Inactivated Polio Vaccine: Supply Update

UNICEF Supply Division

December 2014
The note provides an update on IPV supply for 2014-2015, which is now constrained due to reduced availability from manufacturers and increased visibility on country demand; it includes updates on IPV presentations, prices, prequalification status and the application of the multi-dose vial policy (MDVP) on open vials.

1. Summary

- IPV supply availability for 2014-2015 reduced by 54 million doses from 129 million to 75 million doses. Technical difficulties in scaling-up production and delays in licensing and prequalification account for the decrease.
- Visibility has increased around country demand requirements including preferred product presentations, planned timing of large country introductions and extended use of IPV in Supplementary Immunisation Activities (SIA). Total demand will range between 320-400 million doses, depending upon on the application of Multi-Dose Vial Policy (MDVP) for 2015-2018.
- New data on preservative efficacy allows the MDVP’s application to IPV, thereby permitting 5 and 10 dose vials to be used up to 28 days after opening.
- A constrained supply situation throughout 2015 will generate a supply gap based on planned introductions timelines, but may be mitigated through country or programme-driven delays in introductions in lower risk countries, to ensure introductions in all countries by end of 2015.

2. IPV Supply Availability for 2014 and 2015

IPV supply availability during 2014-2015 has decreased substantially compared to the originally awarded quantities of the two manufacturers through 2018. One manufacturer reduced the quantities available to UNICEF by more than 50%, and now can supply only 40 million doses out of an original award of 90 million doses. The reduced supply availability is due to technical issues affecting the scale-up of bulk production.

The other manufacturer experienced a three-month delay in licensing its 5-dose presentation and acquiring WHO prequalification. The delay reduced availability in 2014 by 4 million doses. However, UNICEF anticipates that total supply availability for 2014-2015 from this manufacturer will still be met.
3. IPV Demand Projections

UNICEF’s IPV supply awards of 441 million doses for 2014-2018 were based on the draft Strategic Demand Forecast, version 9, developed jointly at the global level by Gavi, the Vaccine Alliance (Gavi), UNICEF, WHO, and other members of the Immunization Systems Management Group (IMG) without country input. Based on advice from a Procurement Reference Group, UNICEF made a set of assumptions with regards to preferred product presentations (and consequently wastage rates) and therefore overall requirements at the time of making awards. The forecast includes all Gavi-supported country demand, but excludes countries in the Pan American Health Organization (PAHO) region. In order to ensure sufficient supply capacity, the projected demand for India was included in UNICEF’s supply awards, even though it had assumed India would self-procure and self-fund its purchases. Demand projections also included Middle Income Countries (MICs) that usually procure vaccines through UNICEF, as well as other MICs that had indicated interest in IPV procurement through UNICEF.

As of today, increased visibility surrounding country requirements including confirmation of preferred product presentations has decreased current 2014-2018 demand projection to range between ~320 million to ~400 million doses. A number of factors inform demand projections:

- Very few countries had decided on IPV introduction at the time UNICEF awarded supply. However, a clearer understanding of country introduction plans for IPV is now available, as most Gavi-supported countries have submitted IPV applications. In addition, the IMG has completed the mapping of decision-making processes and planned introduction timelines for countries that are not Gavi-supported.
- Based on applications submitted to Gavi, product preferences and hence wastage rates are available.
India has recently submitted an application to Gavi requesting financial support for vaccine introduction and supply procurement through UNICEF.

Demand increased from previously unforecasted SIA requirements, which were not included in the original awards.

Some countries have delayed IPV introduction on account of programmatic readiness, similar to what was experienced for other new vaccine introductions (i.e., Rotavirus and Pneumococcal Vaccines).

The application of WHO’s multi-dose vial policy (MDVP)\(^1\) will also affect countries’ demand for IPV starting from second half of 2015. New preservative efficacy data from studies conducted by Bilthoven Biologicals and Sanofi Pasteur on the 5-dose and 10-dose vial product presentations show that **both multi-dose vaccine presentations may be used up to 28 days after opening**, provided that the product is appropriately handled and stored. The reduced wastage rates from 50% to 20% for the 10-dose vials and from 30% to 15% for 5-dose vials via applying the MDVP may moderate country vaccine requirements, provided that this policy is implemented in the country either nationwide or for specific immunisation strategies (i.e., fixed sites vs. outreach activities). Updated product presentations incorporating the Vaccine Vial Monitor (VVM) on the vial label will become available from May 2015, and will allow countries to start using vials beyond the end of the session. All vials are currently supplied with the VVM on the cap, which indicates that products shall be discarded at the end of the session or 6 hours, whichever comes first.

A number of uncertainties exist which could affect the future demand for IPV through UNICEF (Table 1).

### Table 1 IPV Introduction Uncertainties and Considerations

<table>
<thead>
<tr>
<th>Uncertainty</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>The MDVP</td>
<td>UNICEF does not know which countries will apply the MDVP, nor whether it applies at the national or sub-national level. UNICEF and WHO are following up with relevant countries to seek clarification.</td>
</tr>
<tr>
<td>Gavi dose calculation</td>
<td>The country dose requirement is calculated based on UN population data and UNICEF/WHO coverage rates. The doses approved by Gavi for some countries are less than in the country applications (by up to 50% for some countries).</td>
</tr>
<tr>
<td>Additional Gavi dose requirement</td>
<td>Gavi has allowed countries to request additional doses if the quantities approved are insufficient to meet the country requirements, the first country to introduce IPV has already requested additional doses.</td>
</tr>
<tr>
<td>MIC Procurement channels</td>
<td>MIC procurement through UNICEF: Some countries have taken steps to secure supply through UNICEF or bilaterally with suppliers, while other countries have not confirmed a procurement channel yet.</td>
</tr>
<tr>
<td>India</td>
<td>Final demand from India in terms of introduction date, dose requirements (based on presentations available) and procurement channel. India will be prioritised for IPV, as it is a Tier 1 country.</td>
</tr>
</tbody>
</table>

### 4. Supply and Demand Imbalance and Actions Taken to Mitigate Implications

Given the uncertainties surrounding future demand, Figure 2 describes the current range of demand with and without the application of MDVP, and includes the country introduction timelines as submitted

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in Gavi applications without factoring in delays. The below graph indicates a moderate supply gap in 2015.

**Figure 2: Estimated Demand and Supply as of December 2014***

Reduced IPV availability for 2014-2015 has necessitated establishing a prioritisation mechanism, which is based on clear and transparent criteria. The mechanism has been endorsed by the Polio Steering Committee (PSC), to be applied for the allocation of IPV as follows:

- Planned SIAs in the three endemic countries,*
- Routine introductions in Tier 1 and 2 countries,
- Routine introductions in Tier 3 and 4,
- Additional unplanned SIAs in endemic countries and SIAs in non-endemic countries.

**Note***: Supply for SIA requirements are capped at 8 million doses for 2014/15.

In order to ensure that all countries can introduce IPV by end-2015 in accordance with the Polio Eradication and Endgame Strategic Plan 2013-2018, UNICEF anticipates that some Tier 3 and 4 countries may be required to delay introductions during 2015.

UNICEF, WHO and Gavi anticipate demand forecasts to continue to evolve based on country decision-making and the finalisation and implementation of IPV introduction plans. UNICEF will share procurement forecasts with manufacturers with supply arrangements on a monthly basis, as per UNICEF’s standard processes. UNICEF will also publish the most current demand forecasts as well as underlying assumptions on a quarterly basis on this website.
5. IPV Presentations and Prices Available Through UNICEF

Currently, four IPV presentations are prequalified by WHO: 1-, 2-, 5- and 10-dose vials. UNICEF has established supply arrangements covering 2014-2018 for the supply of three presentations: 1-, 5- and 10-doses vials (Annex A).

The prices awarded for Gavi-supported countries range from €0.75 ($0.94)\(^2\) per dose in 10-dose vials to $2.80 in single-dose vials. For MICs procuring through UNICEF, prices range from $1.90 per dose in 5-dose vials to €2.40 ($3.00)\(^3\) per dose in 10-dose vials. Prices for 1- and 5-dose vials apply to all countries procuring through UNICEF (Table 2).

Table 2 Awarded Prices by Product Presentation, Manufacturer and Countries as of December 2014

<table>
<thead>
<tr>
<th>Per dose price ranges 2014-2018</th>
<th>Sanofi Pasteur</th>
<th>Bilthoven/SII</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gavi-supported</td>
<td>MICs</td>
</tr>
<tr>
<td>10-dose</td>
<td>€0.75</td>
<td>€1.49 - €2.40</td>
</tr>
<tr>
<td>5-dose(^1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-dose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^{1}\) For Sanofi, a price will be confirmed upon WHO prequalification.

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


6. Availability of IPV in Combination Vaccine

UNICEF has experienced increasing interest from countries for IPV-containing combination vaccines. In addition, a number of countries have expressed concerns about the administration of three doses to be administered during the same visit. At a global level, some IPV-containing combination vaccines are available with acellular pertussis, of which one was prequalified by WHO in December 2014. UNICEF has approached manufacturers but has been notified that the vaccine supply is currently considerably constrained and any quantities could only be made available through UNICEF in 2016, at the earliest.

Based on country interest, UNICEF has issued an expression of interest to manufacturers. UNICEF will issue a note on the responses received shortly.

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

**Resources for planning and IPV**
http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/plan/en/

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

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\(^2\) UN exchange rate as of December 2014: €0.799/$1.00.

\(^{3}\) Ibid.
# ANNEX A

## AWARDED PRODUCT PRESENTATIONS AS OF DECEMBER 2014

<table>
<thead>
<tr>
<th>Vial of 10 doses of IPV</th>
<th>Vial of 5 doses of IPV</th>
<th>Vial of 1 dose of IPV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Sanofi Pasteur</td>
<td>Bilthoven Biologicals B.V.</td>
</tr>
<tr>
<td><strong>Country of manufacture</strong></td>
<td>France</td>
<td>Netherlands</td>
</tr>
<tr>
<td><strong>Date of prequalification</strong></td>
<td>09 December, 2005</td>
<td>28 November, 2014</td>
</tr>
<tr>
<td><strong>NRA of record</strong></td>
<td>ANSM</td>
<td>Medical Evaluation Board (MEB)</td>
</tr>
<tr>
<td><strong>Pharmaceutical form</strong></td>
<td>Liquid</td>
<td>Liquid</td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>10 dose vial</td>
<td>5 dose vial</td>
</tr>
<tr>
<td><strong>Route of administration</strong></td>
<td>Intramuscular injection sub-cutaneous</td>
<td>Intramuscular injection sub-cutaneous</td>
</tr>
<tr>
<td><strong>Vaccine Vial Monitor</strong></td>
<td>VVM7</td>
<td>VVM7</td>
</tr>
<tr>
<td><strong>Shelf life</strong></td>
<td>36 months at 2-8°C</td>
<td>36 months at 2-8°C</td>
</tr>
<tr>
<td><strong>Secondary packaging</strong></td>
<td>10 vials of 10 doses</td>
<td>Akylux tray of 280 vials</td>
</tr>
<tr>
<td><strong>Cold chain volume per dose (cm³)</strong></td>
<td>2.46</td>
<td>4.04</td>
</tr>
<tr>
<td><strong>Preservative</strong></td>
<td>Phenoxyethanol 5mg/ml</td>
<td>Phenoxyethanol 5mg/ml</td>
</tr>
<tr>
<td><strong>Handling of multi-dose vials</strong></td>
<td>WHO recommends that opened vials can be kept up to 28 days</td>
<td>WHO recommends that opened vials can be kept up to 28 days</td>
</tr>
<tr>
<td><strong>Indicative wastage rate</strong></td>
<td>30%</td>
<td>15%</td>
</tr>
<tr>
<td><strong>Status of availability</strong></td>
<td>Limited availability for 2015</td>
<td>Limited availability for 2015</td>
</tr>
</tbody>
</table>


With additional product presentations becoming prequalified by WHO (expected by 2Q 2015) this Annex will be updated.

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