Overview of Polio Vaccine Supply and Demand through UNICEF
Meeting changing supply requirements during the Polio Endgame

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

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

3. **Containment and certification**

4. **Legacy planning**
OPV procured for routine and SIAs and weighted average price, 2000-2015

- A decade of collaboration on innovations to achieve programmatic outcomes
- SAGE reconfirmation 20 October to discontinue use of type 2 containing OPV in April 2016
- Cessation of tOPV market reducing risks and complexities post Switch
Global supply planning with suppliers and partners to mitigate OPV supply risks related to Switch

**Objectives**

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

**Activities**

- First meetings with industry 2014 on Switch; regular updates and transparency (face to face meetings, calls etc.)
- Coordination with GPEI partners to provide accurate forecasting
- Regular monitoring of supply and demand; additional awards
- Coordination with industry & WHO on bOPV registrations
- mOPV2 tender and awards

**Complex undertaking at global scale requiring close coordination, flexibility and full transparency across all stakeholders**
Global demand planning with countries to ensure efficient operationalization of Switch

**Objects**

- Ensuring **no stock outs or delays in routine** due to insufficient or delayed funding for tOPV and bOPV
- **Minimizing residual stocks** of tOPV in countries
- Ensuring **timely delivery of bOPV** for introduction in routine immunization

**Activities**

- Guidance, tools, webinars, workshops
- Requesting tOPV stock levels before deliveries (SIA)
- Confirmation of routine requirements prior to placing purchase orders
- Early bOPV planning to ensure timely availability at sites, monitoring progress to identify challenges for early resolution
- Coordination with partners to ensure timely access for self-procuring countries to bOPV

**Key ask to industry to ensure flexibility and timely access to tOPV and bOPV for all countries, including self-procuring countries**
Ensuring the right quantity of tOPV to meet programmatic needs - avoiding stock outs and over supply

- SIA calendar approved by GPEI September through to Switch requiring +400 mds for Q1 2016 to prevent cVDPV2 post Switch
- Maximising production and building up stocks in 2015 to meet demand
- UNICEF working with partners and countries to take early delivery
## Preventing VDPV2 Emergence: Extensive tOPV SIAs

**Sept 2015-March 2016**

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*Source: WHO*
Rolling out bOPV in +70 countries requires logistics coordination suppliers-freight forwarders-UNICEF

- Regulatory process for label change from SIA to include routine usage concluded in all countries of production
- Shipments for +70 countries for routine introduction planned to be phased between November-March
Meeting OPV requirements for Objectives 1 and 2: 2015 achievements and key challenges

2015 achievements

- Almost 100% of planned and unplanned SIAs met – and in a timely manner
  - Additional awards of +400 mds (including covering a loss of +140 mds from one supplier)
  - Phasing in one new supplier

- Setting the stage for the Switch
  - Expected total 600 mds required during Q1 2016 vs 350 mds Q1 2015 – all doses needed
  - Possible shipping challenges (dry ice, freight capacity, logistics capacity with suppliers etc.)
  - Requires transparency, flexibility and close collaboration to overcome exceptional challenges
WAY FORWARD - 2016 and beyond

- Demand for future years uncertain, dependent on Pakistan, Afghanistan achieving polio-free status, Nigeria/Africa maintaining its polio-free status; outbreaks of cVDPVs
- Review OPV demand with Program for 2016 & 2017 (Q4 2015 – Q2 2016)
- Long-term demand/supply planning, procurement strategy development for post-2017 (Q2 2016)

Next OPV tender projected for 2H of 2016
Meeting changing supply requirements during the Polio Endgame

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3. **Containment and certification**

4. **Legacy planning**
IPV procurement through UNICEF

- 2010-2013 UNICEF procured 100,000-600,000 doses annually on behalf of 2-5 countries

- UNICEF issued the current tender in October 2013 for IPV to support SAGE recommendation for all countries to introduce at least 1 dose of IPV - 126 OPV-only using countries
  - Four manufacturers with a WHO prequalified IPV
  - UNICEF established contracts with two manufacturers for 3 product presentations

- In 2015/2016, UNICEF is set to procure for 83 countries
  - 73 Gavi supported
  - 10 Middle Income Countries

Some self procuring countries only now realising that they are not able to access IPV or IPV containing combination vaccines in global market
IPV supply availability reduced since initial awards leading to supply constraints globally

At time of initial awards, offers from manufacturers projected that there would be sufficient IPV available to allow all countries to introduce before the end of 2015.

Several rounds of reduction from manufacturers caused by
- Under-estimating the time to scale up bulk production
- Long internal lead times for release of product (bulk & finished product)
- Production issues related to fill/finish
- Delays in licensure
Demand for IPV increasing including to achieve eradication outcomes

Demand increase

- IPV required to eradicate wild polio viruses and to respond to cVDVP2 outbreaks - +10 mds
- Set aside reserves for outbreaks post Switch
- Other unplanned demand
  - India
  - MICs
- Starting to materialize: Increased demand from Gavi countries for routine use as originally approved quantities were based on UN data for target population and coverage from WHO/UNICEF

Overall, exceptional commitment from countries to add at least 1 dose of IPV – 46/126 countries introduced between 1st January 2013 until mid October
Supply and demand 2015 – 2016 as of today across all product presentations

IPV monthly demand by product presentation; cumulative supply balance

Additional supply is required to avoid delay in country introductions
Mitigating steps taken to balance supply and demand while achieving programme objectives

- Allocation criteria endorsed by the Polio Steering Committee applied since 2014, prioritizing countries at high risk
- Accelerated review of data on IPV vaccines to assess application of Multidose Vial Policy
- Close follow-up with countries before and after introduction to optimize supply allocations
- Exceptionally, tender issued for India demand to procure locally licensed vaccines for use locally
- Delaying first shipments to July 2016 (post Switch) to around 20-25 countries considered at low risk for reintroduction of polio
- Requesting countries to change product presentations based on availability
- Under current allocation schedule, countries are required to use buffer stocks and to accept additional annual shipments to maximize utilization of available supply
Strategic considerations

- Possible expanded use of IPV in eradication efforts?
- India’s ability to meet short term needs locally?
- Innovations (timelines, implications for supply including prices?)
  - sIPV
  - Fractional dose
How industry can engage with UNICEF to meet the needs of children?

Next tender planned for 2017

High level objectives:
- Affordable prices
- Additional suppliers
- Sufficient supply

Industry can support UNICEF in resolving challenges and meet programmatic objectives by:
- Meeting supply commitments made - communicate transparently and timely on challenges (optimise internal processes for early information?)
- Making additional doses available during 1st half of 2016
- For manufacturers with products in development, provide updates on progress in vaccine development and licensure milestones – and accelerate
Certification of WPV2 Eradication
OPV: Programme and Supply Achievements

Achievements Programme
- Total number of WP1 cases 41 2015 vs 359 in 2014 (Pakistan down to 32)
- No WPV in Nigeria since July 2014 and no WPV in Africa since August 2014
- Number of cVDVP cases has been reduced compared to last year same time (14 in 2015 vs 55 in 2014)
- Nigeria no longer considered endemic (as of last week of September) – only Pakistan and Afghanistan remaining on the list
- Global Certification that indigenous wild poliovirus type 2 has been eradicated (20 September)
- Expected switch from tOPV to bOPV from April 2016

Achievements Supply
- Almost 100% of planned and unplanned SIAs met – and in a timely manner
- Additional awards of 400+ doses in 2015 and securing supply for the planned activities and outbreak responses
- Flexibility from Industry by balancing supply to respond to demand and epidemiology changes
Status on stockpile of mOPV2 for post Switch outbreaks

- Contracts with 2 manufacturers for the bulk types 1, 2 and 3

- Tender issued in Q1 2015 for 100 mds in finished mOPV2 product to be available between March and July 2016

- Awards for 50 mds made, with another 50 mds to be made shortly

- Use of doses in accordance with operational framework established by WHO, with release for any country in case of outbreak upon confirmation from the WHO Director General