Inactivated Polio Vaccine: Supply Update

UNICEF Supply Division

May 2014
1. UNICEF IPV Tender Overview

A tender was issued on 4 October 2013, to cover anticipated IPV demand for 2014-2018. The tender aimed to achieve the following procurement objectives:

- To secure sufficient supply to meet an accelerated introduction of IPV for OPV-using countries procuring through UNICEF, for the period of 2014-2018,
- To achieve affordable prices from 2014 for all presentations,
- To support the development of a healthy IPV market.

The current note is an update of UNICEF’s previous note from January 2014 on IPV supply and tender status. It includes UNICEF’s tender pricing outcome for GAVI-supported countries and Middle Income Countries (MICs); overall volumes awarded; product presentations and availability; as well as an update on IPV containing combination vaccines and product presentations in development.

2. Awarded Quantities

At the end of February 2014, UNICEF awarded a total of 441 million doses of IPV for 2014-2018 based on offered supply and a review of the projected demand. Awards were made to two manufacturers for one product presentation each. The vast majority of supply was awarded in 10 dose vials for 2014 through 2018, with 1 dose vials awarded in limited quantities for 2014 through 2017. The supply of 10 dose vials may be converted in part or in total to 5 dose vials during the tender period, provided that the product presentation is WHO prequalified and based on country demand. Conditional awards were made to two manufacturers to ensure early access to a 5 dose vial presentation, with supply to be initiated upon WHO prequalification. 1 dose vials could be available in greater quantities and at higher prices if countries require this presentation, but it would reduce 5 dose vial supply availability.

3. Supply and Demand Balance

The awards are based on the draft Strategic Demand Forecast (SDF), developed jointly by GAVI, UNICEF, WHO, and other members of the Immunization Systems Management Group (IMG) at a global level and based on the updated country introduction plans. The demand estimates include GAVI-supported countries including India (but excluding countries in the Pan American Health Organization (PAHO) region), as well as MICs that have indicated possible IPV procurement through UNICEF SD.

From 2016, the awarded supply in 10 dose vials may be delivered in 5 dose vials, should this product presentation be WHO prequalified and preferred by countries.

Overall, awarded supply based on current demand assumptions, including product presentations, is sufficient to meet projected demand. For 2014 in particular, UNICEF awarded approximately 16 million doses above estimated demand in order to ensure supply availability for:
- 2014 country introductions,
- First shipments to countries planning 1Q 2015 introductions,
- Unforecasted requirements such as campaigns in endemic countries.

**Figure 1 Estimated Demand and Awarded Supply as of February 2014**

In order to provide incentives for new manufacturers to accelerate IPV development as well as innovative products and presentations, UNICEF left 40 million doses un-awarded for 2018.

### 4. Pipeline Products Including IPV-Containing Combination Vaccines

Several manufacturers submitted offers for IPV's currently in clinical development, including Sabin IPV, for supply from 2017/2018 upon WHO prequalification. No offers were made to UNICEF for alternative dose-sparing product presentations such as adjuvanted IPV or IPV for intradermal delivery, or IPV-containing combination vaccines.

At a global level, IPV-containing combination vaccines are available with acellular pertussis, but they have not yet been prequalified by WHO. Based on some initial country interest, UNICEF has reached out to the two global manufacturers which indicated that overall, the supply of IPV-containing combination vaccines continues to be very constrained in the short term (1-2 years), though there may be more flexibility to supply in the future. UNICEF will develop a strategy for procurement of IPV-containing combination vaccine should demand materialize. However, currently UNICEF does not have supply arrangements in place for these products.
5. Prices

Prices awarded for GAVI-supported countries range from €0.75 ($1.03)\(^1\) per dose in 10 dose vials to $2.80 in single dose vials. For MICs procuring through UNICEF, awarded prices range from $1.90 per dose in 5 dose vials to €2.40 ($3.28)\(^2\) per dose in 10 dose vials. Prices for 1 and 5 dose vials apply to all countries procuring through UNICEF (Table 1).

Table 1 Awarded Prices by Product Presentation, Manufacturer and Countries as of May 2014

<table>
<thead>
<tr>
<th>Price ranges 2014-2018(^{1})</th>
<th>Sanofi Pasteur</th>
<th>Bilthoven/SII</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GAVI-supported</td>
<td>MICs(^{ii})</td>
</tr>
<tr>
<td>10 dose</td>
<td>€0.75</td>
<td>€1.49 - €2.40</td>
</tr>
<tr>
<td>5 dose(^{iii})</td>
<td></td>
<td>$1.90(^{iv})</td>
</tr>
<tr>
<td>1 dose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{1}\) For prices quoted in Euro, UN exchange rate at time of payment will apply.

\(^{ii}\) MIC country prices for Sanofi Pasteur are tiered.

\(^{iii}\) Bilthoven/SII: 5 dose vials have been awarded on condition of WHO prequalification. For Sanofi, a price will be confirmed upon WHO prequalification.

\(^{iv}\) Based on awards, a price of $1.50 is projected to be accessed in 2018.

Awarded prices and country tiers are available at: [http://www.unicef.org/supply/files/IPV.pdf](http://www.unicef.org/supply/files/IPV.pdf)

6. Availability by Product Presentation

Most of the supply available for 2014 and 2015 will be in 10 dose vials starting from May 2014. A limited supply of 1 dose vials will be available from 2Q 2014, but the supply will be prioritised for countries which have already introduced this vial presentation into their programme and countries with low birth cohorts. Additional supply could be made available from 2016 should countries request this presentation. UNICEF expects a limited supply of 5 dose vials to be available from 4Q 2014, pending national licensure and WHO prequalification with increasing supply from 2015 onwards. Starting in 2016, UNICEF expects there will be sufficient 5 dose vial supply should all countries request this product presentation.

7. Lead Times for Country Planning and Accessing Supply

Depending upon preferred product presentation and manufacturer lead times, countries should plan for a 3-9 months lead time for supply of vaccine and include 3-4 months lead time for injection devices. Depending upon the product presentation, lead times vary from 6 weeks to 9 months, from receipt of funds within UNICEF. It should be noted that the lead time for a 10 dose presentation is 9 months for unforecasted demand.

UNICEF is working with GAVI and manufacturers to reduce lead times of the 10 dose vial for GAVI-supported countries.

\(^{1}\) UN exchange rate as of April 2014: €0.73/$1.00.

\(^{2}\) Ibid.
For MICs procuring through UNICEF, the actual timing of supply availability will be confirmed upon receipt of a request for procurement and will depend on preferred product presentations, country size, national licensure requirements, as well as overall supply and demand balance.

8. Country Input Required

Countries should communicate to UNICEF, WHO and GAVI (GAVI-supported countries only):

- Anticipated introduction dates,
- Preferred product presentation,
- Second and third alternative acceptable product presentations, as flexibility may be required to make use of available supply in the early phases of the global scale-up while ensuring early introductions.

Countries are also encouraged to provide updated information on national licensure requirements to UNICEF’s local country office, and to include information on any expedited procedures or waivers allowing manufacturers and partners to take early actions to avoid a delay in vaccine introductions.

9. Demand Forecasts

UNICEF, WHO and GAVI expect demand forecasts to continue to be adjusted based on countries’ decision making and the finalisation and implementation of IPV introduction plans. Procurement forecasts will be provided to manufacturers as per UNICEF’s standard processes on a monthly basis, in addition on a quarterly basis to be published on this website.

For additional information on IPV introduction planning and prices, please refer to the following links:

Planning for IPV introduction – frequently asked questions:  

General information pack and technical briefing materials:  

IPV price and product information:  
http://www.unicef.org/supply/index_57476.html  

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ANNEX A

AWARDED PRODUCT PRESENTATIONS

Table 2 Product Specifications as of February 2014

<table>
<thead>
<tr>
<th></th>
<th>Vial of 10 doses of IPV</th>
<th>Vial of 1 dose of IPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Sanofi Pasteur</td>
<td>Bilthoven Biologicals B.V.</td>
</tr>
<tr>
<td>Country of manufacture</td>
<td>France</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Date of prequalification</td>
<td>09 December, 2005</td>
<td>06 December, 2010</td>
</tr>
<tr>
<td>NRA of record</td>
<td>ANSM</td>
<td>Medical Evaluation Board (MEB)</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>Liquid</td>
<td>Liquid</td>
</tr>
<tr>
<td>Presentation</td>
<td>10 dose vial</td>
<td>1 dose vial</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Intramuscular injection sub-cutaneous.</td>
<td>Intramuscular injection sub-cutaneous.</td>
</tr>
<tr>
<td>Vaccine Vial Monitor</td>
<td>VVM7</td>
<td>VVM7</td>
</tr>
<tr>
<td>Shelf life</td>
<td>36 months at 2-8°C</td>
<td>36 months at 2-8°C</td>
</tr>
<tr>
<td>Secondary packaging</td>
<td>10 vials of 10 doses</td>
<td>Akylux tray of 360 vials</td>
</tr>
<tr>
<td>Cold chain volume per dose (cm³)</td>
<td>2.46</td>
<td>15.7</td>
</tr>
<tr>
<td>Preservative</td>
<td>Phenoxyethanol 5mg/ml</td>
<td>Phenoxyethanol 5mg/ml</td>
</tr>
<tr>
<td>Handling of multi-dose vials</td>
<td>WHO recommends that opened vials of this vaccine should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.</td>
<td>n/a</td>
</tr>
<tr>
<td>Indicative wastage rate</td>
<td>50%</td>
<td>5%</td>
</tr>
</tbody>
</table>

(See [Link](http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/))

With additional product presentations becoming prequalified by WHO (expected by late 3Q 2014) this Annex will be updated.

For further questions or additional information, please contact:

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Other UNICEF information notes can be found at: [Link](http://www.unicef.org/supply/index_54214.html).