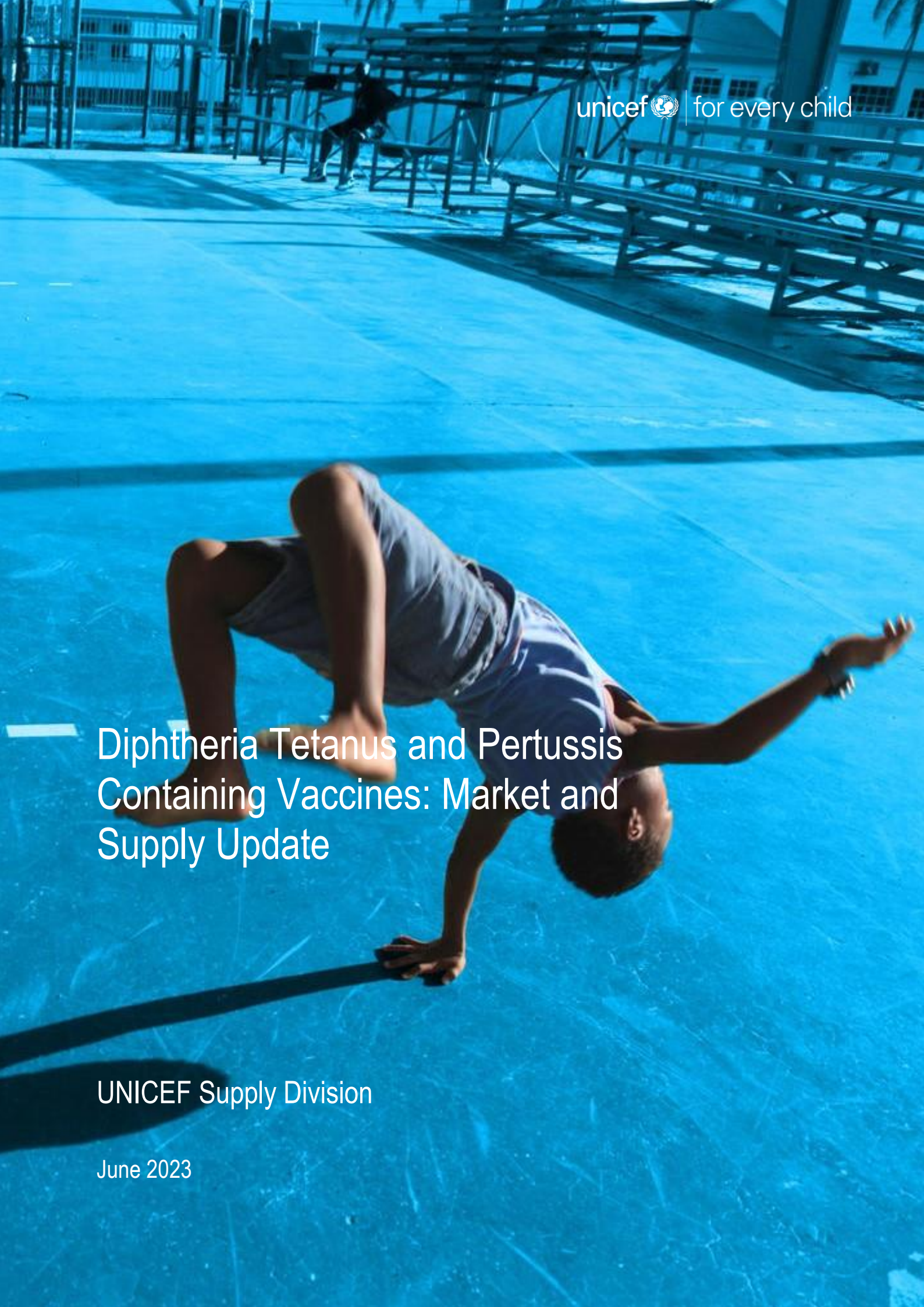

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Diphtheria Tetanus and Pertussis Containing Vaccines: Market and Supply Update

UNICEF Supply Division

June 2023

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This note provides updated information about diphtheria, tetanus, and pertussis-containing vaccines, including pentavalent and hexavalent vaccines. It includes market developments on demand and supply trends, as well as new pipeline products and the interconnected market dynamics between these products and their overall market health considerations.

1. Summary

- UNICEF procures diphtheria, tetanus, and pertussis (DTP) containing vaccines to protect children as part of a country's expanded programme on immunization (EPI) schedule. UNICEF primarily procures DTP-containing vaccines with whole cell pertussis (DTwP), consistent with World Health Organization (WHO) recommendations on pertussis vaccines. Several DTP-containing vaccine formulations exist and have been combined with additional antigens, such as hepatitis B (HepB), Haemophilus influenzae type b (Hib) and Inactivated Polio Vaccine (IPV), to form different combination vaccines.
- The current global supply capacity from manufacturers of DTwP standalone vaccine is sufficient to cover the current global demand. UNICEF procures and supplies approximately 50 per cent of global pentavalent demand, which has been stable at approximately 150 million doses a year since 2017. While there has been good visibility on the volumes of demand, the landscape related to funding has been rapidly changing as countries increasingly self-finance their procurement as they transition from the support from Gavi, the Vaccine Alliance (Gavi). UNICEF anticipates this will likely affect the accuracy of future country demand forecasts given the tightening of governments' fiscal space.
- In 2022 UNICEF concluded the first phase of its DTP-containing vaccine tender, made with the whole cell pertussis antigen (DTwP), for supply in 2023-2027. Besides the three-antigen containing DTwP vaccines, it includes calls for DTwP-HepB-Hib (also known as pentavalent) and DTwP-HepB-Hib-IPV (also known as hexavalent). UNICEF awarded contracts to two suppliers for the three-antigen containing DTwP vaccine and four suppliers for the pentavalent vaccine. UNICEF will issue the second phase of its tender latest by the third quarter of 2024. UNICEF will consider awards for the hexavalent vaccine as they acquire WHO prequalification and following any decisions by Gavi relating to the hexavalent programme, which UNICEF expects in June 2023.
- The weighted average price (WAP) for DTwP-containing vaccines has been subject to increases following a period of relative stability. This has been on account of general global inflationary pressures. The WAP for pentavalent vaccines through UNICEF has increased (+ 6.8 per cent) from an average of $0.88 per dose for 2017-2022 to $0.94 per dose for 2023-2027. The awarded WAP through UNICEF for DTwP standalone for 2023-2024 ($0.18 to $0.19/dose), remains aligned with historical WAPs, while projecting an upward trend over the course of 2025-2027.
- UNICEF will continue to have dialogue with industry and partners to ensure the long-term health of the DTwP-containing vaccine market.

2. Global Market Assessment

DTP vaccines have been part of the EPI vaccination schedule since 1974. This was the first combination vaccine to be developed in 1948, which incorporated the three antigens of DTP into one, thereby reducing the number of inoculations a child had to cope with and increase coverage. These vaccines were later reformulated to include hepatitis B (HepB), and Haemophilus influenzae type B (Hib) to become pentavalent. As new antigens are developed, the number of vaccines incorporated in national EPIs will increase, as they have over time, increasing immunization schedules as they expand. Simplifying child immunization programmes will require more combination vaccines to reduce the immunization burden on children, families, communities, and health systems, in addition to optimising the touch points children need to have with health facilities. Even though there are positive considerations to be had by increasing the number of visits a child pays to health facilities, there are also considerations to be had for the burden on families especially the poorest.

Despite the continued development and success of DTP-containing vaccines, prior to COVID-19, WHO and UNICEF reported that as of the end of 2018, 20 million children worldwide were still missing out on these lifesaving vaccines, which equated to more than 1 in 10 children, globally.[1] COVID-19 also has negatively impacted global vaccination coverage

[1] World Health Organization, *20 Million Children Miss Out On Lifesaving Measles, Diphtheria, and Tetanus Vaccines in 2018*, WHO, Geneva, July 2019.

rates with three doses of DTP (DTP3), resulting in a coverage reduction from 86 per cent in 2019 to 81 per cent in 2021, and increasing "zero-dose" children from 13.6 million 2019 to 18.2 million in 2021.[2, 3] UNICEF currently estimates that 67 million children globally missed out entirely or partially on routine immunization between 2019 and 2021. Of these, 48 million of them missed out entirely.[4] This is undermining and reversing the progress achieved during the previous decade and highlights how any public health gains and benefits from immunization are not a given. Preliminary data for 2021 did not show any signs of any noticeable recovery.[5] Even though these coverage rates could be considered high, it is not sufficient to protect against the outbreaks of these vaccine-preventable diseases, for which a minimum coverage of 95 per cent is needed, globally, across all countries, all communities, and especially **#foreverychild**.[6] WHO also recommends countries to include a fourth DTP booster dose for children between one-six years of age (Table 1).

Table 1 World Health Organization Recommended Routine Immunization Schedules for DTP-containing, HepB and Hib vaccines

Antigen	Primary Series		Booster Doses	
	Doses	Age	Dose	Age
DTP-containing vaccine */†	3	1st year of life	1 DTP-cont.†	12-23 months
			1 Td/DT-cont. vaccine	4-7 years
			1 Td-cont. vaccine	9-15 years
HepB vaccine	1	< 24 hours of life	n/a	
	+2 or +3 ‡	1st year of life		
Hib vaccine	2 or 3 §	6 weeks > 59 months	1 dose following a 2 dose primary series	6 weeks after last dose

Note *: Pentavalent vaccine follows this recommended immunization schedule.
Note †: Hexavalent vaccine follows this recommended immunization schedule, both for the primary series and the first booster dose.
Note ‡: 4th dose depending on country schedules and programmatic considerations.
Note §: 3 doses when combined with DTP-containing vaccines (i.e., pentavalent).
Source: WHO

Several DTP-containing vaccines exist (Table 2), including DTP standalone, tetravalent, pentavalent, and hexavalent vaccines that includes IPV.

Table 2 Description of Different DTP-Containing Vaccines

DTP-Containing Vaccines	Description
DTwP *	A trivalent combination form with *whole cell pertussis antigen.*
DTwP-HepB	A tetravalent combination including *DTwP and hepatitis b* antigens.
DTwP-Hib	A tetravalent combination including *DTwP and haemophilus influenzae b* antigens.
DTwP-HepB-Hib	A pentavalent combination including all antigens described above.
DTaP †	A trivalent combination with *acellular pertussis antigen.*
DTaP-Hib-IPV	A pentavalent combination form with *acellular pertussis and inactivated polio antigens*.
DTaP-IPV	A tetravalent combination form with a*cellular pertussis antigen.*
DTaP-Hib-HepB-IPV	A hexavalent combination form with *acellular pertussis antigen*.
DTwP-Hib-HepB-IPV	A hexavalent combination form with whole cell pertussis antigen - (pipeline under development).

Note *: wP = whole cell pertussis.
Note †: aP = acellular pertussis.
Source: World Health Organization.

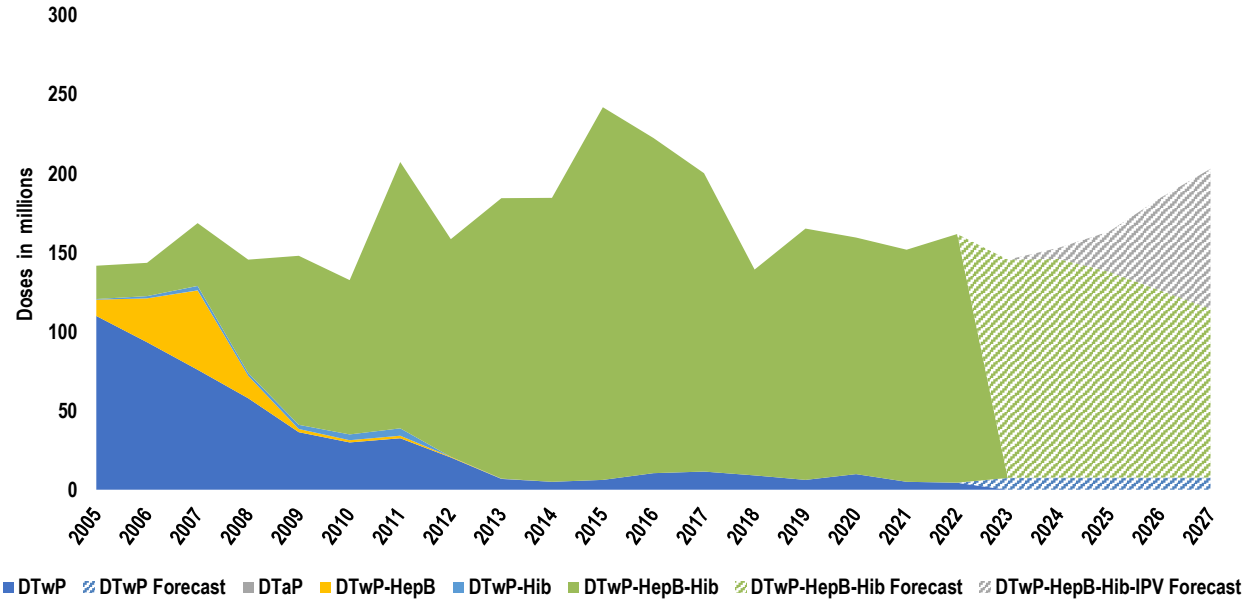
UNICEF primarily procures DTP containing vaccines with whole cell pertussis (wP), which is the vaccine used in most developing countries consistent with WHO recommendations on pertussis vaccines.[7] UNICEF has previously, and exceptionally, procured small quantities of acellular pertussis (aP) vaccine upon specific country requests when available. Most high-income countries (HICs) use DTP combination vaccines based on aP, which is currently more expensive than wP-containing vaccines and has limited global production capacity. Manufacturers use both DTwP and DTaP bulk to produce the different DTP-containing combination vaccines, including pentavalent and hexavalent vaccines.

[2] Zero-dose refers to children who have not received any vaccinations. Children who have not received the first dose of the diphtheria, tetanus and pertussis (DTP1) vaccine are a proxy to describe zero-dose. Children who have not received the third dose (DTP3) are described as under vaccinated.
[3] UNICEF, *State of the World's Children, For Every Child, Vaccination*, UNICEF Innocenti, Florence, April 2023, p. iii.
[4] UNICEF, *State of the World's Children, For Every Child, Vaccination*, UNICEF Innocenti, Florence, April 2023, p. v.
[5] World Health Organization, *Immunization Agenda 2030, Global Report 2021*.WHO, Geneva, 2021.
[6] Follow UNICEF's Twitter account at **#foreverychild**.
[7] World Health Organization, *Pertussis Vaccines WHO Position Paper,* WHO, Geneva, August 2015, p. 398.

Until 2005, DTwP standalone vaccine was predominant with a demand through UNICEF averaging approximately 110 million doses per year. From 2005, countries progressively switched towards the pentavalent vaccine. The growing demand for tetravalent and subsequently pentavalent combination vaccines contributed to this shift. Gavi support further facilitated the increase in demand for combination products by funding certain DTP-containing combination vaccines.

Further changes are foreseeable based on current forecasted demand, the expected introduction of *wP* hexavalent vaccine and the DTwP booster for the second year of life. In 2018, Gavi in principle approved in its Vaccine Investment Strategy (VIS) support for the DTwP booster dose, which was to be implemented at the start of 2021. However, as a consequence of COVID-19 and countries having subsequently shifted their programmatic priorities toward pandemic responses, the rollout of DTP booster doses was delayed. Gavi will re-assess this decision as part of its 2023 VIS, along with other vaccines that are in the pipeline.[8] This decision may impact the demand of DTwP-containing vaccines. Nevertheless, and subject to Gavi's re-evaluation and approval for the support, it will not translate in the additional demand immediately as the roll out may take up to two-three years.

Figure 1 DTwP-containing Vaccine Procurement through UNICEF 2005-2027



Source: UNICEF Supply Division

3. Innovation

- UNICEF will continue to support the market's long-term product pipeline and innovation in the DTwP-containing vaccines market (DTwP, pentavalent and hexavalent), notably the progress toward hexavalent. This will be in accordance with WHO and its Strategic Advisory Group of Experts (SAGE) working group's recommendations and the global partners' strategy to meet programmatic suitability requirements. It will seek to ensure a smooth market transition that does not impact negatively the availability of standalone vaccines (i.e., pentavalent and IPV).
- All WHO prequalified pentavalent manufacturers plan to have a wP based hexavalent product in their product development pipelines, and which are currently at different stages in their development. UNICEF expects WHO's prequalification of their first wP hexavalent product during the third quarter of 2023.
- Gavi had approved its support in principle for the hexavalent vaccine in November 2018, subject to the availability of WHO prequalified products and there being the conditions that can support its successful implementation.[9]

4. Diphtheria, Tetanus, and Pertussis Vaccine

Data indicates that immunity following a three-dose primary vaccination schedule of DTP vaccine wanes over time, and therefore, booster doses are needed to ensure continuing protection.[10] DTP-containing boosters have the potential to avert approximately 106,000 deaths (of which 82 per cent in children under age five years of age) during the period 2021-

[8] Dominic Hein, *Gavi Alliance Update*, UNICEF, Copenhagen, October 2020.
[9] Gavi, the Vaccine Alliance, *Pentavalent, IPV, Hexavalent and DTwP-containing Boosters during 2nd Year of Life Roadmap: Public Summary (2020)*, Gavi, Geneva, April 2020.
[10] Clarke Kristie MD, *Review of the Epidemiology of Diphtheria-2000-2016*, WHO, Geneva, April 2017.

2035. Immunization programmes can provide this vaccine during the second year of life through either DTP or pentavalent vaccines, and potentially through future hexavalent vaccines, if immunogenically and operationally relevant.[11]

UNICEF procures DTwP as a standalone vaccine on behalf of countries for booster dose vaccination during the second year of life. These are mainly on behalf of middle-income countries (MICs) and a handful of countries supported by Gavi through self-financing mechanisms, as currently there is no major donor funded support for this vaccine.

4.1. Current Market Situation

The current global supply capacity from manufacturers of DTwP standalone vaccine is sufficient to cover the current global demand. Bio Farma, Serum Institute of India (SII), and Biological E all produce WHO prequalified DTwP standalone vaccines. Additionally, there are other bulk manufacturers mostly dedicated for DTwP-containing combination vaccines, mainly intended for pentavalent.

The demand for DTwP as a standalone vaccine is relatively low and unpredictable, as the vast majority of the DTwP is used as bulk for combination vaccines. The three WHO prequalified producers of DTwP as standalone vaccines have also a WHO prequalified pentavalent vaccine and, therefore, there is sufficient capacity and possibility to reallocate bulk to respond to any fluctuations in the demand for DTwP as a standalone vaccine. However, to ensure that there is an alignment with the level of demand, the supply availability for DTwP as a standalone vaccine requires continued and close monitoring.

UNICEF does not anticipate there to be any new pipeline manufacturers to enter the market, as the vaccine is not on WHO's list of vaccines for priority prequalification, and as such, WHO is not accepting applications for any prequalification from new manufacturers.

4.2. Diphtheria, Tetanus, whole cell Pertussis Vaccine Supply

Currently three manufacturers (two in India and one in Indonesia) manufacture WHO prequalified DTwP standalone vaccine in 1-, 10- and 20-dose presentations (Table 3). However, the 1- and 20-dose presentations are not actively produced. The demand from countries procuring DTwP through UNICEF is for the 10-dose presentation.

Table 3 World Health Organization Prequalified DTwP Vaccines

Manufacturer	WHO Preq.	Presentation	Course	Formulation	Shelf life	VVM
Serum Institute of India (India)	1995	1-dose ampoule	3-doses	Liquid	24 months	none
	1995	10-dose vial	3-doses	Liquid	24 months	Type 14
	1995	20-dose vial	3-doses	Liquid	24 months	Type 14
Bio Farma (Indonesia)	2001	10-dose vial	3-doses	Liquid	24 months	Type 14
Biological E (India)	2014	1-dose vial	3-doses	Liquid	24 months	Type 14
	2014	10-dose vial	3-doses	Liquid	24 months	Type 14

Source: World Health Organization

UNICEF concluded the first phase of its DTP-containing portfolio tender in the third quarter of 2022 and awarded contracts for the supply of DTwP standalone vaccine to two suppliers for the supply of 21 million doses of the 10-dose presentation over 2023-2025. UNICEF will issue the second phase of its portfolio tender by the third quarter 2024, which will result in awards for the remaining tender volumes for 2025, and full awards for supply in 2026 and 2027.

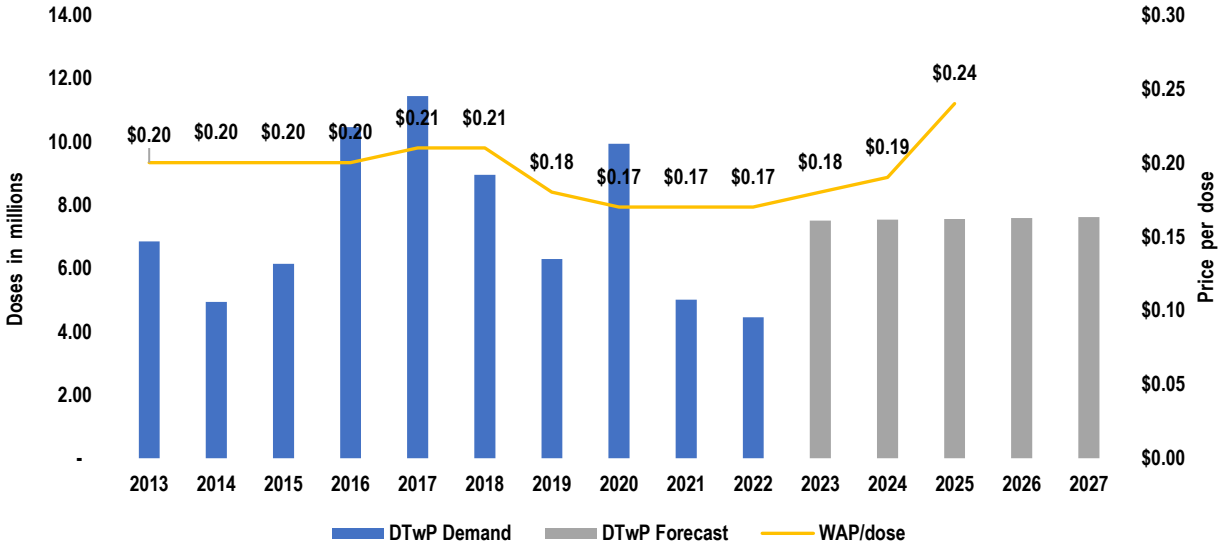
4.3. Demand, Forecast and Pricing

UNICEF supplies DTwP vaccine as standalone on behalf of approximately 25 countries annually. This is mainly for MICs that implement a DTP booster dose vaccination during the second year of life in their national routine immunization programmes. Five MICs account for 70 per cent of UNICEF's total procurement of DTwP standalone vaccine over the course of 2019-2022.[12] Given the small number of countries procuring DTwP standalone vaccine, the impact of their decision in procurement significantly affects the overall volumes through UNICEF. From 2013-2022, the overall demand fluctuated between 5 and 12 million doses per year for an average of seven million doses annually. These demand fluctuations have a minimal impact in the overall market as manufacturers reallocate the bulk based on the forecasted demand.

[11] Gavi, the Vaccine Alliance, *Pentavalent, IPV, Hexavalent and DTwP-containing Boosters during 2nd Year of Life Roadmap: Public Summary (2020)*, Gavi, Geneva, April 2020.
[12] Iraq, Morocco, Ukraine, Uzbekistan, and Zimbabwe.

The DTwP standalone vaccine's WAP per dose was stable from 2013 through 2018 at around $0.20 per dose. In UNICEF's previous tender period for 2019-2022, suppliers offered more favourable pricing, bringing WAP down to approximately $0.17 per dose. Following UNICEF's awards in 2022, UNICEF expected the WAPs for 2023 and 2024 to remain at similar levels as the previous years. However, the prices offered to UNICEF for the outer years of the tender period for 2025-2027 show an upward trend in the WAP starting from 2025 (Figure 2).

Figure 2 DTwP Vaccine Procurement and Demand Forecast through UNICEF 2013-2027



Source: UNICEF Supply Division.

5. Pentavalent Vaccine

Pentavalent vaccine remains the cornerstone of the EPI and Gavi's engagement. Immunization programmes administer pentavalent vaccines in a three-dose schedule having replaced traditional DTP vaccines and other combinations for example DTP-HepB, in many countries (Figure 1). Since 2001, Gavi has encouraged eligible countries to immunize children against HepB and Hib by providing financial support. This fostered the introduction and expanded use of vaccines against HepB and Hib in combination with DTP through pentavalent vaccines.

5.1. Current Market Situation

Follow the delisting of Sanofi Healthcare India's pentavalent vaccine in early 2023, at present, five manufacturers have WHO prequalified pentavalent vaccines. Information and details on the different WHO prequalified vaccines can be accessed through WHO's website here.[13] WHO prequalified vaccines come in different presentations ranging from a 1-dose to 10-dose vial. However, not all the vaccines listed by WHO are available in the market, as availability is driven by demand from countries, and the majority of the demand is mainly for 1 and 10 dose presentations. UNICEF only procures pentavalent in 1- and 10-dose vials.

5.2. Pentavalent Vaccine Supply

The pentavalent vaccine market is considered mature following several years of development and market shaping interventions. As of 2017, all Gavi-eligible countries had introduced the pentavalent vaccine, making the demand landscape more certain and stable. However, the increasing share of country self-financed demand, in addition to self-procurement from countries that are transitioning from Gavi support, results in there being less certainty in their demand and the timing of its realization.

The pentavalent global market is estimated to reach approximately 318.4 million doses in 2023. Lower middle-income countries (LMICs) represent the largest share of this volume, with 175.6 million doses equating to 55 per cent of the volume, followed by upper middle-income countries (UMICs) with 74.2 million doses, equating to 23 per cent, and closely followed by low-income countries (LICs) with 66 million doses, representing 20 per cent. High income countries (HIC) represent the smallest share of the volume, with 2.6 million doses equating to 0.8 per cent.[14]

[13] World Health Organization, *WHO Prequalified Vaccines*, WHO, Geneva, November 2016.
[14] Linksbridge, Global Vaccine Market Model, Seattle, 2023

The market landscape is competitive with the global production capacity of prequalified vaccines estimated to reach approximately 480 million doses per year, largely concentrated in India. The buffer capacity is above 30 per cent of demand and the supply base is diverse across currently five suppliers with WHO prequalified vaccines. These are fully liquid and lyophilized/liquid formulations in various presentations of 1-, 2-, 5- and 10-dose vials (table 4). Not all manufacturers offer all their listed WHO prequalified vaccine presentations to UNICEF. The four UNICEF awarded manufacturers offer pentavalent only in 1- and 10-dose presentations.

Table 4 WHO Prequalified One-dose Pentavalent Vaccine Offers to UNICEF

Company	Presentation	Formulation	VVM	Shelf Life	Cold Chain Vol. (cm^3)
Serum Institute of India	1-dose	Liquid	Type 14	24 months	(old)17.575/(new)14.06
Biological E (India)	1-dose	Liquid	Type 14	30 months	14.7
Panacea Biotec (India)	1-dose	Liquid	Type 14	24 months	15.3
LG Chem (Korea)	1-dose	Liquid	Type 14	36 months	16.8
Sanofi Healthcare India†	1-dose	Liquid	Type 14	24 months	16.8

Note †: Product delisted in 2023
Source: UNICEF Supply Division

Table 5 WHO Prequalified Ten-dose Pentavalent Vaccine Offers to UNICEF

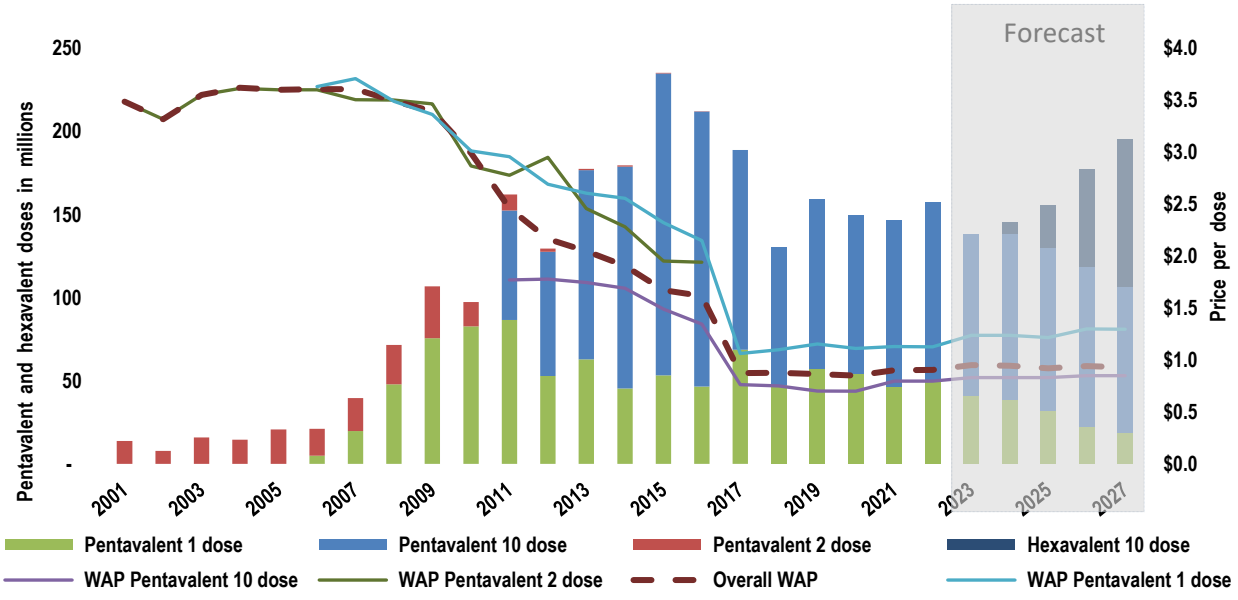
Company	Presentation	Formulation	VVM	Shelf Life	Cold Chain Vol. (cm^3)
Serum Institute of India (India)	10-dose	Liquid	Type 14	24 months	2.109
Biological E (India)	10-dose	Liquid	Type 14	30 months	2.9
LG Chem (Korea)	10-dose	Liquid	Type 14	36 months	3.06
Panacea Biotec (India)	10-dose	Liquid	Type 14	24 months	3.2
Bio Farma (Indonesia)	10-dose	Liquid	Type 14	24 months	4.0
Sanofi Healthcare India (India) †	10-dose	Liquid	Type 14	24 months	4.4

Note †: Product delisted in 2023
Source: UNICEF Supply Division

The supply of pentavalent vaccine availability and production capacity through 2017-2022 greatly exceeded the total aggregated country demand through UNICEF. UNICEF expects the state of supply to remain secure with ample availability across WHO prequalified manufacturers, provided countries give sufficient lead times.

5.3. Demand and Forecast

Figure 3 UNICEF Pentavalent Vaccine Demand, Forecast and Weighted Average Price 2001-2027



Source: UNICEF Supply Division

UNICEF anticipates total forecast demand for 1- and 10- dose pentavalent vaccine presentations to reach approximately 632 million doses during 2023-2027. However, it shows a progressive decline in demand as the market for hexavalent develops, which will be subject to its price affordability in comparison to the cost to immunize with a schedule of three doses of pentavalent, two doses of IPV, for primary series, and a DTP booster in the second year of life. It will also be subjected to a positive decision by Gavi to open a funding window, which would translate into a progressive uptake by Gavi-supported countries from 2024 (Figure 3).

UNICEF concluded a multi-phase portfolio tender in 2022 for the period of 2023-2027 and awarded four manufacturers supply contracts for a total of 538 million doses of pentavalent vaccine in 1- and 10-dose presentations (Table 7). For this period, about ninety per cent of the forecasted pentavalent vaccine demand through UNICEF is for Gavi supported demand for both the Gavi funded vaccine requirements and country co-financing obligations. However, UNICEF anticipates this share to decrease sharply to approximately sixty percent by 2027, as large population countries transition from Gavi support to fully self-finance their pentavalent vaccine requirements. Indications are that these countries will continue to channel their demand through UNICEF for the time being.

Table 7 UNICEF Pentavalent Vaccine Awards per One- and Ten-Dose Presentations 2023-2027

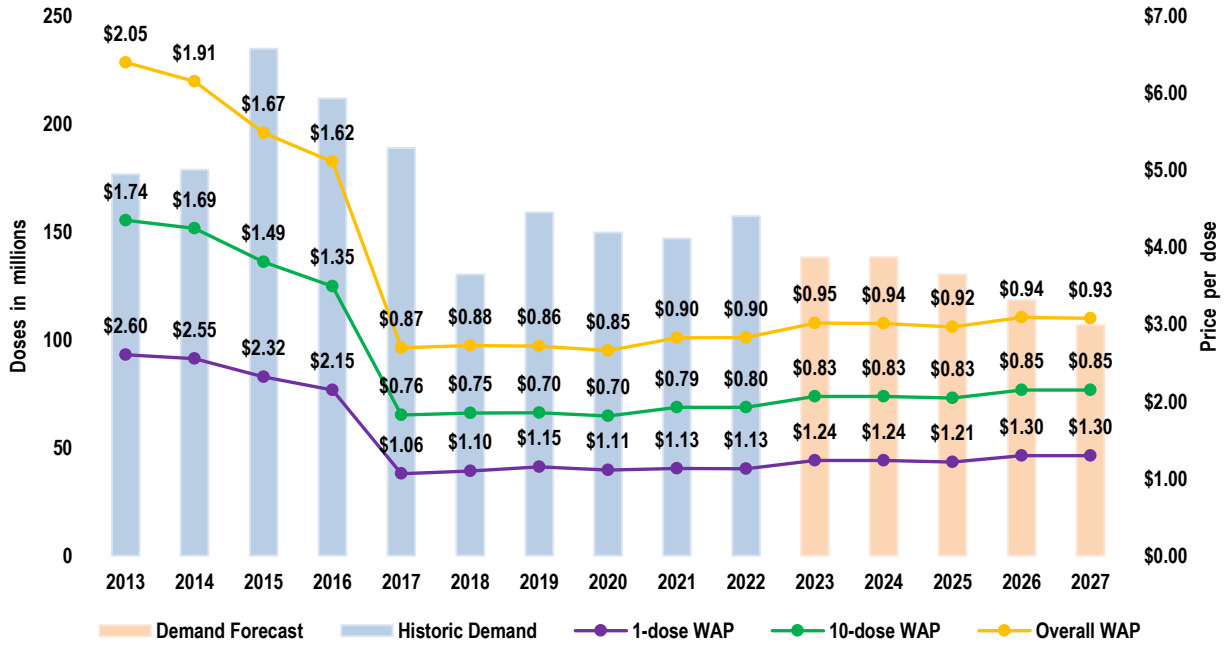
	2023	2024	2025	2026	2027	Total Forecast
1-dose	41,190,000	38,970,000	25,368,000	15,813,000	13,013,000	134,354,000
10-dose	96,870,000	99,300,000	78,800,000	67,053,000	61,789,000	403,860,000
Total	**138,060,000**	**138,270,000**	**104,216,000**	**82,866,000**	**74,802,000**	**538,214,000**

Source: UNICEF Supply Division

Looking beyond the Gavi-supported market segment, UNICEF anticipates the self-financing and MICs demand to remain stable around 15 million doses annually for the period of 2023-2025. For the years 2026 and 2027, as large population countries will transition from Gavi support, their demand is expected to reach forty percent of total procurement through UNICEF.

5.4. Pricing

Figure 4 Pentavalent Demand and Weighted Average Pricing



Source: UNICEF Supply Division

The pentavalent vaccine market's current surplus production capacity, supply availability, and increased market competition has resulted in it reaching several of Gavi's Healthy Market Framework objectives in the current tender. These are notably: accommodating country presentation preferences; maintaining sufficient buffer capacity; maintaining a sufficiently diverse supply base to mitigate supplier and regulatory risks; and maintaining enough suppliers to ensure long-term competition and market health. The current tender also seeks to achieve price reductions; price differential

decreases between 1- and 10-dose presentations; fair opportunity to access vaccines between Gavi and self-financing countries; and an award that represented suppliers that as a composite have a research and development pipeline for vaccines targeted towards the health needs of children living in the poorest countries.

The WAPs for the pentavalent vaccines from the latest tender in 2022 showed a price increase of 6.8 per cent, from the average of $0.88 per dose during the period 2017-2022, and up to $0.94 per dose for the period 2023-2027. UNICEF publishes vaccine prices for each manufacturer holding a long-term arrangement (LTA) with UNICEF, which can be accessed here.[15]

5.5. Issues and Challenges

- The Gavi-supported pentavalent vaccine programme is maturing and demand is becoming more predictable. However, countries that have transitioned from Gavi support need to improve the accuracy of their demand forecasts for supply to avoid the risk of over-production that may in turn undermine the stability in the market and affect pricing.
- As countries transition from Gavi's pentavalent vaccine support, and as the anticipated portion of country co-financing increases, it is important to ensure that vaccines remain affordable for countries. Maintaining fair prices will require continued competition among manufacturers, optimized production, as well as appropriate UNICEF contracting terms.
- The demand for hexavalent vaccine is expected to materialize during the current tender period and will impact the long-term health of the pentavalent market. UNICEF issued its current portfolio tender to manage the challenges that can come from the interdependencies between the different DTP-containing vaccine products and markets.
- The Indian national regulatory authority (NRA) releases over 70 per cent of pentavalent vaccines procured through UNICEF. Therefore, the pentavalent market depends on a continued functional and effective Indian NRA to help monitor and minimize any risks to the disruption of supply.
- Despite all pentavalent vaccines currently procured through UNICEF being interchangeable, there may be programmatic challenges for countries to switch among vial presentations. In addition, increased country-specific vaccine registration requirements can challenge product user flexibility between vaccine manufacturers to meet country programmatic demands.

6. Hexavalent Vaccine

The hexavalent vaccine represents an immunization alternative to current schedules of pentavalent and standalone IPV and the need for fewer vaccination sessions and potentially higher coverage. The delay of polio eradication timelines and subsequently longer use of IPV increases the attractiveness of hexavalent vaccine as it can help reduce the risk of the premature discontinuation of IPV. In October 2021, WHO's SAGE working group meeting on immunization recommended the use of the hexavalent vaccine in a four-dose schedule, and that the wP-hexavalent vaccine could fit in any of the existing primary series of the IPV schedule.

UNICEF has not yet awarded any manufacturer supply contracts for hexavalent vaccine within the first phase of the current tender, as no commercially viable vaccine has yet acquired WHO prequalification. UNICEF might consider awards for hexavalent within the first phase of the tender as vaccines acquire WHO prequalification, and in consideration of Gavi's decision regarding the hexavalent programme, which UNICEF expects in June 2023.

7. Steps Forward

- UNICEF will continue to support manufacturers' long-term product pipeline and innovation, taking into consideration the challenges to both partners and manufacturers in projecting vaccine development timelines.
- UNICEF will continue to have dialogue with industry and partners to ensure the long-term health of the DTwP-containing vaccine market.
- UNICEF and partners will continue collaborating to ensure sustainable access to the bulk of the different antigens required for the production of DTwP-containing vaccines.
- UNICEF will continue to work with countries to ensure greater accuracy in DTwP-containing vaccine demand forecasts based on stock levels, improved wastage rate information, and adjustments in target population and coverage assumptions.
- UNICEF will launch phase II of the DTwP-containing multiphase portfolio tender latest by Q3 2024 for the remaining unawarded quantities of DTwP standalone, pentavalent, and hexavalent vaccines.

[15] UNICEF, *Vaccine Price Data*, UNICEF, Copenhagen, January 2021.

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UNICEF issues market and information notes on products and supplies that are essential for the needs of children, and by extension their families. While some products are easily available and affordable, the availability of others can be limited, or in some instances, non-existent in the quality and price required. UNICEF places a strategic focus on these supplies to shape healthy markets. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, competitive market landscapes, and product quality that is fit for purpose and in the right form for children.