

SUBJECT: CO-FINANCING ARRANGEMENTS FOR INACTIVATED POLIOVIRUS VACCINE (IPV) POST 2020

Agenda item: 09

Category: For Decision

Section A: Introduction

- This report requests the Board to approve a revised risk-based cost sharing support modality for Inactivated Poliovirus Vaccine (IPV) for the post-2020 period, as recommended by the Programme and Policy Committee in May 2019.
- The Board approved in November 2018 support for IPV subject to the availability of funding for the 2021-2025 period and in alignment with the final parameter setting for Gavi 5.0 at the June 2019 Board meeting. The Board considered two support options¹ – full-support or risk-based cost sharing – but preferred to leave this decision open until further clarity on the above conditions was provided. At this time the Board also approved in-principle support for whole cell pertussis (wP)-Hexavalent vaccines.
- In May 2019, the PPC re-considered the two support options retained by the Board and recommended a revised risk-based cost sharing option. This option is described below.

Section B: Co-financing arrangements for Inactivated Poliovirus Vaccine (IPV) post 2020

1. Gavi's engagement in IPV

- 1.1. The Board has taken a number of decisions related to support for IPV since the initial Board approval of an envelope to support the introduction of IPV in all Gavi IPV eligible countries² as part of the polio eradication 'Endgame' strategy³ in November 2013. With this decision, the Board approved a

¹ A third option, that applied standard Gavi eligibility, transition and co-financing policies to IPV was deprioritised as a viable option by the October PPC and November Board because it was deemed that the cost required to countries presented an unacceptable level of risk of premature discontinuation of IPV use in routine immunisation programmes.

² As of 1 April 2019, all 73 IPV eligible Gavi countries have introduced IPV, thus achieving the target set out in 2013. The target date for this achievement was the global tOPV-bOPV (trivalent oral poliovirus vaccine-bivalent oral poliovirus vaccine) switch in April 2016 but was delayed as a result of global supply constraints due to challenges faced by manufacturers to scale up production capacities in line with the increased demand.

³ The Polio Endgame Strategy covered the period 2013-2018. A new strategy has been approved for the period 2019-2023.

series of policy exceptions that included waivers to Gavi's co-financing and eligibility and transition policies that have continued to be the basis for Gavi's IPV support.

- 1.2. Financing for IPV was initially provided by GPEI (Global Polio Eradication Initiative) donors as Gavi had not included IPV in its 2016-2020 strategic period budget and it was considered part of core GPEI work. However, following the Polio Oversight Board's funding request in early 2018, the Board exceptionally approved in June 2018 the use of Gavi core resources to directly finance the funding gap of IPV through the end of 2020. This decision included support for vaccination of missed cohorts and was accompanied by the caveat that it did not imply that Gavi would support IPV post 2020 from its core resources.
- 1.3. At this time, the Board agreed that Gavi has an important role to play in the programmatic integration of IPV into the EPI (Expanded Programme for Immunization) and recommended that the following principles guide the development of support options for IPV post-2020 - a) polio eradication is a global public good and IPV is the global "insurance policy" to mitigate the risk of poliovirus re-emergence; b) Gavi support will aim to align with SAGE recommendations; and c) the level and duration of Gavi support should balance risk of IPV programme discontinuation with the principle of country ownership.

2. PPC consideration of IPV support options retained by the November 2018 Board

- 2.1 Based on the Board agreed principles to develop IPV support options, two specific support modalities were retained by the November 2018 Board. These were:

- a) *Option 1: Full IPV support to countries under existing arrangements*

A continuation of the current IPV support modality, this option would continue to waive Gavi's eligibility and transition and co-financing policies. Under this option, Gavi continues to fully finance IPV for all 70 countries⁴ during the SAGE recommended timeframe, i.e. 10 years following the cessation of bivalent oral poliovirus vaccine (bOPV). This option carries the least risk of potential disruption to IPV programmes but comes at the highest cost to the Alliance and does not enshrine country ownership of the IPV programme.

⁴ The original Board decision in November 2013 approved support for the introduction of IPV in all 73 Gavi eligible countries. Of these, Ukraine was not supported as IPV was already introduced in 2006 and Georgia opted for a combination vaccine not supported by the Alliance. India was provided with one-year catalytic vaccine support from GPEI donors that ended in 2016. Subsequently, the Gavi Board approved additional time-limited support to India in November 2018 for the period 2019-2021.

b) *Option 2: Risk-based cost sharing of IPV*

This option takes into account the epidemiologic risks of poliovirus re-emergence and country ability to share the cost of IPV. Under this option the global withdrawal of bivalent oral poliovirus vaccine (bOPV; occurring 12-18 months after eradication) is used as a trigger for cost-sharing in order to ensure that existing financing for bOPV is not displaced (assumed to be US\$ 0.60 per infant) and used to contribute to the cost of IPV vaccines. In addition, fully self-financing countries would ramp up to full cost of IPV over 5 years starting at US\$ 0.60 per infant.

- 2.2 The PPC debated the risks and opportunities related to both options. Overall, PPC members agreed that Gavi’s support for IPV must not jeopardise the goal of eradication and the importance of considering country opportunity costs that could arise if countries were asked to share the cost of IPV including the impact on the introduction of other new and underutilised vaccines.
- 2.3 The PPC underlined the important future role of IPV-containing, whole-cell pertussis Hexavalent vaccine, both strategically and programmatically to better ensure long-term sustainability and country ownership of IPV.
- 2.4 Following discussion at the PPC, the Committee recommended a revised risk-based cost sharing support option as presented in the table below.

Table 1: IPV standalone support options

Support options	Gavi transition phases			
	Initial Self-financing	Preparatory transition	Accelerated transition	Fully Self-financing
1. Full support	No cost-sharing of IPV			
2. Risk-based cost sharing	No cost-sharing of IPV	No cost-sharing of IPV until bOPV cessation, then \$0.60 per target infant in birth cohort		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
Revised risk-based cost sharing	No cost-sharing of IPV	No cost-sharing of IPV until bOPV cessation, then \$0.60 per target infant in birth cohort		

- 2.5 Under the revised risk-based cost sharing approach, Gavi would continue to fully finance IPV in Initial Self Financing Countries. All other countries – Preparatory transition, Accelerated transition and Fully Self-financing countries – would be expected to contribute the amount they paid for bOPV towards IPV when global withdrawal of bOPV from their immunisation programmes occurs. This option further mitigates the risk of potential IPV programme discontinuation, specifically for Fully Self-Financing countries, by maintaining a flat cost-sharing contribution equivalent to the no-longer required cost associated with bOPV. The country contribution under this cost sharing arrangement would be treated in line with Gavi’s co-financing policy.

3. Considerations and risk mitigation

- 3.1 In November 2018 the Board confirmed that Gavi's primary role with IPV is ensuring the availability of sufficient and affordable vaccine supply and supporting countries to reach and maintain high routine IPV coverage through strengthened service delivery to mitigate the risk of poliovirus re-emergence. This role extends beyond stand-alone IPV and now includes Hexavalent in the future given the Board's in-principle support for this vaccine.
- 3.2 The trigger for country cost-sharing of IPV is global bOPV cessation. Most Gavi-supported countries, with the exception of mainly fragile countries, pay for bOPV. Advocacy with all countries will be required to ensure that funding for bOPV is effectively applied to IPV costs at the time of cessation. For countries that do not fund bOPV, the requirement to contribute US\$ 0.60 to the cost of IPV will present increased risk of country default. In such cases, the Secretariat would apply the co-financing policy and work with partners to help the country come out of default as in previous experiences when countries have defaulted.
- 3.3 It is envisaged that bOPV cessation will occur 12-18 months post certification of polio eradication. If eradication timelines are delayed, the assumed timing of bOPV cessation of 2024 would also be extended, along with Gavi's full support of IPV. Gavi has worked closely over the past several months with GPEI partners to develop the revised Polio Endgame Strategy (2019-2023) and efforts are ongoing to strengthen collaboration between the partnerships and improve routine immunisation delivery in the endemic and priority countries. Furthermore, Gavi's inclusion in the Polio Oversight Board and governance committees will facilitate greater transparency and accountability of strategic and programmatic decisions.
- 3.4 As requested by the PPC, the Board should review the recommended approach in 2022 when additional information related to IPV pricing, Hexavalent development and status of polio eradication will be available.

4. Financial implications of support options

- 4.1 Financial implications associated with this decision for the 2021-2025 period are estimated to be minimal. The cost of the revised risk-based cost sharing option is approximately US\$ 800 million⁵. When considering the 2026-2030 timeframe, the financial implications are approximately US\$ 555 million for standalone IPV and thus 30% lower than Option 1 (Full support)⁶. Delayed eradication timelines could result in Hexavalent vaccine being introduced into routine immunisation programmes before the cost-sharing of IPV is triggered. A funding window for Hexavalent, based on applicable policies

⁵ This compares to the previous estimates provided of US\$ 848 million for Option 1 and US\$ 796 million for Option 2 presented to the Board in November 2018.

⁶ This compares to previous estimates of US\$ 695 million for Option 1 and US\$ 429 million for Option 2. In relative terms the difference between Option 1 and the revised risk-based cost sharing option is 30% versus 60% when Option 2 was compared to Option 1.

and including co-financing will be considered when conditions that define desired future market attributes are met.

- 4.2 During this next strategic period, the market is expected to remain in flux driven by potential variability in the production available from current manufacturers, in the timing of expected arrival of additional manufacturers, the rate of country ramp-up to a second dose of IPV and the timing of initial availability of Hexavalent vaccine. Uncertainties remain around the success rate of manufacturers with IPV and Hexavalent development programmes, and the volumes and prices they will offer. The improvement of IPV supply availability and anticipated price reduction depend largely on these manufacturers. The Secretariat and partners will closely monitor the evolution of these development programmes and their impact on supply, prices and the cost for Gavi and supported countries.
- 4.3 As agreed by the Board in November 2018, funding for IPV will be considered part of Gavi's new vaccine investments for the next strategic period, recognising full programmatic integration of IPV into Gavi's overall immunisation strengthening approach.

Section C: Actions requested of the Board

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

Approve support for inactivated poliovirus vaccine (IPV) based on a risk-based cost sharing approach of IPV between Gavi and countries which takes into account the epidemiologic risks of poliovirus re-emergence and country ability to share the cost of IPV. Under this approach the global withdrawal of bivalent oral poliovirus (bOPV) vaccine is used as a trigger for cost-sharing in order to ensure that existing financing for bOPV is not displaced (assumed to be US\$ 0.60 per infant) from the polio programme. Thus the country financing no longer used for bOPV is used to contribute to the cost of IPV vaccine as follows: *Initial Self-financing countries*: Gavi fully finances IPV doses; *Preparatory transition countries, Accelerated transition countries and Fully Self-Financing countries*: Gavi fully finances IPV until bOPV cessation and at bOPV cessation, country funds US\$ 0.60 per targeted infant with Gavi paying the remainder of IPV costs. This approach will be reviewed by the Board in 2022.

Annexes

Annex A: Country pathways and financial implications

Additional information available on BoardEffect

Appendix 1: Summary of the Hexavalent Board decision and conditions to support

Appendix 2: WHO SAGE recommendations on IPV

Appendix 3: (in October 2018 PPC meeting book): Annex A to Doc 06b WHO country-based assessment of risk of poliovirus re-emergence

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