

SUBJECT: GAVI'S POTENTIAL ENGAGEMENT IN IPV POST 2018

Agenda item: 12

Category: For Decision

Section A: Introduction

- This report requests a decision by the Board to extend Gavi's support for IPV to the end of 2020 under arrangements agreed by the Board in November 2013, and subject to sufficient polio-specific funding being made available. The Programme and Policy Committee (PPC) supported this proposal at its meeting in May 2017 and requested that Gavi's longer-term role in supporting IPV (beyond 2020) be considered as part of the upcoming Vaccine Investment Strategy (VIS). This paper is the product of close collaboration between the Gavi Secretariat and GPEI.

Section B: Gavi's Potential Engagement In IPV Post-2018

- 1.1 In November 2013 the Board decided to support the introduction of inactivated poliovirus vaccine (IPV) in all 73 Gavi-supported countries as part of the polio eradication 'Endgame' strategy. The Board approved support until the end of 2018, which was the projected date of global certification of polio eradication at the time of the Board decision. Subject to polio-specific additional funding being available beyond 2018, support would continue until the Endgame target for stopping vaccination of 2024, or an appropriate exit strategy for Gavi had been identified. Three donors to GPEI (BMGF, UK, Norway) provided US\$ 405 million to fund IPV introduction up to end-2018¹.
- 1.2 The Board approved a series of policy exceptions to allow for the unprecedented introduction timeline and other aspects of IPV support that were different to Gavi's regular vaccine support. These included waivers to the policies on country co-financing and country eligibility. The Board decided that these policy exceptions would be reviewed in 2018.
- 1.3 Applications from all 70 IPV-eligible countries were received and approved for Gavi support within 12 months of the Board decision². However, there have been two significant developments since then:

¹ This is less than the original funding of US\$ 430 million due to exchange rate fluctuations (current funding estimate converted at 28 Feb 2017 FX rate, from GBP (DFID), NOK (Norway) and US\$ (BMGF)).

² India was funded separately, with GPEI providing US\$ 30.6 million through Gavi for one year of catalytic vaccine support ending in 2016; Ukraine had introduced IPV in 2006, and Georgia opted for a combination vaccine not supported by the Alliance.

- (a) Delays in Polio Endgame timelines: With cases of wild poliovirus detected in Afghanistan and Pakistan in 2017, global certification of polio eradication is now projected to take place at the end of 2020 at the earliest, rather than 2018.
- (b) IPV supply shortages: Due to difficulties in scaling-up production capacities, manufacturers have only been able to deliver around half of the IPV supply which was originally expected. This has led to continued delays in introducing IPV in 18 Gavi-supported countries and interruptions to IPV programmes in 15 others. Given ongoing supply shortages, the Strategic Advisory Group of Experts (SAGE) for Immunization recommended in April 2017 that countries consider administering two fractional doses of IPV (fIPV) instead of a single full dose to maximise coverage with the available supply of vaccine. SAGE has also recommended catch-up immunisation for children who have been missed due to supply shortages, when sufficient supply becomes available.

- 1.4 In this context, the Board is asked to approve an extension of Gavi's support for IPV under the current arrangements to the end of 2020, which is the current projected date for certification (and the end of Gavi's current strategy period). This would be contingent on additional funding being made available by GPEI to fully cover the cost – estimated at up to US\$ 250 million³. In addition to a commitment from Norway of US\$ 23 million for 2019, up to US\$ 70 million of unused funding from the 2013-2018 period may be available to cover some of the projected cost to the end of 2020. Therefore, at least US\$ 157 million of additional funding will need to be raised by GPEI to support the extension of Gavi support to 2020.
- 1.5 This extension would help achieve the objectives of the 2013 Board decision and would help to mitigate the risk of countries de-prioritising their IPV programmes. Taking a decision now on extension to 2020 would provide reassurance to countries and manufacturers of Gavi's continued commitment to IPV and to polio eradication in general. A decision not to extend support to 2020 would potentially have negative implications for both countries and polio eradication efforts. Without Gavi's IPV support an alternative implementation mechanism would be required.
- 1.6 The PPC recommended this decision to the Board. It acknowledged the excellent collaboration between GPEI and the Alliance, while emphasising the need for the Alliance to be fully engaged in market shaping for IPV in collaboration with GPEI. The Committee noted SAGE's recommendations on fractional dosing of IPV, dosage and duration and its recommendation that efforts should be made to vaccinate children who have been missed due to supply shortages. It emphasised that decisions on how and when these children would be vaccinated would be a matter for countries to decide

³ The final cost will be determined by a number of key factors including the IPV supply situation, country decisions on switching from full to fractional dose IPV, and the price outcomes of the current IPV tender.

in collaboration with GPEI. The PPC was supportive of Gavi helping countries to implement SAGE recommendations on fIPV and vaccination of missed age cohorts as part of its IPV support whilst noting the programmatic challenges of implementing fIPV in weak immunisation programmes. Committee members also noted the possibility of increased wastage cancelling out cost savings of fIPV and the potential disincentive to manufacturers to invest in production capacity.

- 1.7 The PPC also discussed the issue of support for IPV beyond 2020. At the time of the 2013 Board decision, SAGE recommended to continue the use of IPV for 5 years following the global withdrawal of Oral Poliovirus Vaccine (OPV). With projected certification in 2018 and OPV withdrawal in 2019, this gave a date for cessation of IPV use of 2024. SAGE has recently recommended that the use of IPV continue for 10 years following the withdrawal of OPV, and that countries should include at least two doses of IPV in their routine immunisation schedule, administered as either full or fractional doses. Based on current eradication timelines, which are certification in 2020 and OPV withdrawal in 2021, this would mean continuing IPV use until the end of 2031. The PPC noted that GPEI is currently expected to “sunset” in 2021.
- 1.8 Committee members expressed concern that without GPEI funding for IPV, countries that are transitioning or have transitioned out of Gavi support may find it difficult to finance IPV costs. Committee members recognised the exceptional nature of IPV, that it does not fit with the rest of Gavi’s vaccine portfolio given polio’s low disease burden and the policy exceptions required to support IPV, and that this would need to be looked at carefully when considering support for IPV beyond 2020. The PPC requested the Secretariat to include consideration of Gavi’s support for IPV beyond 2020 in the Vaccine Investment Strategy (VIS) process. The Secretariat will explore how best to consider IPV within the VIS, understanding that it may need to be assessed differently from other vaccines based on its value to the global public good of polio eradication and prevention of re-emergence, rather than its impact on the morbidity and mortality of the disease. At the next PPC meeting in October 2017 and the subsequent Board meeting, the Secretariat will bring a recommendation on a decision framework for the VIS, including considerations related to IPV.

Section C: Actions requested of the Board

The Gavi Alliance Programme and Policy Committee recommends to the Gavi Alliance Board that it:

- **Approve** extending Gavi’s support for IPV from 2018 through 2020 under the arrangements approved by the Board in November 2013, and subject to polio-specific funding being available.

Annexes

Annex A: Implications/Anticipated impact

- Risk implication and mitigation, including information on the risks of inaction
- Funding. There is a risk that GPEI will not raise sufficient funding to fully support the IPV programme to the end of 2020. Mitigation efforts include close partnership with GPEI. If GPEI is unable to provide sufficient resources, the Secretariat would bring this back for PPC and Board discussion.
- Further delays. By agreeing to extend its support for IPV beyond 2018, Gavi continues to be exposed to the risk of further delays in polio eradication, which could further extend the IPV programme and affect associated financial needs.
- Risks of inaction.
- There is a reputational risk to the Alliance of not extending IPV support to 2020 as it may be seen as exiting polio eradication efforts without a sustainable exit strategy, and this negatively affects countries' IPV programmes.
- If there is no extension of support and no further Alliance-wide engagement, and with wide-scale country adoption of fractional dosing, there is a risk that manufacturers may choose not to continue scaling up supply and there would be reduced incentives for new entrants. This could negatively impact the supply and create the potential for prices to increase.
- Impact on countries: If Gavi does not continue IPV support beyond 2018 this may have an impact on IPV introduction plans in Gavi-supported countries as countries may choose to deprioritise IPV. In addition, there is a risk to the sustainability of programmes in countries which have already introduced IPV with Gavi support.

Additional information available on BoardEffect in May 2017 PPC meeting book

Report to the Gavi Alliance Programme and Policy Committee: Gavi's potential engagement in IPV post 2018 (Doc 06)