Market Update

Inactivated Polio Vaccine (IPV)

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Outline of presentation

• Background information
• Update on supply & demand for 2016 & 2017
• Initial forecast for 2018
• Next tender update
Overview of current market for IPV supply

GPEI *Polio Eradication and Endgame Strategic Plan, 2013-2018* called for 126 OPV only using countries to introduce at least one dose of IPV into their immunisation schedule prior to the Switch from tOPV to bOPV

- 5 manufacturers with WHO prequalified product(s)
- Currently UNICEF has LTAs with two manufacturers for 2014 to 2018
  - Sanofi 10 dose vial
  - Serum Institute of India/Bilthoven Biologicals 1 and 5 dose vials
- Other manufacturers are currently not able to offer quantities during this period
Situation up until October 2016

Polio Strategy Committee’s Applied Principles for Allocating the IPV supply

1. Ensure adequate IPV supply to meet current and future needs of Afghanistan, Pakistan to ensure interruption of WPV transmission

2. Sustain use of IPV in routine immunization programme in highest risk countries (Tier 1 and Tier 2)

3. Ensure sufficient quantities of IPV are available for outbreak response post-switch

4. Provide clarity to Tier 3 and 4 countries regarding supply availability so they can adequately plan

Outcome of applying these allocation principles to address earlier reductions in IPV were

1. 50 tier 3 and 4 countries were informed early this year that they would not receive IPV until Q4 2017

2. The availability of doses for SIA & outbreak response were delayed
Supply and demand for 2016 & 2017 reflecting latest reductions in supply

- Consequences are supply gaps in availability in Q1 2017 and in Q4 2017
Interventions agreed with the Polio Strategy Committee: Immediate term Q1 2017

- Outbreak reserve delayed to 2018
  - No IPV available to respond to type 2 outbreaks
  - No additional IPV for SIAs in endemic countries

- Shipments to 12 tier 2 countries delayed by 3 months
  - Some countries will likely have to interrupt programmes

- 4 to 5 tier 1 countries shipment postponed by up to 2 month
  - Likely to stock out at central level
Supply and demand for 2016 & 2017 following interventions

- Supply gap in Q4 2017 continues
Interventions & principles agreed with the Polio Strategy Committee: Longer term Q4 2017

• Ensure that when countries start to receive IPV (again) supply will be sufficient to avoid further interruptions
  – Establish a minimum supply buffer which will be used in projection of when the tier 3 & 4 countries start to receive IPV

• Countries moving to a fIPV 2 dose will be prioritised for (re)supply
  – Reduce the length of time children are not receiving IPV and the size of the birth cohort that has not received a type 2 vaccine

• Countries will be prioritised for IPV supply based on risk:
  1. Tier 3 countries that had introduced to be resupplied
  2. Tier 3 countries that have not introduced will receive first shipments
  3. Tier 4 countries that had introduced to be resupplied
  4. Tier 4 countries that have not introduced will receive first shipments
  5. Catch up of missed children in line with SAGE recommendation
Projected IPV availability and demand for 2018

All manufacturers – prequalified and pipeline - have been contacted about supply availability of 2018

- Demand forecast is based on estimated country requirements
- Catch up requirements: assume 17 months birth cohort for countries that have not introduced and 12 months for countries that will only be resupplied in Q4 2017
IPV tender objectives (DRAFT)

• To improve the health of the market

• To ensure sufficient supply of IPV so that:
  – All countries can provide at least one doses of IPV in their routine programme
  – All children that have not received a doses of IPV at 14 weeks of age since May 2016 have the opportunity for catch up immunisation
  – The GPEI would have access to IPV to respond to outbreaks of WPV and cVDPV

• Achieve a price that will be affordable for countries and donors

• Provide market intelligence to assess feasibility of meeting a policy recommendation of two IPV doses?
HEALTHY MARKETS FRAMEWORK

Healthy Markets Framework

Attribute Tier

1. Supply meets demand

2. Accommodate Country Presentation Preference

3. Buffer Capacity

4. Individual Supplier Risk

5. NRA Risk

6. ↑Total System Effectiveness

7. ↑Long Term Competition

8. ↑Product innovation

Increasing Cost

Cost1 WAP1
Cost2 WAP2
Cost3 WAP3

1. Lowest Theoretical
2. Lowest Reasonable
3. Inadequate Supply

Developed jointly by BMGF, Gavi and UNICEF

Today
IPV tender – Questions for manufacturers

• What should be the duration of the tender?

• When do awards need to be made to ensure sufficient lead times for manufacturers to secure timely supply as of January 2019 (this will determine when the tender should be issued)?

• Given the uncertainties in demand, would manufacturers like to see different scenarios?
What should be the duration of the tender?

• Assumptions on interruption of transmission and OPV vaccine usage:
  – WPV is interrupted in mid-2017
  – Polio free certification will be mid-2020
  – OPV cessation mid-2021

• Should there be a recommendation for a second dose of IPV to be added to the routine schedule this would be before OPV with cessation so for beginning of 2021

• Tender covering requirements until the end of 2021 (3 years) would facilitate offers from manufacturers to meet a 2 dose schedule.
  – This would inform market capacity to meet a possible 2 dose schedule

• Would a tender period for a longer period of time (say 4 years) support manufacturers to make proposals that better meet the objectives?
When do manufacturers need to be informed of awards?

- Manufacturers have indicated that the total production time for IPV from bulk until released product is between 18 to 24 months.

- Using this timeframe
  - tender should be issued in Q1 2017
  - awards concluded by end Q2 2017

Is there flexibility from manufacturers to postpone the tender to the end of 2017? What would be the potential risks to supply if any?

- If the tender issuance was after the SAGE meeting (April or October 2017) where there is expected to be a recommendation on the future IPV schedule and duration of immunisation
  - This would allow for a more accurate estimates of demand to be included in the tender
Given the uncertainties in demand, would manufacturers like to see different scenarios?

• Currently there is a recommendation for at least 1 doses of IPV to be added to routine schedules. However, SAGE may recommend 2 or more doses prior to the withdrawal of OPV. The SAGE recommendation on this is expected in April/October 2017.

• The tender could include 2 scenarios:
  – assuming the current recommendation doses not change
  – if there is a recommendation to add a second dose of IPV at the time of OPV cessation

• There will also be a demand for catch up immunisation for any eligible birth cohort that has not received a dose of IPV since May 2016

• Possible requirements for IPV to be used in response to SIAs and any outbreak of WPV or VDPVs
Current IPV tender timelines

• IPV procurement strategy being developed

• Tender to be issued in Q1 2017 (pre-tender industry consultation)

• Awards to be made by mid 2017