

Adolescent and Adult Tetanus- containing Vaccines: Market and Supply Update

UNICEF Supply Division

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This update provides information on adolescent/adult tetanus-containing vaccines, including global supply, demand and pricing trends, and highlights the transition from tetanus toxoid to tetanus-diphtheria.

1. Summary

- Tetanus is a serious illness contracted through exposure to the spores of the bacterium, *Clostridium tetani*. The bacteria can enter the body through deep cuts, wounds or burns affecting the nervous system. The infection leads to painful muscle contractions¹.
- Diphtheria is an infection caused by the bacterium *Corynebacterium diphtheriae*. In severe cases, the bacteria produce a poison (toxin) that causes a thick grey or white patch at the back of throat. This can block the airway making it hard to breathe or swallow and create a barking cough. The toxin may also get into the blood stream causing complications, inflammation and damage of the heart muscle, inflammation of nerves, kidney problems, and bleeding problems².
- UNICEF procures adolescent and adult tetanus-diphtheria containing vaccines (TdCV) for use in routine immunization (RI) as well as in campaigns supporting Maternal and Neonatal Tetanus Elimination (MNTE), and adult diphtheria prevention. This note provides updated market information on adult TdCV (Td, Tdap, Tdap-IPV).³
- The UNICEF/WHO/UNFPA partnership and the Strategic Plan 2018 - 2020 sought to ensure that at least 53 countries were validated as having eliminated maternal and neonatal tetanus (MNT) by 2020.⁴ As of November 2023, 47 countries out of 59 at risk have eliminated MNT.⁵
- UNICEF, WHO and UNFPA are finalizing their Strategic Plan - Post 2020 for Achieving and Sustaining Maternal and Neonatal Tetanus Elimination (MNTE). The objective is to achieve MNTE in all 12 remaining countries and, subsequently, to ensure that MNTE is sustained in all countries.
- Following outbreaks of diphtheria, WHO has recommended replacing TT vaccine with Td vaccine for a double protection. From 2014 to 2022, with the transition from TT to Td, the demand for Td vaccine through UNICEF multiplied six times. Despite the increased demand of Td vaccine, there is sufficient market supply to meet the demand.
- The tetanus-containing vaccines market is a healthy market with worldwide fifteen manufacturers of Td vaccine and five WHO prequalified vaccines. The WHO prequalified manufacturers have a combined production capacity for Td vaccine of 500 million doses annually.
- In 2022, the tetanus containing vaccine (TCV) global demand across all vaccines was approximately 355 million doses. The global demand for Td vaccine was 316 million doses, approximately 90 per cent of the total demand for TCV. The demand of Td vaccine through UNICEF is, approximately, 40 per cent of the global demand (130-140 million doses)⁶.
- In 2022, UNICEF established long-term arrangements (LTAs) with four manufacturers for the supply of Td vaccines, in 10 and 20 dose vial presentations, to cover the supply period 2023 - 2027.
- In 2023, UNICEF together with Td vaccine suppliers, has been able to secure the required capacity to respond to a diphtheria outbreak in West Africa. Moving forward, continuous monitoring and support from all stakeholders will be required to ensure vaccine availability for both routine and outbreak response.

2. Background

Tetanus is an acute infection caused by the bacterium *Clostridium tetani*, which is endemic worldwide.⁷ It can affect all age groups, but umbilical cord infection during delivery is the most common form, endangering newborn babies and their mothers in resource-limited settings. Case mortality of neonatal tetanus (NT) can reach 100 per cent if untreated and may

¹ [Tetanus \(who.int\)](#)

² [Diphtheria \(who.int\)](#)

³ This note excludes information on DTP, DTP-HepB, DTP-Hib, DTP-HepB-Hib (pentavalent) and DTP-HepB-Hib-IPV (hexavalent).

⁴ World Health Organization, [Maternal and Neonatal Tetanus Elimination: The partnership](#), WHO, May 2022.

⁵ World Health Organization, [Maternal and Neonatal Tetanus Elimination: Progress towards global MNT elimination](#), WHO, May 2022.

⁶ Linksbridge

⁷ World Health Organization, [Tetanus Key facts](#), WHO, Geneva, May 2018.

range from 10–60 per cent even under hospitalized care. There is no natural immunity against tetanus, although clean delivery practices help prevent infection. WHO estimates that 25,000 newborns died from neonatal tetanus in 2018, an 88 per cent per cent reduction from 2000.⁸ However, tetanus deaths, particularly among newborns, are often unreported.

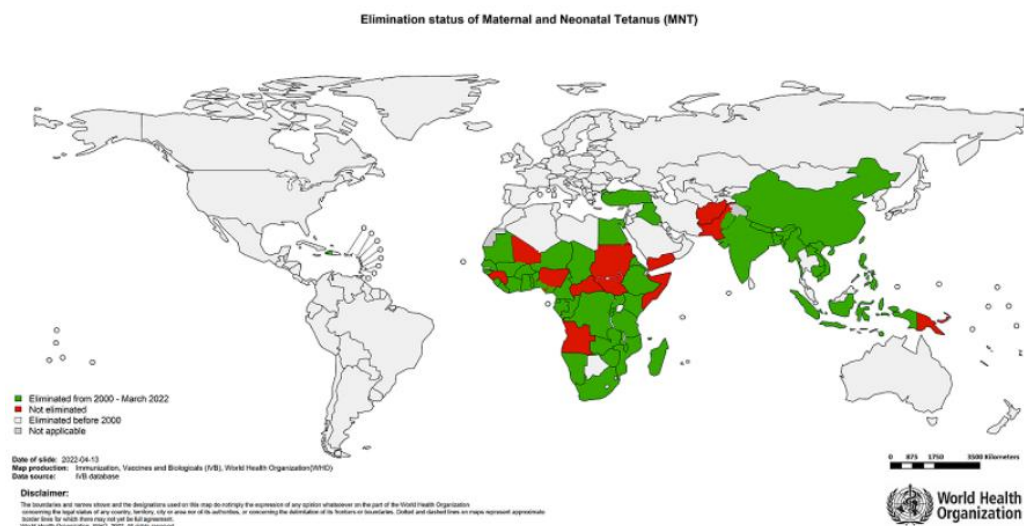
Tetanus can be prevented through immunization with tetanus containing vaccines (TCV), which are included in routine immunization programmes globally and administered during antenatal care contacts. TCV are available as monovalent TT or in combination with other antigens, such as diphtheria, pertussis, Inactivated Polio Vaccine, hepatitis B and Haemophilus influenzae type b vaccines. The new-born is protected at birth if the mother has been vaccinated during or before her pregnancy. Following the administration of sufficient TCV doses to the mother, antibodies pass to the foetus across the placenta and provide protection against NT.

The MNTE initiative

In 1989, the 42nd World Health Assembly called for neonatal tetanus elimination; an ambition expanded 10 years later to include maternal tetanus. The Maternal and Neonatal Tetanus Elimination (MNTE) Initiative was launched by UNICEF, WHO and the United Nations Population Fund (UNFPA) in 1999, revitalizing the goal of MNTE as a public health problem. MNT can be eliminated through immunization and promotion of more hygienic deliveries and cord care practices.⁹

The UNICEF/WHO/UNFPA partnership and Strategic Plan 2018–2020 sought to achieve that at least 53 countries were validated as having eliminated maternal and neonatal tetanus (MNT) by 2020.¹⁰ Since the launch, MNT has been eliminated in 47 countries out of 59 countries at risk (plus partially eliminated in Mali, Nigeria, Pakistan), leaving 12 countries yet to eliminate MNT and lagging the global target for elimination. DR Congo is the latest country to officially eliminate MNT in 2019.¹¹

Figure 1 Country Status of Maternal and Neonatal Tetanus Elimination 2022



The UNICEF, WHO, UNFPA “Strategic Plan – Post 2020” is being finalized to align with IA2030 and Gavi 5.0 to focus on reaching the unreached. The pragmatic goal is to achieve MNTE in all 12 remaining countries and, subsequently, to ensure that MNTE is sustained in all countries. The strategic plan focuses on intensification of immunization of pregnant women (at ANC, EPI and SIA platforms¹²), increasing institutional delivery and skilled birth attendance and identifying and investigating suspected neo natal cases.

⁸ World Health Organization, [Tetanus](#), WHO; Geneva, May 2022.

⁹ MNT elimination is defined as less than one case of neonatal tetanus per 1000 live births in every district, according to the WHO ‘Maternal and Neonatal Tetanus Elimination (MNTE)’

¹⁰ [The partnership \(who.int\)](#)

¹¹ [Progress towards global MNT elimination \(who.int\)](#)

¹² ANC (Antenatal Care), EPI (Essential Program on Immunization), SIA (Supplementary Immunization Activities)

The transition from Tetanus Toxoid (TT) to Tetanus diphtheria (Td)

Following outbreaks of diphtheria in the former Soviet Union and other countries WHO recommended in 1998 replacing TT with Td. The recommendation was later reinforced and restated by the Strategic Advisory Group of Experts (SAGE) on Immunization in 2002 and again in 2016.

In June 2018, WHO and UNICEF issued a joint communique urging countries to transition from TT to Td.¹³ The issuance was followed by focused advocacy and support to countries that were still using TT vaccines in their schedule. As a result, many countries followed the recommendation and replaced their use of TT with Td. In support of WHO's recommendation, and as of January 2020, UNICEF no longer offers TT vaccines and only supports countries in procuring Td vaccines.

DTP booster program

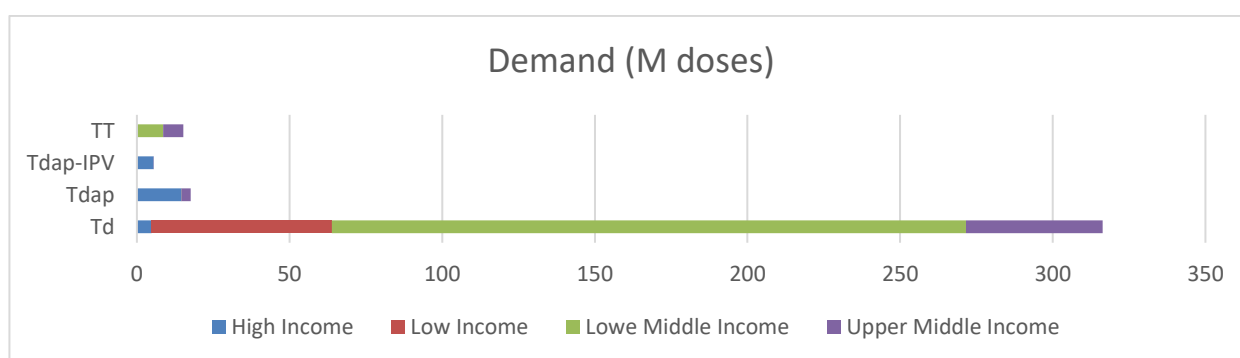
To be protected throughout life, WHO recommends that an individual receives six doses (three primary and three booster doses) of tetanus and diphtheria vaccines. The three primary doses are usually administered in the first year of life with a Pentavalent Vaccine (DTP-HepB-HiB) or Hexavalent Vaccine (DTP-HepB-Hib-IPV). The three booster doses are recommended at 12–23 months of age, 4–7 years of age, and 9–15 years of age, using age-appropriate vaccine formulations¹⁴. With the aim of supporting countries introducing the tetanus and diphtheria boosters in their programs, in 2018, Gavi approved in its Vaccine Investment Strategy (VIS) support for the DTP booster dose program. However, due to COVID-19 pandemic, the rollout was delayed. In June 2023, Gavi recommended to un-pause the program and proceed with the funding, design and roll-out. As countries decide to introduce the boosters in their programs, the overall demand for DTP-containing vaccines may increase, including Td vaccine which can be a vaccine of choice for the second (4-7 years old) and third boosters (9-15 years old).

3 Current market and trends

3.1 Global demand

The Global demand for Td containing vaccines in 2022 was 355 million doses, from which 90 per cent was demand for Td vaccine and the remaining 10 per cent demand for Tdap, TT and Tdap-IPV. The largest share of the demand for Td vaccine comes from low middle-income countries (LMICs) (65 per cent), followed by low-income countries (LICs) (19 per cent), upper middle-income countries (UMICs) (14 per cent) and high-income countries (HICs) (2 per cent). The demand for the other vaccine presentations, mainly Tdap and Tdap-IPV, is driven by high income countries (HICs).

Figure 2 Demand by Vaccine Type and Country Income Group 2022¹⁵



Approximately 55 per cent of the global demand for Td vaccine is self-procured by countries, with India purchasing over 60 per cent of the self-procured volumes. UNICEF SD procures approximately 35 per cent of the global demand and the remaining 10 per cent is procured through PAHO revolving fund.¹⁶

¹³ [WHO/UNICEF Joint Communique, June 2018](#).

¹⁴ 12-23 months either Hexavalent, Pentavalent or DTP vaccine, 4-7 years either DTP or Td vaccine, 9-15 years Td vaccine

¹⁵ GVMM, February 2020

¹⁶ WHO, [global-vaccine-market-report-2022-template-final2.pdf \(who.int\)](#)

The Td containing vaccine market value is estimated at \$733 million in 2022, with 58 per cent of the US\$ market value corresponding to Tdap, 28 per cent Tdap-IPV and only 14 per cent to Td¹⁷. This is due to high prices of Tdap and Tdap-IPV vaccines compared to Td vaccine.

3.2 Global supply

The tetanus-containing vaccines market is a healthy market worldwide. There are five WHO prequalified Td vaccines and two WHO prequalified Tdap vaccines.

Figure 3 World Health Organization Prequalified DTwP Vaccines

Manufacturer	Vaccine	WHO Preq.	Presentation	Formulation	Shelf life	VVM
Serum Institute of India (India)	Td	1995	1-dose ampoule	Liquid	36 months	none
		1995	10-dose vial	Liquid	36 months	Type 30
		1995	20-dose vial	Liquid	36 months	Type 30
Bio Farma (Indonesia)	Td	2011	10-dose vial	Liquid	24 months	Type 30
Biological E (India)	Td	2014	1-dose vial	Liquid	36 months	Type 30
		2014	10-dose vial	Liquid	36 months	Type 30
		2020	20-dose vial	Liquid	36 months	Type 30
BB-NCIPD (Bulgaria)	Td	2006	10-dose vial	Liquid	36 months	Type 14
		2006	20-dose vial	Liquid	36 months	Type 14
Sanofi (France)	Td	1997	10-dose vial	Liquid	36 months	n/a
	Tdap	2017	1-dose vial	Liquid	36 months	Type 30
Glaxo Smith Kline Biologicals SA	Tdap	2013	1-dose vial	Liquid	48 months	Type 30

Source: World Health Organization

The WHO prequalified manufacturers of Td vaccine have a combined production capacity of approximately 500M doses annually, which is largely over the global demand (355M doses in 2022). Based on UNICEF estimates and WHO analysis, there is sufficient supply to meet the global demand for Td, notwithstanding the demand increase due to the switch from TT.

The market is heavily dominated by Indian manufacturers both in terms of volume and value. In terms of product development and innovation, currently there are no Td vaccines in the pipeline.

3.3 Global Pricing

Td is a relatively low-priced vaccine, with a weighted average price (WAP) of US\$0.10/dose through UNICEF and PAHO in 2021.¹⁸ However, the price variability is high for Td containing vaccines due to the high price difference of Tdap and Tdap-IPV vaccines compared to Td vaccines. Td containing vaccines procured by self-procuring HICs have the widest price range (\$7.2 - \$26.5)¹⁸, mainly due to the high market prices of Tdap and Tdap-IPV vaccines. UNICEF procures only Td vaccine, and the prices are fixed for both LICs and MICs.

4 Procurement through UNICEF

4.1 Historical volumes and forecast

UNICEF has been procuring TT and Td vaccines for the last 2 decades for supplementary and routine immunization in 70-100 countries, and although with low forecast accuracy the uptake on the aggregated level throughout the years is relatively reliable.

Over the past decade and until 2016, the demand of TT/Td vaccines fluctuated between 130-150 million doses. In 2017, total demand of TCV through UNICEF reached over 165 million doses and peaked again in 2019 over the 160m. Further in 2020 and 2021 demand decreased significantly to only 114M and 108M doses respectively, due to the impact of COVID

¹⁷ Linksbridge

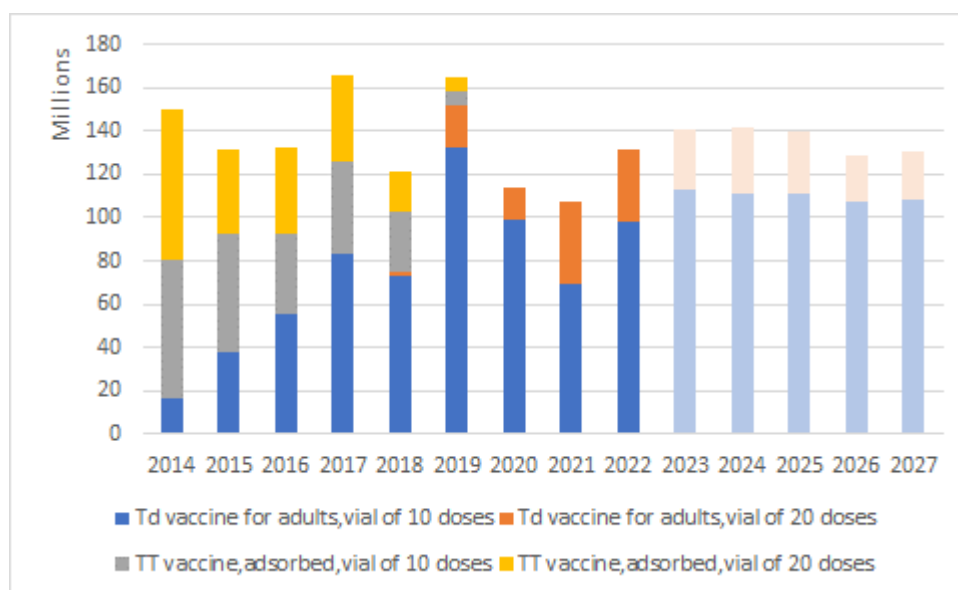
¹⁸ WHO, [Global Vaccine Market Report 2022-template- final \(who.int\)](#)

in the routine immunization services but mainly in the campaigns, which had to be cancelled or delayed. In 2022 the demand recovered slightly reaching almost 132M doses.

In 2023, some countries in West Africa have reported Diphtheria outbreaks and therefore experienced additional demand for Td containing vaccines. As a result, it is expected that the annual demand of Td vaccine through UNICEF will increase up to 141M doses by the end of 2023. While there is enough production capacity in the market to respond to this increase in demand, the lead times for suppliers to increase production (approximately 3-4 months) can be a challenge for rapid interventions.

UNICEF expects the annual demand for Td vaccine through its procurement channels to stabilize between 130-140M doses in the period of 2023-2027. However, this has to be understood in the context of previous low forecast accuracy, together with the uncertainties regarding the requirements to respond to outbreaks and to support the DTWP booster program.

Figure 4 Historical Procurement and Forecast of Td Vaccine through UNICEF



Based on the requirements from countries, UNICEF supplies Td in 10 and 20 dose presentations. During 2020-2022, 75 per cent of the supply of Td vaccine through UNICEF has been on the 10-dose presentation, and the remaining 25 per cent on the 20-dose presentation. The 20-dose presentation is frequently used for campaigns, and it is manufactured only for national programs supported by UNICEF, hence the importance of especially accurate forecasts for this presentation.

The demand is mainly driven by routine immunization needs, with supplementary immunization activities (SIAs) constituting historically 10-20 per cent of the total demand. 75-80 per cent of the overall UNICEF procurement is self-financed by the countries and the remaining 20-25 per cent is financed by UNICEF through program requests, which are mainly to support MNTE campaigns.

In 2022 UNICEF carried out a new tender to establish long-term arrangements (LTAs) for the supply of Td vaccines in 10 and 20 dose presentations for supply during the period 2023-2027. As a result, UNICEF awarded LTAs to four WHO prequalified manufacturers for total annual awards of 135-140M doses (2023-2025) and total awards for 50 per cent of the forecasted demand in 2026-2027. Despite the diversification of awards, there is a high dependency on the Indian market and Indian NRA, as the two suppliers with largest capacity and awards (80 per cent of the total awards for 2023-2025) are Indian manufacturers.

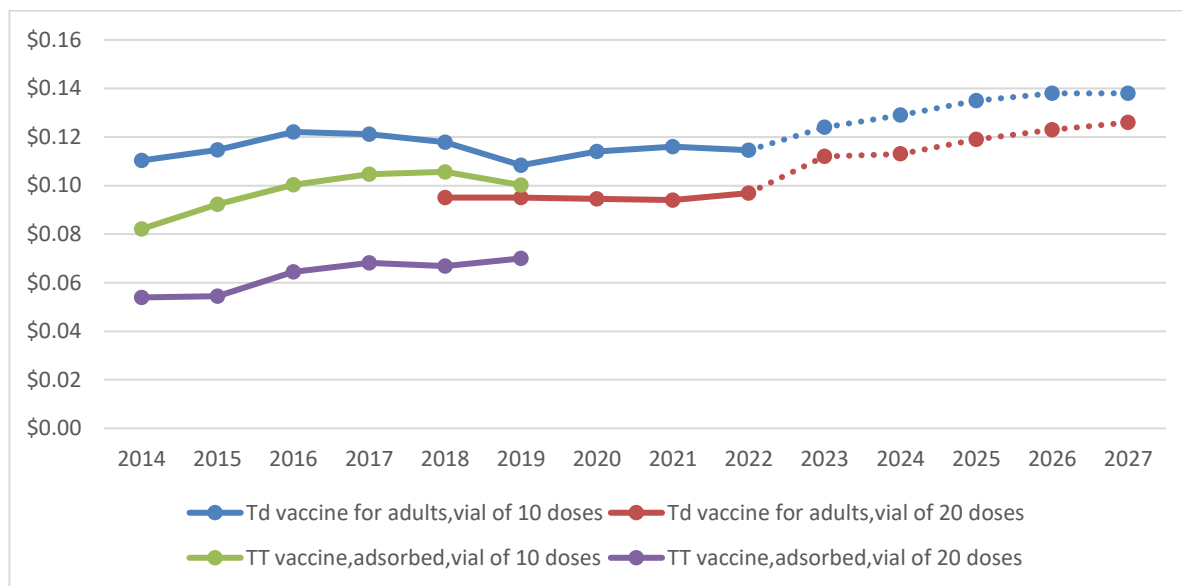
4.2 Historical pricing through UNICEF and future considerations

The weighted average price (WAP) for Td vaccines has been very competitive over the years, maintaining a relatively stable price between \$0.11-\$0.12/dose for the 10-dose presentation and between \$0.09-\$0.10/dose for the 20-dose

presentation. The 2020 WAP for Td vaccine in 10 dose presentation was only \$0.04 higher than the WAP for TT vaccine in 2019, allowing countries to switch from one vaccine to the other without major financial implications.

Considering the price points of awards recently made by UNICEF, the projected WAP for the period 2023-2027 anticipates a smooth increment which can be attributed to inflation and rising production costs.

Figure 5 Historical Weighted Average Price and Forecast through UNICEF 2014- 2027



5 Sustainable Procurement

Sustainable procurement is an approach to procurement that incorporates the three sustainability pillars of social, economic, and environmental impact considerations. It goes beyond the more familiar “green” public procurement, to ensure that all products and services procured support local economic and social development, with the least environmental impact, and the best value for money.

UNICEF originally launched its Procedure on Sustainable Procurement in 2018, and more recently in 2023, has issued a revised version making the implementation of sustainable procurement mandatory across the organization. UNICEF’s vision is that:

- By 2025, UNICEF is a major contributor to and practitioner of UN sustainable procurement, and that sustainable procurement is a fundamental approach to UNICEF’s supply and logistics operations.
- By 2030, UNICEF’s supply function demonstrates measurable contributions to the [Strategy for Sustainability Management in the United Nations System 2020-2030](#) (Phase I and II) and in achieving the SDGs through sustainable procurement.

UNICEF’s Guidance Note on sustainable procurement was launched in 2021, and an updated version will be issued in 2024.

As of May 2023, UNICEF has included environmental and social sustainability aspects in all tenders for vaccine procurement. Further updates should be expected in the future, including performance monitoring of manufacturers in sustainability criteria.

6 Issues and challenges

- **Accuracy of the forecast:** The lack of visibility on funds availability and the uncertainty on plans for supplementary activities in remaining MNTE countries has created in the past difficulties for countries to provide an accurate forecast.
- **Regulatory requirements in receiving countries:** The regulatory environment could be a potential barrier to delivery in some countries – either due to non-availability of licensed product or lack of licensed product.
- **Individual Supplier's risk:** One of the major players in Td market is a state-owned supplier which has in the past prioritized supplying to the national market over other markets.
- **High dependency on Indian NRA:** A large portion of the global market availability and 80 per cent of UNICEF's awards for supply of Td vaccine (2023-2027) are dependent on the Indian market and Indian NRA releases.
- **Outbreaks:** There is enough production capacity in the market to respond to increase in demand. However, the lead times for suppliers to increase production can be several months which, together with funding availability, can be a challenge for rapid outbreak response.

7 Steps forward

- UNICEF continues to monitor changes in countries demand forecasts and choice of procurement channel to adjust supply allocations with manufacturers where possible.
- It is important for countries to keep UNICEF informed on plans for campaigns, especially if Td20 is product of choice, as manufacturers produce this product upon UNICEF confirmation of requirements and timing.
- UNICEF encourages countries to continue to improve their country planning and prioritize vaccine budgeting and financing to ensure accurate forecasting and timely access to vaccines.
- UNICEF advises countries to communicate any plans to change vaccine registration requirements, or switch vaccine presentations in a timely and explicit manner. Countries requiring vaccine registration are encouraged to consider applying expedited registration procedures for vaccines that are WHO prequalified.
- In Q2,2025 UNICEF will re-assess the demand for 2026-2027 and additional volumes may be awarded in line with the updated forecast.
- UNICEF will continue working with partners to address the supply challenges in response to the diphtheria outbreak in West Africa.
- UNICEF is working with Gavi, governments, and donor partners to leverage various mechanisms that will bolster regional manufacturing and will continue to engage with regional manufacturers to provide global market intelligence and information on procurement processes.

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Other UNICEF information notes can be found at: <https://www.unicef.org/supply/market-notes-and-updates>

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. Ensuring a sustainable planet for children continues to be a priority for UNICEF, including through its operations and supply management. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, environmental sustainability, and product quality that is 'fit for purpose' and in the right form for children.