

Gavi-supported pneumococcal conjugate vaccines profiles to support country decision making

Pneumococcal and Rotavirus Working Group

Gavi Secretariat and partners, July 2019

This resource is complementary to Gavi's **Detailed Product Profiles (DPPs) for WHO prequalified vaccines**
<https://www.gavi.org/about/market-shaping/detailed-product-profiles/>

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 July 2019.

Please send comments or questions 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/

Definitions

2019/2020 price per dose (USD)	Price in USD per individual vaccine dose based on available data. This price is an indicative 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 utilised.
2019/2020 price per fully immunised person (USD)	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)
2019/2020 wastage adjusted price per fully immunised person (USD)	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.
Cold chain volume per fully immunised person (cm³)	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)
Wastage adjusted cold chain volume per fully immunised person (cm³)	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, either WHO prequalified, or expected to be prequalified

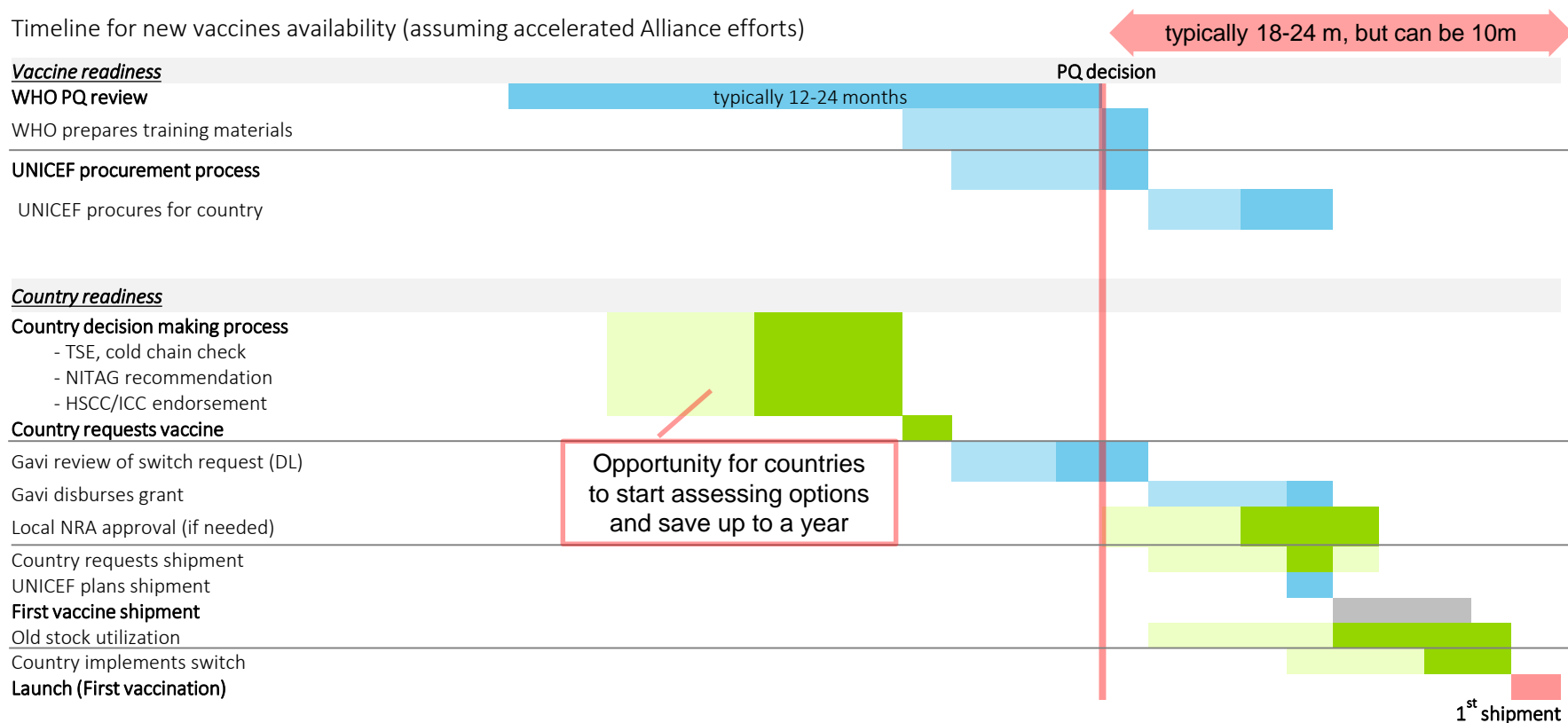
Trade name	Pneumosil		Prevenar 13		Synflorix
Type	Pneumococcal conjugate vaccine				
Manufacturer	Serum Institute of India Pvt. Ltd.	Serum Institute of India Pvt. Ltd.	Pfizer Inc.		GlaxoSmithKline Plc.
NRA	Central Drugs Standard Control Organization (CDSCO, India)	Central Drugs Standard Control Organization (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	WHO prequalification expected in Q1-Q2 2020	WHO prequalification expected in Q1-Q2 2020	2010	2016	2017
Availability	Expected to be available, with planning, in late 2020.	Expected to be available, with planning, in late 2020.	Available, with planning	Available, with planning	Available, with planning
Photo of the vial					

The availability of new vaccines is linked to country decision making speed

Gavi starts offering a new vaccine when it enters PQ review.

Countries starting the decision making process before PQ decision will be ready to receive the new vaccine up to a year earlier than waiting after PQ decision. A country switch will be conditional to a positive PQ outcome.

Timeline for new vaccines availability (assuming accelerated Alliance efforts)



Vaccine composition and clinical profile

The most recent WHO Position Paper for PCV referred to the currently pre-qualified PCVs: Synflorix (GSK's PCV10) and Prevenar 13 (PCV13). The PCV10 manufactured by Serum Institute of India (SII), called Pneumosil, is currently under review by WHO and expected to receive a pre-qualification decision in Q1-Q2 2020.



Organisation mondiale de la Santé

Weekly epidemiological record Relevé épidémiologique hebdomadaire

22 FEBRUARY 2019, 94th YEAR / 22 FÉVRIER 2019, 94^e ANNÉE
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<http://www.who.int/wer>

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

Vaccins antipneumococques conjugués chez les nourrissons et les enfants de moins de 5 ans: note de synthèse de l'OMS – février 2019

*“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: https://www.who.int/immunization/policy/position_papers/pneumococcus/en/

Although PNEUMOSIL and Synflorix are both 10-valent vaccines, designated as PCV10, the serotypes contained in each vaccine differ.

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

Vaccine cost (direct) at “Gavi price”

The cost estimated below 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 new [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/EUR*)</i> «Gavi price» with procurement via UNICEF SD	Expected at \$ 3.50**	Expected at \$ 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>	\$ 10.50**	\$ 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>	\$ 11.67**	\$ 6.52**	\$ 10.42	\$ 9.62	\$ 9.95
<i>Parameters for WHO calculator</i> WHO Vaccines Wastage Rates Calculator ***	PCV10 (1 dose vial)	(not yet available)	PCV13 (1 dose vial)	PCV13 (4 dose vial)	(missing in the calculator)

*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.

** **Final price to be confirmed after signature of Long Term Agreement between UNICEF SD and the manufacturers.**

Price is volume-dependant and may be higher in launch period.

***Session frequency assumptions: 20% of service points with daily sessions, 70% with 2 sessions per week, 10% with 2 sessions per month

Cost and co-financing implications of switch options

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 ³	Drivers of direct financial cost	Estimated impact on financial cost of vaccine co-financing ¹ :	
			Country in initial self-financing	Country in transition, or fully self-financing
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 ⁴	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 ⁴	Marginal difference ⁴
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 ² per dose No price commitment post Gavi transition	Marginal difference ⁴	Likely 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 ² per dose No price commitment post Gavi transition	No difference	Likely 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 ⁴
Synflorix in 4 doses / vial > Pneumosil in 5 doses / vial	(None of key relevance)	Price reduction from US\$ 3.05 to US\$ 2.00 ² per dose No price commitment post Gavi transition	No difference	Likely 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 ⁴

¹ assuming fully vaccinated children (lower coverage rates would result in lower cost).

² final price to be confirmed after signature of Long Term Agreement between UNICEF SD and the manufacturers

³ assuming fully vaccinated children, and standard wastage rates

⁴ 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.

Manufacturers' pricing commitments for transitioned countries

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](#)

Vaccine	Manufacturer	Commitment Duration	Summary of Conditions
Synflorix	GSK	10 years ¹	Country introduced with Gavi support ² Country already using GSK product May procure through UNICEF Price freeze (=price paid during last year of support)
Pneumosil	SII	-	No commitment
Prevenar 13	Pfizer	For PCV, doses can be procured under the AMC up to 2027 ⁴	All countries can access AMC price if procured through UNICEF, independently from their current presentation or whether they have already introduced or not. ³

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.**

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

² Gavi support = country and Gavi co-financing

³ <https://www.gavi.org/library/gavi-documents/supply-procurement/faq--pfizer-pricing-commitments-for-countries-transitioning-out-of-gavi%E2%80%99s-financial-support/>

⁴Contingent 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.”¹

An analysis of data from 22 studies in LMICs showed that vaccination with PCV10 and PCV13 is cost-effective from the perspective of both health care providers and society.²



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](#)

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

² 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, VVM, volume per fully immunised person)

Trade name	Pneumosil		Prevenar 13		Synflorix
Presentation	1 dose/vial, liquid	5 doses/vial, liquid	1 dose/vial, liquid	4 doses/vial, liquid	4 doses/vial, liquid
Shelf-life¹	36 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C
Cold chain volume per fully immunised person (cm³)	51	11	37.8	11.7	8
Vaccine vial monitor type¹	Type 30				
Handling open vials¹	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 to 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 to 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 to 8°C)
WHO PQ link	Expected in 2020	Expected in 2020	https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=221	https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=317	https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=341
Photo of carton/packaging (comparable scale)					

1 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 (risks of incorrect preparation or incorrect delivery)

	Pneumosil	Pneumosil	Prevenar 13	Prevenar 13	Synflorix
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 WHO training for details)	1	2	1	2	2
Need for dose measurement	No	Yes	No	Yes	Yes

Key references

WHO [Prequalification](#) information

UNICEF [pneumococcal market note](#)

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"> • <u>Your Country's officer</u> • Adam Cohen, cohen@who.int
Total System Effectiveness approach for decision making	WHO	<ul style="list-style-type: none"> • <u>Your Country's officer</u> • Siobhan Botwright, botwrights@who.int
Vaccine wastage rates, WHO wastage rates calculator	WHO	<ul style="list-style-type: none"> • Souleymane Kone, kones@who.int
Availability, Shipment, Prices	UNICEF SD	<ul style="list-style-type: none"> • <u>Your Country's officer</u> • Abraham Ntow, akntow@unicef.org • David Kiambi Mutuerandu, dkmutuerandu@unicef.org
Eligibility, Price commitments	Gavi Secretariat	<ul style="list-style-type: none"> • <u>Your Country's Senior Country Manager</u> • Veronica Denti, Sr Programme Manager, vdenti@gavi.org • Markus Beck, Sr Programme Manager, mbeck@gavi.org