Frequently Asked Questions (FAQs) on Pneumococcal vaccine support

November 2016

1. Which countries are eligible for pneumococcal vaccine support?

All 73 Gavi countries can have access to pneumococcal vaccines through Gavi under the terms and conditions of the Advance Market Commitment (AMC).[1] In order to be eligible to apply, the national WHO/UNICEF estimate of DTP3/Penta3 coverage for 2015 (WUENIC, released in July 2016) must be greater than or equal to 70%.

Specific conditions apply across countries:

1. Countries with an average Gross National Income per capita (GNI pc) over the past three years equal to or below **US$1,580** are eligible to apply and will receive the following support from Gavi once approved[2]:
    - Pneumococcal vaccine for routine immunisation programmes in a three dose schedule (3+1 or 2+1);
    - Associated vaccines supplies (i.e. auto-disable (AD) syringes, reconstitution syringes and safety boxes); and
    - A Vaccine Introduction Grant (VIG), which is a one-time grant to support the costs related to new vaccine introduction.

    → In 2017, these countries are **Comoros**, **Korea DPR**, and **Tajikistan**.
2. Countries that surpass the GNI pc threshold defined above in 2017 may apply for pneumococcal vaccine support from Gavi for one last time in 2017 (the "grace year") and for a maximum period of five years only, and are also eligible for the support outlined above.
3. Countries that have entered the transition process or have transitioned out of Gavi support and are not already approved for pneumococcal vaccine support are also able to apply for pneumococcal vaccines through Gavi. These countries will need to fully fund the costs of the vaccine from the outset (price determined by the AMC "tail price" at a maximum of US$3.50 per dose) and are not entitled to receive a VIG.

    → In 2017, these countries are **Bhutan, Cuba, Indonesia, Sri Lanka, Timor Leste, and Vietnam.**

See Section 3 and Annex 3 of the General Guidelines for more information. **A simplified application process will apply to countries in the transition process and those that have transitioned out of Gavi support, including separate guidelines available on the Gavi website.**

[1] More information on the Advance Market Commitment is available at: www.gavi.org/funding/pneumococcal-amc/
[2] Gavi uses World Bank GNI data (based on the Atlas method) released in July of each year. This data is for the annual GNI of a country in the previous year (i.e. in July 2016, the World Bank releases GNI data for 2015). Thus, for eligibility to apply in 2017, Gavi will consider the GNI data for 2013, 2014 and 2015.

2. Is a country eligible to apply for pneumococcal vaccine support if it is in the transition process or has transitioned out of Gavi support?

All 73 Gavi countries can have access to pneumococcal vaccines through Gavi under the terms and conditions of the AMC.

Transition countries that have crossed the GNI pc eligibility threshold but comply with the DTP3/Penta3 coverage threshold of 70% (see FAQ 1), can still apply for PCV support and access Gavi's AMC price, determined by the AMC "tail price" and set at a maximum of US$3.50 per dose. These countries will need to fully fund the costs of the vaccine and procurement of the vaccine needs to be carried out by UNICEF Supply Division (SD). These countries are not entitled to receive a VIG.

For further information, please see the **separate guidelines for pneumococcal vaccine support for countries that are in the accelerated transition phase or have transitioned out of Gavi support**.

3. What is the timeline of the application process?

The application process and corresponding timeline for PCV support in 2017 is summarised in Table 1 below.

Table 1: Key application-related timelines

	Round 1	Round 2	Round 3
Cut-off for submission of country applications for review at next IRC meeting	18 Jan 2017	3 May 2017	8 Sep 2017
IRC application review dates	8-17 Mar 2017	14-23 Jun 2017	3-17 Nov 2017
Gavi decision	by Jun 2017	by Nov 2017	by Mar 2018

Decision letters are sent shortly after the Gavi decision. Section 5 of the General Guidelines provides a more detailed description of the application process and anticipated timelines for all types of support.

4. Following Gavi approval, when should countries expect to introduce the vaccines?

Under the mandatory requirements for submitting an application to Gavi, the projected introduction date must be no later than two years from formal notification of Gavi approval. As a general rule:

- Countries should expect a lead time of at least 5-6 months from application submission to approval/ issuance of the Decision Letter.
- The VIG is typically disbursed within 4-6 months after Gavi approval/ the issuance of the Decision Letter, with a goal of disbursing the funds at least 6 months prior to the target introduction date.

This means that it will usually not be feasible for a country to introduce less than 15-18 months after the Gavi application submission deadline.

5. Is there sufficient supply of pneumococcal vaccine?

Gavi currently does not anticipate any supply constraints for either pneumococcal conjugate vaccine (PCV), PCV10 or PCV13, in the coming years.

6. How would potential delays in introductions due to supply constraints impact the duration of support from Gavi? Or co-financing requirements?

In the unlikely event of insufficient supply availability, and if the introduction date is postponed based on the date originally indicated in the application, the number of years of approved Gavi support will remain unchanged, irrespective of any transition from Gavi support. Gavi will work closely with countries and their partners to help address any such situations. Once supply is confirmed and discussions take place to confirm the new introduction timeline, Gavi will request an updated introduction plan and the most up-to-date version of the comprehensive Multi-Year Plan (cMYP) from the country. The requirement to co-finance the vaccine will begin only once the supply commences and will increase in line with the standard co-financing policy.

7. In a supply constrained situation, how does Gavi determine which country gets supplies first?

Where supply for pneumococcal and other vaccines is constrained, Gavi employs an allocation mechanism to determine the sequence in which countries will be allocated vaccines. This is based on country disease burden and DTP3 coverage rates.

8. Following a vaccine introduction, can countries switch to another product presentation when it becomes available?

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. In such cases a country may also apply for an additional grant to facilitate this transition. Product switch requests are submitted through the country portal as part of the annual renewal cycle or, if urgent, through a letter to Gavi and the procurement partner (UNICEF).

9. Can countries self-procure PCV vaccines?

In order to access the terms and conditions (including pricing) of the AMC, the procurement of PCV must be carried out by UNICEF SD. Self-procurement of PCV by countries is therefore not possible with Gavi support. Vaccine devices can however be self-procured by countries. If a country's negotiated price for devices is lower than the amount of financial support provided by Gavi, the country shall invest the excess funds in the immunisation programme and report on the use of these funds in subsequent monitoring reports to Gavi.