Inactivated Polio Vaccine: Supply Update

UNICEF Supply Division

May 2018
1. Summary

- 2018 is the first year that UNICEF will be able to fully meet routine requirements, based on increase in supply availability.
- However, supply availability remains constrained because of additional demand, including for catch up immunization.
- While UNICEF continues to secure supply throughout 50 high-risk countries, UNICEF had to postpone or suspend IPV introduction into the expanded programme on immunization (EPI) for 35 countries out of 85 procuring IPV through UNICEF. UNICEF has since informed the countries affected by the shortage that supply is now available. It allows 17 countries to introduce IPV, and a further 18 countries, which previously had their supply interrupted in April 2016, to now reintroduce.
- Based on the outcome of the tender and a limited supplier base, UNICEF expects prices to increase from 2019 through to 2021.
- UNICEF only expects new manufacturers to enter the market around 2020 with World Health Organization (WHO) prequalified vaccines. This will increase UNICEF’s supplier base, and supply availability through UNICEF, and support the implementation of a two-dose schedule prior to OPV cessation.
- Subsequently, UNICEF anticipates vaccine prices from the new manufacturers to be similar to current levels from the second half of the tender period as new manufacturers enter the market and make supply available to UNICEF.
- UNICEF does not anticipate a market with multiple suppliers and sufficient supply capacity to fully meet programmatic requirements of at least two doses of IPV to materialise before 2023.

2. Current Supply Situation

The availability of stand-alone IPV continues to be constrained globally in 2018 and is not sufficient to meet all programmatic needs. However, due to a considerable increase in supply from manufacturers in 2018, as compared to earlier years, UNICEF expects supply availability to be sufficient to meet the requirements of all countries procuring through UNICEF for one dose of IPV in their routine immunization programmes. In addition, UNICEF secured a reserve of 2 million doses of IPV for campaign activities to address circulating vaccine derived type 2 polioviruses (cVDPV2) in the remaining polio endemic countries. While the Global Polio Eradication Initiative (GPEI) currently does not recommend using IPV for outbreak response, because of supply shortages, GPEI reviews each country’s request before doses are released.

Manufacturers have only supplied 46% of the contracted quantities with UNICEF for the period 2014 to 2018 (see figure 1). There are two main reasons for the continued constrained supply:
manufacturers were not able to supply as planned, and at the same time, programmatic demand increased unexpectedly.

Both manufacturers reduced their supply availability because of unforeseen technical challenges. They had to rapidly scale-up production to more than double their production level for 126 OPV-only using countries to introduce at least one dose of IPV. Secondly, there was unexpected demand for IPV used in outbreak response in endemic countries to stop wild polio virus, and to respond to outbreaks of cVDPV2. UNICEF provided a total of 20 million doses for these activities, which had not been included in the original tender forecast.

Figure 1 Long-term Arrangements versus Actual and Forecast Supply 2014-2018

UNICEF projects supply availability to improve from 2017 to 2018 by 50%, and for the first time, could reach up to 60 million doses. Based on this increase, as of Q1 2018 UNICEF has offered supply to 35 countries that did not have access to IPV because of the need to prioritise available supply to countries most at risk. Of these 35 countries, 10 have already started immunization with IPV in Q1 2018, and a further 24 countries plan to introduce IPV in Q2/Q3 2018. One country decided to introduce in 2019.

WHO’s Strategic Advisory Group of Experts (SAGE) on Immunization recommended in October 2017 that countries that have not had access to IPV, should provide catch up immunizations to the affected birth cohorts since the switch from the type 2 containing trivalent Oral Polio Vaccine (tOPV) to the bivalent OPV (bOPV) in April 2016. SAGE recommends that catch up immunizations should be offered as soon as the supply availability allows. Based on supply offers received in response to UNICEF’s recent tender, UNICEF projects that IPV supply should be available towards the end of 2019 and through 2020 in sufficient quantities for the 35 countries to have the opportunity to offer catch up immunization of the eligible population. UNICEF anticipates being able to inform countries in early Q3 2018 of when doses are expected to become available.
3. UNICEF’s 2019-2022 IPV Tender Outcome Update

3.1. Tender Objective and Background

As UNICEF’s current contracts expire by the end of 2018, and in consideration of manufacturer’s production lead times, UNICEF issued a tender in July 2017 for stand-alone IPV covering the period of January 2019 to December 2022. The main objectives of the tender were:

- To ensure sufficient supply of IPV for countries procuring through UNICEF.
- To achieve a price that is affordable for countries and donors.
- To expand the supplier base to stimulate a healthy market and enhance Vaccine Security, which is the uninterrupted, sustainable supply of affordable vaccines of assured quality.

3.2. Tender Outcome and Initial Awards

With UNICEF’s initial awards, UNICEF has been mindful of the state of supply since 2014, which has affected immunization programmes in many countries, including for the first time the interruption of supply for a vaccine newly introduced into routine schedules. Therefore, a key consideration for UNICEF was to secure supply from manufacturers with products that are already WHO prequalified, with the expectation that countries have access to uninterrupted supply to fully implement the recommended one dose of IPV in their programmes.

Compared to the prices acquired under the last 2014-2018 IPV tender, prices for 2019 will be higher for all presentations from existing manufacturers. Table 1 shows a summary of the initial awards and weighted average price (WAP).

Table 1 Summary of Initial Awards for 2019 to 2022 and Weighted Average Price

<table>
<thead>
<tr>
<th>Present</th>
<th>2019</th>
<th></th>
<th>2020</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No of Suppliers</td>
<td>Doses</td>
<td>WAP</td>
<td>No of Suppliers</td>
</tr>
<tr>
<td>1 dose</td>
<td>1</td>
<td>1,500,000</td>
<td>USD 3.50</td>
<td>1</td>
</tr>
<tr>
<td>5 dose</td>
<td>1</td>
<td>20,000,000</td>
<td>USD 2.95</td>
<td>1</td>
</tr>
<tr>
<td>10 dose</td>
<td>1</td>
<td>20,000,000</td>
<td>EUR 1.81</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>41,500,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Present</th>
<th>2021</th>
<th></th>
<th>2022</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No of Suppliers</td>
<td>Doses</td>
<td>WAP</td>
<td>No of Suppliers</td>
</tr>
<tr>
<td>1 dose</td>
<td>1</td>
<td>1,500,000</td>
<td>USD 2.80</td>
<td>1</td>
</tr>
<tr>
<td>5 dose</td>
<td>1</td>
<td>15,000,000</td>
<td>USD 3.10</td>
<td>1</td>
</tr>
<tr>
<td>10 dose</td>
<td>1</td>
<td>33,000,000</td>
<td>EUR 2.18</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>49,500,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

The price increases from suppliers were explained as necessary to offset the considerable investments they made over the past four years to scale up production capacity, and to address unforeseen challenges during this process. UNICEF expects that as WHO prequalifies new products from manufacturers, and supplies become available through UNICEF at lower prices, towards the end of the tender period the WAP per product presentations will reach levels similar to 2018 (Table 2).
UNICEF anticipates it will publish prices for 2019 to 2022 for awarded products per supplier and presentation in Q2 2018 as soon as UNICEF has concluded contracts with suppliers. UNICEF pricing data can be accessed here: https://www.unicef.org/supply/files/2018_03_09_IPV.pdf.

While ensuring uninterrupted supply to countries, another critical objective for UNICEF is to expand the supplier base and to improve the health of the market. UNICEF has carefully reviewed the demand and the offers for supply availability, including from pipeline manufacturers. As an outcome of this analysis, which included a review of the feasibility of timelines and quantities indicated by new manufacturers, UNICEF left considerable quantities unawarded from 2021 onwards (Table 2). UNICEF considers the unawarded quantities and timing should provide considerable incentives for pipeline manufacturers to continue efforts to have WHO prequalify their products as soon as possible, and accelerate activities that could help achieve this objective.

Table 2: Summary of Awarded and Unawarded Quantities for 2019 to 2022

<table>
<thead>
<tr>
<th>Quantities (Doses)</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tender Demand</td>
<td>112,800,000</td>
<td>69,380,000</td>
<td>134,500,000</td>
<td>136,150,000</td>
<td>452,830,000</td>
</tr>
<tr>
<td>Initial Awards</td>
<td>41,500,000</td>
<td>51,500,000</td>
<td>49,500,000</td>
<td>49,500,000</td>
<td>212,000,000</td>
</tr>
<tr>
<td>Unawarded Quantities</td>
<td>71,300,000</td>
<td>17,880,000</td>
<td>85,000,000</td>
<td>86,650,000</td>
<td>240,830,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

Due to the inability to secure sufficient supply to meet the demand for 2019 for catch-up immunizations, this demand will be carried forward and expected to be spread out across 2019 and 2020. Therefore, the demand in 2020 will be higher and thus the actual unawarded quantities in 2020 will be greater than indicated in the table above.

3.3. Summary of Proposals Received

UNICEF received proposals from 11 vaccine manufacturers, which all offered to supply prequalified IPV to UNICEF during the tender period. In addition to the current two manufacturers that have been supplying UNICEF for the period 2014 to 2018, UNICEF received proposals from nine manufacturers that expect to have their IPV products prequalified by WHO and have supply available to UNICEF before 2023. Based on the proposals received from manufacturers, table 3 shows the number of new products by presentation that are expected to achieve prequalification by WHO based on national licensure in country of production.

Table 3: Number of New Products by Presentation Expected to be Prequalified by WHO

<table>
<thead>
<tr>
<th>Presentation</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 dose</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>10 dose</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
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</tbody>
</table>

Source. UNICEF Supply Division

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Based on the past experience with regards to the challenges of scaling up production of IPV with experienced manufacturers, to ensure that supply continues to be sufficient to meet the programmatic needs, UNICEF will closely monitor the progress on critical milestones towards prequalification, and capacity expansion across all pipeline manufacturers as well as current manufacturers as applicable. Any additional awards to existing and new manufacturers will take into consideration the manufacturing production lead times as well as performance, prices and other award criteria as listed in the tender document, while ensuring the uninterrupted supply of IPV.

As new manufacturers have their products WHO prequalified and receive awards, UNICEF expects to achieve one of its main tender objectives: an affordable price for countries and donors. Table 4 shows the range of prices that have been offered by presentation.

Table 4: Prices Offered by Presentation from Manufacturers with a Product in Development for Gavi-Supported Countries

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Price Range per Dose*</th>
</tr>
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<tbody>
<tr>
<td>1 dose vial</td>
<td>USD 1.50 to USD 2.50</td>
</tr>
<tr>
<td>5 dose vial</td>
<td>USD 0.998 to USD 1.10</td>
</tr>
<tr>
<td>3 manufacturers</td>
<td>USD 1.11 to USD 2.528</td>
</tr>
<tr>
<td>10 dose vial</td>
<td>USD 1.00 to USD 2.50</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

Note*: Non-USD denominated prices were converted to USD at the UN official rate of exchange in March 2018, published at https://treasury.un.org.

Some manufacturers offer different prices for Gavi supported countries and countries that have not been supported by Gavi (tiered pricing). UNICEF will publish this information once contracts have been established, noting that indicative prices may change subject to the volumes awarded.

With the number of manufacturers currently having IPV in clinical development, and based on the volumes offered, UNICEF expects that IPV vaccine supply will be sufficient to meet the SAGE recommendation that all countries should have at least 2 doses of IPV in their immunization programmes at the time of OPV cessation.

4. Steps Forward

- UNICEF and partners to communicate to countries when doses are expected to be available for catch up immunization.
- UNICEF will closely monitor with pipeline manufacturers the progress towards having products prequalified by WHO and expected timing of supply to UNICEF.
- Prices from the initial awards will be published when long-term arrangements have been concluded (expected by May 2018).
- Next update in six months or sooner if there are significant demand changes for the IPV standalone market.

For further questions or additional information, please contact:

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Other UNICEF information notes are found at: http://www.unicef.org/supply/index_54214.html.