

Inactivated Polio Vaccine: Supply Update

UNICEF Supply Division

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Inactivated Polio Vaccine Supply and Demand Update September 2016

This note provides an update on **inactivated polio vaccine (IPV)** supply and demand for 2016-2018. UNICEF projects supply to be constrained through 2017 on account of reduced availability from manufacturers and increased country demand. To manage the shortage in supply, all Tier 3 and Tier 4 countries procuring through UNICEF will not receive IPV until 4Q 2017, except those that administer IPV as a first dose in polio vaccination schedules.

1. Summary

- UNICEF had originally awarded 111 million doses a year for 2016 and 2017. However, as of May 2016, manufacturers could only confirm 50 million doses for 2016 and 55 million doses for 2017, representing a reduction through UNICEF of 55 percent and 51 percent respectively.
- UNICEF made additional awards in 2015 to two Indian suppliers with locally licensed vaccine for in-country supplies, increasing total availability in 2016 by nine million doses to 59 million doses.
- Manufacturers continue to report technical difficulties in scaling-up IPV bulk production, accounting for the reduction.
- Consequently, UNICEF is allocating all available vaccine supply against criteria established by the Global Polio Eradication Initiative's (GPEI) Polio Oversight Board (POB).¹
- All Tier 3 and Tier 4 countries procuring through UNICEF that do not give IPV as a first dose in their polio vaccination schedules, will not receive IPV until 4Q 2017.
- UNICEF anticipates the current IPV constrained supply to persist through at least end-2017.

2. Background

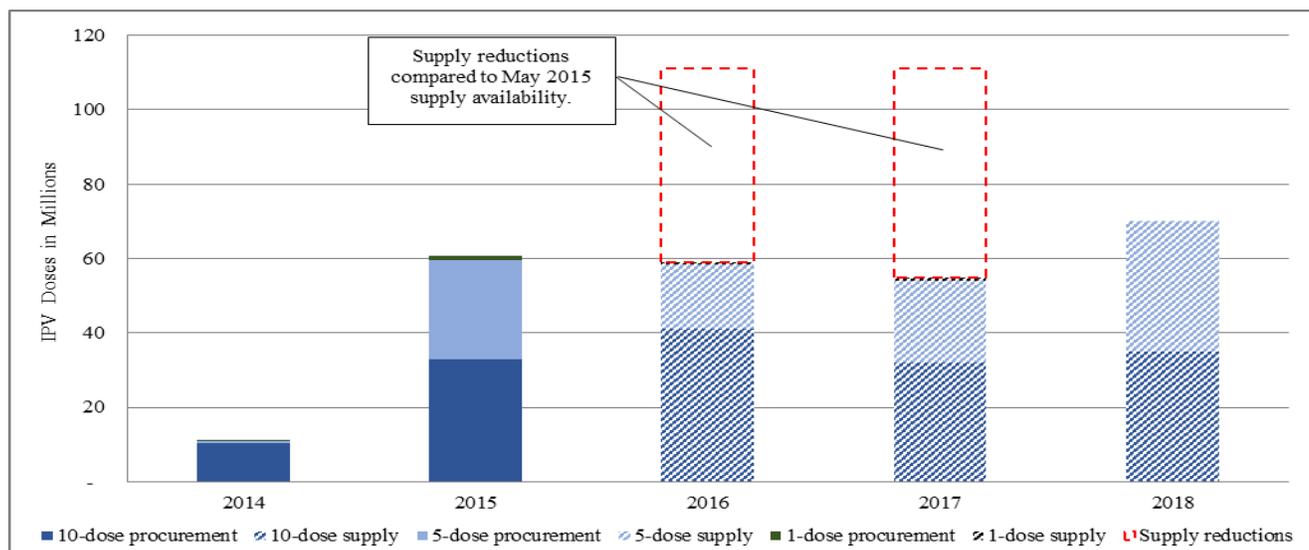
In October 2012, the World Health Organization's (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) advised all countries to introduce at least one dose of IPV into their routine immunization (RI) programmes prior to the global withdrawal of type 2 containing oral poliovirus vaccines (OPV2) by April 2016. Most countries planned to introduce IPV into their national RI programmes by end-2015. As of June 2016, 106 new countries, out of 126, have introduced IPV into their schedule from 2013, which makes IPV the new vaccine with the fastest uptake to date.

3. IPV Supply Availability for 2016 and 2017

IPV supply availability in all product presentations decreased substantially for 2016 and 2017 compared to UNICEF's initial quantities awarded to manufacturers. UNICEF anticipates supply availability to reach 50 million doses for 2016, and 55 million doses for 2017, having reduced from 111 million doses per year when compared with the original awards (Figure 1). When adding locally sourced supply for in-country deliveries in India, total available supply increased to 59 million doses against total awarded doses of 120 million doses. One global manufacturer reduced the quantities available to UNICEF over 2016-2017 by 76 million doses, to reach 64 million doses, from an original award of 140 million doses. The manufacturer in question will separately supply some doses bilaterally to two of Gavi's, the Vaccine Alliance (Gavi), self-producing countries. Another manufacturer reported a 50 percent reduction in availability compared to their original award.

¹ The POB consists of representation by the heads of agencies from the GPEI (Bill and Melinda Gates Foundation (BMGF), Centers for Disease Control and Prevention (CDC), Rotary, UNICEF and WHO).

Figure 1 UNICEF IPV Procurement and Forecast Supply Availability by Product Presentation 2014-2018*

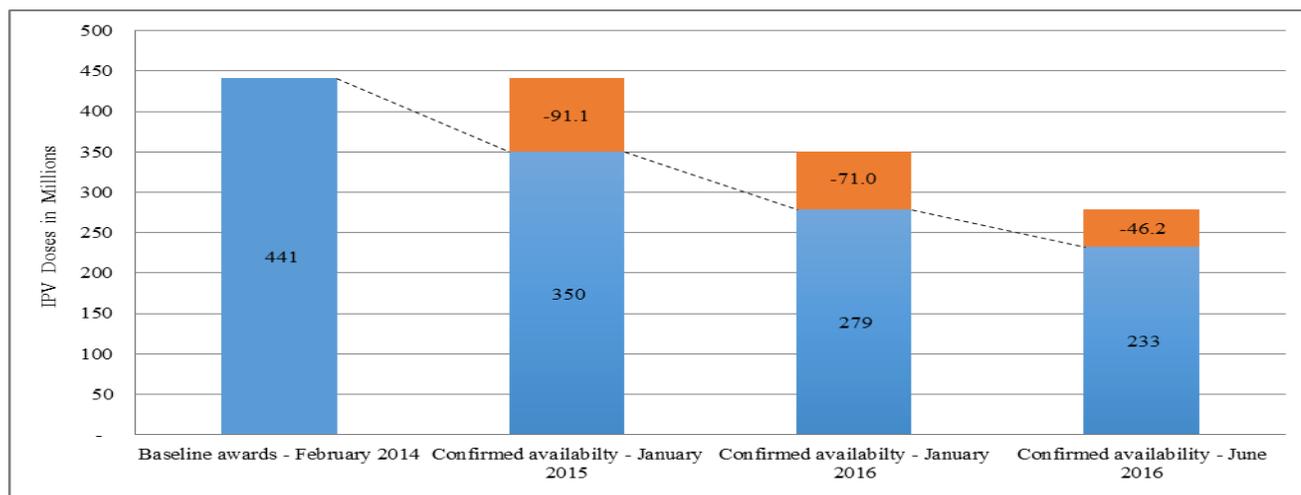


Source: UNICEF Supply Division.

Note*: Total 2016 forecast supply includes the additional 9 million doses awarded under the India specific tender.

Doses procured in 2014-2015 reflects the number of doses placed on purchase orders as per standard reporting instead of doses delivered. For 2015, as in any other year, some of the doses procured were for delivery in the 2016. Due to the reduced supply availability in 2016, UNICEF cancelled a number of doses placed on purchase order for 2015 in 2016. So even though UNICEF procured 60.6 million doses in 2015 (Figure 1), total doses delivered were 47.9 million. 2016 and 2017 quantities (Figure 1) reflect forecast projections against confirmed supply from the manufacturers. Quantities for 2018 reflect awarded supply on long-term arrangement (LTA). Forecasted availability is expected to be available by October 2016. Figure 2 describes the incremental step changes to overall 2014-2018 supply availability to date (June 2016).

Figure 2 Incremental Changes to IPV 2014-2018 Supply Availability Over 2014-2016 Compared to Initial Awards†



Source: UNICEF Supply Division.

Note†: Figure 2 does not reflect the additional 9 million doses awarded under the India specific tender.

The most recent reductions in supply availability were communicated to UNICEF in February 2016.² A number of factors experienced by manufacturers account for delayed and reduced supply availability. They include technical issues affecting the scale-up of bulk production; delays in the release of bulk and finished products; the installation of new equipment used for scaling up filled and finished product; as well as competing priorities within manufacturers. Each reduction or delay in supply availability triggers a review of total supply and demand with partners to identify the consequences and possible mitigation measures.

4. IPV Demand Projections

Most countries procuring through UNICEF established IPV RI introduction plans for end-2015. The plans included detailed timelines for vaccine launch, training activities, advocacy, and social mobilisation. Out of the 83 countries that planned to procure through UNICEF, UNICEF has supplied 63 with IPV. However, due to constrained IPV supply availability, the remaining 20 countries are required to postpone IPV introductions until 4Q 2017.

There are a number of critical assumptions and inputs that inform UNICEF's current aggregate projections in demand:

- Countries RI demand is currently projected and capped based on WHO/UNICEF national immunization coverage estimates and coverage rates. UNICEF anticipates actual country demand could be higher after country IPV introduction, as some WHO/UNICEF country data (i.e. target population and/or coverage rates) are considerably below the estimates provided by the countries in their application to Gavi for support to cover the costs of vaccine procurement.
- UNICEF does not expect a change in how country requirements are calculated, until the supply situation improves, anticipated for 2018. However, it may be necessary to increase IPV allocations to Tier 1 and 2 countries to avoid stock outs, should the quantities approved for countries turn out to be too low.
- In addition to the Gavi-funded demand for IPV, GPEI established forecasts for IPV use in Supplementary Immunization Activities (SIAs) in polio-endemic countries and outbreak response to circulating vaccine-derived poliovirus type 2 (cVDPV2) following the switch. GPEI estimates requirements to reach 11 million doses by the end of 2017.
- Furthermore, 16 middle-income countries (MICs) have requested IPV supply through UNICEF, of which 14 are countries that do not usually procure vaccines through UNICEF. Nine of these MICs have been promised catalytic support by GPEI in the form of 12-months' worth of IPV supplies.

2016-2018 IPV demand forecasts assume that 12 MICs will continue to procure through UNICEF after they conclude GPEI's 12-month catalytic support for vaccine procurement. UNICEF also anticipates that India will self-procure IPV from 4Q 2016. UNICEF assumes vaccine requirements for SIAs and outbreak response of approximately five million doses annually (through 2017-2018).

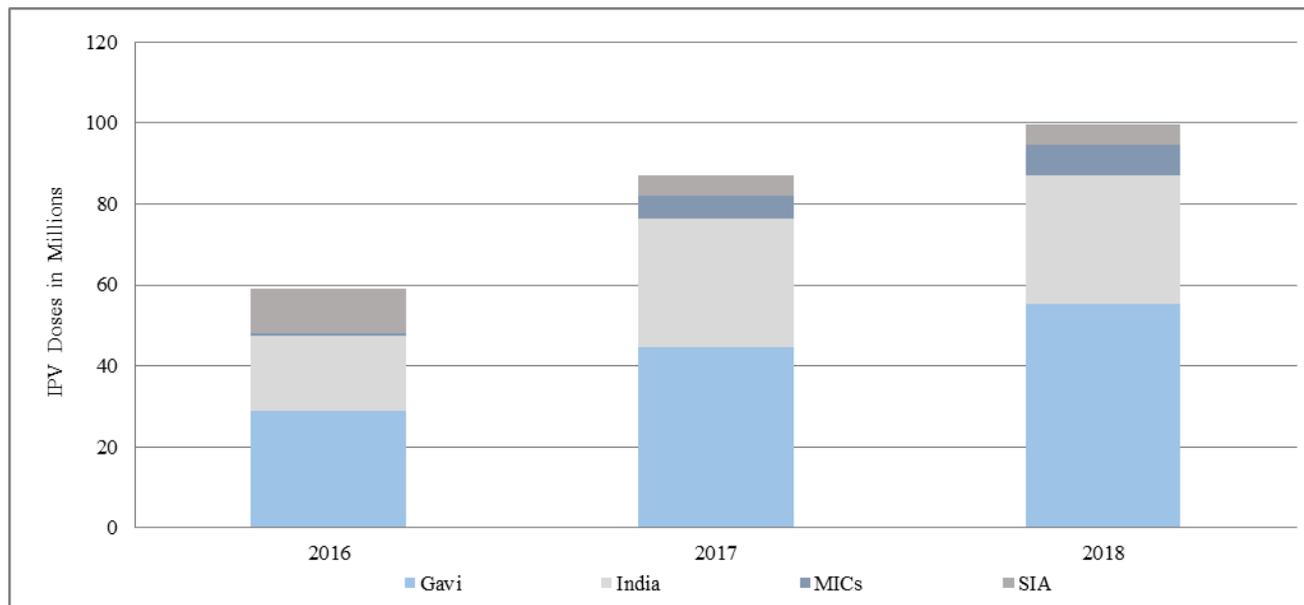
The current forecast assumes Gavi will continue to recommend and financially support a one-dose schedule for the 71 Gavi-supported countries through end-2018,³ though the SAGE Polio Working Group will review the forecast assumptions by 4Q 2017. The forecast does not include doses that may be needed to cover birth cohorts that have not received doses of IPV in countries that will only introduce in 4Q 2017, or due to any programme interruptions due to supply shortages. The forecast also includes

² UNICEF, [Inactivated Polio Virus: Supply Update](#), UNICEF, Copenhagen, May 2015.

³ Two of Gavi's 73 countries (Georgia and Ukraine) have decided to introduce in a combination vaccine, and so are not supported through Gavi for a one-dose schedule.

demand from India, although as aforementioned UNICEF assumes that India will self-procure and self-finance as of Q4 2016.

Figure 3 IPV 2016-2018 Demand Forecast



Source: UNICEF Supply Division.

UNICEF, WHO, and Gavi, anticipate demand will continue to change as countries roll out IPV through their RI programmes. The Immunization Systems Management Group (IMG) will review any requests from Tier 1 and Tier 2 countries requiring additional doses above the quantities approved in line with established criteria, as any adjustments will affect the GPEI’s ability to fulfil vaccine requirements for other strategies. Given current supply constraints, UNICEF requests all countries to manage their IPV supplies carefully and to reduce wastage as much as possible.

5. Supply and Demand Imbalance and Actions Taken to Mitigate Implications

UNICEF anticipates IPV supply constraints to remain at least through 2017 based on current estimates. While UNICEF and partners continue to work with manufacturers to improve supply availability, UNICEF does not foresee additional supply materialising before 2019 from either current manufacturers, or new manufacturers with products in development. As a result, UNICEF considers the management of demand to be the only means of mitigation at this time while continuing to work with current suppliers.

Since October 2014, grouping countries into tiers based on the level of risk of a cVDPV2 outbreak continues to be the main consideration by which UNICEF allocates the limited supply that is available.

In October 2015, SAGE recommended OPV2 withdrawal to proceed despite constrained IPV supply (Annex B). Since SAGE made its recommendation supply has been further reduced, and lead times for access to IPV supply have increased for some countries. As such, the POB endorsed the principles of allocating available IPV supplies that best meet the polio programme’s goals, as follows:

- To ensure adequate IPV supply meets the current and future needs of remaining polio endemic countries, Afghanistan and Pakistan, to enable the interruption of wild poliovirus transmission.

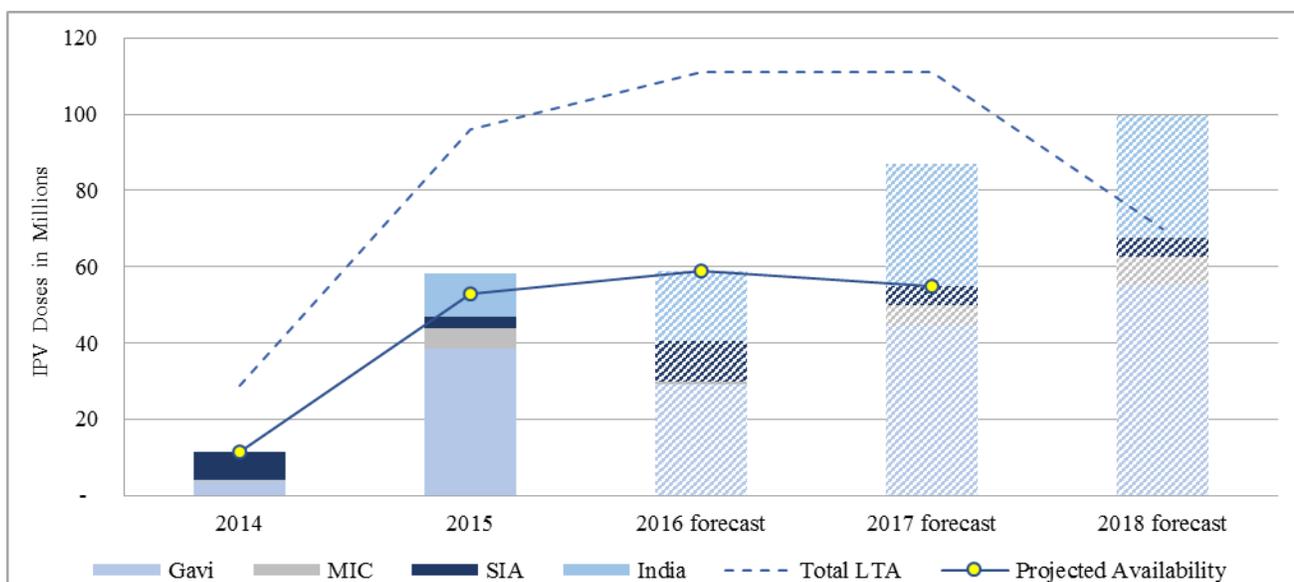
- To sustain IPV use in RI programmes in countries at highest risk (Tier 1 and Tier 2) countries.⁴
- To ensure sufficient IPV quantities are available to support outbreak response after the switch from trivalent OPV (tOPV) to bivalent OPV (bOPV).
- To clarify and inform lower-risk (Tier 3 and Tier 4) countries of supply availability and delivery timelines to support effective programme planning and avoid ad-hoc delays.

The implications of the POB recommendation for countries procuring through UNICEF are:

Effective April 6th, 2016, all IPV shipments to countries considered at lower risk of a circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak after the switch from tOPV to bOPV (Tier 3 and Tier 4 countries) are stopped until sufficient supplies become available, currently anticipated by 4Q 2017.

IPV revised supply availability decreased substantially compared to UNICEF’s initial LTAs with suppliers, and consequently demand has been suppressed for 2015 through to 2017 (Figure 4).

Figure 4 IPV 2014-2018 Supply, Availability, and Suppressed Demand‡



Source: UNICEF Supply Division.

Note‡: Total 2016 projected availability includes the additional 9 million doses awarded under the India specific tender.

Table 1: Overview of Countries Procuring IPV through UNICEF Affected by Delays

	Tier 3 countries	Tier 4 countries
Countries that have already introduced IPV	Bangladesh, Burundi, Côte d’Ivoire, Guinea-Bissau, Iran, Nepal, Senegal, Sudan.	Bhutan, Cabo Verde, Comoros, Djibouti, DPR Korea, Gambia, Lesotho, Maldives, Morocco, Pacific Islands, Sao Tome and Principe, Seychelles, Sri Lanka, Swaziland.
Countries that are yet to introduce IPV	Angola, Burkina Faso, Egypt, Eritrea, Liberia, Mongolia, Sierra Leone, Tajikistan, Turkmenistan.	Ghana, Kyrgyzstan, Malawi, Moldova, Rwanda, Tanzania, Togo, Uzbekistan, Viet Nam, Zambia, Zimbabwe.

Source: UNICEF Supply Division.

⁴ World Health Organization, [Definition and Rationale of Risk Tiers for IPV Introduction](#), WHO, Geneva, October 2013.

The suspension of shipments until 4Q 2017 will affect all Tier 3 and Tier 4 countries procuring IPV through UNICEF that do not have IPV as the first dose in their national programmes (Table 1).

UNICEF and WHO have directly informed all affected countries. Programmatic guidance is available for all affected countries in an information note entitled “[the introduction of IPV, the OPV switch, and risk mitigation](#)” available here:

http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/Update_on_supply_constraints_for_IPV-APRIL2016-final.pdf

6. Pricing

UNICEF publishes IPV prices for Gavi supported and non-Gavi countries, and is available [here](#). SAGE concurred in April 2014 that the published prices 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.

7. Additional Awards for 2018 and New Tender for 2019 onwards

In February 2014, UNICEF decided not to fully award the projected demand for 2018 based on indications that new suppliers and new technologies could become available (e.g. fractional doses, adjuvanted or Sabin IPV). UNICEF is presently assessing the market before proceeding with any additional awards in 3Q 2016.

UNICEF anticipates issuing a new tender for IPV requirements covering 2019 onwards in 1Q 2017. UNICEF will consult with partners and industry as to the duration period of the tender, together with other strategic aspects, as well as different demand scenarios.

8. Availability of IPV in Combination Vaccines

UNICEF has registered increased interest from countries for IPV-containing combination vaccines. At a global level, some countries have licensed IPV-containing combination vaccines with acellular pertussis (aP), of which one acquired WHO prequalification in December 2014. UNICEF issued an expression of interest to industry end-2014 to understand supply availability timelines. Industry responses indicate that vaccine supply is currently considerably constrained, and any quantities would only be available through UNICEF as of 2018. UNICEF issued a tender for aP combination vaccines in February 2016. The outcome reconfirmed that the earliest availability would be 2018 for a combination IPV with aP, and at the earliest, 2019 for a novel vaccine with whole cell pertussis (wP).

For additional information on IPV introduction planning and prices, please refer to the following links:

Resources for planning and IPV:

http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/

IPV price and product information:

http://www.unicef.org/supply/index_57476.html

http://www.unicef.org/supply/files/Product_Menu_31_March_2015.pdf

ANNEX A

AWARDED PRODUCT PRESENTATIONS AS OF SEPTEMBER 2016

	Vial of 10 doses of IPV	Vial of 5 doses of IPV	Vial of 1 dose of IPV
Manufacturer	Sanofi Pasteur	Bilthoven Biologicals B.V.	Bilthoven Biologicals B.V.
Country of manufacture	France	Netherlands	Netherlands
Date of prequalification	09 December, 2005	28 November, 2014	06 December, 2010
NRA of record	ANSM	Medical Evaluation Board (MEB)	Medical Evaluation Board (MEB)
Pharmaceutical form	Liquid	Liquid	Liquid
Presentation	10 dose vial	5 dose vial	1 dose vial
Route of administration	Intramuscular injection sub-cutaneous	Intramuscular injection sub-cutaneous	Intramuscular injection sub-cutaneous
Vaccine Vial Monitor	VVM7	VVM7	VVM7
Shelf life	36 months at 2-8°C	36 months at 2-8°C	36 months at 2-8°C
Secondary packaging	10 vials of 10 doses	Akylux tray of 280 vials	Akylux tray of 360 vials
Cold chain volume per dose (cm ³)	2.46	4.04	15.7
Preservative	Phenoxyethanol 5mg/ml	Phenoxyethanol 5mg/ml	Phenoxyethanol 5mg/ml
Handling of multi-dose vials	WHO recommends that opened vials can be kept up to 28 days	WHO recommends that opened vials can be kept up to 28 days	n/a
Indicative wastage rate	20%	15%	5%
Package insert	http://www.who.int/immunization_standards/vaccine_quality/IMOVAX_Polio_sanofi_pasteur_product_insert_Sept_2009.pdf	http://www.who.int/immunization_standards/vaccine_quality/pq_282_IPV_Bbio_PI.pdf?ua=1	http://www.who.int/immunization_standards/vaccine_quality/pq_231_ipv_1dose_bb_product_insert_nov2012.pdf
Status of availability	Limited availability for 2016-2017	Limited availability for 2016-2017	Limited availability for 2016-2017
Price per dose	Gavi-supported countries €0.75 MICs €1.49 - €2.40	\$1.90§	\$2.80

Note§: based on awarded quantities, UNICEF anticipates countries to access a price of \$1.50 in 2018.

A list of WHO prequalified vaccines can be viewed here: https://extranet.who.int/gavi/PQ_Web/

Awarded prices are available on the UNICEF web site at: <http://www.unicef.org/supply/files/IPV.pdf>

ANNEX B

SAGE Recommendation for OPV2 Withdrawal to Proceed Despite Constrained IPV Supply

In October 2015, SAGE emphasised the switch should proceed despite any delays in country IPV introduction. SAGE based its recommendation on the following compelling risk management rationale:

- IPV has a limited role in preventing Vaccine Derived Polio Virus type 2 (VDPV2) emergence. Its primary value is in minimising the occurrence of paralytic disease in any VDPV2 outbreak after the switch. This value will increase with time after the switch, as the birth cohorts that have not received OPV2 increase;
- The risk of VDPV2 emergence is principally being reduced by an extensive calendar of tOPV supplementary immunization activities in the months before the switch in 43 countries;
- In addition to tOPV campaigns, the highest risk (Tier 1 and Tier 2) countries will introduce IPV before the switch;
- The countries affected by the delay in availability are in lower risk Tier 3 and Tier 4 countries. Population immunity against OPV2 is high in these countries (due to consistently high RI coverage) so the risk of cVDPV2 emergence and spread is minimal;
- All countries will receive IPV supplies within approximately three to five months of the switch. Countries can conduct catch-up vaccination campaigns when sufficient supply is available;
- Finally, global stock of monovalent OPV2 and IPV is available for outbreak response in the event of a VDPV2 detection in any country after the tOPV-bOPV switch.

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Other UNICEF information notes can be found at: http://www.unicef.org/supply/index_54214.html.