Diphtheria Tetanus and Pertussis Vaccine Supply Update

UNICEF Supply Division

November 2015
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This update provides information on diphtheria, tetanus and whole cell pertussis (DTwP) vaccines. Countries seeking to procure DTwP vaccines through UNICEF should expect up to a six-month lead-time for delivery on account of low global demand and single-sourced supply. The update includes acellular (DTaP) information, and highlights some countries’ difficulties in DTaP procurement.

1. Summary

- The DTwP vaccine market remains fragile, characterized by low-demand volumes and a limited supply base. From 2012 through 2015 (November), UNICEF has relied on one manufacturer with World Health Organization (WHO) prequalified DTwP vaccine. DTwP vaccine lead-time for delivery from UNICEF’s sole manufacturer can be up to six months from purchase order placement.
- 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 during 2013-2014, mainly as countries switched to other DTwP combination vaccines. UNICEF anticipates country supply to reach approximately 5.8 million doses for 18 countries during 2015.
- DTaP vaccine procurement through UNICEF has been negligible. However, as global supply availability is increasingly limited, some countries, notably middle-income countries (MICs) that traditionally self-procure DTaP vaccine, have sought procurement assistance through UNICEF, as they can no longer secure DTaP vaccine supply through their regular channels. UNICEF may seek to establish aP-containing vaccine long-term arrangements (LTAs) in 2016 to facilitate country access to these vaccines.

2. Background & Procurement History

DTP vaccines have been part of the Expanded Programme of Immunization (EPI) vaccination schedule since 1974. 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. WHO also 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.

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Table 1 Description of Different DTP-Containing Vaccines

<table>
<thead>
<tr>
<th>DTP-Containing Vaccines</th>
<th>Description</th>
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<tbody>
<tr>
<td>DTwP</td>
<td>A whole cell pertussis vaccine.</td>
</tr>
<tr>
<td>DTwP-HepB</td>
<td>A tetravalent combination including hepatitis b antigens.</td>
</tr>
<tr>
<td>DTwP-Hib</td>
<td>A tetravalent combination including haemophilus influenzae b antigens.</td>
</tr>
<tr>
<td>DTwP-HepB-Hib</td>
<td>A pentavalent combination form.</td>
</tr>
<tr>
<td>DTaP</td>
<td>An acellular pertussis vaccine.</td>
</tr>
<tr>
<td>DTaP-Hib-IPV</td>
<td>A pentavalent combination including inactivated polio antigen.</td>
</tr>
<tr>
<td>DTaP-IPV</td>
<td>A tetravalent combination form.</td>
</tr>
<tr>
<td>DTaP-Hib-HepB-IPV</td>
<td>A hexavalent combination form.</td>
</tr>
</tbody>
</table>

Source: WHO.

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 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 (November 2015), procurement through UNICEF has reached 5.8 million doses for 18 countries and territories, four of which (Egypt, Morocco, Uzbekistan and Zimbabwe) account for more than 80% of UNICEF’s total procurement. However, future DTwP vaccine demand remains uncertain. Current demand only covers the routine requirements of the 18 countries that implement a DTwP one-dose
booster vaccine schedule in their national routine immunization (RI) programmes (Figure 2). The reduced access to standalone DTwP vaccine risks these countries’ ability to secure sufficient supply to implement WHO’s recommended booster dose.

Figure 2 DTwP Vaccine Procurement through UNICEF 2005-2015 (November)

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 one offered standalone DTwP vaccine through UNICEF during 2013-2015 (Figure 3).

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

Source: UNICEF Supply Division.
The manufacturer requires a confirmed purchase order to allocate the necessary DTwP bulk to produce the requisite DTwP standalone vaccine and a six-month lead-time for delivery from purchase order placement. The lead-time for delivery includes 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 2012-2015

Since 2012, UNICEF has procured small quantities of DTaP vaccine for one country (Armenia) (Figure 4), sourcing supply from a single manufacturer. However, since 2014, a number of countries, notably MICs that traditionally self-procure, 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.

Source: UNICEF Supply Division.

Based on increased country interest for DTaP-containing vaccine procurement through UNICEF, and the global challenges faced by these countries to secure the vaccines directly, UNICEF issued a request for Expression of Interest (EoI) to industry in 2014. UNICEF sought DTaP and IPV-containing vaccine availability information from both existing and future manufacturers.

DTaP-containing vaccine manufacturers advised UNICEF through the EoI 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 EoI highlighted that:

- Some manufacturers plan to start or scale-up DTaP-containing combination vaccines production.
- Supply would not be available through UNICEF in 2015.
- Some manufacturers may offer UNICEF limited quantities in 2016 through 2018, if they have stocks available after having served their direct markets.

UNICEF may issue a tender for DTaP-containing vaccines in 2016 to establish supply arrangements to meet the needs of requesting countries.

3.4 Pricing

Despite the decline in DTwP vaccine demand, limited DTwP vaccine availability, and a restricted supply base through UNICEF, DTwP vaccine’s weighted average price (WAP) per dose was stable from 2013 through 2015 (November) at US$ 0.20 per dose (Figure 5). UNICEF’s continuous engagement with the sole manufacturer of awarded DTwP vaccine to share demand visibility, as well as UNICEF’s continuous follow-up with countries to improve demand certainty, has contributed to ensure access to this vaccine at stable prices.
By contrast, the DTaP vaccine WAP per dose was US$ 8.00 from 2012 and 2013, and increased by approximately 10% to reach US$ 8.75 in 2014 on account of the cost of maintaining a limited low production volume (Figure 4). As UNICEF has only procured DTaP vaccines for one country, UNICEF cannot state much in the way of pricing strategies for the vaccine with respect to country per capita income levels.

Figure 6 Low-Income and Middle-Income Country DTwP Vaccine Procurement through UNICEF 2015

Eighty-eight per cent of UNICEF’s 2015 DTwP vaccine procurement was on behalf of MICs (Figure 6). 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.

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.
- DTwP vaccine supply through UNICEF is limited and relies on a sole manufacturer offering WHO prequalified DTwP vaccine. Countries seeking to procure DTwP vaccine through UNICEF will need to confirm their demand and accept lead-time of several months for delivery.
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 monitor DTP vaccine supply markets to assess supply availability that could result in alternative sources of relevant products, or new incoming procurement inquiries to UNICEF respectively. UNICEF will communicate any substantive changes to partners, stakeholders and industry accordingly.
- UNICEF will continue to engage partners and closely monitor programme direction, and the implications of implementing WHO’s booster dose recommendation, which could impact standalone DTwP vaccine demand, and signal industry to increase availability accordingly.
- UNICEF Country Offices and countries need to include a six-month 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 2016 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  Dorcas Noertoft  Aadrian Sullivan  
Chief, Vaccine Centre  Contracts Specialist  Information Management  
UNICEF Supply Division  UNICEF Supply Division  UNICEF Supply Division  
+45 45 33 58 90  +45 45 33 57 76  +45 45 33 57 68  
hdeehan@unicef.org  dnoertoft@unicef.org  asullivan@unicef.org

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