MARKET UPDATE

Oral Polio Vaccines

UNICEF Vaccine Industry Consultation
19 September 2019
bOPV supply and demand update
The trajectory towards global polio eradication continues to provide unique challenges, requiring UNICEF and suppliers to continue close partnership.

Last notification of WPV + 3 years → certification + 12 months → OPV campaigns and withdrawal.
General declining trend in demand over 10 years

2013-2017 tender: Additional awards required due to optimistic (low) forecasts and outbreaks
Next steps as shared at Vaccine Industry Consultation 2018; and status

✓ Tender to be issued for mOPV1 for delivery 2019-2020 (October 2018), 60-80Mds, first delivery in January 2019

    UPDATE: Around 56Mds delivered to Pakistan, 6Mds pending to Afghanistan – at this point in time, no programmatic recommendation for additional needs

✓ Review and endorsement by the Global Polio Eradication Initiative of the Placeholder Calendar for Supplementary Immunization Activities (October)

    ✓ UNICEF to go back to all bidders requesting reconfirmation of terms and conditions

    ✓ Additional awards anticipated for 2019-2022 at this stage
bOPV tender issued 2016, to meet demand from 2018 through to cessation – assuming last case 2016/2017

Suppliers reconfirmed offers in 2018, extending through 2023/2024
Additional awards made in Q1 2019 in support of meeting tender procurement objectives, while balancing demand risks

Procurement objectives
• To secure sufficient supply of OPV to meet demand through eradication and OPV cessation – for planned activities, in case of delayed eradication and secure buffer for unplanned demand
• To guide the cessation of the OPV market in a responsible manner while maintaining affordability – minimize risks of early market exits, minimize risk of financial loss due to residual stocks

Outcome/results
• Awarding an additional 2,315Mds, on top of 2,815Mds awarded in 2017; and through to 2022
• Number of awarded suppliers gradually declining over time from seven in 2019 to five in 2022, maximizing bulk producers

Evaluation criteria in line with the original tender, with a focus on securing continued bulk production, product presentations, licensure portfolio, flexibility to secure buffer, price etc.
Short term: Unplanned changes in demand materializing from Q2 2019 against bOPV awards of around 1.1 billion doses

Reduction in demand due to cancellation of activities, competing country priorities and budget constraints

- Pakistan: Delays in and cancellation of activities
- Afghanistan: Cancellation of activities/interruption of program
- Nigeria: Cancellation of campaigns
- DRC: Cancellation of campaigns
- Low/medium risk countries: Cancellation of campaigns in low risk countries due to GPEI budget constraints

Overall reduction in demand in 2019 a minimum of 300Mds

Activities with suppliers and countries to better balance supply and demand in 2019

- Reducing availability: i) postponing some production to 2020; ii) releasing supply to GoI; and iii) reallocating capacity to mOPV2 production
- UNICEF working with countries to accept products with short shelf life
- UNICEF stays committed to utilize produced quantities, but requesting flexibility to carry forward some 2019 awarded doses to 2020 – expecting that all doses can be consumed during 1H 2020
- Applying an equal distribution of reduced utilization - to the extent possible based on country licensing requirements
Next steps; securing sufficient OPV supply through to cessation

• UNICEF continues to monitor developments in demand and supply, working with i) the GPEI to be on top of changes and ensure the program understands the impact to suppliers of such changes; ii) working with countries on supply acceptability; and iii) with suppliers to ensure appropriate levels of supply

• UNICEF is currently reviewing with suppliers the bOPV requirements through the end of 2019; to discuss carry over supply in the context of good faith agreements; and to discuss and optimize production plans for 2020 to ensure best utilization of capacity – a close partnership will continue to be required, mitigating risks on both sides while maintaining affordability, flexibility and supply

• Pending the availability of an updated GPEI SIA calendar in October 2020, UNICEF to reassess requirements with the intent to make awards post 2022 – to provide visibility to suppliers on future needs. UNICEF will consult with industry prior to making additional awards

• Market Note to be issued during Q4 2019 providing an update on how UNICEF assesses the current status of the bOPV supply and demand market
mOPV2 – update on stockpiles
The purpose of the global stockpiles of monovalent Oral Polio Vaccine is to ensure timely supply of vaccines to respond to outbreaks of specific poliovirus types at a time when OPV is no longer used in routine immunization systems.

Establishment of the mOPV2 stockpile was a SAGE requirement for the withdrawal of type 2 containing vaccines – the Switch from tOPV to bOPV. Establishment of the mOPV1 and mOPV3 stockpiles is in progress; to be in place before withdrawal of bOPV, 4 years after last detection of WPV.

WHO governs the global stockpile of bulk and finished mOPVs. Day to day management of the stockpile is carried out jointly by UNICEF and WHO.
Cumulative requirements for mOPV2 by year indicates a doubling of released doses 2016-2018; and year do date above 2018 deliveries.
Expanding the supplier base to the global stockpile to meet increasing demand to benefit from mOPV2 bulk produced before the switch

<table>
<thead>
<tr>
<th></th>
<th>GlaxoSmithKline</th>
<th>Sanofi Pasteur</th>
<th>Bio Farma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation/doses</td>
<td></td>
<td>Vial of 20 doses</td>
<td></td>
</tr>
<tr>
<td>Shelf life</td>
<td>9 years/-20°</td>
<td>24 months/-20°</td>
<td>24 months/-20°</td>
</tr>
<tr>
<td>Date of prequalification</td>
<td>11/05/2011</td>
<td>14/01/2016</td>
<td>21/06/2019</td>
</tr>
<tr>
<td>Vaccine Vial Monitor</td>
<td>Type 2</td>
<td>Type 2</td>
<td>Type 2</td>
</tr>
<tr>
<td>Secondary Packaging</td>
<td>Carton/100 vials/2,000 ds</td>
<td>Carton/10 vials/200 ds</td>
<td>Carton/50 vials/1,000 ds</td>
</tr>
<tr>
<td>Cold Chain Volume</td>
<td>0.48 cm³/dose</td>
<td>0.49 cm³/dose</td>
<td>0.55 cm³/dose</td>
</tr>
<tr>
<td>Doses in stockpile</td>
<td>4.1Mds</td>
<td>0</td>
<td>42.8Mds</td>
</tr>
<tr>
<td>Date of agreement on production, storage, delivery</td>
<td>11/06/2016</td>
<td>08/10/2018</td>
<td>27/06/2019</td>
</tr>
</tbody>
</table>

- Increasing demand for mOPV2 provides a risk because of long production lead times, challenges to provide accurate forecasting and securing budgets
- mOPV2 production also competes with bOPV production, in particular for countries with strict acceptability criteria and large volumes
Finished product in pipeline for supply to the mOVP2 stockpile is above 200Mds, allowing to meet the 100Mds buffer requirements end of year....
However, should demand continue to increase by a factor 2 between 2019 and 2020, the stockpile will be depleted in Q1 2020!
Way forward to secure sufficient supply of OPV2 to respond to outbreaks in an increasing number of countries

Reassessing mOPV2 vaccine requirements by October
- Expecting to be required to secure all released available mOPV2 bulks which is not yet under UNICEF contracts for the stockpiling
- Possibly, to request production of additional mOPV2 bulk vaccine for stockpiling
- GPEI to identify alternative countries willing to accept mOPV2 filling; identify suitable fillers of available mOPV2 bulk, fast track registration and prequalification of finished product for stockpiling

Accelerate clinical development of nOPV2 vaccine
- New genetically modified vaccine in phase II clinical development, with expected reduced risk of reseeding the virus and cause new outbreaks
- Accelerate availability for the stockpile; ensure SAGE programmatic recommendation; ensure WHO authorization for use of the vaccine as soon as possible
In conclusion...

- bOPV now awarded through to 2022, however, due to delay in eradication, UNICEF expects that the program will need supply through 2025 at least
  - Short term drop in demand in 2019 due to multiple causes, requires close coordination and risk mitigation between UNICEF and suppliers

- Reassessment of bOPV supply and demand is currently planned for 2nd half of 2020, with the intent to make additional awards for 2023/2024 – to provide visibility to suppliers

- mOPV2 demand is over and above what was planned pre-switch - UNICEF is in the process of securing additional available bulk for the stockpile; additional supply will be urgently required for the next 12-18 months