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

The COVID-19 vaccine produced by Janssen (Johnson & Johnson) is manufactured in several sites including in the United States of America (USA), India, South Africa, and Europe. Depending on the place of manufacture, the Janssen vaccine may arrive in the country frozen at -20°C or already thawed at +2–8°C. It is essential that recipient countries are aware of the different shipping conditions, vaccine handling conditions, expiry dates, and shelf life of these vaccines, as both presentations may be in the supply chain simultaneously.

This job aid details the steps to be taken for the proper recognition, distribution, and handling of Janssen vaccine products.

Key points:

- COVID-19 Vaccine Janssen is supplied through COVAX mechanisms: regular COVAX supply allocation and/or United States Government (USG) donations.
- COVID-19 Vaccine Janssen doses produced in the USA and donated by the USG are delivered to countries thawed at +2–8°C. Allocated doses produced outside the USA will be delivered to countries frozen at -20°C. These vaccine products are the same, but they will have different expiration dates depending on the condition at delivery (i.e. frozen vs thawed) and will therefore require different storage conditions.
- The United States Food and Drug Administration (USFDA) approved the 11-month shelf life for the USA-produced COVID-19 Vaccine Janssen doses stored at +2–8°C. Information on the expiration is accessible through the QR code and shipping document.
- COVID-19 Vaccine Janssen produced outside the USA has a 24-month shelf life when stored at -25°C to -15°C. Within 24 months of shelf life, the vaccine can be stored for 11 months at 2°C to 8°C. The expiration date is stamped on the label.
- Clear messaging and training are needed for the vaccine implementation teams of national immunization programmes (NIP) to understand that, regardless of the source of the vaccine and the expiration date information on the packaging, the vaccine product is the same. This is important to avoid misperceptions regarding the quality of the vaccine product in case the two differently labelled products are supplied in the country at the same time.

1 https://extranet.who.int/pqweb/vaccines/who-recommendation-janssen-cilag-international-nv-belgium-covid-19-vaccine-ad26cov2-s
1. Overview

COVID-19 vaccination aims to effectively prevent severe coronavirus disease, hospitalization, and death by vaccinating vulnerable populations, starting with those at the highest risk of severe disease and death. Implementing good practices in vaccine management is important to minimize vaccine wastage and ensure that vaccine quality is maintained during storage, transport, and vaccination sessions.

COVID-19 Vaccine Janssen was recommended for use by WHO under Emergency Use Listing (EUL) on 12 March 2021. Since then, the COVAX Facility has coordinated the allocation of this vaccine to Advance Market Commitment (AMC) participating countries. In addition, to support the rollout of this vaccine, the USG is also donating vaccine doses internationally through a direct delivery mechanism.

The vaccines supplied through the COVAX mechanism, and the USG donation are the same product, however with a difference in the name (“COVID-19 Vaccine Janssen” for COVAX and “Janssen COVID-19 Vaccine” in the USA) as well as in the label based on the temperature at which the vaccine is shipped to recipient countries.2

The USG donated vaccine has received EUA from the USFDA The US-labelled vaccine vials will be transported thawed from the USA to the recipient countries at +2–8°C with an 11-month shelf life from the date they were thawed. The expiration date can be validated through the QR code found on the vaccine label.

The vaccine recommended under the WHO EUL will be delivered to AMC participating countries frozen at -20°C with a 24-month shelf life. Once the vaccine is thawed and stored at +2–8°C, it has a shorter shelf life of 11 months. The expiration date on the label will have to be updated after moving the vaccine vials from -20°C to +2–8°C storage temperature (application of “dynamic labelling”).

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

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2 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.
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>-25°C and -15°C/-20°C (freezer)</td>
<td>24 months or until expiration date</td>
</tr>
<tr>
<td>Thawed unopened vaccine</td>
<td>+2–8°C (refrigerator)</td>
<td>WHO EUL: 11 months after removal from freezer</td>
</tr>
<tr>
<td></td>
<td>Do not refreeze</td>
<td>EUA USFDA*: 11 months after removal from the freezer</td>
</tr>
<tr>
<td>Thawed opened vial (after the first puncture)</td>
<td>+2–8°C (refrigerator or WHO pre-qualified passive container)</td>
<td>Up to 6 hours after the first puncture</td>
</tr>
</tbody>
</table>

* Emergency Use Authorization by the United States Food and Drug Administration.

3. Differences in the labelling of COVAX and USG-supplied vaccine

3.1 COVAX supplied COVID-19 Vaccine Janssen

The COVAX Facility supplies -20°C labelled vaccine which is delivered to countries frozen at -25°C to -15°C. The expiration date on the label will be the end date of the 24-month shelf life if the vaccine is kept frozen at this temperature.

3.2 USG donated/labelled Janssen COVID-19 Vaccine

The USG donates +2–8°C labelled vaccine, which is the temperature at which the vaccine will be delivered to recipient countries. There is no expiration date on the label. Instead, the expiration date is accessible through the QR code and shipping documents. The shelf life is based on the date the vaccine was thawed and stored at +2–8°C. To ensure the remaining shelf life is communicated to vaccine stores at lower levels and service points, the expiration date has to be manually written on the carton and noted in the shipping document after validation through the QR code. The supply officer should ensure this procedure is performed before distributing the vaccine from the national/central vaccine store.

The date should be clearly noted on the vaccine cartons. If it is handwritten, a permanent ink pen or marker should be used. The date should be clearly legible and visible at a specific location on the carton. The space around the lot number is the recommended site to mark the expiration date. Care must be taken to ensure the lot number remains visible. Ensure availability of permanent markers/pens if to be done manually. Stickers with printed expiration dates may also be used (the programme should provide specific instructions).

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[^1]: Janssen COVID-19 vaccine explainer
[^2]: For USG donated vaccine, validate expiration date through the QR code and shipping documents. USFDA approved 9-month expiration for the US-produced vaccine stored at +2–8°C. Countries receiving USG donations will be informed about the 9-month expiration date.
[^3]: Alternatively, the expiration date by batch/lot number can also be accessed through the Janssen COVID-19 Vaccine Expiry Checker (vaxcheck.jnj) page.
4. Dynamic labelling of the vaccine expiration date for doses delivered frozen at -20°C

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

Dynamic labelling is the process of manually updating the vaccine expiration date as the vaccine moves from -20°C to +2–8°C storage temperatures. The expiration date should be updated before storing the vaccine in the refrigerator to thaw, as the expiration date originally indicated on the outer packaging is no longer valid and must be crossed out. The new expiration date must be clearly written using a permanent ink pen/marker, and it should correspond to the end date of the approved remaining shelf life at +2–8°C storage temperature.⁶

If the approved maximum storage duration of 11 months for thawed COVID-19 Vaccine Janssen under WHO EUL exceeds the original expiration date of the vaccine at a frozen state, the original expiration date must be adhered to.

**Example: Original expiration date of vaccine stored at -20°C is 31 December 2023**

If vaccine is transferred from -20°C to 2–8°C storage on 31 August 2022, the new expiration date will be 31 July 2023 (i.e. 11 months later, which represents the end of the shelf life for vaccine under WHO EUL). **Do not use the vaccine beyond 31 July 2023.**

Use before: 31 December 2023
31 July 2023

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⁶ [Preparing and Storing the COVID-19 Vaccine Janssen](https://www.immunizationacademy.org/resources) (Immunization Academy, 2021).
5. Managing storage and shelf life of +2–8°C and -20°C labelled vaccine supplies upon delivery

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

5.1 Vaccine delivered thawed at +2–8°C

The vaccine delivered thawed should be stored in a refrigerator and transported at +2–8°C temperature. The vaccines should not be refrozen. This vaccine should be used within the dynamic expiry date as outlined in section 4.

Due to the limited shelf life, **this vaccine should be distributed first** to different facilities and fully used during immunization sessions before considering thawing another quantity of the frozen COVID-19 Vaccine Janssen.

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

5.2 Vaccine delivered frozen at -20°C

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

In vaccine stores at lower levels with the capacity for storing at -20°C, it is recommended that the vaccine is kept frozen at this temperature to maximize its shelf life. This will help alleviate the storage burden at the central level.

Keeping the vaccine frozen eliminates the risk of exposing the vaccine to a higher temperature that may compromise its potency and generate wastage. This will also allow health workers ample time to plan and coordinate vaccination sessions and optimize the use of the vaccine.

Deliver thawed vaccine only when the service facility is ready to receive it and implement vaccination sessions.

If both frozen and thawed vaccines become available at lower-level stores and service facilities, make sure that the **earlier thawed vaccine is distributed and used first (apply the first expiry, first out [FEFO]),** regardless of the vaccine source (i.e. COVAX or USG donation).

**Marked expiration dates should always be checked and updated as needed** before transporting and using the vaccine supply.

6. General considerations in managing COVID-19 Vaccine Janssen labelled and delivered at different storage temperatures (i.e. -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 the capacity to store vaccines at -20°C. This is necessary to identify transit hubs to keep vaccines frozen and maximize shelf life while allowing health workers time to prepare and organize vaccination sessions.
- Upon receipt of pre-shipment advice, pay attention to the labelling information and temperature condition at which the vaccine will be delivered. Use this information to plan for the transportation and distribution
of vaccines. Ensure enough cold chain storage capacity in working order 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 or -20°C), and the storage temperature recording in transit. Perform other procedures for vaccine arrival as indicated in the standard operating procedures (SOPs). Immediately report any temperature excursions recorded during transport.

- If both -20°C and +2–8°C labelled vaccines are received, make sure the +2–8°C labelled vaccine is distributed and used first to facilitate full utilization within the remaining shelf life.

- Ensure that the country immunization programme has an SOP for noting expiration dates on vaccine labels before distributing to lower store levels.

- Since the vaccine vials do not have a vaccine vial monitor (VVM), implement good practice in monitoring vaccine storage and transport temperatures.\(^7\)\(^8\)

- Immediately report any temperature excursions to the supervisor for appropriate action. If such an excursion occurs, keep the vaccine in the cold chain but in a location away from other vaccines, label “DO NOT USE”, and document the detail (i.e. temperature and duration of the excursion). In case of a brief, low magnitude, temperature excursion, the vaccine is likely to still be viable. National policies and SOPs should be followed.

- Implement good practices in vaccine stock management, such as implementation of the first expiry, first out (FEFO) principle. As thawed vaccine has a shorter shelf life, the vaccine delivered at +2–8°C should be distributed and used first before using the frozen vaccine stored at -20°C.

- Ensure planned vaccination sessions are aligned with the vaccine delivery schedule to facilitate full utilization of vaccine supply within its remaining shelf life.

- Ensure compliance with the safety reporting process.\(^9\)

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\(^8\) [Vaccine management handbook](https://www.who.int/publications/i/item/2017-06-04) (WHO, 2017).