

4 The Market Shaping Goal

Shape markets for vaccines and other immunisation products to achieve moderate or high levels of healthy markets dynamics.

Gavi-GPEI Supply and Procurement Roadmap *Inactivated Polio Vaccine (IPV)*

Public Summary

The Need for IPV

World Health Organisation (WHO) prequalified IPV is essential to successfully eradicating polio across the globe, an effort that has already cost \$20 billion worldwide.

Although the oral poliovirus vaccine (OPV) is currently being used to interrupt transmission of wild poliovirus (WPV), the OPV is a live attenuated product that can in rare occasions cause outbreaks of vaccine-derived polio. Therefore, the Global Polio Eradication Initiative (GPEI) can't rely on it to maintain a polio-free world after WPV has been certified as eradicated.

GPEI is planning to stop using OPV as soon as possible after WPV has been certified as eradicated, which is expected to occur in 2020 or 2021. At that point, IPV will be needed to ensure that the poliovirus is never reintroduced.

However, today's IPV market is fragile, without enough near-term supply for all countries to have access to at least one full dose of IPV in their routine immunisation programmes. Longer-term demand, as well as preference for future product choices, carry some degree of uncertainty.

Gavi and market shaping implications

Gavi has been supporting polio since November 2013, through the introduction of IPV into routine immunisation programmes. Due to the exceptional nature of polio eradication, Gavi has defined a number of policy exceptions for IPV. It has planned its support with an assumption that polio eradication will be successful and that use of IPV and any other type of polio vaccine could finish when targets are achieved.

Gavi's support for IPV is currently expected to end in 2024, based on a 2014 recommendation by the WHO Strategic Advisory Group of Experts on Immunisation (SAGE) that IPV is used for at least five years after OPV is ceased. However, in April 2017, SAGE changed this recommendation to ten years. Gavi policy options and timing will be reassessed in 2018.

This roadmap does not address financing for IPV after 2020; a collaboration between GPEI, Gavi, and polio donors is tackling this question. We recognise the high impact of financing on demand variability and factor this funding uncertainty into scenario planning.

We develop our supply strategy, however, based on the assumption that there will be adequate funding for IPV in 2021–2025 after GPEI's financial support concludes in 2020. This roadmap only examines the need for IPV and IPV-combination vaccines. It does not address the need for OPV or novel OPV.

Market overview

The IPV supply and procurement Roadmap is based on the following assumptions about polio eradication and policy choices:

- GPEI achieves interruption of WPV transmission in 2017 or soon after, i.e., the endemic countries of Afghanistan, Nigeria and Pakistan see their last polio cases, and no other countries experience wild polio outbreaks in 2017-2018.
- The Global Certification Commission (GCC) certifies WPV eradication in 2020–2021 and WHO stops using OPV altogether in 2021–2022.
- No containment or outbreak event puts polio eradication at risk after certification.
- Countries continue with one full dose schedule as supplies allow or move to two fractional IPV (fIPV) doses to accommodate supply shortages in the short term.
- Countries that have not been able to introduce IPV before the switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) as well as countries that stopped receiving IPV from April 2016 implement 'catch-up campaigns' to ensure protection of missed cohorts against type 2 polio as supplies allow.

- Based on SAGE's 2017 recommendation, countries with polio-essential facilities (PEF) will continue to maintain IPV immunisation to meet WHO Global Action Plan requirements (to minimize poliovirus facility-associated risk). All other countries will use IPV for at least ten years or longer after OPV cessation based on cost, risk and other needs.

Demand analysis

In the immediate term (2017- 2019), demand for one full dose of IPV will not be met due to highly constrained supply. These constraints provide impetus to countries to consider two doses of fIPV as a means to provide protection against type 2 poliovirus.

The rate at which countries will start moving to fIPV, however, is unclear. Countries that consider fIPV programmatically unsuitable will receive full-dose IPV as soon as supply becomes available.

By 2020, all countries are forecast to have access to either one dose of IPV (i.e. at least Tier 1 countries) or two doses of fIPV (i.e. all other countries) in routine immunisation and enough supply to immunize missed birth cohorts due to the previous constraints.

Post-certification (2021+) IPV demand is more uncertain: all countries will be recommended to implement a two-dose regimen (either full-dose or fIPV) at least one year prior to OPV cessation.

Some countries may continue to use two doses of fIPV in routine immunisation because of cost advantages, whilst others may switch to a two full-dose regimen when supply is available.

Less cost-sensitive countries that plan to immunise with IPV for at least 10 years, or indefinitely, may move to wP-based IPV- combination vaccine, if available.

Supply and Gap analysis

There is no probability of supply meeting one-dose demand in 2017–2019 in most scenarios, as suppliers of WHO-qualified IPV have failed to meet recent supply commitments to UNICEF, and other manufacturers of WHO-qualified IPV don't currently serve UNICEF or Pan American Health Organization (PAHO).

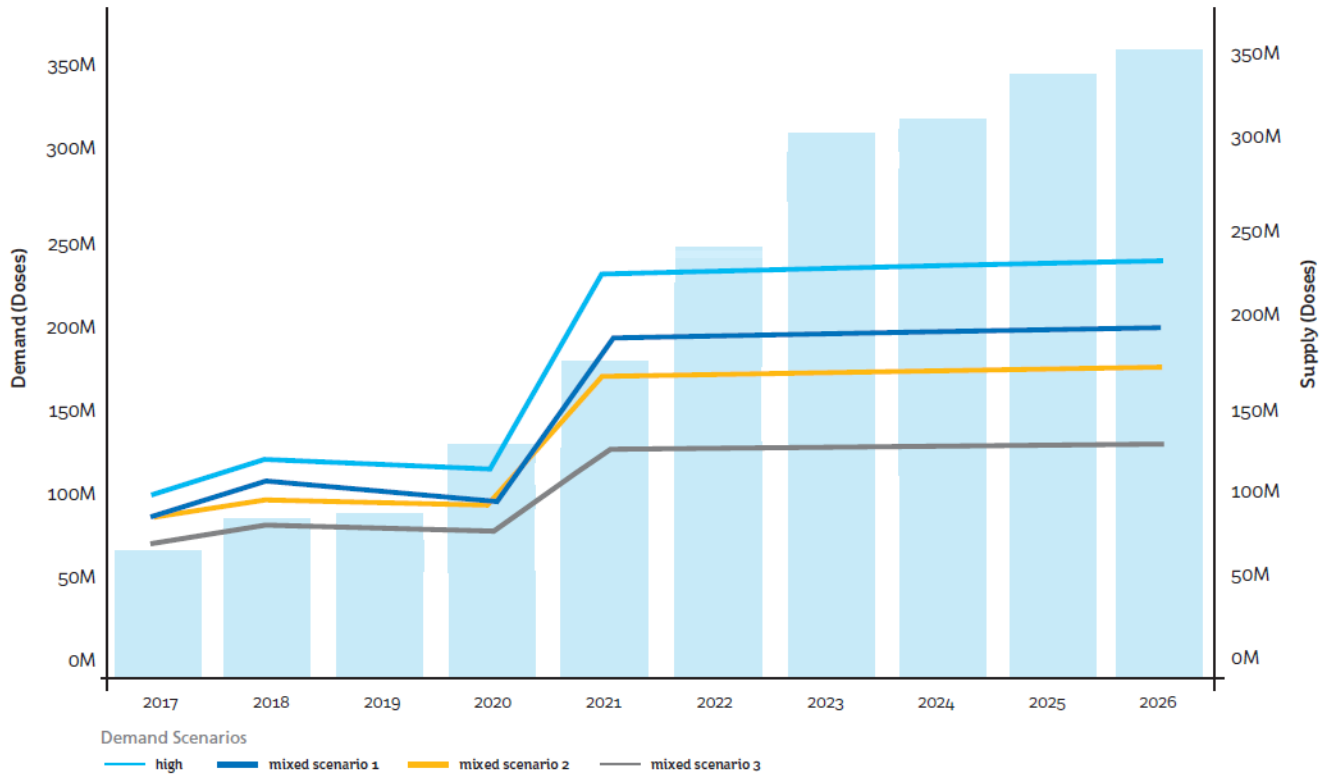
The earliest improvement in the supply situation is likely to come in 2020–2021 when new vaccines achieve WHO prequalification and combined annual supply from new entrants is approximately 80–100 million doses. At that point, Tier 1 countries can start moving to two full doses; and by 2023, all countries are expected to be able to switch to two full doses.

From 2023–2024, IPV markets will start to experience excess capacity when as many as five new manufacturers come to market. The probability of supply meeting demand rises to 100 percent in 2023, with a peak surplus in 2025 of 78 million doses in our high-demand scenario.

IPV Demand Scenarios and Base Case Supply estimates

Demand estimates are based on four potential routine scenarios:

1. Routine High Demand (light blue): one full dose for all countries in 2017–2020 and two full doses 2021+
2. Mixed Scenario 1 (dark blue): India, Sri Lanka, Bangladesh use two doses of fIPV. Remainder of countries have a full-dose schedule
3. Mixed Scenario 2 (yellow): India, Bangladesh and Sri Lanka as well as 21 countries that haven't introduced IPV as of January 2017 on two doses of fIPV. Remainder on one full dose in 2017–2020 and two full doses 2021–2026
4. Mixed Scenario 3 (grey): Tier 1 countries on one full dose in 2017–2020 and 2 full doses from 2021. Remainder on two fIPV doses



Price analysis summary

UNICEF publishes IPV prices for countries procuring through UNICEF, and is available [here](#).

In the short-term, market conditions are not favourable for declining IPV prices but by 2020-21 competition from new entrants will provide more favourable conditions for price declines. From 2023 market conditions and stability are expected to enable lowest pricing. At this time, we expect pricing to stabilise before polio immunisation ceases, with some countries transitioning to IPV-containing combination vaccines for long-term use.

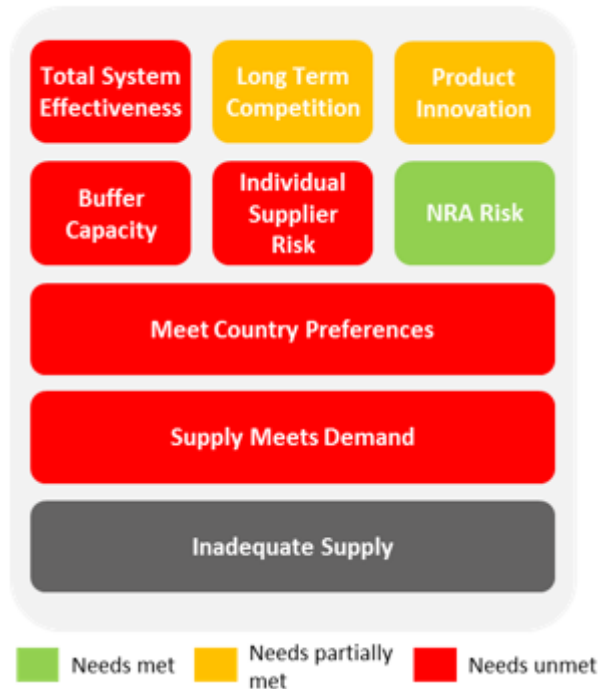
Healthy Markets Analysis

The current IPV market health is low because most of the attributes are either unmet or partially met (as illustrated in the healthy market framework). The major market need is to improve supply to give all countries access to at least one dose of IPV in routine immunisation and to enable immunization of missed birth cohorts. Country preferences for one full dose and vial sizes are also not met due to supply shortages. In this context, any production issue with a supplier constitutes a high risk because there is no buffer capacity.

Moving forward, the demand and supply balance will likely improve by 2020-2021 with the arrival of new manufacturers, which will help secure buffer capacity and leverage competition to drive vaccine affordability. Depending on the choice of fIPV versus full-dose vaccine, country vaccine presentation preferences may change over time.

Gavi's aim is to support actions that will result in the greatest number of children immunised. Given existing knowledge on the current and future vaccines and future market, the market shaping interventions that will have the greatest positive impact on the IPV market will increase supply in line with current country preferences, improve pricing dynamics, while supporting the availability of new innovative vaccines.

Healthy market framework:



Supply and Procurement Objectives and Target Outcomes

The supply and procurement objectives were analysed and prioritised according to timeframe, to potential market shaping impact, and to Gavi's potential capacity to influence the market.

1st priority Objective: balance of supply and demand. High supply constraints resulted in postponing IPV introduction in 18 countries procuring through UNICEF and interrupting supply in 18 other countries. Gavi aims to ensure that sufficient supply of vaccine is available to meet demand and country presentation preference, through five market shaping target outcomes:

- Sufficient supply is available for all GPEI countries to introduce IPV by end of 2018 and sustain the programmes in 2019–2020.
- Domestically produced vaccines satisfy demand in self-procuring countries in line with country product preferences.
- At least four medium to large scale manufacturers supply GPEI/Gavi markets from 2021 with combined capacity of 200M doses to enable a two-dose demand
- Country product presentation preferences for vials are met
- Long-term adequate buffer capacity from 2023+

2nd priority Objective: cost of vaccine to Gavi and countries. To minimise the costs of immunisation, Gavi should seek competitive prices for future suitable vaccines from manufacturers offering the best value considering country product presentation preference. This results in two target outcomes:

- New IPV manufacturers offer prices in line with (confidential) targets.
- Weighted average price decreases to a (confidential) target value from 2021.

3rd priority Objective: appropriate and innovative vaccines. The use of intradermal fIPV can be considered as a barrier to introduction in some countries. Furthermore, many manufacturers are considering development of IPV-containing combination vaccines. This results in two market shaping target outcomes:

- The issues related to delivery and adoption of fIPV devices are addressed.
- Manufacturers' strategies for hexavalent are influenced by a unified GAVI and partners strategic position on hexavalent vaccines.

Information is a cross-cutting objective and strategic enabler for all vaccines. Due to supply constraints, some countries have already or will use fIPV which will impact demand forecasts. Over the next two years, we will have more visibility on demand in these countries and short-term demand forecasts will have to be updated to ensure transparency and synchronization among Alliance partners, countries, and relevant manufacturers. Furthermore, changes in the dates of polio eradication and subsequently OPV cessation will have an important impact of IPV demand which will need to be communicated.

- Optimise communication between Gavi partners and manufacturers.
- Demand forecasts are shared and detailed assumptions are discussed with the stakeholders that are relevant to market shaping outcomes.
- UNICEF deliver timely IPV market notes to inform Alliance partners (available [here](#)).

Supporting Stakeholder Action Plan

A concerted action plan ensures the coordination between Gavi Alliance stakeholders, designed to lead to the achievement of the above supply and procurement objectives.

- Engage suppliers to find practical short-term supply solutions that reduce the risk of countries postponing IPV introduction.
- Engage incumbent and new manufacturers of IPV to facilitate decisions on long-term supply capacity.
- Support the development, registration, scale-up and roll-out of appropriate new IPV for GPEI and Gavi countries.
- Engage potential future suppliers of IPV to develop vaccines with product characteristics and prices that are competitive against the vaccine that is currently preferred by countries.
- Undertake an independent evaluation of the use of fIPV (e.g., vials used, wastage, and coverage) in relevant countries and with relevant partners.
- Support the development of new technologies that target innovative vaccines, potentially through R&D investments, technical support, and identification of commercial partners.
- Update quarterly short-term forecasts and communicate with relevant stakeholders to ensure transparency and synchronisation between Alliance partners, countries, and manufacturers.