How to verify the expiration date for Pfizer-BioNTech COVID-19 Vaccine paediatric formulation using the QR code?

Background

For most COVID-19 vaccine products a short shelf life, generally 6 months from the date of manufacture, was initially approved under Emergency Use Listing (EUL) mechanism. As more data on vaccine stability became available, shelf life for some COVID-19 vaccine products were approved for extension by recognized regulatory bodies.

When initially approved under EUL, the paediatric Pfizer-BioNTech COVID-19 Vaccine\(^1\) stored at ultra-low temperature (ULT), ranging from -90°C to -60°C had a shelf life of 9 months from the manufacturing date, which was first extended to 12 months. On 6 January 2023, the shelf life was further extended to 18 months for the same storage condition. This extension may apply also to the initial supply already delivered to countries, which requires their additional regulatory approval to accept and allow the use of the vaccine supply beyond the labelled expiry date.\(^2\) This flexibility would enable countries to increase opportunities to use the existing vaccine supply and vaccinate more people at risk, while minimizing vaccine wastage and public resources, until the labelling of shelf life is modified.

Paediatric formulation of Pfizer-BioNTech COVID-19 vaccine is produced in different manufacturing sites, including in the USA and Europe, and can come in different packaging. Irrespective of manufacturing site and packaging, all products are equivalent in that they have the same formulation. However, the US-based manufacturer uses labelling different from the standard WHO recommendation\(^3\) and does NOT use expiry date on the label/packaging (normally marked as EXP). Instead, the date printed along with the lot number on the paediatric Pfizer-BioNTech COVID-19 Vaccine primary (label) and secondary (carton) packaging reflects the \textit{manufacturing date} (marked as MFG). In addition, the secondary packaging (carton) contains a QR code which, when scanned, will lead to the manufacturer’s website with information on the valid expiry date, based on the 18-month shelf life at ULT storage. Some AMC countries have already received a supply of Paediatric Pfizer-BioNTech COVID-19 Vaccine with the QR code and printed manufacturing date. Subsequent shipments

\(^{1}\) The Pfizer-BioNTech COVID-19 vaccine Tris-Sucrose (paediatric formulation) vial comes with an orange cap and vial label with orange border.

\(^{2}\) As per standard regulatory principles, WHO does not recommend use of vaccines beyond their labelled expiry date. However, based on public health needs and the assessment of scientific data done by relevant regulatory authorities of reference under Emergency Use Listing (EUL), the extension of expiration date may be applied retroactively to previously produced vaccine batches of the Pfizer-BioNTech COVID-19 vaccine. All countries accepting the vaccine donation/supply must have the 12 months shelf life at ULT and the use of QR code for determining the vaccine expiration date approved by their NRA, based on their own evaluation of the product dossier, and/or informed by the decisions of the FDA and EMA. Based on their scientific assessment, both FDA and EMA applied the 9 to 12, and now up to 18-month shelf-life extension retroactively to previously produced vaccine vials, packaged with an expiration date on the label and carton. Countries are strongly encouraged to carefully evaluate benefits and risks and refer to the decision of their NRA if considering to use the vaccines impacted by the retroactive shelf-life extension.

\(^{3}\) WHO standard recommendation on vaccine labels includes a printed expiry date on both vaccine vial label and packaging cartons.
of Pfizer-BioNTech COVID-19 Vaccine will solely have the manufacturing date and a QR code as a source of information on expiry date and remaining shelf life if stored at ULT.

The purpose of this job aid is to provide practical guidance for health workers, typically national-level logisticians, on how to verify the expiration date for Paediatric Pfizer-BioNTech COVID-19 vaccine stored in ULT using the QR code and manufacturing date information, to enable them to competently monitor and manage the supply and ensure efficient utilization of vaccine.

Key points:
- Authorized shelf life for paediatric formulation of Pfizer-BioNTech COVID-19 Vaccine stored at -90°C to -60°C is 18 months from the manufacturing date.
- Certain lots of paediatric vaccine vials (orange cap) have the manufacturing date printed on the label (MFG) and NOT the expiry date (EXP). The expiry date of the vaccine lot can be verified by scanning a QR code printed only on the carton. A written standard operating procedure (SOP), including this job aid, must be in place to guide the health workers on how to verify and track the expiry date.
- Country programmes that have received the vaccines before the shelf-life extension was authorized, which have the expiry date printed on the label and the carton, are encouraged to refer to their National Regulatory Authorities (NRA) to determine if the retroactive application of shelf-life extension for Pfizer-BioNTech COVID-19 Vaccine paediatric formulation is acceptable.
- Dynamic labelling (see Step 8 below) should be applied when the vaccine is moved from -90°C to -60°C ULT freezer to +2°C to +8°C refrigerator.
- At the service facility level and before use, health workers should check the dynamic label/marked expiration date to ensure the vaccine is still good to use.
- If the verified vaccine expiry date at ULT storage (-90°C to -60°C) is less than 10 weeks (2.5 months) when the vaccine is moved from the ULT to the refrigerator (+2°C to +8°C) and thawed, the verified expiry date should be respected (i.e. dynamic labelling will not be applied).

### Paediatric Pfizer-BioNTech COVID-19 vaccine shelf life based on different storage temperatures

<table>
<thead>
<tr>
<th>Vaccine storage temperature</th>
<th>Shelf life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen, stored at -90°C to -60°C</td>
<td>18 months from the manufacturing date</td>
</tr>
<tr>
<td>Thawed unopened vaccine, stored at +2°C to +8°C⁴</td>
<td>10 weeks from the date vaccine was thawed</td>
</tr>
<tr>
<td>Thawed opened vial, stored at +2°C to 8°C</td>
<td>Up to 6 hours after the first puncture</td>
</tr>
</tbody>
</table>

⁴ Do not refreeze the vaccine!
How to verify vaccine expiry date using the QR code?

To access the expiry date information, health workers should have a mobile device (‘smartphone’ or tablets), with access to the internet or network, and with downloaded QR scanner and reader application\(^5\). To verify the expiry date for each vaccine lot, health workers should do the following.

1. Locate the QR code on the carton. Access the camera on your mobile device and direct it at the QR code.

2. The mobile device should scan the QR code automatically. Click on the link that appears on your screen, to connect you to the Pfizer-BioNTech COVID-19 Vaccine website (http://www.cvdvaccine.com).

3. Once on the Pfizer-BioNTech COVID-19 Vaccine website, in the section for healthcare professionals on the left side of the screen select “COVAX” in the dropdown menu with the list of countries. Do not select your own country. By clicking on “COVAX”, you will be redirected to the COMIRNATY\(^\circledR\) homepage.

4. On the COMIRNATY\(^\circledR\) homepage, on the right side of the screen, click on the “Expiry date information” button to access a new page with information on the expiry date for each of different COMIRNATY\(^\circledR\) vaccine formulations.

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\(^5\) Multiple applications that support QR code scanning/reading for different mobile operating systems are available for downloading from the internet free of charge.
5. Scroll down to find the type of vaccine product you need to verify the expiry date for, i.e. for Tris/Sucrose paediatric formulation, packaged in vials with manufacturing date on the label (MFG), and with MFG and QR code printed on the carton. Find the table listing printed date of manufacture (MFG) on vial and carton in the left column and corresponding expiry date in the right column. If your vaccine vial has expiry date (EXP) printed on the vial label and carton, this table does not apply.6

<table>
<thead>
<tr>
<th>Printed Date of Manufacture (MFG)</th>
<th>Expiry Date (EXP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021/01/01</td>
<td>Apr 16, 2022</td>
</tr>
<tr>
<td>2021/02/01</td>
<td>May 17, 2022</td>
</tr>
<tr>
<td>2021/03/01</td>
<td>Jun 10, 2022</td>
</tr>
<tr>
<td>2021/04/01</td>
<td>Jul 12, 2022</td>
</tr>
<tr>
<td>2021/05/01</td>
<td>Aug 14, 2022</td>
</tr>
<tr>
<td>2021/06/01</td>
<td>Sep 15, 2022</td>
</tr>
<tr>
<td>2021/07/01</td>
<td>Oct 16, 2022</td>
</tr>
<tr>
<td>2021/08/01</td>
<td>Nov 18, 2022</td>
</tr>
<tr>
<td>2021/09/01</td>
<td>Dec 20, 2022</td>
</tr>
<tr>
<td>2021/10/01</td>
<td>Jan 21, 2023</td>
</tr>
</tbody>
</table>

Look for the correct expiry date

6. In the left column of the table, find the manufacturing date which is printed on your vaccine vial label and carton. In the same row, in the right column of the table, you will find the appropriate expiry date which corresponds to the printed date of manufacture. For Tris/Sucrose paediatric formulation this date reflects an 18-month shelf life for vaccine stored in a ULT freezer at -90°C to -60°C.

7. Read the expiry date carefully and mark it on each carton using a permanent marker, a sticker, or other long-lasting method, before storing the cartons in the ULT freezer.

8. When you move the vaccine out of the ULT freezer to a refrigerator to thaw, the marked expiry date on the carton must be updated (‘dynamic labelling’), to reflect the 10 weeks (2.5 months) shelf life at +2°C to +8°C. Make sure to correctly apply dynamic labelling:

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6 If your vaccine vial has expiration date (EXP) printed on the vial and carton, scroll down to the bottom of ‘expiry date information’ webpage (https://www.comirnatyeducation-covax.com/expiry-date-information) and verify the updated expiration date, if approved by your National Regulatory Authorities.
If a 10-week period is within the expiry date marked on the carton, cross it out and mark as not valid. Write down the new expiry date which would be 10 weeks (2.5 months) from the date the vaccine was removed from the ULT to thaw.

If a 10-week period is longer than the expiry date marked on the carton, respect the marked date as valid and do not change.

- It is important that the expiry date is easily visible to cold chain officers and vaccine handlers.
- This information allows responsible officers to:
  - properly apply the earliest expiry-first out (EEFO) principle when distributing vaccines to lower levels;
  - correctly update the expiration date when vaccine is moved from ULT freezer to refrigerator (‘dynamic labelling’); and
  - determine if the vaccine is still useable or not.

**How to proceed if the QR code on the carton/label cannot be read or does not link to the Pfizer-BioNTech COVID-19 Vaccine website?**

In case the manufacturing date (MFG) is printed on the carton/label and the QR code on the carton cannot be read with the mobile device or does not link to the Pfizer-BioNTech COVID-19 Vaccine website, if you have an alternative electronic device at your disposal, type [https://www.cvdvaccine.com/](https://www.cvdvaccine.com/) in the address bar of your web browser and follow the steps from the Step 3 above.

In case you do not have an electronic device or internet connection and the manufacturing date (MFG) is printed on the carton/label, calculate the expiry date considering the following:

- Manufacturing date is displayed as month and year of manufacture and includes the indicated month: for example 09/2022 includes the entire month of September, and the date of expiry reflects the last day of the month.
- Expiry date can be calculated by adding 17 months to the 1st manufacturing month, to reflect 18-month shelf life for storage at ULT. For example, expiry date for vaccine with manufacturing date 09/2022 is 01 September 2022 + 17 months = 29 February 2024. Therefore, the date 29 February 2024 should be marked on the carton as the expiry date for vaccine stored at ULT.
- This applies only if the manufacturing date (MFG) is printed on the carton/label. If the expiry date (EXP) is printed on the carton/vial label, this calculation does not apply and the new expiry date as approved by the local NRA is used.

**General considerations in managing paediatric Pfizer-BioNTech COVID-19 Vaccine**

**National and sub-national level:**

- Ensure adequate regulatory approval for acceptance and deployment of this vaccine are obtained prior to shipment.
- Assess existing ULT freezer storage capacity at national and subnational levels.
- Map the locations of cold chain equipment with capacity to store vaccines at ULT. This is necessary for identification of transit hubs to keep vaccine at ULT during transport and maximize its shelf life, while allowing health workers the time to prepare and organize vaccination sessions. Review the pre-shipment advice and use the information to plan for transportation, storage and distribution of the vaccine supply.
• Upon receipt of the vaccine supply, make sure to validate vaccine quantity, document the temperature logs during transit, and check the manufacturing or expiration date through the QR code, with consideration to the NRA approval status.
• Perform other procedures for vaccine arrival as indicated in the standard operating procedures (SOPs).
• Ensure that the country immunization programme has a SOP for verifying and including expiration dates on vaccine labels before distributing to lower store levels.

Health-facility level:
• Immediately report any temperature excursions recorded during transport to the supervisor for appropriate further 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. Follow your national policies and SOPs.
• Since the vaccine does not have a vaccine vial monitor (VVM), implement good practice in monitoring vaccine storage and transport temperatures.7,8
• Implement good practices in vaccine stock management, including application of the earliest expiry, first out (EEFO) principle.
• Ensure planned vaccination sessions are aligned with the vaccine delivery schedule to facilitate full utilization of the vaccine supply within its remaining shelf life.

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