Instructions on Gavi's process for the renewal and multi-year approval of vaccine support

Key audience

Immunisation programme managers, CSOs supporting service delivery, Alliance partners, Gavi Secretariat country teams

About this guidance

Use these instructions to (1) understand the changes in Renewals processes with the shift from annual to multi-year approvals and (2) complete the country-reporting and inputs requirements for the Renewals cycle in 2022. The process will result in approvals of vaccine doses for existing routine immunisation programmes for the next five years. This process is not expected to be repeated until the end of the five-year period.

Table of Contents

1. Introduction: transition from annual to multi-year approvals

This section provides an overview of what routine immunisation vaccine Renewals will look like for countries this year and for the next 5-years

As part of the operationalisation of Gavi's 2021-2025 strategy ("Gavi 5.0"), Gavi is transitioning from an annual cycle of vaccine renewals to a multi-year renewal and approval approach (multi-year approval, MYA). This shift aims to improve longer-term planning for countries and to streamline processes required to renew on-going vaccine support. In 2022, most countries will have vaccine requirements determined for the period of 2023-27[1].

With the multi-year approvals of vaccine support, three key changes are being introduced to the renewals process:

(1) Gavi will provide standard references for each parameter[2] for each vaccine programme which will serve as a baseline for calculating the multi-year approval (and a default only if a country does not submit a Renewal request).
   - Gavi is providing these standard references to assist in the estimation of five-year vaccine quantities. Provision of these standard references does not replace country forecasting processes, nor does it replace the need for countries to regularly monitor vaccine consumption, programme performance, and update vaccine dose forecasts.
   - Multi-year vaccine approvals are able to be changed during the five-year period, as and when more information (e.g., from such monitoring processes) is available. More detail on flexibility of approvals and subsequent adjustments is provided in this document.

(2) Countries can choose to accept these parameters ("standard references") or suggest alternatives with justification. Scenarios for when alternatives to these standard references may be supported are provided below, including the required accompanying documentation to justify exception requests.

(3) Renewal volume calculations will be completed in Excel by the country and submitted via the Country Portal. For countries who choose to accept the standard references, no changes to the Excel file will be required – instead, countries may simply click the tick box on the Country Portal that confirms standard references are accepted.

Following the renewal request, volumes will be reviewed and recommended for funding by Gavi's High-Level Review Panel (HLRP):

- Decision Letters (DLs) will initially cover a 2-year period (i.e., 2023-2024), with annual letters thereafter which will cover the subsequent two years (i.e., 2024-2025).

[1] In exceptional circumstances this period will be shorter, for example if Gavi support is scheduled to end beforehand due to the country transitioning out of Gavi support.

[2] Namely population, coverage, wastage, and buffer, collectively called 'parameters' in this document.

- Annual reviews of vaccine requirements will continue with emphasis on monitoring of vaccine usage alongside programmatic performance. The HLRP reviews will provide an opportunity for adjustments to multi-year approvals when warranted.
- Renewal of additional doses to immunise refugee populations is guided by the FER Policy and will remain on an annual cycle.

2. Overview of countries' vaccine renewals requests and reporting requirements in 2022 and subsequent years

2.1 Vaccine renewals requests and reporting requirements for countries in 2022

Requests for renewal of vaccine support to be made in 2022 are to cover the period from 2023-2027 inclusive. All countries receiving Gavi vaccine support must submit the required information for vaccine renewal via the Country Portal. Countries are requested to provide the following inputs:

- **Stock reporting:** End of year stock information must be reported by 31 March 2022
- **Parameters and volume inputs:** This information must be submitted by 11 May 2022. Countries are requested to review and respond to initial standard references provided by Gavi for each parameter of each vaccine programme. Where alternative parameters are requested, countries must provide accompanying supporting documentation. Full, step-by-step guidelines on this are detailed below in Section 3 – please review and follow these for the most efficient process.
- **Signatures:** The vaccine renewal request must be signed by the Minister of Health and the Minister of Finance[3] or delegated authority, to indicate commitment to co-financing obligations.

2.2 Vaccine renewals and reporting requirements for countries from 2023-onwards

Annual Renewals requests will not happen for the next 5-years since volumes for 2023-2027 will have been determined in the 2022 Renewal Request cycle. This simplifies Renewal Request processes for the next 5-years.

From 2023 - 2027, what was previously an annual renewals process will shift focus towards regular monitoring of vaccine consumption alongside programmatic performance. Formal stock reporting requirements will continue on at-least an annual basis (more frequent for some countries). Adjustments will be considered to approvals in the instance that vaccine consumption and programmatic information signal a significant over- or under- vaccine approvals. When these signals arise, an exchange will take place to understand the drivers and re-evaluate the multi-year approval quantities. Small normal fluctuations in consumption and need will usually be expected to be efficiently addressed by some flexibility to shift vaccine dose approvals between

[3] Countries requesting the renewal of IPV support only, do not need to provide the signature of the Minister of Finance or delegated authority.

years i.e., "borrowing" or "postponing" doses from different approval years within the 5-year MYA period.

3. Detailed guidelines for vaccine renewals requests in 2022

This section provides:

- **Details on the sources used to generate the standard references included in the country-specific Renewals file available on the Country Portal**
- **Detailed guidelines for requesting alternative parameters to standard references, for population, coverage, wastage, and buffer parameters. Following these guidelines, and attaching the documentation with the application, is a pre-requisite for alternatives to be considered by Gavi.**

Review of standard references

Gavi will provide the country with initial estimates for population, coverage, wastage, and buffer for each programme already introduced in a country in Excel format. This file will be made available in the Country Portal, which users can access via the Country Portal in the section "Renew support" – "Vaccine Support (NVS) renewal request".

These initial estimates are based on standard references, as detailed below. Countries are requested to review these estimates and either:

- **Endorse the use of these initial estimates:** if they align with country routine immunisation expectations, through clicking a button in the Country Portal to accept standard references.
- **Propose alternative parameters with accompanying documentation:** If the country disagrees with a specific parameter, or multiple parameters, the country is requested to complete the Excel sections labelled as "Country Request" and provide clear documentation for all alternative parameters, following the guidance detailed below (Section 3.1-3.4). This documentation will be reviewed by Gavi to determine whether to use the initial estimate or country-provided alternative. Gavi may also seek additional information via email in some circumstances where the case country documentation is initially deemed insufficient.

Kindly note that standard references are not provided for HPV due to the complexities of the programme[4].

Standard references

When new information becomes available over time that substantially changes standard references for a country, there will be an opportunity for MYA volumes to be adjusted to reflect

[4] See page 10 for further information.

this new information. For example, the UN World Population Prospects 2021 release is expected in 2022, and WUENIC estimates are published annually in July. Either the country or Gavi may reach out to initiate this conversation during the course of the 5-year approval period.

Gavi may review and adjust standard references if deemed necessary.

Parameter	Source	Values used
Population	UN World Population Prospects (UN WPP)	Two population figures are provided for each year for 2023-2027: birth cohort and surviving infant estimates. These are taken from the medium-variant UN WPP 2019 release, and surviving infants are calculated by births – infant mortality.
Coverage	WUENIC	Maximum of 2019 or 2020 WUENIC-reported coverage (recognising potential pandemic impact) with 1% coverage growth year on year for 2023-2027 for the relevant vaccine/dose or the closest proxy based on immunisation schedule, e.g., for PCV first-dose we use DTP1 and for PCV third-dose we use PCV3.
Wastage	WHO normative estimates	Available as Annex 1_Guidance on Wastage (ENG) from WHO. Where a range is provided the midpoint is used.
Buffer	Gavi normative value	25% of assumed annual vaccine need, i.e., 3 months
Top-level adjustment	Above mentioned standard references are compared to historic average shipments and the difference (historic average shipments – standard reference) is calculated. Where there is a significant difference, a short-term adjustment factor may apply. In these cases, countries are encouraged to explain these differences by providing alternative parameters.	

Requesting alternative parameters

Countries must attach accompanying documentation to support requests for alternative parameters. Country requests for alternatives to standard parameters that are accompanied by robust (described in tables as **strong**) documentation may be approved for up-to the full 5-year MYA window. Country requests may be approved for a shorter period, with follow-ups requested that will then allow consideration of extending the request to the full period, e.g., if documentation fits the criteria described for **medium**. Requests with **insufficient** documentation are unlikely to result in adaptation to the provided standard references. Where this is the case, countries are encouraged to develop sufficient documentation to request a revision later during the MYA period (2023-2027).

Guidelines and documentation requirements for country requests for alternative parameters to standard references are described below for population, coverage, wastage, and buffer.

3.1 Population

Countries are required to provide documentation based on the following guidelines for alternative population parameter requests:

Situation	Required documentation

Estimates of numbers of children, used in-country (e.g., produced and adopted by National Statistics Office or equivalent) differs from latest UN World Population Prospects (WPP) estimates	• **Strong**: Country provides final results of recent census not yet taken into account in latest WPP estimates, ideally including results and adjustments from post-enumeration surveys and/or demographic analysis.
	• **Medium**:
	  ○ Country provides preliminary results from a recent census that has not been included in WPP estimates. **Or**
	  ○ Country provides well documented projections from last census that likely include recent survey or administrative-based data and provides verification documentation of approach. **Or**
	  ○ Country provides results of spatial modelling approaches to production of estimates, based on integration of recent survey data with satellite and other geospatial data, together with verification documentation of approach.
	• **Insufficient**: Country provides estimates based on simplistic projections from a census conducted ten or more years ago.

Demonstration of endorsement and consistent use of these population figures across country health (and other) programmes is advantageous, in addition to the documentation detailed above.

3.2 Coverage

Please note that where alternative coverage parameters are requested, the denominator used to compute official coverage estimates will need to be cross-referenced against the population parameter estimates to ensure consistency.

Two situations may be considered for coverage parameters adaptations:

Situation	Required documentation
Recent vaccination coverage survey conducted in-country differs from WUENIC estimate and/or has not yet been taken into account by WUENIC	• **Strong**: Country provides finalised results of (a) Demographic and Health Surveys (DHS), (b) Multiple Indicator Cluster Surveys (MICS) or (c) equivalent survey conducted within the last 2 years. • **Medium**: Country provides draft results of DHS or MICS, or equivalent survey, conducted within the last 2 years.

	• **Insufficient**: Country provides results of a population-based household survey with sampling and survey methods not comparable to DHS/MICS, or results of a non-population-based household survey.
Official **coverage estimate differs from WUENIC estimate** and/or has **not been taken into account by WUENIC** *Note that given the rigor behind WUENIC estimates, no documentation is considered to be 'strong' for this situation and alternative estimates justified through this situation may not be deemed sufficient.*	• **Medium**: Country provides well documented triangulation assessment of most likely coverage based on any combination of survey-based estimates, administrative coverage, or other data sources, and provides verified documentation of approach to determine official coverage. • **Insufficient**: Country provides assessment based solely on administrative coverage and/or the estimate exceeds 100%

3.3 Wastage

Adaptations to the provided wastage rates may be granted if one of the following four conditions applies and can be demonstrated with the required documentation. Please note that these scenarios aim to enable adaptations to standard reference wastage rates for the short term, where current levels may be accepted with improvements planned over time, and long-term only if there is clear evidence that requested levels are accurate and represent country's actual needs, supported by strong and comprehensive vaccine management systems.

Situation	Required documentation
Recent wastage rate study/ assessment conducted in-country to determine country-specific wastage rates by antigen and for each level of the supply chain.	• **Strong**: Finalised and adopted (EPI Core Group or Interagency Coordination Committee {ICC}) results of a country-specific Wastage Rate Study/ Assessment that was conducted within the last 2 years and was based on the WHO Vaccine Wastage Study guidelines • **Medium:** Finalised and endorsed by the National Logistics Working Group (NLWG) but not yet adopted (by the EPI Core Group or ICC) results of a country-specific Wastage Rate Study/ Assessment that was conducted within the least 2 years and was based on the WHO Vaccine Wastage Study guidelines • **Insufficient**: Wastage Rate Study/ Assessment outputs shared with insufficient documentation of approach; or Wastage Rate Study/ Assessment results that were not based on the WHO Vaccine Wastage Study guidelines
Adoption and use of **WHO Vaccine Wastage Rate calculator to calculate and monitor vaccine wastage rates** for the country-specific context	• **Strong:** Inputs and outputs from use of WHO Vaccine Wastage Rates Calculator by antigen including report(s) of forecast accuracy/ performance of Calculator outputs compared to measured wastage for the preceding period (e.g., 12-months)

(service delivery and supply chain structure) by antigen.	• **Medium:** Inputs and outputs from use of WHO Vaccine Wastage Rates Calculator by antigen • **Insufficient:** Anecdotal analyses of vaccine wastage without using either the Wastage Rate calculator or an evidence-based calculation of vaccine wastage
Adoption of **active monitoring of vaccine wastage, stock levels, and consumption rates** to estimate required country-specific antigen-specific wastage levels	• **Strong:** Adopted monthly reports (i.e., validated and adopted by EPI) covering a 12-month period (or longer) detailing stock transactions, consumption trends, and wastage rates per antigen requested from national to district levels of the supply chain. • **Medium:** Aggregate or monthly reports pending adoption covering a 12-month period (or longer) or aggregate reports for 12 months (or longer) detailing stock transactions, consumption trends, and wastage rates per antigen requested from national to district levels of the supply chain. • **Insufficient:** Preliminary data analyses covering a period of less than 6-months of stock transactions, consumption trends, and wastage rate data from national to district levels of the supply chain.

Adoption of **programmatic strategies to reach every child/ zero-dose** and missed populations that could necessitate reasonable additional wastage including comparison to current status-quo vaccine wastage levels.
 	
Countries that have/are implementing programmatic strategies to reach every child/zero-dose and missed communities that may require more stock and potentially result in reasonable additional wastage. *Note that they should submit proof of these executed/planned programmatic interventions and pre-determined target populations as supporting documents.*
	• **Strong:** Adopted monthly reports (validated and adopted by EPI) covering a 12-month period (or longer) detailing stock transactions, consumption trends, and wastage rates per antigen requested – to show current wastage rates including documentation showing approved routine immunisation enhancement activities with clearly defined targets, status of implementation and adherence to Multi-Dose Vial Policy (MDVP) including implementation plan (where required), and impact on expected wastage rates.
	• **Medium:**
	  ○ Documentation showing approved routine immunisation enhancement activities, with clearly defined targets and impact on expected wastage rates compared to normative wastage rates
	  ○ **Or** verified or unverified reports covering a period of less than 6-months of stock transactions, consumption trends, and wastage rate data including documentation showing approved routine immunisation enhancement activities, with clearly defined targets.
	• **Insufficient**: No/ insufficient evidence of routine immunisation enhancement strategy, targets, or progress with implementation. No mention of implementation/adherence with MDVP and planned implementation steps and timelines.

For all situations above, countries that have not adopted, or have adopted but have variable levels of adherence to the multi-dose vial policy (MDVP), are encouraged to submit:

- A statement indicating the status of adoption/implementation of the MDVP
- A plan for implementation of the policy with clear targets within which the country would have fully implemented the policy I.e. "By 20XX country X would have implemented MVDP and be using 4% for single dose vials and 7% for multi-dose vials by 20XX"

3.4 Buffer

Adaptations to the standard provided 25% buffer rate may be granted if one of the following two conditions applies and can be demonstrated with the required documentation. Please note that these scenarios aim to enable adaptations to the standard buffer rates for the short-term, where current levels may be accepted with improvements planned over time, and long-term only if there is clear evidence that requested levels are accurate and represent country's actual needs, supported by strong and comprehensive vaccine management systems.

Situation	Required documentation
Countries that have/are implementing **programmatic strategies to reach every child/zero-dose and missed communities** that could necessitate pre-positioning additional buffer stock.	• **Strong**: Country provides historical buffer utilisation analysis covering a period of 12 months or longer, from at least central to district levels, demonstrating justifiable need for different (increased) buffer considerations • **Medium:** Country provides historical buffer utilisation analysis cover a period of at least 6 months, from the central and regional (provincial) levels only, demonstrating justifiable need for different (increased) buffer considerations • **Insufficient**: No historic buffer utilisation analysis shared.
Countries have adopted **modified supply intervals** (i.e., increased time period between supply arrivals) that necessitate additional buffer.	• **Strong:** Country provides verified proof (signed by National EPI Director & National SC Manager) of implementing modified supply interval and supply period including stock performance trend analysis to show that these modified supply intervals have not resulted in stock incidents (overstock, increased expiry rate or increased wastage rate) • **Medium:** Country provides verified proof (signed by National SC Manager) of implementing modified supply interval and supply period including stock performance trend analysis to show that these modified supply intervals have not resulted in stock incidents (overstock, increased expiry rate or increased wastage rate) • **Weak:** Unverified proof of implementing modified supply interval and supply period and/or no stock performance trend analysis shared to show that these modified supply intervals have not resulted in stock incidents

HPV Renewals approach

Since standard references are not provided for HPV programmes, all countries with an HPV programme are requested to:

1. Provide 2021 consumption-derived parameters for population, coverage, wastage, and buffer – to understand historic programme performance
2. Request population, coverage, wastage, and buffer parameters for 2023-2027. These do not need to have as detailed documentation as for requesting alternatives to standard references. However, any supporting documentation may be well-received to help allocate available supply.

These inputs should be entered into the Excel with all country-programme information, and re-uploaded to the Country Portal once complete.

Signatures and commitment to co-financing obligations

Based on the standard reference parameters and volumes the indicative value of the requested Gavi support in US $ and the associated co-financing requirement per year from the country is detailed in the Renewals Excel file. Countries are requested to review these commitments and provide the Minister of Health, Minister of Finance or delegated authorities signatures as a commitment to the required co-financing. The excel file is available in the Gavi Country Portal.

As this calculation will subsequently be adjusted for existing stock and remaining shipments to give a final approval for 2023 and future years, and a final split of Gavi support and required co-financing, it is to be treated as indicative. Co-financing requirements may be subject to change during the course of the MYA period.

4. Renewal of phased campaign support

In cases where a country is receiving support for multi-year phased campaign support, the campaign-related vaccine information and requirements, such as stock levels, updated target population to be vaccinated etc., will be provided to the country separately by the Gavi Senior Country Manager, for review and validation.

5. Vaccine switches (product, presentation, schedule, or use)

Vaccine switches remain governed by the existing policy and switches, as well as introductions, are possible throughout the entire multi-year approval period. More guidance on switches is available through your Senior Country Manager. Details of available vaccine presentations are described in the Detailed Product Profiles.