Current DTP Supply & Outlook

UNICEF Supply Division

January 2013
DTP Vaccine Supply Update – January 2013

A more recent note covering DTP exists. Please visit http://www.unicef.org/supply/index_54214.html

1. Summary

- UNICEF’s access to DTP continues to decrease, with current reliance down to one remaining supplier with WHO pre-qualified vaccine in 2013. This increases the risk and fragility of the market, and has reduced the market’s ability to accommodate any incremental procurement requests through UNICEF.
- The dedication of existing bulk supplies of WHO-prequalified DTP to the manufacture and development of other DTP-containing vaccines, in addition to the removal of some supplies from the market, has reduced the availability of standalone DTP products.
- The 2013-2015 tender closed in mid-2012 with a forecasted vaccine requirement of 12 million doses for 2013, which has decreased from 32 million doses procured in 2012.
- Recent demand for an additional 5 million doses of DTP through UNICEF, contrary to trend, is challenging the market’s ability to supply on an ad hoc basis, and may result in near-term product shortage.

2. Background & Procurement History

DTP has been part of the Expanded Programme of Immunisation (EPI) vaccination schedule since 1974,¹ and historically has had a solid supply base. For the purpose of this document, DTP refers to whole cell pertussis (DTwP). UNICEF primarily procures DTwP containing vaccines and only exceptionally has procured DTaP vaccine upon specific request from countries. DTwP bulk is incorporated into 4 different forms and combinations:

- DTwP (a whole cell vaccine);
- DTwP-HepB (a tetravalent combination including hepatitis antigens);
- DTwP-Hib (a tetravalent combination including *haemophilus influenzae* antigens);
- DTwP-HepB-Hib (a pentavalent combination form)

Until 2005, the demand for DTP through UNICEF averaged approximately 110 million doses per year, fluctuating between 136 and 81 million doses. Since 2005, however, the demand through UNICEF for DTP as a standalone vaccine has declined substantially. The growing demand for tetravalent and subsequently pentavalent combination vaccines has principally contributed to this shift. The increased combination product demand has largely been led by GAVI funding of other DTP-containing vaccines.

The 2012 demand through UNICEF for standalone DTP represented 17% of DTP-containing vaccine orders and its share is expected to decrease further. Many suppliers have as a consequence allocated their existing DTP bulk supplies to the development and manufacture of other DTP-containing vaccines.

The declining demand for DTP supplied through UNICEF makes it difficult to accurately identify the threshold of lower baseline, “steady-state” requirements. By 2014, UNICEF expects that the baseline level demand for DTP procurement through UNICEF will have decreased and stabilised to approximately 6 million doses per year. UNICEF anticipates that this amount will cover the routine requirements of the 18 countries that implement one dose of DTP as a booster vaccine in their routine national immunisation programmes.

Within this context, the reduction in availability of DTP also has global implications. It is now more difficult for UNICEF to accommodate requests on behalf of countries that normally self-procure. Two Middle Income Countries have sought supply of UNICEF-procured DTP by up to an additional 5 million doses. This has tentatively increased UNICEF’s total requirement in 2013 for DTP from 12 million doses to 17 million doses.

UNICEF anticipates a significant challenge to the market’s near-term ability to meet these needs as a result of any potential incremental demand for WHO-prequalified DTP, and which may also lead to a near-term supply shortage. As of 2013, UNICEF’s DTP manufacturer base has decreased to one remaining supplier (from two suppliers in 2012 and three in 2010), and through which un-forecasted orders require significant lead time.


3.2 Supplier Base

During the past 6 years, there have only been 3 suppliers with WHO-prequalified DTP (Bio Farma, Indonesia; Sanofi Pasteur, France; and Serum Institute of India, India), but only one supplier now maintains availability (Bio Farma) through UNICEF.

There are no new suppliers of WHO-prequalified DTP expected in the near future.

Of the three suppliers with WHO pre-qualified DTP, Bio Farma is able to increase their supply of DTP if orders are placed in advance with a lead time of 4 months. Serum Institute of India retains a sizeable capacity to produce DTP.
3.3 Issues / Challenges to Address

• In mid-2012, UNICEF concluded its tender for 2013-2015 DTP for a projected requirement of 24 million doses. The spread of the requirement over the three years is 12 million doses for 2013 and 6 million doses forecast for each subsequent year 2014 and 2015. The contract for the procurement of the full 24 million doses of DTP has also been completed.
• For 2013, in addition to the forecasted requirements of 12 million doses, UNICEF has been requested to supply an additional 5 million doses reflecting a global shortage and as a consequence of recent developments in some countries.
• Some suppliers are prioritising the use of their DTP bulk in other DTP-containing (combination) vaccines, while others have withdrawn supplies from the market. This leaves UNICEF reliant on one supplier for WHO-prequalified DTP, which limits flexibility for any reactive response and increases the risk of a possible product shortage.

4. Steps Forward

To identify additional supply to cover up to the additional 5 million dose requirement, the following items are being closely followed:

• WHO has recently published its vaccine prequalification priority list for 2013-2014 and identifies DTwP as a “High Priority” vaccine, reflecting, in part, its declining supply security.2 For 2011-2012, DTwP had been ranked as “Low Priority”.
• If additional suppliers do indeed become WHO-prequalified for DTP, UNICEF will continue to track whether DTP bulk is directed towards standalone or combination product. (Note: The process to prequalify vaccines can take up to 18 months to complete).
• As UNICEF gains additional visibility regarding any potential new market entrants, it will consult with partners to assess the programmatic and epidemiological impact of accelerating the

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availability of standalone DTP supplies in the latter years of the currently contracted supply (if possible).

- UNICEF will continue to monitor ex-UNICEF supply markets to assess any incremental supply availability or shortages which could result in alternative sources of product or new incoming procurement inquiries to UNICEF, respectively. Any substantive changes will continue to be communicated to partners, stakeholders and industry.

- UNICEF will explore with partners and suppliers the potential attractiveness of any supply arrangements which will give suppliers the confidence of the continued importance of the DTP-market.

- Offices and countries should continue to monitor stock levels and wastage and should give early indication if support is needed.

For further questions or additional information, please contact:

Meredith Shirey
Chief, Vaccine Centre
UNICEF Supply Division
+45 3527 3033
mshirey@unicef.org

Hans Christiansen
Contracts Specialist
UNICEF Supply Division
+45 3527 3084
hchristiansen@unicef.org

Aadrian Sullivan
Information Management
UNICEF Supply Division
+45 3527 3048
asullivan@unicef.org

Information notes can be found: [http://www.unicef.org/supply/index_54214.html](http://www.unicef.org/supply/index_54214.html).