

Acceptance of available traditional vaccine supply with reduced shelf-life

Interim guidance

1 March 2021



Introduction

The COVID-19 international public health emergency temporarily interrupted routine immunization activities and led to the cancellation or postponement of both preventive and outbreak response campaigns in many countries. With fewer immunization activities being undertaken, particularly during the first half of 2020, the utilization rate of vaccine stocks declined in many countries. At the same time, countries were unable to receive vaccine supplies on time due to country lockdowns and disruption to local and international air freight. These conditions have affected the supply and demand balance and could yield serious consequences both on the ability of countries to effectively re-establish immunization services and on manufacturers' capacity to produce new batches of vaccines for future use.

Many vaccine manufacturers are reaching, or have already reached, their maximum storage capacity, and are unable to continue production until a reasonable flow of finished product out of their warehouses is re-established, further exacerbating the matter of reduced shelf-life vaccine stocks at all levels of the supply chain and increasing the risk of inadequate supply availability at a global level, as a result of reduced production.

Many countries have re-initiated routine immunization activities and started to implement or plan catch-up campaigns to reach the population that missed out on immunization during the first half of 2020. It is important to ensure countries will have enough supply of vaccines to carry out the planned vaccination activities and protect the population from vaccine-preventable disease outbreaks.

One of the measures to mitigate the risk of future global vaccine shortage, high vaccine wastage and in-country stock outs is for countries to consider accepting supply of vaccines with reduced shelf-life. Some countries have certain requirements for remaining shelf-life (RSL) upon importation of vaccines, e.g. two thirds of shelf-life, 50%, a minimum of 12 months. In a recent publication on COVID-19, the World Health Organization (WHO) advises countries to consider accepting delivery of vaccines used in routine immunization with reduced shelf-life (1).

During the Fifty-fourth WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP), the Expert Committee members adopted the *Points to consider for setting the remaining shelf-life of medical products upon delivery* guideline (WHO Technical Report Series, No. 1025, Annex 8, 2020, Appendix 1). Procurement agencies, regulators, health programme managers and other stakeholders are encouraged to refer to this document, which contains information on the recommended minimum shelf-life for medical products upon delivery, including comprehensive guidance intended to facilitate the national authorization of importation of medical products, where applicable, to promote and support the efficient processing of medical products in the supply chain at all levels, to prevent wastage and stock out, and to ensure that barriers to access and supply of medical products are addressed (2).

This interim guidance is intended to guide Member States in making decisions and developing appropriate strategies to accept and manage traditional vaccines (herewith referred to as “vaccines”) with reduced shelf-life. COVID-19 vaccines are currently not within the scope of this guidance.

WHO and UNICEF recommendation

To mitigate global vaccine shortages and in-country vaccine wastage and to ensure that future demand for traditional vaccines can be met, WHO and UNICEF recommend that countries, as a temporary measure, review and reduce requirements for the minimum shelf-life of vaccines imported into the country. Vaccines meet potency requirements through to the end of the month declared as the expiry date. Vaccine vials are good to use up to this time, provided that the following conditions are met:

- the vaccine vial monitor (VVM) does not indicate that the vaccine needs to be discarded;
- the label is intact; and
- the vial has not been damaged.

The recommended minimum RSL of medical products at the time of dispatch and upon delivery, based on the outcome of risk assessment, is presented in Table 1. This illustrates several scenarios to guide countries in managing supply based on the total shelf-life (TSL) of medical products. The total shelf-life of a product is based on results from testing during stability (and, where relevant, sterility) studies under specified conditions. The storage and transport conditions stipulated by the manufacturer should be followed, to ensure product quality is maintained (3).

Table 1. Recommended minimum remaining shelf-life (RSL) upon delivery			
Total shelf-life (TSL)	RSL at the time of dispatch from manufacturer's premises	RSL at the time of delivery at port of entry of country	RSL at time of delivery at end-user level
48 months < TSL ≤ 60 months	40 months	30 months	12 months
36 months < TSL ≤ 48 months	30 months	24 months	12 months
24 months < TSL ≤ 36 months	20 months	15 months	6 months
12 < TSL ≤ 24 months	9 months	7 months	3 months
TSL ≤ 12 months	Special arrangements and conditions apply		

Most traditional vaccines are prequalified by WHO with 24–36 months’ shelf-life. For planned campaign activities and outbreak response, accepting vaccines with 7 months’ RSL at the port of entry should be considered based on the above, irrespective of the vaccines’ total shelf-life.

Country-level risk mitigation strategies

The following are proposed risk mitigation options for countries to reduce wastage as a result of handling a vaccine with reduced residual shelf-life:

- Expedite/accelerate customs clearance processes by reviewing customs-related barriers to facilitate early and safe arrival of vaccines at the national stores.

- Where national regulations limit the distribution of a vaccine below a certain residual shelf-life, coordinate with the national regulatory authorities, national formulary, audit etc. and issue temporary exceptions as needed. Re-adjust distribution principles in countries as required.
- Closely monitor vaccine utilization and wastage, the remaining shelf-life and VVM status of vaccine stock at all levels of the supply chain, following the “first expiry, first out” (FEFO) principle. Use of electronic stock management systems can facilitate easy tracking and tracing of stocks and improve stock data visibility for effective allocation and distribution of vaccines.
- Subject to more predictable availability of commercial air freight and cargo space for international shipments, countries are recommended to accept delivery of more frequent shipments of smaller quantities, which can be used before expiry.
- Given the continued ad hoc closures of some air corridors, ensure close coordination and monitoring of all shipments, prioritizing deliveries of vaccines whenever possible (4).
- Activities under which countries should accept and use vaccines with reduced residual shelf-life:
 - planned vaccination campaigns of short duration (e.g. outbreak response for measles/polio);
 - vaccination in acute humanitarian emergencies (5);
 - catch-up vaccination activities.
- Consider targeting a wider age cohort, with attention to vaccinating unvaccinated individuals or those who missed an immunization session when planning for a catch-up vaccination or mass vaccination campaigns (6). Implementing vaccination campaigns in humanitarian emergency settings poses extra challenges and requires adapting plans to the different vaccines, securing adequate logistics and resources and engaging different partners.
- Countries are encouraged to sensitize health workers and build their confidence to ensure they understand that it is safe to administer vaccines until they reach their expiration date and best practices in vaccine management are implemented to maximize potency and use of vaccines before they expire.

UNICEF and manufacturers' risk mitigation strategies

- UNICEF and manufacturers, in agreement with the receiving country, may plan shipments that combine vaccine with longer shelf-life and vaccine with reduced residual shelf-life. The quantity of vaccine with reduced shelf-life should be agreed upon with the receiving country based on an assessment of immediate needs, type and timing of planned immunization activities, and vaccine-specific utilization and wastage rates.
- In close communication with countries on their supply needs and funding availability, UNICEF Supply Division and manufacturers will ensure that delivery plans reflect the need for timely replenishment of national stocks of vaccines for both routine and supplementary immunization activities.

Any changes envisaged to forecasted volumes should be communicated to UNICEF Supply Division without delay to ensure realignment of country needs to maximize the use of the currently available supply, recognizing that vaccine production lead times are typically up to 18 months. Self-procuring countries are encouraged to communicate regularly with suppliers and can contact WHO (mi4a@who.int) to signal any major issues, changes in forecasts or need for support.

In the current pandemic situation, it should also be noted that the lead time to secure international airfreight capacity has also increased from approximately 2 weeks to 4 weeks on average, therefore careful supply planning is more critical than ever. Nevertheless, this situation too, is evolving with the evolving context of the pandemic.

The decision on the minimum shelf-life requirement of vaccines with a reduced residual shelf-life should be guided by a risk assessment and made based on specific country contexts, including projected lead time, frequency of vaccine deliveries and schedule of supplementary immunization activities (7).

Acknowledgement

The WHO and UNICEF regional and country offices; Gavi, the Vaccine Alliance; the Bill & Melinda Gates Foundation; and representatives from Member States are hereby acknowledged for their valuable inputs during the consultation process and drafting of this document.

Methods

The guidance and recommendations contained in this document are based on published WHO Technical Report Series No. 1025, Annex 8: *Points to consider for setting the remaining shelf-life of medical products upon delivery*, published on 20 April 2020 (2), and *WHO Policy on remaining shelf-life of medical products upon delivery*, working document QAS/19.788/Rev.1, dated July 2019 (3). The first draft of the policy document developed in January 2019 was circulated to the Interagency Pharmaceutical Coordination Group (IPC) representatives and interested parties, and has undergone public consultation, following WHO procedures in developing policies and recommendations. The document was presented during the Fifty-fourth meeting of the WHO ECSPP.

The proposed risk mitigation strategies were a product of consultations with various subject matter experts from UNICEF and WHO headquarters, regional and country offices, Member States and other partners.

Contributors

- **WHO headquarters:** Pascale Monique Abie, Kamal Ait-Ikhlef, Daniel Brigden, Tania Cernuschi, Diana Chang-Blanc, Rolando Dominguez Morales, Johanna Fihman, Christine Halleux, Lisa Hedman, Souleymane Kone, Ann Lindstrand, Maricel de Quiroz-Castro, Alejandro Ramirez Gonzalez, Carmen Rodrigues Hernandez.
- **UNICEF headquarters:** Anne Sophie Bonefeld, Michaela Briedova, Heather Deehan, Reza Hossaini, Ian Lacey, Ian Lewis, Yalda Momeni, Robin Nandy, Ann Ottosen, Adama Sawadogo, Benjamin Schreiber, Michelle Seidel, Ousmane Tamba Dia.

Declaration of interests

There were no conflicts of interest.

Funder

Funded by UNICEF and WHO.

References

- 1 WHO (2020) Maintaining essential health services: operational guidance for the COVID-19 context

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_24065

