

# Gavi-supported PCV profiles to support country decision making

Pneumococcal and Rotavirus Working Group  
*Gavi Secretariat and partners, July 2020*

This resource is complementary to Gavi's **Detailed Product Profiles (DPPs) for WHO prequalified vaccines**  
<https://www.gavi.org/our-alliance/market-shaping/product-information-vaccines-cold-chain-equipment>

The primary objective of the Detailed Product Profiles (DPPs) is to provide countries with easy access to up-to-date and comprehensive information on Gavi-supported vaccines. Countries are encouraged to consider factors beyond procurement cost and impact on country co-financing requirements: the DPPs include information on vaccine presentations, pricing, indicative wastage rates, manufacturers, cold chain volume and handling. This information will help countries decide which vaccine presentation is the best 'fit' for inclusion in their immunisation programme. Selecting a vaccine that is the most programmatically favorable for a specific country's context contributes to the sustainability of an immunisation programme. The DPPs are referenced in the 2019 New Vaccine Support guidelines and available on the Gavi website.

The secondary objective of the DPPs is to provide an overview of all vaccine products that are either WHO prequalified (WHO PQ) or in review for WHO prequalification. The format of the DPPs was created specifically to allow countries to compare WHO PQ vaccine products, fully informing them of their options.

Information contained in the DPPs comes from a variety of sources including the Gavi Secretariat, WHO PQ vaccine webpages, WHO position papers and UNICEF's product menu for vaccines supplied by UNICEF for Gavi-supported programmes. The Gavi Secretariat will ensure the information in the DPPs is kept up-to-date as new products become WHO pre-qualified and are available to receive Gavi-support. The DPPs will be updated on a fixed schedule (approximately every 6 months) or with more frequency if required.

**THE INFORMATION CONTAINED IN THESE SLIDES AND THE DPPs IS CURRENT AS OF June 2020.**

Please send comments or questions [dpp@gavi.org](mailto:dpp@gavi.org)

Additional resources relevant for assessing vaccines and presentations:

- **Guidelines on Reporting and Renewal of Gavi support:**  
<https://www.gavi.org/support/process/apply/report-renew/>
- **WHO position paper**  
[https://www.who.int/immunization/policy/position\\_papers/pneumococcus/en/](https://www.who.int/immunization/policy/position_papers/pneumococcus/en/)

# Definitions

<b>2019/2020 price per dose (USD)</b>	Price in USD per individual vaccine dose based on available data. This price is an <b>indicative</b> vaccine price prepared by the Gavi Secretariat to be used by countries for planning purposes. Price exclusively covers the vaccine dose and does not cover associated expenses including but not limited to freight, cold-chain costs, administrative costs and wastage. In cases in which there are multiple suppliers of the same presentation of the vaccine, or when there is a range of prices offered by the same supplier of the vaccine, a weighted average price (WAP) is used.
<b>2019/2020 price per fully immunised person (USD)</b>	The price per dose (USD) is multiplied by the total number of doses required for a completed vaccine schedule, according to the WHO recommended vaccine schedules (WHO position papers)
<b>2019/2020 wastage adjusted price per fully immunised person (USD)</b>	Price per fully immunized person (USD) adjusted to account for vaccine wastage. The price adjustment factors in the projected cost of wasted vaccine for each administered dose. The wastage rate utilized in the calculation is <u>indicative</u> only and needs to be replaced by the country specific actual wastage rate or estimate. This value should not be used for planning purposes without considering the coverage rate, as this would overestimate needs.
<b>Cold chain volume per fully immunised person (cm<sup>3</sup>)</b>	The cold chain volume is multiplied by the total number of doses required for a completed vaccine schedule, according to the WHO recommended vaccine schedules (WHO position papers)
<b>Wastage adjusted cold chain volume per fully immunised person (cm<sup>3</sup>)</b>	The cold chain volume per fully immunized person is adjusted to account for vaccine wastage.

# Select criteria to assess pneumococcal conjugate vaccines

(relevance of criteria may vary by country)

## **1. Availability**

1. WHO prequalified pneumococcal conjugate vaccines supported by Gavi
2. New vaccines pathway from PQ decision to first shipment

## **2. Clinical profile**

## **3. Cost (direct)**

1. Waste-adjusted price per dose / per fully immunised child
2. Co-financing amount
3. Sustainability (long term agreements on price and availability)
4. Cost-effectiveness

## **4. Storage and transport**

1. Cold chain requirements and implications

## **5. Programmatic administration considerations**

# Available pneumococcal vaccines supported by Gavi

Trade name	PNEUMOSIL		Prevenar 13		Synflorix
Type	Pneumococcal conjugate vaccine				
Manufacturer	Serum Institute of India Pvt. Ltd.		Pfizer Inc.		GlaxoSmithKline Plc.
NRA	Central Drugs Standard Control Organization (CDSCO, India)		European Medicines' Agency (EMA)		European Medicines' Agency (EMA)
Presentation	1 dose/vial, liquid	5 doses/vial, liquid	1 dose/vial, liquid	4 doses/vial, liquid	4 doses/vial, liquid
WHO PQ decision	2019		2010	2016	2017
Availability	Available, with planning.	Available, with planning.	Available, with planning	Available, with planning	Available, with planning
Photo of the vial					

## Vaccine composition and clinical profile

Serotypes	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F
PNEUMOSIL (PCV10)	x			x	x	x	x	x	x		x	x	x
Prevenar 13 (PCV13)	x	x	x	x	x	x	x	x	x	x	x	x	x
Synflorix (PCV10)	x		x	x		x	x	x	x	x		x	x



**Pneumococcal conjugate vaccines in infants and children under 5 years of age: WHO position paper – February 2019**

*“PCV10 and PCV13 have comparable immunogenicity and impact on IPD, pneumonia and NP carriage due to shared vaccine serotypes. While differences were found in their immunogenicity and impact on the 3 serotypes included in PCV13 and not PCV10 and on serotype 6C, there is currently insufficient evidence that the 2 vaccines differ in their impact on overall pneumococcal disease burden.”*

*“Both PCV10 and PCV13 have substantial impacts against pneumonia, vaccine-type IPD and NP carriage. There is at present insufficient evidence of a difference in the net impact of the 2 products on overall disease burden. PCV13 may have an additional benefit in settings where disease attributable to serotype 19A or serotype 6C is significant. **The choice of product to be used in a country should be based on programmatic characteristics, vaccine supply, vaccine price, the local and regional prevalence of vaccine serotypes and antimicrobial resistance pattern.”***

Source: WHO position paper

Note: The most recent WHO Position Paper for PCV was issued in February 2019, before PNEUMOSIL (SII’s PCV10) was prequalified. The paper only referred to Synflorix (GSK’s PCV10) and Prevenar 13 (PCV13).

[https://www.who.int/immunization/policy/position\\_papers/pneumococcus/en/](https://www.who.int/immunization/policy/position_papers/pneumococcus/en/)

# Vaccine cost (direct) at “Gavi price”

All PCV vaccines procured through UNICEF under the AMC will be available at the price(s) shown in this document (or at the latest price published) until all doses procured through AMC contracts are exhausted.

For information on AMC, please refer to this [link](#).

The cost estimated includes the cost of devices. The country specific waste-adjusted cost will vary depending on the country's own wastage rate for each presentation. To estimate the wastage rate please use the [WHO Vaccines Wastage Rates Calculator](#)

<i>Trade name</i>	PNEUMOSIL		Prevenar 13		Synflorix
<i>Presentation</i>	1 dose/vial, liquid	5 doses/vial, liquid	1 dose/vial, liquid	4 doses/vial, liquid	4 doses/vial, liquid
<i>Price per dose (USD<sup>1</sup>)</i> «Gavi price» with procurement via UNICEF SD	\$ 2.95	\$ 2.00	\$ 3.30	\$ 2.90	\$3.05
<i>Doses per fully immunised person</i>	3	3	3	3	3
<i>Price per fully immunised person (USD)</i>	\$ 8.85	\$ 6.00	\$ 9.90	\$ 8.70	\$ 9.15
<i>Indicative wastage rate</i>	5%	8%	5%	8%	8%
<i>Waste-adjusted price per fully immunised person (USD)</i>	\$ 9.32	\$ 6.52	\$ 10.42	\$ 9.62	\$ 9.95
<i>Duration of AMC contracts<sup>2</sup></i>	up to 2029		up to 2027		up to 2024

1) The price in US dollars reflects conversion at a currency exchange rate of 1.218 USD/EUR, which reflects an average across a 5-year period (Bloomberg projected foreign exchange rates). The actual exchange rate that will be utilised to calculate the USD price at the moment of the transaction may vary.

2) AMC doses can be procured by UNICEF on behalf of Gavi countries until this date

# Manufacturers' pricing commitments for transitioned countries

These commitments are independent of, and complementary to, the AMC agreements

Vaccine	Manufacturer	Commitment Duration	Summary of Conditions
Synflorix	GSK	10 years <sup>1</sup>	<ul style="list-style-type: none"> <li>Country introduced with Gavi support<sup>2</sup></li> <li>Country already using GSK product</li> <li>May procure through UNICEF</li> <li>Price freeze (=price paid during last year of support)</li> </ul>
PNEUMOSIL	SII	-	No price commitment
Prevenar 13	Pfizer	2025 <sup>3</sup>	<ul style="list-style-type: none"> <li>Countries that have introduced the multi-dose vial Prevenar 13 with Gavi support and are transitioning to fully self-financing.</li> <li>Countries that introduce the multidose vial Prevenar 13 after the end of Gavi support and are already fully self-financing.</li> <li>Countries that have introduced using a different manufacturer's product and wish to switch after transitioning to fully self-financing.<sup>3</sup></li> </ul>

Manufacturer pricing commitments are 'public announcements' made during the last Gavi replenishment, they are not legally binding.

This information is meant for the convenience and benefit of countries **and should not give a false sense of assurance that Gavi is "guaranteeing" prices, and that prices are determined for every single product and country.**

<sup>1</sup> From date of transition to fully self-financing, where the country receives no Gavi support

<sup>2</sup> Gavi support = country and Gavi co-financing

<sup>3</sup> <https://www.gavi.org/sites/default/files/document/faq--pfizer-pricing-commitments-for-countries-transitioning-out-of-gavi%25e2%2580%2599s-financial-supportpdf.pdf>

<sup>4</sup>Contingent on replenishment and renewal of sufficient PCV contracted volumes with Gavi/UNICEF

## Vaccine cost-effectiveness

*“The cost–effectiveness of PCV use depends on many factors, including the burden of disease, vaccine effectiveness, indirect effects, vaccination coverage, vaccine price, delivery costs and schedule.”<sup>1</sup>*

*An analysis of data from 22 studies in LMICs showed that vaccination with Synflorix (PCV10) and Prevenar 13 (PCV13) is cost-effective from the perspective of both health care providers and society.<sup>2</sup>*

*The cost-effectiveness according to product choice will depend on country characteristics, including local serotype prevalence and coverage rates achieved with different schedules.” [WHO position paper on PCV, Feb 2019](#)*

<sup>1</sup> Chaiyakunapruk N, et al. Cost effectiveness of pediatric pneumococcal conjugate vaccines: a comparative assessment of decision-making tools. BMC Med. 2011;9:53.

<sup>2</sup> Saokaew S, et al. Cost effectiveness of pneumococcal vaccination in children in low- and middle-income countries: a systematic review. Pharmacoeconomics. 2016;34(12):1211–25.

# Storage and transport

(shelf life, vaccine vial monitor (VVM), volume per fully immunised person)

Trade name	PNEUMOSIL		Prevenar 13		Synflorix
<b>Presentation</b>	1 dose/vial, liquid	5 doses/vial, liquid	1 dose/vial, liquid	4 doses/vial, liquid	4 doses/vial, liquid
<b>Shelf-life<sup>1</sup></b>	36 months at 2 - 8 °C				
<b>Cold chain volume per fully immunised person (cm<sup>3</sup>)</b>	51	11	37.8	11.7	8
<b>Vaccine vial monitor type<sup>1</sup></b>	Type 30				
<b>Handling open vials<sup>1</sup></b>	n.a.	Opened vials may be kept for use in subsequent immunization sessions (up to 28 days from the withdrawal of the first injection if held at 2 - 8 °C)	n.a.	Opened vials may be kept for use in subsequent immunization sessions (up to 28 days from the withdrawal of the first injection if held at 2 - 8 °C)	Opened vials may be kept for use in subsequent immunization sessions (up to 28 days from the withdrawal of the first injection if held at 2 - 8 °C)
<b>WHO PQ link</b>	<a href="https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=384">https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=384</a>	<a href="https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=385">https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=385</a>	<a href="https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=221">https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=221</a>	<a href="https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=317">https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=317</a>	<a href="https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=341">https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&amp;ID=341</a>
<b>Photo of carton/packaging (comparable scale)</b>					

<sup>1</sup> Source: WHO PQ webpage: WHO updates these webpages as new information on products becomes available. Please refer to the WHO PQ website for the most up-to-date information. For presentations not yet WHO prequalified, data is based on discussions with manufacturers and partners in 2017.

# Programmatic administration considerations

	<b>PNEUMOSIL</b>	<b>PNEUMOSIL</b>	<b>Prevenar 13</b>	<b>Prevenar 13</b>	<b>Synflorix</b>
Vaccine presentation	1 dose/vial, liquid	5 doses/vial, liquid	1 dose/vial, liquid	4 doses/vial, liquid	4 doses/vial, liquid
Dose quantity	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
Preparation steps (see <a href="#">WHO training</a> for details)	1	2	1	2	2
Need for dose measurement	No	Yes	No	Yes	Yes

Multiple preparation steps and need for dose measurement may increase risk of incorrect preparation or incorrect delivery, and thus require more training & supervision.

# Cost and co-financing implications of switch options for PCV

Gavi estimates, **to be confirmed country by country**. May vary after the first year of implementation if wastage rates vary.

Switch option	Programmatic changes that impact cost <sup>1</sup>	Drivers of direct financial cost	Estimated impact on financial cost of vaccine co-financing <sup>2</sup> :	
			Country in initial self-financing	Country in transition, or fully self-financing
Prevenar 13 in 1 dose/vial > PNEUMOSIL 13 in 1 dose /vial	(None of key relevance)	Price reduction from US\$ 3.30 to US\$ 2.95 per dose	No difference	Less costly
Prevenar 13 in 1 dose/vial > Prevenar 13 in 4 doses /vial	Reduction in refrigerated capacity Marginal wastage rate increase Slight increase in administration complexity	Price reduction from US\$ 3.30 to US\$ 2.90 per dose	Marginal difference <sup>3</sup>	Likely less costly
Prevenar 13 in 1 dose/vial > Synflorix in 4 doses / vial	Reduction in refrigerated capacity Marginal wastage rate increase Slight increase in administration complexity	Price reduction from US\$ 3.30 to US\$ 3.05 per dose Different duration of price commitment post Gavi transition	Marginal difference <sup>3</sup>	Marginal difference <sup>3</sup>
Prevenar 13 in 1 dose/vial > PNEUMOSIL in 5 doses / vial	Reduction in refrigerated capacity Marginal wastage rate increase Slight increase in administration complexity	Price reduction from US\$ 3.30 to US\$ 2.00 per dose No price commitment post Gavi transition	Marginal difference <sup>3</sup>	Less costly
Prevenar 13 in 4 doses /vial > PNEUMOSIL in 5 doses / vial	(None of key relevance)	Price reduction from US\$ 2.90 to US\$ 2.00 per dose No price commitment post Gavi transition	No difference	Less costly
Prevenar 13 in 4 dose/vial > Synflorix in 4 doses / vial	(None of key relevance)	Price increase from US\$ 2.90 to US\$ 3.05 per dose Different duration of price commitment post Gavi transition	No difference	Marginal difference <sup>3</sup>
Synflorix in 4 doses / vial > PNEUMOSIL in 5 doses / vial	(None of key relevance)	Price reduction from US\$ 3.05 to US\$ 2.00 <sup>2</sup> per dose No price commitment post Gavi transition	No difference	Less costly
Synflorix in 4 doses / vial > Prevenar 13 in 4 dose/vial	(None of key relevance)	Price reduction from US\$ 3.05 to US\$ 2.90 per dose Different duration of price commitment post Gavi transition	No difference	Marginal difference <sup>3</sup>

<sup>1</sup> assuming fully vaccinated children, and standard wastage rates

<sup>2</sup> assuming fully vaccinated children (lower coverage rates would result in lower cost), actual as of 2019

<sup>3</sup> less than 10% difference

This table shows the switch options that are most applicable to all Gavi countries with ongoing vaccination. More switch options may be displayed in future editions.

## Key references

WHO [Prequalification](#) information

UNICEF [pneumococcal market update](#)

Gavi [Detailed Product Profiles](#)

WHO materials: <https://www.who.int/immunization/diseases/pneumococcal/en/>

## Key contacts for questions

Area of expertise	Agency	Person to contact, role, email
Vaccine clinical profile	WHO	<ul style="list-style-type: none"><li>• <u>Your Country's officer</u></li><li>• Jenny Waldorff, <a href="mailto:walldorfj@who.int">walldorfj@who.int</a></li></ul>
Total System Effectiveness approach for decision making	WHO	<ul style="list-style-type: none"><li>• <u>Your Country's officer</u></li><li>• Siobhan Botwright, <a href="mailto:botwrights@who.int">botwrights@who.int</a></li></ul>
Vaccine wastage rates, WHO wastage rates calculator	WHO	<ul style="list-style-type: none"><li>• Souleymane Kone, <a href="mailto:kones@who.int">kones@who.int</a></li></ul>
Availability, Shipment, Prices	UNICEF SD	<ul style="list-style-type: none"><li>• <u>Your Country's officer</u></li><li>• Abraham Ntow, <a href="mailto:akntow@unicef.org">akntow@unicef.org</a></li><li>• David Kiambi Mutuerandu, <a href="mailto:dkmutuerandu@unicef.org">dkmutuerandu@unicef.org</a></li></ul>
Eligibility, Price commitments	Gavi Secretariat	<ul style="list-style-type: none"><li>• <u>Your Country's Senior Country Manager</u></li><li>• Veronica Denti, Sr Programme Manager, <a href="mailto:vdenti@gavi.org">vdenti@gavi.org</a></li><li>• Markus Beck, Sr Manager, <a href="mailto:mbeck@gavi.org">mbeck@gavi.org</a></li></ul>