SUBJECT:	**GAVI'S SUPPORT FOR INACTIVATED POLIO VACCINE (IPV) POST-2020 AND FOR INDIA 2019-2021**
Agenda item:	12
Category:	For Decision

Section A: Introduction

- This report three decisions by the Board related to Inactivated Poliovirus Vaccine (IPV), as recommended by the Programme and Policy Committee (PPC) in October 2018. The first two decisions (Section B) pertain to potential IPV support post-2020, and request the Board to approve support for IPV in Gavi-70 countries from 2021 that takes into account the principles retained by the Board in June 2018. The Board is also asked to provide an in-principle decision to support IPV-containing whole-cell pertussis Hexavalent vaccine (Hexavalent) when it becomes available, as part of future IPV support. Lastly, the Board is requested to approve a recent funding request from the Government of India to cost-share IPV for three years (2019-2021) due to a significant, unanticipated price increase.

Section B: Support for IPV post-2020

1. Gavi's engagement in IPV

1.1 The Board's first decision related to engagement with IPV was taken in November 2013 when it approved a funding envelope for all Gavi IPV eligible countries as part of the polio eradication 'Endgame' strategy[1]. With this decision, the Board approved a series of policy exceptions including waivers to Gavi's Co-financing policy and Eligibility and Transition policy. Financing was provided by GPEI (Global Polio Eradication Initiative) donors as it was considered core to the GPEI programme and Gavi had not included IPV in its 2016-2020 strategic period budget.

1.2 A number of subsequent Board decisions have been made related to IPV (see Appendix 4), with the latest in June 2018, where the Board approved to exceptionally fund IPV with core Gavi resources through 2020, with the caveat that it did not imply Gavi support for IPV post-2020. At this time, the Board was supportive of the following principles to guide Gavi's engagement with IPV post-2020: polio eradication is a global public good and IPV is the global "insurance policy" to mitigate the risk of poliovirus re-

[1] Of 73 countries, 70 are currently supported by Gavi: Ukraine was not supported as IPV was already introduced in 2006; Georgia opted for a combination vaccine not supported by the Alliance; and India, although eligible, agreed to fund their own programme but later requested and was provided one-time catalytic vaccine support from GPEI donors that ended in 2016.

emergence; Gavi support should be aligned with SAGE recommendations; and the level and duration of Gavi support should balance risk of IPV programme discontinuation with principles of country ownership.

1.3 The original 2013 Board decision also specified that any requests from India related to IPV would be considered separately by the Board. Hence, India's request for IPV support for 2019-2021 is presented separately in Section C.

2. Progress towards global polio eradication

2.1 Wild poliovirus (WPV) remains endemic in three countries – Afghanistan, Nigeria and Pakistan and significant challenges still remain to stop transmission. Faced with continued WPV transmission and an increasing number of vaccine-derived poliovirus (VDPV) outbreaks [2], eradication timelines have been further delayed.

2.2 Based on current epidemiological data, the earliest that polio eradication could be certified is 2022, the required three years from the last WPV case. GPEI is currently updating the Endgame Strategy for the period 2019-2023 to assess whether current strategies, functions, and activities are valid and sufficient to achieve eradication. The revised strategy will be taken to the World Health Assembly in May 2019 and developed into an investment case that is not anticipated to include IPV.

2.3 A recent Polio Independent Monitoring Board (IMB) report[3] underlines the need for enhanced programmatic and strategic alignment between GPEI-Gavi, specifically at the country-level. Gavi is therefore participating in the revision of the polio Endgame Strategy with the aim of improving collaboration between the partnerships to strengthen routine immunisation delivery in the poorest performing countries and subnational localities. This exercise will also ensure strategic and programmatic alignment with Gavi's new strategy from 2021-2025 (Gavi 5.0).

2.4 The recent IPV tender covering the period 2019-2022 has resulted in significant price increases (between 60% and 140%). Such increase in prices raise the risk of IPV programme discontinuation and poliovirus re-emergence in high-risk, self-procuring countries, with India being an example.

3. Potential support for IPV and Hexavalent post-2020

3.1 The PPC echoed feedback from Board members, country stakeholders and technical experts that Gavi has a key role to play in addressing the overall risk of poliovirus re-emergence. This is by ensuring the availability of sufficient and affordable IPV supply and supporting countries to reach and maintain high IPV coverage in national routine immunisation schedules with

[2] Vaccine-derived poliovirus (VDPV) outbreaks are ongoing in DR Congo, Somalia, Kenya, Niger, Nigeria and Papua New Guinea (PNG).
[3] Independent Monitoring Board of the Global Polio Eradication Initiative, *How to cut a long story short: 16th Report*, October 2018.

strengthened service delivery. Some PPC members also encouraged Gavi to explore alternative financing mechanisms that would mobilise and deploy dedicated resources for IPV given its unique role in polio eradication.

3.2 The importance of considering country opportunity costs that could arise if countries were asked to share the cost of IPV was also highlighted during Board member consultations and reiterated by the PPC, including the negative impact this could have on the introduction of other new and underutilised vaccines.

3.3 Maintaining a healthy market for IPV standalone must remain the priority for the Alliance in the effort to eradicate polio. However, sufficient supply of IPV-containing, whole-cell pertussis (wP) Hexavalent would be expected to allow potential introductions in Gavi-eligible countries from approximately 2024. PPC members underlined that Hexavalent, as a combination product, offers an important opportunity to ensure that IPV antigen is sustainably integrated into routine systems, particularly given the unknowns related to eradication timelines. Moreover, the PPC confirmed that Gavi is best placed to manage the pace of uptake of Hexavalent vis-à-vis evolving future supply. In addition, Gavi has a role in ensuring the market for stand-alone IPV stays as healthy as possible – particularly given current supply constraints – as well as the market for Pentavalent, and vaccines containing D, T, P, HepB and Hib antigens[4].

3.4 Gavi's proposed support to Hexavalent would be subject to conditions that define desired future market attributes; these are outlined in the draft Gavi Hexavalent vision paper found in Appendix 3.

4. Proposed standalone IPV support options post-2020

Table 1 summarises the proposed options for post-2020 IPV standalone support and Hexavalent support when it becomes available. The full set of assumptions for each of the support options can be found in Appendix 1.

Option 1: Full IPV support to countries under existing arrangements

4.1 This option is the status quo and entails continuing to waive Gavi's Eligibility and Transition and Co-financing Policies. Under this option, Gavi continues to fully finance IPV for all 70 countries during the SAGE recommended timeframe (10 years after bOPV cessation). This option carries the least risk associated with trade-offs and potential IPV programme interruption but comes at the highest cost to the Alliance.

Option 2: Risk-based cost sharing of IPV

4.2 This option takes into account the epidemiologic risks of poliovirus re-emergence and country ability to share the cost of IPV. This option uses the global withdrawal of bivalent oral polio virus (bOPV) vaccine as a trigger for

[4] Depending on final Vaccine Investment Strategy (VIS) decisions related to diphtheria (D), pertussis (P) and tetanus (T) containing booster doses, Hexavalent will be considered as an immunisation alternative to other combined vaccine products.

cost-sharing in order to ensure that existing financing for bOPV vaccines is not displaced (assumed to be US$ 0.60 per infant) from the polio programme and used to contribute to the cost of IPV vaccines.

Option 3: Application of standard policies to IPV

4.3 This option entails applying standard Gavi eligibility and transition and co-financing policies to IPV.

Hexavalent support (assumed from 2024)

4.4 The aim of this option is to facilitate country transition to Hexavalent when it becomes available by offering co-financing support incentives. Given the risk of IPV discontinuation (due to general low risk of re-emergence for certain countries) and current market dynamics, it is proposed that Fully Self-financing countries would be prioritised for access to the vaccine. As additional supply becomes available, countries in accelerated transition would be given the option to introduce Hexavalent followed by Preparatory transition and Initial Self-financing countries.

Table 1: Country financing for proposed support options by Gavi transition phases

<table>
<tr><th rowspan="2">Support options</th><th colspan="4">Gavi transition phases</th></tr>
<tr><th>Initial Self-financing</th><th>Preparatory transition</th><th>Accelerated transition</th><th>Fully Self-financing</th></tr>
<tr><td colspan="5">IPV stand-alone</td></tr>
<tr><td>1. Full support</td><td colspan="4">No cost-sharing of IPV</td></tr>
<tr><td>2. Risk based</td><td>No cost-sharing of IPV</td><td colspan="2">No cost-sharing of IPV until bOPV cessation, then $0.60 per target infant in birth cohort</td><td>No cost-sharing of IPV until bOPV cessation, then $0.60 per target infant in birth cohort and ramp up over 5 years to full IPV cost</td></tr>
<tr><td>3. Standard Policies</td><td colspan="4">Full application of Gavi’s Eligibility and Transition, and co-financing Policies starting in 2021</td></tr>
<tr><td colspan="5">When Hexavalent becomes available</td></tr>
<tr><td>Hexavalent</td><td colspan="2">Application of Gavi’s eligibility and transition, and co-financing Policies from introduction</td><td colspan="2">Linear ramp-up over 7 years to full cost of Hexavalent from introduction</td></tr>
</table>

Financial implications of support

4.5 Estimated procurement costs of the three stand-alone IPV support options to countries and Gavi for the next two strategic periods, Gavi 5.0 (2021- 2025) and Gavi 6.0 (2026-2030), are presented in Table 2. The estimates factor out countries’ bOPV contributions following cessation (from 2024).

Table 2: Estimated net procurement costs[5] of support options for IPV standalone, 2021-25 and 2026-30 (excluding India)

IPV standalone	2021-2025 (Gavi 5.0)		2026-2030 (Gavi 6.0)	
	Gavi	Country	Gavi	Country
1. Full IPV support	848	-	695	0
2. Risk-based IPV support	796	-	429	76
3. Standard policies	526	249	260	245

All figures are in million US$

4.6 Table 3 presents the financial implications (also for Gavi 5.0 and 6.0) of the gradual introduction of Hexavalent from 2024 on top of the three standalone IPV support options. As the introduction of Hexavalent effectively replaces Pentavalent, country contributions to this vaccine as well as bOPV are removed. Hence, costs shown are net of all antigens other than the IPV – whether as standalone initially or as part of Hexavalent from 2024.

Table 3: Estimated net procurement costs[6] of support options for IPV with switch to Hexavalent, 2021-25 and 2026-30 (excluding India)

IPV with switch to Hexavalent	2021-2025 (Gavi 5.0)		2026-2030 (Gavi 6.0)	
	Gavi	Country	Gavi	Country
1. Full IPV support	858	-	701	0
2. Risk-based IPV support	828	-	619	12
3. Standard policies	526	283	214	418

All figures are in million US$

5. PPC consideration of post-2020 IPV support options

5.1 While continuation of full IPV support (Option 1) represents the highest cost to Gavi, a majority of PPC members believed this to be the most appropriate support option given the global public good priority of polio eradication and the desire to minimise any risk of IPV programme discontinuation. Committee members in favour of this option evoked concerns of opportunity costs related to the introduction of other new and underutilised vaccines should countries be required to cost-share IPV. There were however, a number of committee members who believed that the principle of country cost-sharing was important and that all but the poorest Gavi-eligible

[5] In the initial years incremental costs to countries net of bOPV costs are zero or negative in some cases and labelled "-".

[6] In the initial years, incremental costs to countries net of bOPV and pentavalent costs are zero or negative in some cases and labelled "-". Cost estimates are based on a 3-dose primary schedule to compare with SAGE's recommended 2-dose primary IPV schedule at 4 months and at least 4 months later. While currently there is not a WHO position paper on IPV-containing Hexavalent vaccines, the WHO Polio Vaccines position paper (March 2016) recommends a 4-dose IPV schedule when using a primary series of 6, 10 and 14-weeks followed by a booster dose of IPV provided after an interval of ≥ 6 months. It is therefore possible that a fourth dose of Hexavalent will be required to achieve adequate poliovirus immunogenicity levels. If this is the case, Hexavalent vaccines would be assessed in the context of the benefits and additional costs associated with all antigens contained in the combined formulation and any support decision related to diphtheria (D), pertussis (P) and tetanus (T) containing booster doses.

countries (i.e., initial self-financing) should be required to contribute to the cost of IPV (Option 2).

5.2 PPC members were in agreement with the VIS Steering Committee to rule out Option 3 – the application of standard eligibility and transition and co-financing policies to IPV – voicing their concerns that this would carry the highest opportunity costs and likely greatest risk of premature discontinuation of IPV in routine programmes.

5.3 India is not included in this proposal or financial projections, as any decision relating to India is to be considered by the Board separately.

Section C: India's request for IPV support (2019-2021)

6. Funding request and PPC considerations

6.1 In 2014, India was approved for 12 months of support to introduce IPV with catalytic funding provided by GPEI donors. Since this support ended in 2016, the Government of India (GoI) has been self-financing IPV.

6.2 As experienced by Gavi, GoI's recent domestic tender saw a significant price increase of over 80%. This places additional burden on GoI's immunisation budget[7] and jeopardises their efforts to strengthen routine immunisation and scale up other life-saving vaccines (rotavirus, PCV, MR). GoI therefore requested Gavi support for at least 50% of the IPV cost for the next three years, at which time the global vaccine prices are expected to drop back to the current levels (see Appendix 6). A similar request was sent to WHO/GPEI but it was declined and redirected to Gavi.

6.3 In October 2018, the PPC was presented a set of options ranging from no funding to cost-sharing for three years as requested (at an estimated US$ 40 million for Gavi), or for a shorter duration[8]. A number of considerations were noted by the PPC, which informed their recommendation to the Board to approve the use of core resources to cost-share IPV in India for three years (2019-2021):

a) High risk of poliovirus re-emergence in India and therefore to the global eradication agenda, if India were to discontinue the IPV programme;

b) The nature of these special circumstances with global IPV supply and pricing issues, under which GoI is seeking funding support from the global community for a limited duration;

[7] Note India's immunisation expenditure on transitioned Gavi-supported interventions including new vaccines and selected HSS interventions had at least tripled from 2016 to over US$ 270 million in 2018.

[8] India's IPV funding request discussed as part of the PPC's review of the progress of the Gavi-India strategic partnership (2016-2021). See PPC Doc 05a on BoardEffect.

c) Recognition of India's contribution to the global community by adopting IPV as part of the Endgame Plan and by adopting fractional dosing amid global supply constraints, thereby freeing up ~17 million doses/year of supply for other countries;

d) Risks to Gavi's long-standing partnership with India – a country that has demonstrated extraordinary political commitment to immunisation and programmatic achievements, and its contribution to ensuring global vaccine security and maximising procurement savings for Gavi;

e) As an equity issue: India remains a Gavi IPV eligible country and is seeking limited cost-sharing support, while the Board has already approved full support for the other 70 eligible countries through 2020 at its June 2018 meeting.

6.4 The PPC also encouraged Gavi to work with GPEI towards ensuring sustainable pricing for all countries in the long term. Gavi noted the arrival of new manufacturers from 2020 should help secure additional capacity and drive vaccine affordability, which is expected to benefit both Gavi-supported and transitioned countries.

Section D: Actions requested of the Board

IPV support post-2020[9]

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

a) **Approve**, subject to the availability of funding for the 2021-2025 period following Gavi's replenishment for that period, support for inactivated poliovirus vaccine (IPV) under the arrangements agreed by the Board in November 2013 (Option 1 in paragraph 4.1) ;

b) **Approve**, in-principle support for IPV containing whole-cell pertussis Hexavalent vaccine (Hexavalent) for the administration of IPV, diphtheria, tetanus, whole-cell pertussis, hepatitis B and Haemophilus influenza b antigens, subject to a vaccine being licenced, recommended for use by WHO, WHO pre-qualified and that market attributes support the successful implementation of Hexavalent;

[9] Majority positions on the recommendation (presented as Option 1 to the PPC) were expressed by the PPC members representing the Bill & Melinda Gates Foundation, Civil Society Organsations, UNICEF, the World Bank and the EMRO constituency. The Board member from the UK/Qatar constituency, attending the PPC member as an observer, indicated his constituenices' preference for this option. Minority positions (in favour of Option 2 as presented to the PPC) were expressed by the PPC members representing the Norway/Netherlands/Sweden and Germany/France/Luxembourg/EC/Ireland constituencies. The Board member from the US/Australia/Japan/Korea (Rep. of) constituency, attending the PPC member as an observer, indicated her constituenices' preference for Option 2 as presented to the PPC.

c) **Note** that the financial implications associated with these decisions are expected to be approximately US$ 850 million (of which an estimated US$ 848 million is dedicated to standalone IPV) for the period 2021-2025 and that, given that financing for IPV was not included in the investment case for the replenishment in 2015, funds for IPV support beyond 2020 should be considered as additional to other Gavi investments.

India's request for IPV support[10]

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

- **Approve**, further to its decision on exceptional Gavi support for IPV from 2013 for Gavi eligible and graduating countries and the risks to the polio eradication agenda, the use of core resources (in an amount estimated at US$ 40 million based on current projections) to support inactivated poliovirus vaccine (IPV) in India for the period 2019-2021.

Additional information available on BoardEffect

Appendix 1: Assumptions for financial implications

Appendix 2 (in October 2018 PPC meeting book): Annex A to Doc 06b *WHO country-based assessment of risk of poliovirus re-emergencec*

Appendix 3 (in October 2018 PPC meeting book): Annex B to Doc 06b *Draft Alliance strategic vision paper on Hexavalent (2018)*

Appendix 4 (in October 2018 PPC meeting book): Annex C to Doc 06b *Gavi Board decisions on IPV*

Appendix 5 (in PPC Library – Additional materials for October 2018 PPC meeting): Appendix 1 to Doc 06b *Results from stakeholder consultations*

Appendix 6 (in October 2018 PPC meeting book): Annex B to Doc 05a *Letter from the Government of India to Gavi on IPV funding support*

[10] Minority positions on the recommendation were expressed by the PPC members representing the Norway/Netherlands/Sweden and Germany/France/Luxembourg/EC/Ireland constituencies. The PPC member from the CSO constituency abstained from the decision-making process.