vaccine, the United States of America government (USG) will be donating vaccine doses to several countries across the globe.
The vaccine supplied through the COVAX mechanism and USG donation are the same vaccine product, with a difference in the name (COVID-19 Vaccine Janssen for COVAX and Janssen Covid-19 Vaccine in the US) and labelled differently based on the temperature at which the vaccine is shipped to recipient countries.

The USG donated vaccine has received Emergency Use Authorization (EUA) from the United States Food and Drug Administration (USFDA). The US-labelled vaccine doses will be transported from the USA to the recipient countries at +2-8°C temperatures (thawed), whereas vaccine doses recommended under WHO EUL, will be delivered to AMC participating countries at -20°C temperature (frozen).

Dynamic labelling will be applied to track the remaining shelf-life after moving the vaccine supply from -20°C to +2-8°C storage temperature.

The aim of the COVID-19 vaccination is to effectively prevent severe coronavirus disease, hospitalization and death by vaccinating as many vulnerable populations as possible. In the context of limited vaccine supply, implementing good practices on vaccine management is important to prevent vaccine wastage and ensure that vaccine quality is maintained for administration during vaccination sessions.

**The scope of this job aid is limited to the COVID-19 Vaccine Janssen** through both USG donations and Covax regular mechanism. The purpose is to guide countries in managing the delivery and storage of the vaccine labelled and delivered in different storage temperatures. Countries are encouraged to include this job aid in the training/orientation of health workers in-charge of managing the storage and distribution of the vaccine and implementing the vaccination sessions.

**2. Janssen vaccine shelf life based on storage temperatures**

<table>
<thead>
<tr>
<th>Vaccine condition</th>
<th>Storage temperature</th>
<th>Shelf life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen vaccine</td>
<td>Keep at -25°C and -15°C / -20°C (freezer)</td>
<td>24 months or until the expiration date</td>
</tr>
<tr>
<td>Thawed unopened vaccine</td>
<td>Keep at +2 °C to +8°C (refrigerator). Do not refreeze.</td>
<td>4.5 months after removal from freezer(^2)</td>
</tr>
<tr>
<td>Thawed opened vial (after first puncture)</td>
<td>Keep at +2 °C to +8°C (refrigerator or WHO pre-qualified passive container)</td>
<td>Up to 6 hours after the first dose has been withdrawn</td>
</tr>
</tbody>
</table>

\(^1\)Janssen COVID-19 vaccine explainer.

\(^2\) For USG donated doses, validate expiration date through the QR code and shipping documents. USFDA approved 6 months expiration for the US-produced vaccine doses stored at +2-8°C. Countries that received USG donation will be informed about the new expiration date, which can be validated via QR code.

\(^3\) Doses supplied through COVAX mechanism coming from non-US manufacturing sites continues to have 4.5 months shelf life until EMA/EUL approve the extension of the shelf life to 6 months for all vaccine lots.
3. Difference on the labelling of COVAX and USG supplied vaccine

3.1 COVAX supplied COVID-19 Vaccine Janssen:
Currently, the COVAX Facility will be supplying the -20 °C labelled vaccine, which will be delivered to countries frozen at -25°C to -15°C. The label will have an expiration date, which is the end date of the 24-month shelf life if the vaccine is kept frozen at this temperature. It is possible that future donations of vaccine stored at +2-8°C will go through the COVAX Facility to support equitable distribution of vaccine.

3.2 USG donated/labelled Janssen COVID-19 Vaccine:
The USG will be donating the +2-8°C labelled vaccine, which corresponds to the temperature the vaccine will be delivered to recipient countries. There is no expiration date on the label. Instead, the expiration date will be accessible through the QR code and shipping documents. The expiration is based on the date the vaccine is kept in a refrigerator at +2-8°C. To ensure the expiration date is communicated to the lower vaccine stores and service points, the expiration date has to be manually indicated on the carton after validation through the QR code. Supply officer should ensure this procedure is performed prior to distributing the vaccine from the national/central vaccine store.

<table>
<thead>
<tr>
<th>Vial label</th>
<th>Carton label</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Vial label" /></td>
<td><img src="image2.png" alt="Carton label" /></td>
</tr>
</tbody>
</table>

![Figure 1. Differences on the labels of Janssen vaccine approved for use under EUL and EUA.](image3.png)

4Alternatively, the expiration date by batch/lot number can also be accessed through the Janssen COVID-19 Vaccine Expiry Checker (vaxcheck.jnj) page.
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The date should be clearly noted on the vaccine cartons. If to be handwritten, the date should be clearly legible and visible at a specific location on the carton with appropriate pens made available (program should provide specific instructions). The space around the lot number is the recommended site to mark the expiration date. Care must be taken to ensure lot number remains visible. Ensure availability of stickers, pens/markers, if to be done manually.

4. Implementing the dynamic labeling of vaccine expiration date

Dynamic labeling applies to every vaccine batch that is removed from the freezer, regardless of the source of supply. It must be performed as soon as the vaccine is taken out from the freezer to thaw and be stored in a refrigerator at +2-8°C temperatures. Never return thawed vaccine back into the freezer.

Dynamic labeling is the process of manually updating the vaccine expiration date as the vaccine moves from -20°C to +2-8°C storage temperatures. Updating the expiration date should be done before storing the vaccine in the refrigerator. If the vaccine supply is received frozen at -20°C, once the vaccine is thawed, the expiration date originally indicated on the outer packaging is no longer valid and must be crossed out. A new expiration date must be clearly written using permanent ink pen, which corresponds to the end date of the approved remaining shelf life at +2-8°C storage temperature.

If the approved (currently 4.5 months for COVID-19 Vaccine Janssen under EUL as of 4 August 2021) maximum storage duration for thawed vaccine exceeds the original expiration date corresponding to the 24-month shelf life of the vaccine at frozen state, the original expiration date must be adhered to.

Example:

If the original expiration date at -20 °C is 31 March 2022 (e.g. 24 months shelf life from manufacturing date):

When vaccine is moved from -20 °C to +2°C to +8°C storage on 15 August 2021, the new expiration date will be 31 December 2021 (end of 4.5 months shelf life). Do not use the vaccine beyond 31 December.

5. Managing storage and shelf life of the -20°C and +2-8°C labelled vaccine supply upon delivery

After performing the standard procedures for receiving the vaccine arrival, the responsible officer should determine under which temperature the vaccine must be stored.

5.1 Vaccine delivered at +2-8°C:

This vaccine should be stored in a refrigerator and transported at +2-8°C temperature. This vaccine should be used within the dynamic expiry date as outlined in section 4 above.

5 Preparing and Storing the COVID-19 Vaccine Janssen (immunizationacademy.com)
Due to the limited shelf life, this vaccine should be distributed first to the different facilities and fully consumed during immunization sessions before considering thawing another batch of the frozen COVID-19 Vaccine Janssen.

Ensure that microplans are made to facilitate full consumption of the vaccine within the remaining shelf life. In addition, the vaccine distribution from the national store to the peripheral stores and planned vaccination sessions should be harmonized.

5.2 Vaccine delivered at -20°C:

After performing the procedures for receiving the vaccine arrival, immediately store the vaccine in a freezer at -20°C temperature.

Vaccine stores with the capacity for storing at -20 °C are recommended to keep the vaccine frozen at this temperature to maximize its shelf life. This will help alleviate the storage burden at the central level and allow more batches of vaccines to be delivered in country.

Keeping the vaccine frozen eliminates the risk of exposing the vaccine to higher temperature that may compromise vaccine potency and generate vaccine wastage. This will also allow health workers ample time to plan and coordinate the vaccination sessions so that more target populations could be served.

Consider delivering thawed vaccine only when the receiving service facility is ready to implement the immunization sessions soon after vaccine receipt.

If both frozen and thawed vaccines become available at the lower level stores and service facilities, make sure the earlier thawed vaccine will be distributed and used first (apply first expiry, first out) regardless of the vaccine source (e.g. COVAX or USG donation).

Marked expiration date should always be checked and updated, as necessary, before transporting and using the vaccine supply.

6. General considerations in managing COVID-19 Vaccine Janssen labelled and delivered in different storage temperatures (e.g. –20°C and +2-8°C) - Country preparedness.

- Ensure adequate regulatory approval for deployment of both -20°C and +2-8°C labelled vaccine supplies are obtained prior to shipment.
- Assess existing cold chain capacity for -20°C storage at national and subnational levels.
- Make sure to map the locations of cold chain equipment with capacity to store vaccines at -20 °C. This is necessary to identify transit hubs to keep vaccine at this temperature and maximize shelf life while allowing health workers time to prepare and organize vaccinations sessions.
- Upon receipt of pre-shipment advice, pay attention to the labeling information and temperature condition at which the vaccine supply will be delivered. Use this information to plan for transportation and distribution of vaccines. Ensure enough cold chain capacity is available to store the vaccine at both -20°C and +2-8°C temperatures.
- Upon receipt of the vaccine supply, make sure to validate and document the temperature label indicated on the packaging, the expiration date indicated in the shipping document (at +2-8°C as well as at -20°C) and the storage temperature recording in transit. Perform other procedures for vaccine arrival as indicated in the standard operating procedures (SOP). Immediately report any temperature excursion recorded during transport.
• If both -20°C and +2-8°C labelled vaccine supplies are received, make sure the +2-8°C labelled vaccine is distributed and used first to facilitate full consumption within the remaining shelf life.
• Ensure that the country immunization program has made provisions for noting expiration dates on the US-labelled vaccine.
• Since the vaccine does not contain a vaccine vial monitor (VVM), implement good practices in monitoring vaccine storage and transport temperatures.  
• Any temperature excursion should be reported immediately for appropriate action. If such occurred, keep the vaccine in the cold chain but in separate location and label with a message indicating that the vaccine has been exposed to heat and awaiting decision if still good to use. In some cases, temperature excursion is brief and not high enough to damage the vaccine potency. In such cases, regulatory authority may recommend the vaccine is still safe to use.
• Implement good practices on vaccine stock management, such as the implementation of the first expiry, first out (FEFO) principle. As thawed vaccine has shorter shelf life; the vaccine delivered at +2-8°C should be distributed and used first before using the vaccine stored in -20°C freezer.
• Ensure planned vaccination sessions are aligned with the vaccine delivery schedule to facilitate full consumption of the vaccine supply within its remaining shelf life.
• Ensure compliance with the safety reporting process.  

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6 Job aid: How to manage COVID-19 vaccines without VVM at vaccination service points?
7 Vaccine management handbook.
8 COVID-19 vaccines safety surveillance manual.