

PNEUMOCOCCAL VACCINES AMC PRICE REQUEST GUIDELINES

FOR COUNTRIES THAT HAVE TRANSITIONED OUT OF GAVI SUPPORT¹

Purpose of this document:

This document provides detailed guidelines on requests to access the AMC Tail Price for pneumococcal conjugate vaccines (PCV) for countries that have transitioned out of Gavi support and remain eligible through the Advance Market Commitment (AMC).

1. OVERVIEW OF GAVI SUPPORT FOR PNEUMOCOCCAL VACCINES

WHO recommends that pneumococcal vaccines be given priority in childhood immunisation programmes, especially in countries with under-five mortality of greater than 50 per 1,000 live births. Country-specific disease burden and cost-benefit analyses are some of the additional factors that need to be assessed when considering the introduction of pneumococcal vaccines.

In June 2010, the Gavi Board approved that all 73 Gavi-eligible countries, will continue to have access to pneumococcal vaccines through Gavi under the terms and conditions of the Advance Market Commitment (AMC), even once they have crossed Gavi's eligibility threshold and are no longer eligible for new financial support from Gavi, regardless of whether they have already or not yet introduced PCV, provided they fully self-finance the doses and their DTP3 coverage is greater than or equal 70%.²

1.2. Eligibility

Countries that have completely transitioned out of Gavi support, and in either case are not yet approved for pneumococcal vaccine support, will continue to be able to request the pneumococcal vaccines AMC Tail Price through Gavi under the terms and conditions of the AMC.

In accordance with Gavi's current eligibility policy, **only countries with DTP3 coverage levels greater than or equal to 70%, based on the latest WHO/UNICEF estimates can apply to Gavi for accessing pneumococcal vaccines at the AMC Tail Price.**

Eligible requests are submitted by the national government, for routine nationwide implementation, including requests with phased scale-up. Subnational introductions, such as regional or pilots, are not accepted. Requests are accepted all year round. To inform demand forecast which provides visibility into supply requirements, requests are to be submitted by January 1, 2020. Requests submitted after January 1st 2020 will be reviewed and may still be granted access to the Tail Price, but without guarantee of full supply being available, because if the demand volume is not covered by existing supply agreements, there may not be sufficient time to run a new call for supply offers and have it signed by December 31st, 2020.

Countries that have transitioned out of Gavi support and wish to apply for pneumococcal vaccine support will need to fully fund the costs of the vaccine from the outset. The vaccine price that these countries will pay under the AMC is determined by the AMC Tail Price and is set at a **maximum of US\$ 3.50 per dose.** Please refer to the Detailed Product Profiles for additional information on price. Countries will also need to

¹ and India.

² The AMC for pneumococcal vaccines is an innovative finance mechanism designed to stimulate the development and manufacture of pneumococcal vaccines for developing countries. For more information please see www.gavi.org/funding/pneumococcal-amc/

fund the cost of syringes, safety boxes and freight. Gavi will not provide Vaccine Introduction Grants (VIGs) to these countries.

In order to access pneumococcal vaccines under the terms and conditions of the AMC, **procurement must be done through UNICEF Supply Division (SD), i.e. self-procurement is not possible.** If the country wishes to self-procure pneumococcal vaccines, it will not be able to access the AMC Tail Price.

1.4. Available pneumococcal vaccines and vaccination schedule

Three WHO-prequalified pneumococcal conjugate vaccines (PCV) are currently available with Gavi support, which show comparable vaccine efficacies for serotypes contained in the vaccines, according to WHO:

- 10-valent (PCV10) in a 4-dose vial;
- 13-valent (PCV13) vaccine in a 4-dose vial; or
- 13-valent (PCV13) vaccine in a 1-dose vial.

Vaccination schedule³

For PCV administration to infants, WHO recommends 3 primary doses (the 3p+0 schedule); or 2 primary doses plus a booster (the 2p+1 schedule).

If the 3p+0 schedule is used, vaccination can be initiated as early as 6 weeks of age with an interval between doses of 4-8 weeks, with doses given at 6, 10, and 14 weeks or at 2, 4, and 6 months, depending on programmatic convenience. If the 2p+1 schedule is selected, the 2 primary doses should be given during infancy as early as 6 weeks of age at an interval preferably of 8 weeks or more for the youngest infants and 4-8 weeks or more between primary doses for infants aged ≥ 7 months. One booster dose should be given between 9-15 months of age.

In choosing between the 3p+0 and 2p+1 schedules, countries should consider locally relevant factors including the epidemiology of pneumococcal disease, the likely coverage, and the timeliness of the vaccine doses.

In 2015, SAGE reviewed the evidence on the administration of multiple injectable vaccines during the same visit and found that evidence supports co-administration. Therefore, countries should not make modifications to recommended immunisation schedules with the aim of preventing multiple injections during the same visit when such modifications are not evidence-based. To this extent, countries should provide training to health-care workers on vaccine co-administration practices (e.g. techniques to mitigate pain at the time of vaccination, information about safety and effectiveness of vaccines when co-administered, effectiveness and value of multiple vaccine injections, etc.) and develop a communication strategy to address vaccine hesitancy and refusals.

2. Request process

The national Coordination Forum (Inter-Agency Coordinating Committee/Health Sector Coordination Committee (ICC/HSCC) or equivalent body), including any technical EPI advisory groups such as the NITAG, should be closely involved in the process of deciding whether to introduce the pneumococcal vaccine to ensure that all information and options have been taken into account, and to guide effective integration of immunisation initiatives.

³ www.who.int/immunization/position_papers/PP_pneumococcal_April_2012_summary.pdf

The step-by-step request process is as follows:

- 1. Country to download the materials:** The request form can be found on the Gavi website at www.gavi.org/support/apply or requested by contacting proposals@gavi.org.
- 2. Country to submit request:** The request form should be completed by the relevant ministries (e.g. Ministry of Health and Ministry of Finance) in close collaboration with the Coordination Forum (ICC, HSCC or equivalent body), as well as all other national stakeholders. Complete requests must be submitted by EPI via email to proposals@gavi.org, any time of the year.
- 3. Ad-hoc Independent Review Committee to review requests:** requests are reviewed to ensure that mandatory requirements have been met, that the information submitted is valid and consistent, and that technical considerations have been accounted for. If questions arise, a call with the EPI will be organised to allow for quick clarifications directly with countries.
- 4. AMC Secretariat to assess supply implications and to communicate the outcome to country:** the assessment includes whether the volume requested can be supplied through existing contractual agreements, or whether it triggers a new Call for Supply Offer.

As a general rule, countries should expect a time of 3 months from request submission to outcome communication, and then a further six months (minimum) between Gavi's communication to the first delivery of vaccines and devices. Timing of delivery of the vaccine will depend on the volume of demand and availability of supply. After communication of approval of the programme, **countries will be expected to work directly with UNICEF SD for procurement of vaccines and devices and development of shipment plan.**

3. Request requirements

The following requirements apply to each country requesting to benefit from the terms and conditions of the AMC to access PCV:

1. DTP3 coverage levels must be greater than or equal to 70%, based on the latest WHO/UNICEF estimates.
2. The request must be signed by the Ministry of Health and by the Ministry of Finance.
3. The decision to introduce or scale-up the PCV vaccine must be supported by the NITAG and endorsed by the national coordination forum (Inter-Agency Coordinating Committee/Health Sector Coordination Committee (ICC/HSCC) or equivalent body). These groups should be closely involved in the process of deciding whether to introduce or scale-up the pneumococcal vaccine to ensure that all information and options have been taken into account, and to guide effective integration of immunisation initiatives.
4. Countries should provide a brief **new vaccine introduction (or vaccine scale-up) plan** that should include evidence that sufficient cold chain capacity is available to accommodate the pneumococcal vaccine.
5. Countries must provide confirmation of the financial sustainability of the introduction of PCV.
6. Countries must choose a preferred PCV vaccine presentation from the available Gavi ones listed in the Detailed Product Profiles, specify the planned month and year of introduction, as well as the total amount of doses requested and an alternative acceptable presentation, as applicable. Detailed Product Profiles are available at: <http://www.gavi.org/library/gavi-documents/supply-procurement/detailed-product-profiles/>.
7. Countries requests must reflect routine nationwide PCV vaccination. Subnational introductions, such as regional or pilots, are not accepted. Phased nationwide introductions are accepted.

8. Countries seeking to benefit from the terms and conditions of the AMC to access PCV must commit to procure through UNICEF SD.
9. Countries must introduce within 2 years of receiving Gavi's approval to access the AMC Tail Price.

4. Vaccine procurement

Eligible countries seeking to benefit from the terms and conditions of the AMC to access PCV must procure through UNICEF SD. **Self-procurement of PCV by countries is therefore not possible through the AMC.** Procurement through UNICEF SD Procurement Services is governed by the Memorandum of Understanding (MoU) signed between UNICEF and each country. Information on Procurement Services through UNICEF can be found at: http://www.unicef.org/supply/index_procurement_services.html.

If the country already has a valid MoU with UNICEF, this agreement would be, in principle, automatically applicable. For those countries with no previous experience in procurement through UNICEF, and for any needed clarification, please contact:

Procurement Services Centre
UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn
Copenhagen
Denmark
E-mail: psid@unicef.org
Fax: +45 3526 9421
Tel: +45 4533 5500

5. Vaccine cost

Countries applying through this mechanism will pay the AMC Tail Price from the outset of the programme. Under the AMC, the Tail Price ceiling is set at a maximum of US\$ 3.50 per dose. In addition, countries will pay all fulfilment costs to UNICEF SD in accordance with the Memorandum of Understanding between UNICEF and each country. Fulfilment costs are the extra costs incurred in supplying vaccines, in addition to the cost of the vaccine itself, and typically include freight and insurance, and any other applicable cost or fees as per the applicable Memorandum of Understanding.

6. Vaccine introduction planning

WHO provides generic templates which include key areas for countries to consider in introducing a new vaccine. Please refer to the following WHO guidance documents:

WHO Pneumococcal vaccine information: <http://www.who.int/ith/diseases/pneumococcal/en/>

WHO position paper on pneumococcal conjugate vaccines:

<http://www.who.int/immunization/documents/positionpapers/en/index.html>

Introduction of pneumococcal vaccine:

for PCV13:

http://www.who.int/immunization/diseases/pneumococcal/training_materials_intro_PCV13/en/

for PCV10:

http://www.who.int/immunization/diseases/pneumococcal/training_materials_intro_PCV10/en/

SAGE recommendation on multiple injectable vaccines in a single vaccination visit:

<http://www.who.int/wer/2015/wer9022.pdf?ua=1>

7. Monitoring and reporting requirements

Countries accessing pneumococcal vaccines directly through the AMC are required to submit the Joint Reporting Form to WHO and UNICEF each year in a timely manner.

Countries should also continue to monitor the number and proportion of children in the target population immunised against previously set targets, vaccine wastage rates, and vaccine stocks (from routine monitoring systems and periodic independent surveys).

Countries may also consider conducting a Post Introduction Evaluation (PIE) 6-12 months after vaccine introduction. This would have to be financed by the country.

Annual forecasting process

In order to procure pneumococcal vaccine at the AMC Tail price, the country is required to communicate their annual dose requirements in the annual forecasting exercise that will be conducted by the respective UNICEF Country Office (June-September).

Changes in introduction plans and/or coverage

Countries should communicate any significant changes in plans, as endorsed by the Coordination Forum (HSCC/ ICC or equivalent body). Changes may include accelerated or delayed introduction or increases or decreases in vaccine use. Revised plans and any urgent matters, especially those impacting vaccine requirements, should be brought to the attention of the local WHO and UNICEF offices, UNICEF SD and Gavi secretariat.

Changes in presentation of a vaccine

After a country has introduced a vaccine, it may request a switch to a different product presentation of a routine vaccine containing the same antigen. Product switch requests are to be submitted together with a rationale explaining the reason for the switch through a letter to the Gavi Secretariat and UNICEF SD.