OPV/IPV supply and demand, including planning for the switch from tOPV to bOPV

Vaccine Manufacturer Consultation
October 2014, Copenhagen
Meeting changing supply requirements during the Polio Endgame in collaboration with suppliers

- **Detect and interrupt all poliovirus transmission**
  - 1) Secure availability of OPV including urgent delivery of the appropriate type of OPV to stop WPV transmission and interrupt cVDPVs

- **Strengthen immunization systems and withdraw OPV**
  - 2) Securing sufficient supply of tOPV and bOPV during the phased withdrawal of all OPVs starting with tOPV in April 2016
  - 3) mOPV2 stockpile and response capacity (finished product)
  - 4) At least 1 dose of affordable IPV available in OPV only using countries

- **Containment and certification**
- **Legacy planning**
OPV delivery for routine and SIAs and weighted average price, 2000-2014

- Product development and transitions illustrate interdependence between program strategies, epidemiology and supply
- Vaccine price continues to a focus for donors
- OPV demand for self-procuring countries (India, Indonesia, etc) + PAHO accounts for ~ > 1 billion doses
Additional awards have ensured timely availability to meet unplanned increased demand

- Increased awards for 2013 and 2014 to ensure response capacity
- Potential additional awards for 2015 to be made in coming months - to be based on licensing requirements, lead times, price etc.
- Additional awards required for 2016-2017 at a later stage
OPV demand forecasts and supply availability for 2014 up to Q1 2015 ensures buffer requirements

- Highly constrained supply situation in 2013 continued in 1H of 2014 for tOPV but improved after Q1 for bOPV
- Stocks building up temporarily across suppliers to meet Q1 2015 requirements
- Constraints in storage capacity has led to production stops, dialogue ongoing
- Continued flexibility required with regards to lead times for vaccine types as outbreaks could change requirements
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- Legacy planning
Supply requirements to be planned for the April 2016 Switch

- **2014**
  - End July SAGE WG
  - March-April Last cVDPV case

- **2015**
  - May WHA
  - SEPTEMBER
  - Switch Announcement
  - GO / Postpone

- **2016**
  - Late 2015 / Early 2016 Large scale tOPV campaigns
  - APRIL SWITCH
  - 6 months
  - Global Go – Switch
  - Switch POSTPONED to 2017
  - Continue tOPV until low season 2017

- **2017**
  - 2017 Low Season SWITCH

**Use of OPV products**
- Routine with tOPV; SIAs with bOPV or tOPV

**Production of OPV products**
- Availability of type 2 bulk + finished tOPV for SIAs + routine
- Production of bulk/finished mOPV2 for stockpile

**Production of OPV products**
- bOPV for routine + SIAs mOPV2 for type 2 outbreaks
Flexibility, good coordination, and transparency required to ensure supply security and timely delivery

**Sufficient OPV for SIAs, routine, and stockpile**
- Potential spike in tOPV demand in months before switch
- Need to build up bOPV buffer
- Potential demand changes

**Risk of excess stocks of tOPV after switch**
- Challenge of balancing risk of shortages vs excess supply

**Uncertainties in programmatic milestones**
- Not in line with industry timelines - requires contingency planning
- Delayed switch will require a demand of at least 500 million doses of additional tOPV for a 1 year delay
Objectives for supply management for the global tOPV/bOPV Switch

**Global supply planning**

- Ensuring sufficient global supply of tOPV for SIA activities and routine before the switch
- Minimizing residual stocks of bulk type 2 and tOPV with manufacturers
- Ensuring sufficient global bOPV supply to roll out in all countries for routine requirements before March 2016
- Ensuring available supply of filled and released mOPV2 before April 2016

**Efficient operationalization of the switch**

- Minimizing residual stocks of tOPV in countries
- Ensuring no stock outs in routine due to insufficient funding or delays in deliveries
Considerations for efficient implementation of the switch

Procurement processes and timelines for timely accessing bOPV for routine
  • Through UNICEF vs. self-procuring countries

Managing stock levels with countries
  • Monitor stock levels throughout 2015

Pre-positioning bOPV stocks
  • Logistically complex operation for suppliers, freight forwarders, UNICEF

Registration requirements for bOPV a consideration
What are we doing to ensure a smooth transition

• Strategy development focusing on risk mitigation for both global supply and upstream operational implementation

• Working with Partners on global forecasting to provide as clear as possible projections for the Switch

• Preliminary discussions with industry on Switch planning and potential contingency and risk mitigation requirements

• Participating in various work streams (IMG implementation group, communications, financing) on Switch planning to ensure supply component integral for planning with countries
Asks for manufacturers

Due to planned switch and dynamic nature of program, continued uncertainty on longer term demand including split by type
- Flexibility required regarding lead times for split 2H 2015/2016
- Updated information on licensing status?
- Continued early communication on constraints
- Ensure buffer of supply related to switch
- What strategies could be considered to ensure no shortages of product and to minimize risks of excess stocks

Current tender covers projected requirements including for 2017
- When would manufacturers need to have visibility on OPV requirements 2018 and beyond?
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WHA ask in 2012 for the Endgame Strategic Plan required IPV introductions in 126 countries globally within 20 months.
Why IPV as part of Endgame Strategic Plan?

- All countries to introduce at least 1 dose of IPV in routine schedule to mitigate risk associated with withdrawal of type 2 component of OPV
- Single dose of IPV at 14 weeks of age with DTP3, in addition to OPV3 or OPV4
- Countries have flexibility to consider other schedules
- GAVI supports 1 dose of IPV
Recap of tender and objectives

A tender was issued October 2013 in line with the Procurement Strategy, which was shared with all partners.

The strategy outlined **three procurement objectives**:

- To **secure sufficient supply** to meet an accelerated introduction of IPV for OPV-using countries procuring through UNICEF, for the period of 2014-2017/2018;

- To **achieve affordable prices** from year 1 for all presentations; and

- To support the development of **a healthy IPV market**.

Awards concluded end February, and contracts finalized.
Based on IPV awards and projected demand early 2014, a comfortable supply situation

Towards a healthy market
- Two manufacturers awarded to supply 1, 5 and 10 dose vials
- A third manufacturer expected to be awarded when product is WHO pre-qualified
- Quantity left unawarded in 2018 for manufacturers with pipeline products
- Sufficient supply to meet projected demand based on assumptions
...6 months later, changes in supply and demand required the IMG to discuss criteria for prioritisation.

**Short term supply changes**
- Availability 2014-2015 (-50 mio. ds)
- Delayed availability (3 months)

**Short term demand changes**
- Delayed introductions (-)
- SIA requirements (+ 8-9 mio. ds)
While near term supply is challenging, considerable momentum from countries to introduce before end 2015

- 27 GAVI countries approved
- 37 new applications submitted

**Country product preferences**
- 31 x 10 dose
- 17 x 5 dose
- 13 x 1 dose
Routine introductions may still be feasible in countries procuring through UNICEF by end 2015

Prioritisation criteria as endorsed by Polio Steering Committee in principle

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

*SIA requirements to be capped at the current level

Under the following assumptions, introductions in 2015 can take place:
• Multi Dose Vial policy to be applied and implemented April and July 2015
• Introductions in several tier 3 and 4 countries to be postponed
• Supply does not have to be released to self procuring priority countries
• Additional supply released for India

Any additional supply will contribute to the continued momentum
Prices for IPV 2014-2018 for supply through UNICEF

**Strategic Advisory Group of Experts, April 2014**

‘Concurred that these represent the best possible IPV prices in the near term and constitute a firm basis for proceeding with the goal of global IPV introduction by the end of 2015 as an integral part of the polio endgame strategy.’

<table>
<thead>
<tr>
<th>Product presentation</th>
<th>Validity of price</th>
<th>GAVI supported countries</th>
<th>LMIC/MIC countries</th>
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<tbody>
<tr>
<td>1 dose vial</td>
<td>2014-2017</td>
<td></td>
<td>$2.80</td>
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<tr>
<td>5 dose vial</td>
<td>2014-2017</td>
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<tr>
<td>5 dose vial</td>
<td>2018</td>
<td></td>
<td>$1.50-$1.90</td>
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<tr>
<td>10 dose vial</td>
<td>2014-2018</td>
<td>€0.75</td>
<td>€1.49-€2.40/</td>
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</tbody>
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Prices and country tiers are published at [http://www.unicef.org/supply/files/IPV.pdf](http://www.unicef.org/supply/files/IPV.pdf)
IPV containing combination vaccines

- Some requests to UNICEF for combination vaccines with IPV to avoid 3 injections per visit (to note: currently at least 1 dose is recommended)

- UNICEF issued an expression of interest to have updated market information for IPV containing vaccines including timelines and price indications

- Currently combination vaccines with IPV not yet prequalified by WHO

- Globally, combination vaccines with IPV contains aP. wP IPV combinations are in early development (expected to reach the market earliest 2020)
Asks for manufacturers

Additional IPV doses to be made available for meeting the supply gap in 2014-2015?

Visibility on availability of combination vaccines for the future
In conclusion

**OPV**
- Sufficient supply to meet programmatic requirements
- Stock levels increasing to meet Q1 2015 needs
- Additional awards may be required

**From tOPV to bOPV**
- Strategic supply planning to ensure appropriate vaccines
- Support supply planning and country transitions

**IPV**
- Countries are stepping up to WHA commitments
- Short term supply gap for 2014-2015 of +10 million doses
- Demand management required to meet end 2015 introductions
Thank you