

<b>SUBJECT:</b>	<b>IPV IN INDIA</b>
<b>Report of:</b>	Hind Khatib-Othman, Managing Director, Country Programmes
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<b>Agenda item:</b>	11
<b>Category:</b>	For Decision
<b>Strategic goal:</b>	SG1 - Underused and new vaccines

## **Section A: Overview**

### **1. Purpose of the report**

- 1.1 This report provides an update on recent developments regarding India's plans to introduce Inactivated Polio Vaccine (IPV).
- 1.2 This report requests Board approval for Gavi to utilise additional funds, to be provided by the Global Polio Eradication Initiative (GPEI), in order to offer India catalytic support for the introduction of IPV.

### **2. Recommendations**

#### 2.1 The Gavi Board is requested to:

- (a) **Note** that the Global Polio Eradication Initiative ("GPEI") considers that timely introduction of IPV in India, a Tier 1 country, will be very important in achieving the goals of the Polio Eradication & Endgame Strategic Plan.
- (b) **Approve** the recommendations of the November 2014 Independent Review Committee (IRC) regarding the application for introduction of IPV in India for the period 2015-2018 (the "India IPV Programme") subject to the following conditions:
  - i. All IRC requested recommendations being addressed;
  - ii. GPEI making available the full amount of financing required (the "GPEI Amount") to provide catalytic support for the first 12 months of India's IPV Programme estimated to be up to US\$ 50 million ; and

- iii. The Government of India (Gol) committing to fund the difference between the funds required for the India IPV Programme and the GPEI Amount and continue to fund IPV in accordance with WHO recommendations when Gavi support ends.
- (c) **Endorse**, subject to the conditions in b) above being met, a net increase in programme budgets by up to the GPEI Amount to provide catalytic support for the vaccine purchase of (part of) the India IPV Programme for the period 2015-2018. (This endorsement would constitute acknowledgement of such budget amounts but would not constitute a funding approval, decision, obligation or commitment of Gavi or its contributors.)
- (d) **Approve**, subject to the conditions in b) above being met, a net increase of near-term programme liabilities (a sub-component of endorsed programme budgets) by up to the GPEI Amount to provide catalytic support for the vaccine purchase of (part of) the India IPV Programme for the period 2015-2016.
- (e) **Request** the Secretariat, GPEI, the Government of India and other partners to make the necessary arrangements for the timely implementation of the India IPV Programme.

### 3. Executive summary

- 3.1 In November 2013, the Gavi Board approved a funding window for IPV to allow Gavi eligible and graduating countries to apply for support to introduce a dose of Inactivated Polio Vaccine (IPV) to their routine immunisation programmes, in line with the Polio Endgame Strategy. This decision stipulated that any application from India related to IPV would need to be considered by the Board.
- 3.2 Funding for IPV support was provided to Gavi by donors of GPEI. Budget estimates excluded India as previous indications from Gol were that the country would fully finance IPV introduction and roll-out through domestic resources.
- 3.3 In September 2014, the Gol unexpectedly submitted an application to Gavi for nationwide support for IPV from September 2015 – the planned introduction date – through 2018. India is eligible for new vaccine introduction support from Gavi. India's IPV application has undergone technical review by the IRC and is recommended for "approval with recommendations".
- 3.4 India's IPV introduction is considered critical by GPEI to global achievement of Endgame timelines, the phased withdrawal of OPV (oral polio vaccine) and global polio eradication. It is therefore recommended that appropriate catalytic support of Gol's application be considered to ensure timely introduction of the vaccine.

- 3.5 Catalytic support to Gol will only be possible if GPEI provides additional financial resources to Gavi in the amount of the proposed support. An additional conditionality for the Gavi approval of the programme would be the commitment of Gol to fully finance the IPV programme upon conclusion of Gavi support.
- 3.6 Gol's decision to seek Gavi support for IPV comes on the heels of ambitious pronouncements to introduce 3 other vaccines important to India's national immunisation programme: measles and rubella (MR), Japanese encephalitis (adult) and rotavirus. Introduction of these vaccines will result in a substantial increase of the national vaccines budget.

#### 4. Risk implication and mitigation

- 4.1 If catalytic support is not provided to Gol, there are two primary risks which would be raised. Both of these risks would be mitigated by providing catalytic support for introduction of IPV:
- (a) India, classified as a Tier 1 country and at highest risk for VDPV (vaccine-derived poliovirus) emergence, delays its IPV introduction, jeopardising the attainment of global Polio Eradication Endgame timelines and placing the country at elevated risk for poliovirus circulation.
  - (b) Gol's ambitions to introduce other new vaccines of public health importance would likely need to be scaled back due to limited budgetary capacity.
- 4.2 Based on the latest available information, UNICEF Supply Division (UNICEF SD) projections for 2015 suggest there will not be sufficient supply of prequalified IPV vaccine to meet India's needs and the needs of all other countries vis-à-vis introduction dates included in country applications. As a Tier 1 country, India's IPV introduction would be prioritised over countries with lower risk (i.e., Tiers 2, 3 and 4) and IPV introduction in the lower risk countries may need to be delayed. However, it is expected that all countries would still be able to introduce by end 2015, in line with the Polio Endgame timelines. The risk posed to lower priority countries – both Gavi and non-Gavi countries – will need to be mitigated through strong coordination between countries, GPEI and the Immunisation Systems Management Group (IMG), in which Gavi plays an active role.
- 4.3 There is a risk that Gol funding for IPV in India may not be available after Gavi support ends. This would present risks to managing the potential emergence of VDPV if Gol bridge funding is delayed or interrupted. Risk in this area can be mitigated by ensuring there is a firm commitment from the Gol to assume IPV costs when Gavi support finishes, before any Gavi funds are committed.

## 5. Financial implications: Business plan and budgets

- 5.1 The estimated cost of providing India with the full requested amount of support for IPV is US\$ 96-160 million over 2015-2018, depending on the product presentation and wastage rate.<sup>1</sup>
- 5.2 Based on discussions with GPEI, Gavi has costed and is proposing to provide catalytic introduction support estimated at approximately US\$ 50 million to India for 12 months over the 2015-2016 period with the following assumptions:
- (a) Nationwide introduction from September 2015, with Gavi support until August 2016;
  - (b) Procurement of Gavi supported vaccine through UNICEF SD;
  - (c) Target population will be calculated based on UN population data and WUENIC 2013 forecasts (as per other countries receiving IPV support from Gavi);
  - (d) The 5-dose presentation<sup>2</sup> will be provided with a 15% wastage rate at the UNICEF SD price of US\$ 1.90 per dose (excluding freight)
  - (e) Support is for the vaccine and freight only and does not include support for syringes or safety boxes (consistent with previous vaccine support to India);
  - (f) No vaccine introduction grant will be provided.
- 5.3 There is no impact expected on the business plan budget.

## **Section B: Content**

### 6. Background

- 6.1 In November 2013 the Gavi Board opened a funding window for IPV to allow the Gavi Secretariat to invite Gavi eligible and graduating countries (the “Gavi IPV Eligible Countries”), in line with the Global Polio Eradication Initiative (GPEI) Endgame Strategy 2013-2018, to submit country proposals for support. The Gavi Board also approved using a funding envelope mechanism consistent with the principles of the Gavi Alliance Programme Funding Policy to fund approved IPV applications with the exception that any application from India related to IPV will be considered by the Board.
- 6.2 While India is considered eligible for IPV support from Gavi, Gol had previously indicated that they would fund IPV introduction and

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<sup>1</sup> Assuming India will follow WHO's guidance on the multi-dose vial policy guidance for IPV. If this is not the case, the cost of full requested support would be increased to approximately US\$ 193M.

<sup>2</sup> The 10 dose presentation would be less expensive (estimated 12 months support with 20% wastage is approximately US\$ 30M).

consequently no funds were included for India in Gavi's ring-fenced IPV programme budget approved by the Board in November 2013.

- 6.3 In September 2014, India submitted an application for Gavi to support national rollout of IPV from September 2015 to December 2018 for a total request of US\$ 160 million<sup>3</sup>, including US\$ 5 million for its vaccine introduction grant.
- 6.4 India's new government has publicly announced its intentions to introduce 4 new vaccines by the end of 2015 (IPV, measles and rubella, Japanese encephalitis (adult) and rotavirus vaccines) as well as expand pentavalent vaccine use throughout the country (Gavi is providing catalytic support to India's pentavalent programme). This renewed commitment to immunisation will have significant positive impact on lives saved and global vaccine introduction targets. It will also result in a multiple fold increase in the domestic "vaccines budget". With new allocations from the finance ministry not expected until early 2017 when the next 5 year plan is enacted, GoI now looks to Gavi to provide support to enable the country to meet global timelines as part of the Polio Endgame.
- 6.5 Gavi-GPEI support for India would provide the GoI with additional time to include resources required for IPV introduction in the national budgets and the next 5-year budget cycle as well as work through local procurement processes. Without this support, there is a risk that India's ability to achieve the Endgame's timelines would be compromised.
- 6.6 If external support for IPV introduction is not obtained, GoI's ambitious new vaccine introduction agenda would likely need to be scaled back.
- 6.7 The GoI is waiting for feedback from Gavi before finalising plans for IPV introduction, including financial requirements.
- 6.8 Gavi is developing a comprehensive strategy to guide engagement with India taking into account the complexities of possible new vaccine support requests and upcoming graduation from Gavi support. This strategy will be developed and presented to the Board in 2015.

## **7. Status of India's IPV application to Gavi**

- 7.1 India's application to Gavi for IPV support was submitted to the November Independent Review Committee (IRC) for a technical review. The IRC was briefed that Gavi approval would be subject to Gavi Board approval, as well as the availability of financing.
- 7.2 The IRC reviewed the application and recommended "approval with recommendations". The recommendations refer to more detailed state-level introduction plans including timelines, clarifications regarding the cohort size, wastage rates, vaccine presentation, RI/penta/IPV synergies,

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<sup>3</sup> Calculation based on vaccine support (including freight, excluding devices) from September 2015 to December 2018, 5-dose presentation (India's preferred presentation) procured through UNICEF SD, 25% buffer, 15% wastage (applying MDVP) and a target population based on UN population data and WUENIC 2013 forecasts (as per other countries receiving IPV support from Gavi).

Effective Vaccine Management (EVM) assessment/improvement plan implementation and communication strategies. It is expected that India will be able to address the IRC's recommendations in sufficient time for the IPV introduction in September 2015.

### **Section C: Implications**

#### **8. IPV supply for India and other countries**

- 8.1 In its Gavi application, India requested procurement of IPV through UNICEF Supply Division (UNICEF SD). UNICEF SD did originally include India in its 2014 IPV tender and awards included volumes for India to ensure supply capacity and sufficient lead times to manufacturers (in spite of expectations that India would self-procure the vaccine through a national tender process). While India's vaccine requirements were included in awards they were then released from UNICEF's contracts, as planned based on earlier assumptions on India's procurement plans.
- 8.2 Due to reduced and delayed supply availability during 2014-2015, the Polio Steering Committee (PSC) and the Immunisation Systems Management Group (IMG) have agreed to prioritise supply needs in Tier 1 and 2 countries over Tier 3 and 4 countries, and therefore supply for India would be prioritised.
- 8.3 Based on the latest available information, UNICEF SD projections for 2015 suggest there will not be sufficient supply of prequalified IPV vaccine to meet India's needs and the needs of all other countries vis-à-vis introduction dates included in country applications.
- 8.4 It is expected that additional doses will become available due to country driven delays in introduction timelines, as experienced for other vaccines. At the same time, it is expected that a number of countries will require additional doses in order to meet their coverage targets. In sum, it is likely that some lower-risk country introductions would need to be delayed to ensure all countries – including India – are able to introduce by the Polio Endgame timeline of end of 2015.
- 8.5 Assuming the WHO policy on the use of opened multi-dose vaccine vials is implemented in all countries, it is envisaged that all countries will be able to introduce the vaccine in-line with the Polio Endgame Strategy. However supply will be tight and require close monitoring and management.
- 8.6 Therefore, supply – even in the near term – is unlikely to impede India's planned introduction (September 2015). However supply planning for all countries would greatly benefit from a rapid decision on India support. The supply of IPV from 2016 onwards is expected to be sufficient to cover routine introduction needs of all countries, including India, procuring through UNICEF SD.

## 9. Impact on Gavi stakeholders

- 9.1 A decision on the provision of catalytic IPV support for India would allow UNICEF SD, manufacturers and the partners to finalise the supply planning for IPV. In addition, a confirmed IPV introduction date from India is a key part of planning by GPEI and partners for the global trivalent to bivalent OPV switch scheduled to take place in April 2016.
- 9.2 Providing catalytic support for India IPV introduction will require GPEI to find the required financing from within their budget. This may put some strain on GPEI finances given they have not yet been fully funded against their 2013-2018 target of US\$ 5.5 billion as well as unforeseen expenditures associated with extensive polio outbreaks response activities.

## 10. Impact on Secretariat

- 10.1 A decision on catalytic IPV support for India would allow the Secretariat to finalise discussions with the Gol. The impact on the Secretariat can be managed utilising existing financial and human resources.

## 11. Legal and governance implications

- 11.1 An agreement will need to be entered into with GPEI to secure funding for the catalytic support to the IPV programme in India.

## 12. Consultation

- 12.1 There has been extensive discussion and consultation with GPEI and IMG.
- 12.2 Further discussions will be required with the Gol to ensure that Gavi receives appropriate assurances that the Gol is committed to continue funding IPV after Gavi support ends. This needs to be confirmed prior to Gavi's disbursement of funds.
- 12.3 A recommendation to provide catalytic funding to India for IPV will also be discussed at the Polio Oversight Board meeting on 12 December 2014.

## 13. Gender implications

- 13.1 The IRC noted that there is no information on gender and equity issues in the IPV proposal, although reference was made to the latest cMYP 2013-2017 which outlined that *“there are significant inequities in vaccination coverage in different states based on various factors related to individual (gender, birth order), family (area of residence, wealth, parental education), demography (religion, caste) and the society (access to health care, community literacy level) characteristics”, and “there is a clear gender coverage differential as reported by different surveys. Boys generally have higher vaccination coverage than girls as reported by most surveys conducted across the country.”*

13.2 It is not anticipated that the provision of catalytic support for IPV introduction would have significant gender implications.