Oral Polio Vaccine Supply Outlook for 2014

UNICEF Supply Division

February 2014
Oral Polio Vaccine (OPV) Supply Outlook for 2014 – February 2014

This update reports on anticipated 2014 OPV supply availability for intensified polio eradication activities and highlights actions taken to meet country demand.

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

1. Summary

- During 1H 2014 (especially 1Q), OPV supply through UNICEF is insufficient to meet all country requirements. As a result, in November 2013, WHO and UNICEF reviewed the 2014 SIA calendar to prioritize available supply and presented the revised SIA calendar to WHO’s Eradication Management Group (EMG) to ensure that the most critical needs are met, while also retaining adequate emergency response capacity.
- Additional revisions to the SIA calendar were presented to the EMG in December 2013, when, due to financial shortfalls (for commodity purchases and operational activities), it became apparent that only 1.35 billion doses are currently expected to be funded for 2014. As a result, some activities during 2H 2014 have either been cancelled or postponed.
- UNICEF does expect that, contingent on additional funding materialising later in the year, 2014 demand should remain at 2013 levels or higher (approximately 1.74 billion doses). Intensified eradication activities as a result of the continued risk of polio outbreaks and the re-importation of wild poliovirus (WPV) in the Horn of Africa and the Middle East and sustained campaigns in endemic countries continue to contribute to high demand.
- UNICEF has taken measures to increase supply for 2H 2014 with an additional 460 million doses awarded, with additional availability starting mid-2Q 2014, accessing currently available manufacturer production capacity for WHO prequalified vaccine. UNICEF will continue to work with all partners to assess supply prioritisation aiming to increase buffer supply from 100 million to 200 million doses across tOPV and bOPV by end 2Q 2014. The total awarded supply for 2014 is 1.926 billion doses.
- Making additional awards on a timelier basis against manufacturers’ original offers should support avoidance of continuing supply constraints, particularly in the first half of subsequent calendar years. Given the current trends of increasing demand compared to forecast, UNICEF has awarded an additional 100 million additional doses of OPV for 2015 to one manufacturer who required greater than 12 months lead time to increase their supply. UNICEF will work with WHO and other GPEI partners to review 2015 demand and awards during 1Q 2014 to ensure adequate lead time for all manufacturers. These actions should generate improved flexibility for timely response to emergent and substantially increased needs.

2. Balancing Demand and Supply in 2014

UNICEF’s previous July 2013 and November 2013 OPV Supply Updates provide general market background and updates on 2013 demand and describe actions UNICEF and partners have taken to mitigate current supply constraints, including substantially increased awards during 2013. As detailed later in the note, supply availability has surpressed demand in 1H 2014, and, despite the epidemiological need for campaign activity on account of re-established transmission, subsequently limited operational funding has further reduced demand (by ~250-300 million doses), particularly in 2H 2014. All together, planned 2014 OPV requirements are currently 1.35 billion doses (Figure 1).
Table 1 Key 2014 Demand Details by Geography¹

<table>
<thead>
<tr>
<th>Country</th>
<th>Details</th>
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| Nigeria          | • Planned SIA demand is 362 million doses.  
• Current best estimates are 65 million doses for 1Q; 122 million doses for 2Q; 75 million doses for 3Q; and 105 million for 4Q. Additional requirements for 1Q have already been supplied through end-of-2013 procurement.  
• 2 national campaign activities (NIDs) and 7-8 sub-national campaign activities (SNIDs) are anticipated during 2014.  
• 15 million doses to be supplied for emergency outbreak response preparedness. |
| Pakistan         | • Planned SIA demand is 363 million doses.  
• Current quarterly best estimates are 149 million doses for 1Q; 50 million doses for 2Q; 31 million doses for 3Q; and 133 million 4Q.  
• 5 NIDs, 3-4 SNIDs and 9-10 Short Interval Additional Dose Strategy (SIADS) are anticipated during 2014.  
• 20 million doses to be supplied for emergency outbreak response preparedness. |
| Horn of Africa   | • Planned SIA demand is 65 million doses compared to previous estimated 2014 demand of 124 million for follow-up vaccination activities to the outbreak experienced in 2013.  
• Current quarterly best estimates are 38 million doses for 1Q and 27 million doses for 2Q.  
• Some activities have been either postponed / on-hold compared to original plan. |
| Afghanistan      | • Total SIA demand is 63 million doses.  
• Current best estimates are ~16 million doses for each quarter.  
• 8 million doses to be supplied for emergency outbreak response preparedness. |
| Middle East      | • Demand remains uncertain. Any spread affecting the wider Middle East region and Europe could lead to a substantial increase in OPV demand during the year.  
• OPV vaccine licensing in this region is a challenge for vaccine supply.  
• Current best estimates are 25 million doses for 1Q and 10 million doses for 2Q out of originally planned demand of 54 million which had also been initially concentrated in 1Q.  
• Estimates for 3/4Q are yet to be determined. |
| Remaining Global Demand | • Remaining planned global demand is 183 million doses compared to 413 million in the original plan, and have been re-scheduled / reduced pending resolution of operational funding.  
• Preparedness measures by some countries and regions which neighbour polio outbreaks are expected to increase polio vaccination coverage, leading to increases in demand, coupled with baseline population data corrections and revised wastage rates.  
• Current best estimates are 46 million doses for 1Q; 102 million doses for 2Q; 13 million doses for 3Q; and 22 million for 4Q. |

¹ Table 1 is based upon latest estimates as of the note’s publishing date, which remains subject to change / latest update from WHO and countries.
During 1H 2014, OPV supply will be constrained. Production capacity for 1Q is maximized, with no increase possible. In addition, some manufacturers have informed of availability schedule changes at short notice, and risk reducing availability of OPV further. In November 2013, WHO and UNICEF reviewed the December 2013 and 2014 SIA calendar taking into consideration supply availability and proposed changes. In order to manage supply during 1H 2014 and maintain an adequate buffer to respond to polio outbreaks, immunization activities have been prioritized together with partners and countries for:

- SIAs in endemic countries.
- Countries currently experiencing polio outbreaks.
- Countries bordering polio outbreak and/or endemic countries or those categorised as a high-risk outbreak country.

Proposed changes were endorsed by the Eradication Management Group (EMG), and presented to the WHO Representatives meeting in Geneva, 18-20 November 2013. Subsequently, due to financial shortfalls, funded demand forecasts were reduced to the current levels (1.35 billion), and the revised expectations were again presented to the EMG. These plans will continue to be discussed with partners and countries, and the remaining activities, including those in low-risk countries may be postponed to later in the year or cancelled subject to funding and vaccine availability. In retrospect, access to quantities through earlier increased 2014 awards, for example at the beginning of 2013, may have provided improved supply availability. Improved visibility on long-term demand expectations will better inform the award strategy and timing going forward.

From 2Q 2014, UNICEF expects supply availability to improve as a result of additional awards made throughout 2013 (for 2014) and additional production capacity becoming available. The supply planning coordination group comprised of WHO, UNICEF, Bill and Melinda Gates Foundation (BMGF) and Centers for Disease Control and Prevention (CDC) will continue to monitor supply and identify possibilities for additional activities as well as reinstating suspended, reduced or cancelled activities subject to levels of supply availability. UNICEF recently awarded 100 million doses for 2015 to one manufacturer which required 12-months lead time to scale-up additional supply. As current UNICEF 2015 awards are now 1.120 billion doses, a timely review of 2015 requirements and supply availability could inform actions to be taken during 1Q 2014 in order to support adequate supply to better meet 2015 country demand, particularly if the current demand is expected to increase from currently forecasted levels.

3. Supply and Capacity

Taking into account the above considerations, UNICEF currently anticipates deliveries approaching at least 1.45 billion doses for 2014 (including 100 million doses of general buffer quantities for emergency outbreak response). This represents a decline of ~250-300 million doses compared to previous plans in November, predominantly in 2H 2014 on account of funding shortfalls. While some 1Q activities have been postponed to later in the year, meeting country demand, in particular some of the originally planned 2H 2014 activities, may remain dependent on increased operational or other funding materialising. Actions that should improve 2014 supply context include:

- UNICEF increased 2014 award allocations from 1.270 billion to 1.926 billion doses (Table 2) in order meet both planned and unforecasted needs.
- One manufacturer anticipates opening an additional production line to produce an additional (annual) 250 million doses above current capacity.
- WHO is also working with the two de-listed manufacturers to re-instate WHO prequalification in order to increase global filling capacity.
- One de-listed manufacturer anticipates obtaining WHO prequalification by 3Q 2014.
- Quarterly planning meetings (among other analyses) may serve as catalysts for supply allocation pending resolution of funding issues in addition to awards for new production capacity, as needed.

**Figure 2 2014 Supply (Awards) Versus 2014 Requirements**

![Figure 2 2014 Supply (Awards) Versus 2014 Requirements]

Source: UNICEF Supply Division.

**Table 2 Current 2014 UNICEF Awards to OPV Manufacturers**

<table>
<thead>
<tr>
<th>Polio Vaccine</th>
<th>Company</th>
<th>Awards in Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>tOPV 10 ds</td>
<td>GlaxoSmithKline (Belgium)</td>
<td>40,000,000</td>
</tr>
<tr>
<td></td>
<td>Sanofi Pasteur (France)</td>
<td>20,000,000</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>60,000,000</strong></td>
</tr>
<tr>
<td>tOPV 20 ds</td>
<td>Bio Farma (Indonesia)</td>
<td>70,000,000</td>
</tr>
<tr>
<td></td>
<td>GlaxoSmithKline (Belgium)</td>
<td>156,000,000</td>
</tr>
<tr>
<td></td>
<td>Haffkine Bio-Pharm (India)</td>
<td>280,000,000</td>
</tr>
<tr>
<td></td>
<td>Sanofi Pasteur (France)</td>
<td>154,000,000</td>
</tr>
<tr>
<td></td>
<td>Serum Institute of India</td>
<td>197,500,000</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>857,500,000</strong></td>
</tr>
<tr>
<td>bOPV 20 ds</td>
<td>Bio Farma (Indonesia)</td>
<td>100,000,000</td>
</tr>
<tr>
<td></td>
<td>GlaxoSmithKline (Belgium)</td>
<td>204,000,000</td>
</tr>
<tr>
<td></td>
<td>Haffkine Bio-Pharm (India)</td>
<td>114,710,000</td>
</tr>
<tr>
<td></td>
<td>Sanofi Pasteur (France)</td>
<td>246,000,000</td>
</tr>
<tr>
<td></td>
<td>Serum Institute of India</td>
<td>250,000,000</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>914,710,000</strong></td>
</tr>
<tr>
<td>mOPV 20 ds</td>
<td>Novartis (Italy)</td>
<td>94,000,000</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>94,000,000</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Sub-Total Vaccines</strong></td>
<td><strong>1,926,210,000</strong></td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

UNICEF anticipates that the above mentioned actions will also result in an increased tOPV/bOPV buffer supply to secure emergency response capacity to polio outbreaks.

Following the 2014 awards, Figure 3 depicts current OPV supply availability and timing, including by OPV type. Additional supply is expected to come on-line during mid-to-end 2Q. Additionally, the figure presents currently awarded supply versus offered supply. Securing timely availability of additional supply in order to meet a revised demand scenario requires awards being made with adequate lead-time.
Figure 3 2014-2017 UNICEF OPV Supply Availability (and Timing) versus Demand

Source: UNICEF Supply Division.

Figure 4 describes the planned monthly deliveries taking into consideration the availability per Figure 3. Those activities which were postponed or reduced pending additional funding are denoted as “Uncertain” and are concentrated in 2H 2014. UNICEF looks forward to increased visibility on those plans.

Figure 4 2014 UNICEF OPV Monthly Delivery Forecast

Source: UNICEF Supply Division.

4. Issues / Challenges

- The issues and challenges highlighted in UNICEF’s previous November 2013 OPV Supply Update which reference insufficient availability, the need for further consultations on programmatic requirements versus supply, and the risk of changes to manufacturer planned production and release schedules remain valid.
- The restrictive regulatory-driven issuance of OPV product licenses in certain key endemic and high-risk countries with immunity gaps is a growing cause for concern, particularly for bOPV, which is licensed in fewer countries.
- Future increases in supply capacity are in part dependent upon anticipated WHO prequalification of de-listed manufacturers and sufficient access of fillers to OPV bulk ingredient, of which there is a limited base.
• Some country requirements cannot be fully met due to limited operational funding and finite supply during 1H 2014.

Table 3 Major Challenges in the OPV Market and Supply Chain

<table>
<thead>
<tr>
<th>Issues</th>
<th>Action</th>
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| • Some key endemic and high-risk countries have restrictive regulatory frameworks to license OPV product. | • Endemic and high-risk countries are encouraged to license or grant temporary import waivers to WHO prequalified manufacturers able to supply OPV.  
  • Allocations of supply to countries will be made from relevant supplies and manufacturers accordingly. |
| • The risks of potential polio outbreaks, substantial OPV response demand, as well as changes in epidemiology, are difficult to predict and remain high. | • UNICEF undertakes quarterly planning meetings with partners to review demand and epidemiology data.  
  • UNICEF undertakes regular monitoring of OPV supply by type and assesses the need for conversion. |
| • Risk of changes to manufacturer planned production and release schedules.       | • UNICEF will continue to conduct regular communication with manufacturers and hold regular meetings with WHO while waiting for new production capacity to be made available and to use it if demand requires. |

5. Steps Forward

• UNICEF and partners will continue to review and map all vaccine requirements. Anticipated constrained OPV supply during 1H 2014, notably during 1Q 2014 requires directing available OPV supply to the highest priority countries (endemic countries, re-importation countries, and countries at-risk). Identifying additional sources of funding to support operations will be critical to ensuring activities that have been postponed or temporarily deferred are re-scheduled during 2H 2014.
• RI requirements remain a priority. However, UNICEF may request flexibility on shipment timing for countries with sufficient stock at the central level in order to meet urgent routine and campaign requirements of other countries as governed by supply availability.
• To increase availability in accordance with prevailing epidemiological data in endemic and high-risk countries, UNICEF anticipates the actions taken to date will result in an increased tOPV/bOPV buffer supply by mid-year 2014 to secure emergency response capacity to polio outbreaks.
• UNICEF and partners will continue to encourage countries to license or grant temporary import waivers to WHO prequalified manufacturers with a capacity to supply OPV.
• Current 2015 awards total 1.120 billion doses. A timely review of 2015 requirements and supply availability could inform actions to be taken during 1Q 2014 in order to better support adequate supply availability to meet all 2015 country demand.

For further questions or additional information, please contact:

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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).