

Diphtheria Tetanus and Pertussis Vaccine Supply Update

UNICEF Supply Division

October 2016

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This update provides information on diphtheria, tetanus, and whole cell pertussis (DTwP) vaccines and UNICEF's long-term arrangement issuance to two manufacturers with significant production capacity. Lead times for delivery through UNICEF have now reduced to eight weeks. DTP vaccine containing acellular pertussis (DTaP) availability through UNICEF remains limited and currently unavailable through 2018.

1. Summary

- The DTwP vaccine market remains fragile, characterized by low-demand volumes. While multiple DTwP vaccine manufacturers of WHO prequalified DTwP exist, only two currently offer prequalified DTwP vaccine through UNICEF.
- DTwP vaccine lead-time for delivery from manufacturers through UNICEF has reduced from six months to eight weeks from purchase order placement, as a result of additional supply availability, and procurement no longer being dependent on a single manufacturer.
- However, globally, standalone DTwP vaccine availability has decreased as manufacturers allocate existing DTwP bulk to produce DTwP-containing combination vaccines, particularly pentavalent DTwP-containing combination vaccines with antigens against Hepatitis B and *Haemophilus Influenzae* type b.
- UNICEF DTwP vaccine procurement since 2012 declined from approximately 20 million doses to reach an average 5 million doses per year, mainly as countries switched to other DTwP combination vaccines.
- Countries continue to seek to secure access to DTaP combination vaccines through UNICEF. However, global supply availability remains very limited and currently unavailable through UNICEF. UNICEF anticipates earliest availability end 2018-2019.

2. Background & Procurement History

DTP vaccines have been part of the Expanded Programme of Immunization (EPI) vaccination schedule since 1974.¹ Historically, several manufacturers with sufficient supply met global DTP vaccine demand. UNICEF primarily procures DTwP-containing vaccines, and has previously exceptionally procured small quantities of DTaP vaccine upon the specific request from one country. Manufacturers use both DTwP and DTaP bulk to produce different DTP-containing combination vaccines (Table 1).

WHO recommends DTP vaccination with a three-dose schedule. Whereas both DTwP and DTaP vaccines have excellent safety profiles and equivalent effectiveness in preventing disease in the first year of life, aP vaccine conferred immunity wanes more rapidly compared to wP. WHO recommends countries currently administering wP-containing vaccines to continue with the same, and recommends countries to include a fourth DTP booster dose for children between one-six years of age in accordance with programmatic considerations and local epidemiology.²

¹ World Health Organization, [Global Routine Vaccination Coverage](#), WHO, Geneva, November 2011.

² World Health Organization, [Pertussis Vaccines: WHO Position Paper](#), WHO, Geneva, August 2015, p. 455-6.

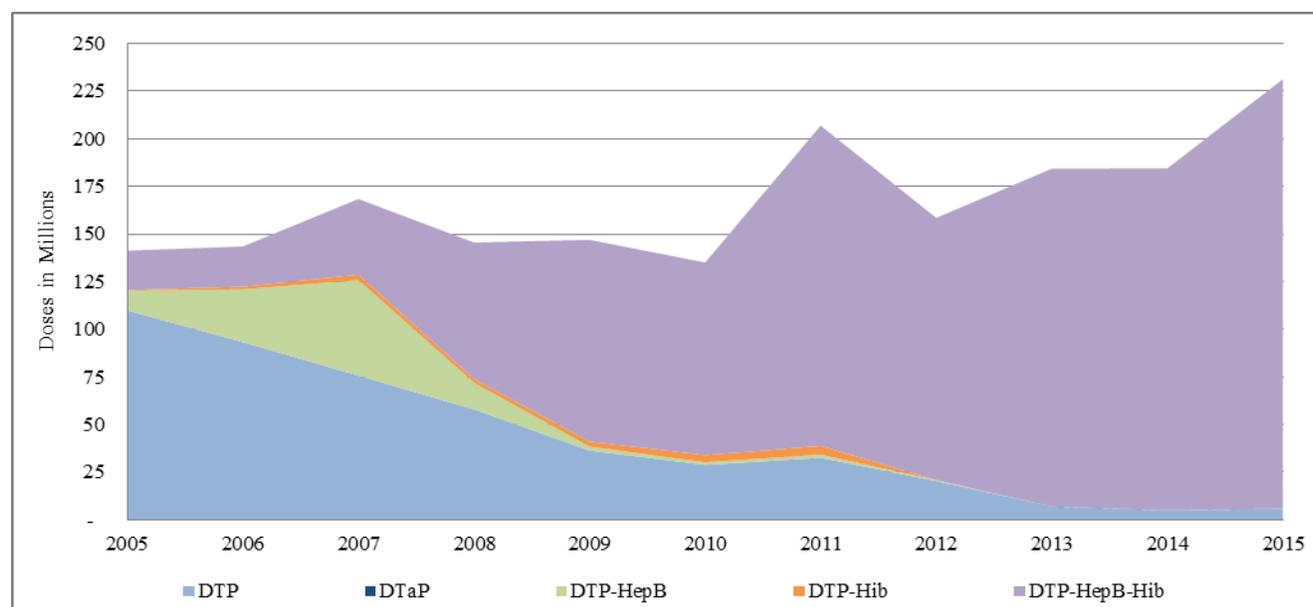
Table 1 Description of Different DTP-Containing Vaccines

DTP-Containing Vaccines	Description
DTwP	A whole cell pertussis vaccine.
DTwP-HepB	A tetravalent combination including hepatitis b antigens.
DTwP-Hib	A tetravalent combination including haemophilus influenzae b antigens.
DTwP-HepB-Hib	A pentavalent combination form.
DTaP	An acellular pertussis vaccine.
DTaP-Hib-IPV	A pentavalent combination including inactivated polio antigen.
DTaP-IPV	A tetravalent combination form.
DTaP-Hib-HepB-IPV	A hexavalent combination form.

Source: World Health Organization.

Until 2005, DTwP vaccine demand through UNICEF averaged approximately 110 million doses per year fluctuating between 81-136 million doses. Since 2005, DTwP vaccine demand through UNICEF as a standalone vaccine declined substantially to reach the current demand of approximately 5 million doses per year. The growing demand for tetravalent, and subsequently pentavalent combination vaccines, principally contributed to this shift. Gavi, the Vaccine Alliance (Gavi), helped facilitate increased demand for combination products by funding certain DTwP-containing combination vaccines. The forecast demand through UNICEF for standalone DTwP vaccines during 2015 represents approximately 4% of total DTwP-containing vaccine orders.

Figure 1 DTP-Containing Vaccine Procurement through UNICEF 2005-2015



Source: UNICEF Supply Division.

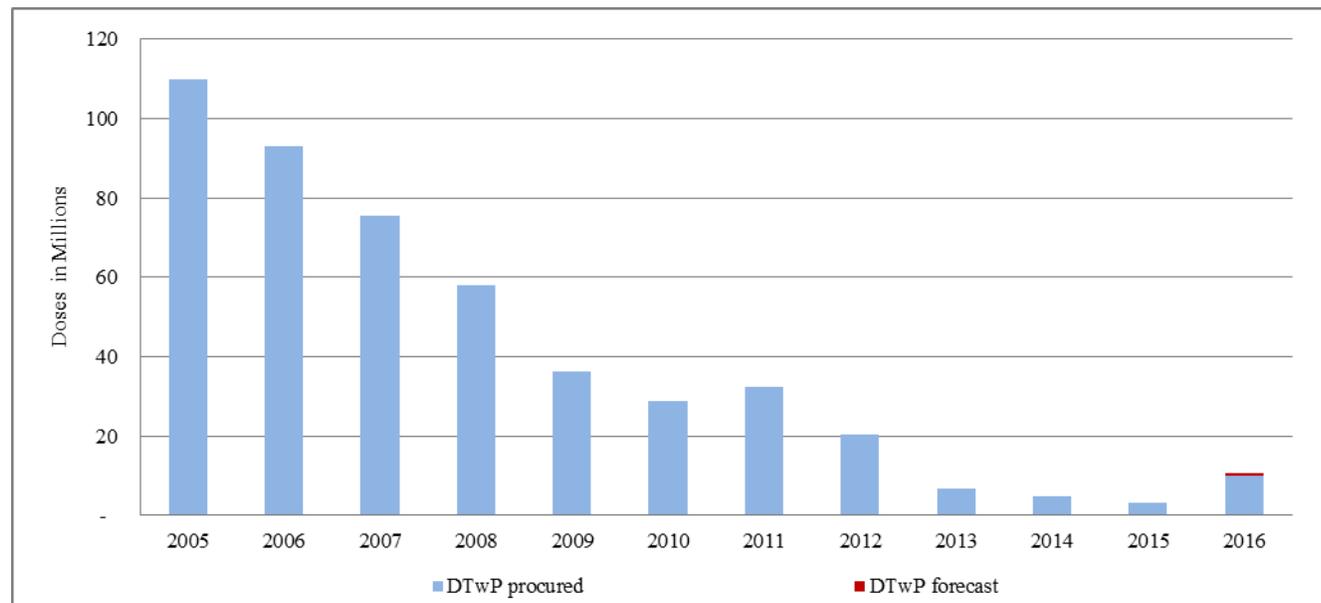
3. Current Market Situation

3.1 DTwP Vaccine Demand

To date (October 2016), procurement through UNICEF has reached 9.9 million doses for 24 countries, and UNICEF anticipates demand reaching 10.5 million doses during 2016. The considerable increase in volume is due to increased supply availability from an additional manufacturer offering DTP vaccine through UNICEF, as well as to a slight increase in country demand. Current demand only covers the routine requirements of the 24 countries that implement a DTwP one-dose booster vaccine schedule in

their national routine immunization (RI) programmes (Figure 2). Five countries (Egypt, Morocco, Ukraine, Uzbekistan, and Zimbabwe) account for more than 80% of UNICEF’s total procurement.

Figure 2 DTwP Vaccine Procurement through UNICEF 2005-2016 (October)

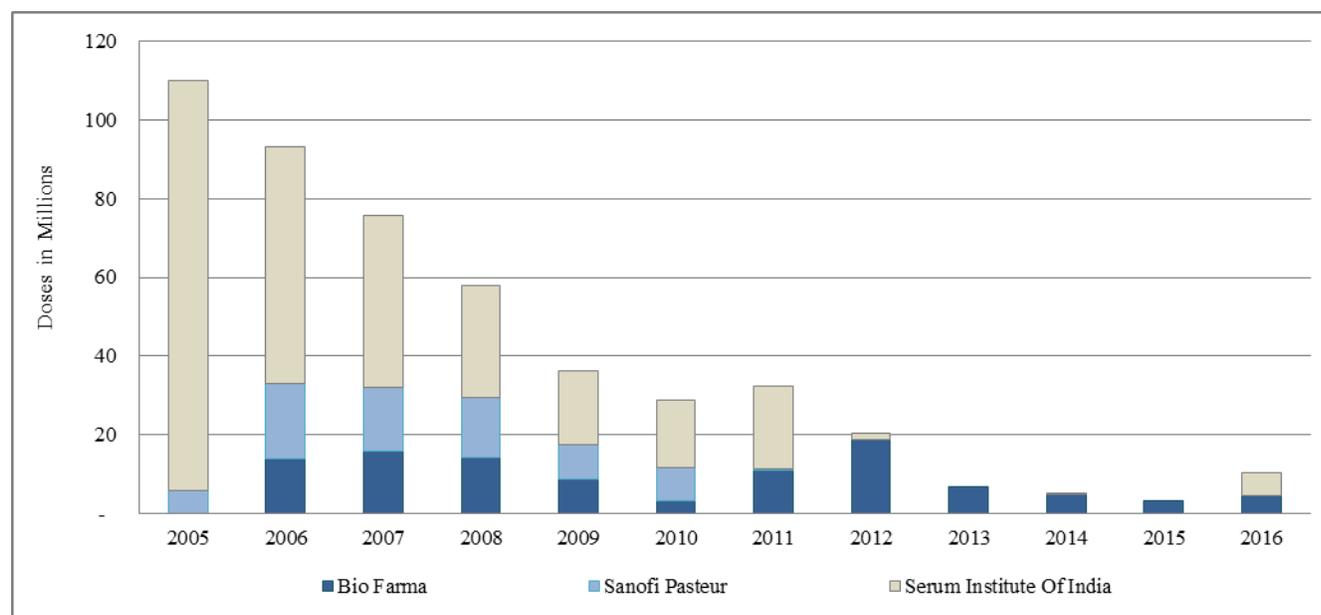


Source: UNICEF Supply Division.

3.2 DTwP Vaccine Manufacturer Base

Manufacturers use DTwP bulk to produce other DTwP-containing combination vaccines (i.e. pentavalent), thus while there are currently four WHO prequalified DTwP vaccine manufacturers, only two offer standalone DTwP vaccine through UNICEF during 2016 (Figure 3).

Figure 3 Manufacturers Supplying DTwP Vaccine through UNICEF 2005-2015 (November)

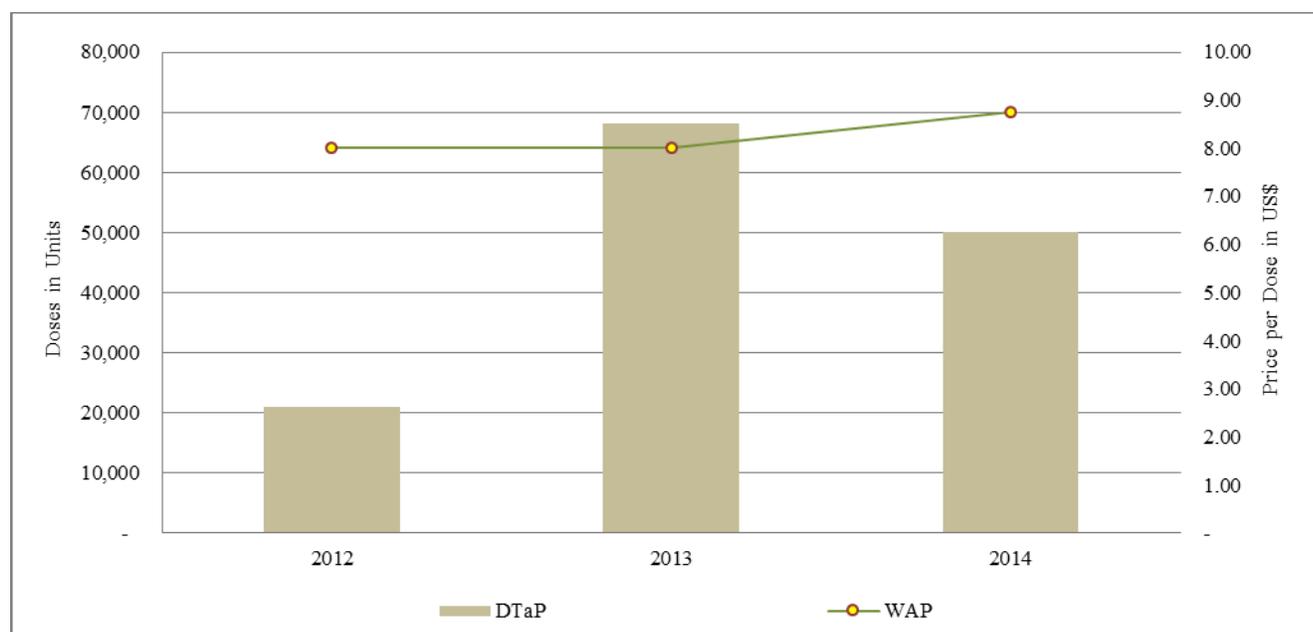


Source: UNICEF Supply Division.

DTP Supply availability increased as it is no longer being dependent on a single source. The additional supply offered from a second manufacturer enabled UNICEF to reduce the lead-times for delivery from six months to eight weeks, as procurement is no longer queued and dependent on a single manufacturer’s production capacity. The lead-times for delivery include vaccine production, quality assurance, regulatory approval, batch release, and shipment. Countries seeking to procure DTwP vaccine through UNICEF need to transfer funds taking into consideration the required lead-time for delivery.

3.3 DTaP-Combination Vaccine

Figure 4 DTaP Vaccine Procurement through UNICEF 2012-2014



Source: UNICEF Supply Division.

Since 2012, UNICEF has procured small quantities of DTaP vaccine for one country (Armenia) during 2012-2014 (Figure 4), sourcing supply from a single manufacturer. UNICEF has not procured any DTaP during 2015-2016. However, since 2014, a number of countries, notably MICs that traditionally self-procure this vaccine, have shown interest in procuring aP-containing combination vaccines for their immunization programmes through UNICEF, due to noted difficulties in securing sufficient DTaP-containing combination vaccine supply through their own regular procurement channels.

Based on this increased country interest for DTaP-containing vaccines through UNICEF, and the global challenges faced by these countries to secure the vaccines directly, UNICEF issued a request for proposal (RFP) to industry in 2016. UNICEF sought access to DTaP-containing vaccines as well as information on both existing and future manufacturers. UNICEF did not receive any offers for supply. DTaP-containing vaccine manufacturers advised UNICEF that there would not be regular availability through UNICEF until 2018. Manufacturers advised DTaP vaccine demand now outstrips supply capacity, and access through UNICEF would only be possible when DTaP vaccine production capacity has increased. The RFP highlighted that:

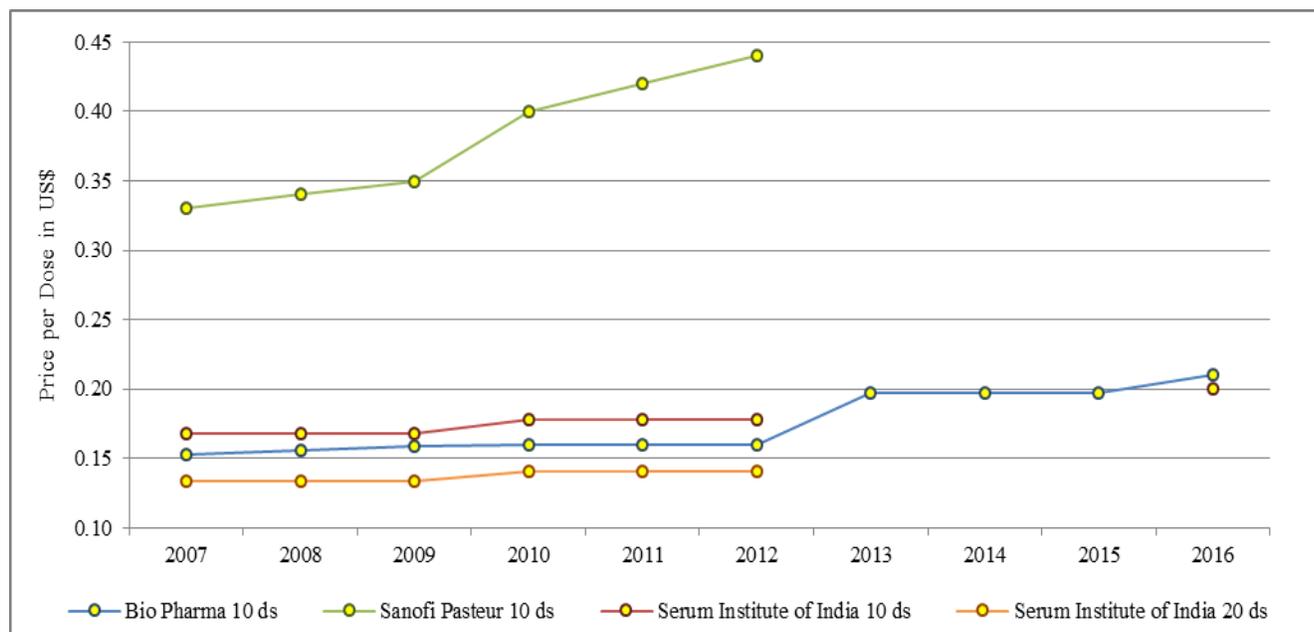
- Some manufacturers plan to start or scale-up DTaP-containing combination vaccines production.
- Supply would not be available through UNICEF in 2016-2017.

- Some manufacturers may offer UNICEF limited quantities in 2016 through 2018, if they have stocks available after having served their direct markets.

3.4 Pricing

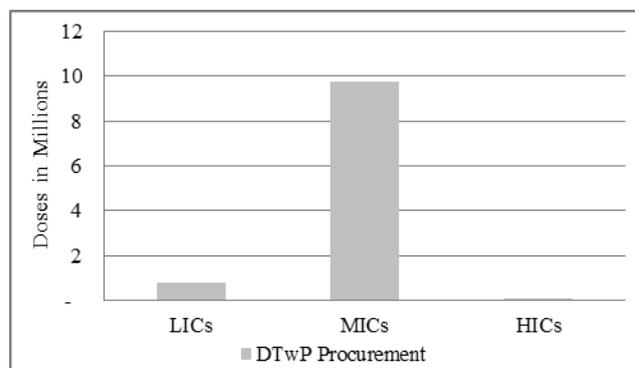
Despite the global decline in DTwP vaccine demand compared to 2005, and relatively limited DTwP vaccine availability, DTwP vaccine’s weighted average price (WAP) per dose was stable from 2013 through 2016 (October) at US\$ 0.205 (Figure 4).

Figure 4 DTwP Vaccine WAP per Dose through UNICEF



Source: UNICEF Supply Division.

Figure 5 Low-Income, MICs and High-Income Country DTwP Vaccine Procurement through UNICEF 2016



Ninety-three per cent of UNICEF’s 2016 DTwP vaccine procurement was on behalf of MICs (Figure 5). One high-income country also procured through UNICEF (Seychelles). Manufacturers do not make any price distinction between low-income countries (LICs) or MICs. Manufacturers offer LICs the same pricing as MICs, irrespective of their per capita income levels, and whether or not they access donor support (e.g. from Gavi) for other vaccine programmes.

Source: UNICEF Supply Division.

Countries procure DTP as a booster dose in accordance with WHO recommendations requiring three DTP doses to prime, and one dose at four-six years as a booster. Whereas MICs are able to implement this recommendation, LICs mostly focus on ensuring children receive their three doses of DTP-containing vaccine with Pentavalent (DTP-HepB-Hib, Figure 1). Very few LICs seek to access a fourth booster dose using DTP.

4. Issues / Challenges

- Some manufacturers continue to prioritise the use of their DTwP bulk to produce other DTwP-containing combination vaccines, resulting in limited availability for use in DTwP standalone vaccine production.
- While availability of DTwP vaccine through UNICEF has improved considerably compared to 2014-2015, countries seeking to procure DTwP vaccine through UNICEF are encouraged to continue to plan the delivery of their requirements taking into consideration the manufacturers lead-times for delivery of about eight weeks.
- UNICEF has registered increasing requests for, and country interest in, DTaP-containing vaccine procurement. However, DTaP vaccine manufacturers do not currently offer availability through UNICEF in the short-term.

5. Steps Forward

- UNICEF will continue to engage partners and closely monitor programme direction, and the implications of implementing the WHO booster dose recommendation, which could affect standalone DTwP vaccine demand, and signal industry to increase availability accordingly.
- UNICEF Country Offices and countries need to include an eight-week lead-time for delivery in their planning and ensure funds are available in a timely manner to secure DTwP standalone vaccines.
- UNICEF may issue a tender in late 2017 for DTaP-containing vaccines to see if UNICEF can establish supply arrangements to meet the needs of the requesting countries.

For further questions or additional information, please contact:

Heather Deehan
Chief, Vaccine Centre
UNICEF Supply Division
+45 45 33 58 90
hdeehan@unicef.org

Dorcas Noertoft
Contracts Specialist
UNICEF Supply Division
+45 45 33 57 76
dnoertoft@unicef.org

Aadrian Sullivan
Information Management
UNICEF Supply Division
+45 45 33 57 68
asullivan@unicef.org

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