The note provides an update on IPV supply and demand for 2014-2018. UNICEF projects a constrained supply situation through to the end of 2016. Changes to supply availability through UNICEF and aggregate forecasted demand imply that some lower-risk countries will only be able to introduce IPV into their routine programmes later than planned, during early 2016.

1. Summary

- IPV supply availability through UNICEF for the period 2014-2015 has reduced by 57 million doses from 129 million as compared to awards made in March 2014 to 72 million doses across the 1-, 5-, and 10-dose vial presentations.
- The latest supply figures represent a 2 million-dose decrease in availability compared to the previous most recent Supply and Demand update (December 2014) for the 2014-2015 period. Technical difficulties in scaling-up IPV bulk production for both manufacturers account for the overall reduction since December 2014.
- Visibility of country demand has improved, including better understanding of preferred product presentations, the planned timing of large country introductions, and use of IPV in Supplementary Immunisation Activities (SIAs). However, guidance on the potential dose requirements and timing of use of IPV in outbreak response remains to be confirmed.
- In November 2014, new data on preservative efficacy confirmed the applicability of the Multi-Dose Vial Policy (MDVP) to IPV, permitting the use of 5- and 10-dose vials up to 28 days after opening, which reduces projected wastage.
- UNICEF now projects total demand for 2015-2018 through UNICEF to range from 310 to 350 million doses. This includes the decreased demand from countries expected to apply the MDVP for 2015-2018, as well as the previously unforeseen and additional demand from countries originally assumed to self-procure IPV quantities.
- Given the current demand forecasts and supply availability estimates, all high- and medium-risk countries, can still introduce IPV during the remainder of 2015. However, the constrained supply situation during 2015, projected to continue through to the end of 2016 as well as the uneven distribution of supply from one supplier in 2016, necessitates delaying the first shipments of IPV to ten low-risk countries until the end-4Q 2015. Any further reductions to- or delays in the timing of- IPV supply availability, and/or any increases to country demand (e.g. for additional SIAs, or from countries originally assumed to self-procure) could necessitate additional delays to other country introductions.


IPV supply availability decreased substantially compared to the original quantities awarded to the two manufacturers through 2018. One manufacturer reduced the quantities available to UNICEF in 2014-2015 by more than 50%, and can now only supply 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, which reduced the availability in 2014.
In late-March 2015, UNICEF received new information about supply availability for 2015 and 2016 due to technical issues affecting the scale-up of bulk production. It included the expected gradual scale up of manufacturing by one manufacturer throughout 2016. Figure 1 provides supply availability by product presentation per year for the period 2014-2018.

**Figure 1 IPV Supply Availability by Product Presentation 2014-2018***

![Figure 1](image1.png)

Source: UNICEF.

**Note***: The quantities shown for 2017 through 2018 are the awarded quantities, as actual availability is not confirmed.

Figure 2 describes the incremental step changes to overall 2014-2018 supply availability to date (mid-May 2015).

**Figure 2 Incremental Changes Over Time to 2014-2018 Supply Availability Compared to Awards***

![Figure 2](image2.png)

Source: UNICEF Supply Division.

### 3. IPV Demand Projections

UNICEF based the 442 million doses of IPV supply it awarded for 2014-2018 on the draft Strategic Demand Forecast (SDF), version 9, developed jointly at a global level by Gavi, the Vaccine Alliance
(Gavi), UNICEF, WHO, and other partners without country input. UNICEF made a set of assumptions with regards to preferred product presentations (and consequently wastage rates) to establish overall country requirements at the time of making the awards based on advice from a Procurement Reference Group. 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 was assumed that India would self-procure and self-fund its IPV purchases. Demand projections also included demand for IPV from Middle Income Countries (MICs) that usually procure vaccines through UNICEF, as well as other MICs that have indicated an interest in UNICEF’s IPV procurement.

Originally, very few countries had decided on IPV introduction at the time UNICEF made awards. As of mid-May 2015, UNICEF has increased its visibility of country demand with cumulative projected demand 2014-2018, which is now expected to range from 310 million to 350 million doses. A number of factors inform the latest demand projections:

- Country introduction plans for IPV are now available, as all Gavi countries have submitted IPV applications to Gavi for funding support. Based on applications submitted to Gavi, product preferences and wastage rates are available for 65 countries procuring through UNICEF including India.
- India unexpectedly submitted an application to Gavi requesting financial support for vaccine introduction and vaccine procurement through UNICEF. The Gavi Board approved a funding provision of 12 months catalytic support, which further clarifies a portion of near-term demand.
- In addition, the IMG has completed the mapping of decision-making processes, planned introduction timelines and supply requirements for the 25 countries that are not Gavi-supported but eligible for 12 months catalytic support, of which 9 will be supplied through UNICEF.
- SIA requirements, which were not included in the original awards have now been assessed and factored in.
- Some countries have delayed the timing of their IPV introduction on account of programmatic readiness.
- UNICEF received additional demand from countries that were expected to self-procure.

UNICEF also expects to receive additional requests for use of IPV in SIAs to support polio eradication efforts in endemic countries as well as for outbreak response efforts before and after the switch from tOPV to bOPV. Dose requirements particularly for outbreak response and timing of supply availability is yet to be confirmed.

The application of WHO’s MDVP by most countries is expected to reduce countries’ demand for IPV starting from 2H 2015.¹ 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 by applying the MDVP is projected to reduce country vaccine requirements, provided that this policy is implemented in the country. The reduction in requirements will depend on if the policy is applied nationwide or for specific immunisation strategies only (i.e., fixed sites vs. outreach activities). Updated product presentations incorporating new Vaccine Vial Monitors (VVMs) on the vial label will be available shortly from both manufacturers, and will allow

countries to start using opened multi-dose vials beyond the end of the session in which they are opened. To date, all vials have been 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. Countries that have already introduced the vaccine with the VVM on the cap may have to retrain health care workers to ensure that the limited supply of multi-dose presentations is used to the maximum extent.

A number of uncertainties exist which could affect the future demand for IPV through UNICEF (Table 1). These uncertainties have yet to be fully factored in to the forecasts.

Table 1 IPV Introduction Uncertainties and Considerations

<table>
<thead>
<tr>
<th>Uncertainty</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<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 requested by countries through their applications (by up to 50% for some countries). 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>SIA and outbreak response requirements</td>
<td>Additional doses may be required for SIAs in endemic countries. In April 2015, SAGE endorsed a recommendation to use IPV with tOPV in case of new eVPDs occurring between September 2015 and April 2016. IPV will also be required with mOPV2 post switch in case of an outbreak. The timing of supply and quantity requirements are subject to confirmation by the programme.</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

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

Based on the above-mentioned changes to IPV supply availability and expected demand, UNICEF undertook a close review of expected supply and demand with partners in April 2015. The aim of the review was to plan allocations of the limited supply, such that at a minimum, there would be sufficient IPV for routine introductions in those countries at higher risk of polio outbreaks, and sustained supply of IPV for those countries that had already introduced the vaccine.

Figure 3 illustrates the revised supply availability and the suppressed demand following the review process by UNICEF and partners. The demand also assumes the application of MDVP in all but a few countries that have confirmed not to apply the policy.

Figure 3 IPV Available Supply & Suppressed Demand as of May 2015 with MDVP

Source: UNICEF Supply Division.
The review by UNICEF and partners resulted in the establishment of clear and transparent criteria that were endorsed by the Polio Steering Committee (PSC) to prioritize the limited supply. The criteria are as follows:

- 1<sup>st</sup> priority: Planned SIAs in the three remaining endemic countries,
- 2<sup>nd</sup> priority: Routine introductions in Tier 1 and 2 countries,
- 3<sup>rd</sup> priority: Routine introductions in Tier 3 and 4,
- 4<sup>th</sup> priority: Additional unplanned SIAs in endemic countries and SIAs in non-endemic countries.

In order to ensure that all high- and medium-risk countries can introduce IPV by end-2015 in accordance with the Polio Eradication and Endgame Strategic Plan 2013-2018, UNICEF with partners have been required to communicate to some Tier 3 and 4 countries that current supply availability requires them to postpone introductions compared to their original plans. As part of this communication, 10 countries were informed that they will only receive their first vaccine deliveries in December 2015, allowing them only to introduce in early 2016. This affected earlier targets to have all countries introduce IPV by October 2015, but the current plans should still allow all countries to introduce at least 1 dose of IPV into their routine immunization schedule prior to the switch from tOPV to bOPV (“the Switch”) that is planned for April 2016.

UNICEF, WHO and Gavi anticipate demand forecasts to continue to evolve based on country readiness to introduce and uptake following introductions, as well as a clearer understanding of IPV requirements for other purposes, e.g. SIAs, in response to outbreak of cVDPV2. UNICEF continues to share procurement forecasts with relevant manufacturers on a monthly basis, as per UNICEF’s standard processes. This note also serves towards UNICEF’s commitment to publish the most current demand forecasts as well as underlying assumptions on a quarterly basis on the UNICEF 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-dose vials (Annex A).

The prices awarded for Gavi-supported countries range from €0.75 ($0.83)<sup>2</sup> 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 ($2.65)<sup>3</sup> 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&lt;sup&gt;i&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-dose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>i</sup> For Sanofi, a price will be confirmed upon WHO prequalification.

<sup>a</sup> Based on awarded quantities, a price of $1.50 is projected to be accessed in 2018.


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<sup>2</sup> UN exchange rate as of May 2015: €0.904/$1.00.

<sup>3</sup> Ibid.
6. Availability of IPV in Combination Vaccine

UNICEF has experienced increasing interest from countries for IPV-containing combination vaccines. A number of countries have expressed concerns about the administration of three or more doses (e.g. of IPV, DTP-containing vaccine, and pneumococcal vaccines) to be administered during the same visit as a reason to favour IPV-containing combination vaccines. 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 issued an expression of interest to industry to understand the timelines for supply availability. The responses from industry indicate that vaccine supply is currently considerably constrained and any quantities of these combination vaccines could only be made available through UNICEF in 2018.

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
### 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>20%</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)