Gavi
The Vaccine Alliance

Dr. Shri Jagat Prakash Nadda
Union Minister
Ministry of Health and Family Welfare
155 - A, Nirman Bhavan
New Delhi - 110108
India

5 June 2015

Dear Minister,

Decision Letter: India's Proposal to Gavi, the Vaccine Alliance

I am writing in relation to India's proposal to Gavi for New Vaccines Support (NVS) for Inactivated Polio Vaccine (IPV) which was submitted to the Gavi Secretariat in September 2014.

In November 2014 your application was reviewed by the Gavi Independent Review Committee (IRC) which recommended "Approval with Recommendations" of your application.

In December 2014, the Gavi Board agreed to provide 12 months of catalytic support for India's IPV programme. The Gavi Board decision was subject to three conditions, which have now been met:

i) The Ministry of Health and Family Welfare has satisfactorily addressed the IRC's comments in its letter dated March 5, 2015.
ii) The Global Polio Eradication Initiative (GPEI) has made available to Gavi additional financing for catalytic support for the first 12 months of India's programme.
iii) The Government of India has committed to continue to fund IPV when Gavi supports ends in a letter to GPEI dated January 30, 2015.

It is my pleasure to inform you that Gavi has approved catalytic support for IPV for a national introduction from October 2015, as specified in the Appendices to this letter.

The Appendices include the following important information:
Appendix A: Description of approved Gavi support to India
Appendix B: Financial and programmatic information per type of support
Appendix C: A summary of the IRC Report
Appendix D: The terms and conditions of Gavi support

GAVI Alliance | 2 chemin des Mines 1202 Geneva Switzerland | Tel. +41 22 909 6500 Fax +41 22 909 6555 | www.gavialliance.org info@gavialliance.org

Gavi and GPEI have noted the Government of India's preference for a 5-dose vial of IPV. However, the global availability of 5-dose vials is insufficient to meet the full IPV requirements of India, therefore India has been allocated a combination of 5-dose and 10-dose vials. Annex B1 sets out the Programme Terms in respect of the 5-dose vials and Annex B2 sets out the Programme Terms in respect of the 10-dose vials.

Please do not hesitate to contact my colleague Dirk Gehl (dgehl@gavi.org) if you have any questions or concerns.

Yours sincerely,

Hind Khatib-Othman
Managing Director, Country Programmes

cc: The Minister of Finance
Comissioner (UIP), MoHFW
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division

Appendix A

Description of Gavi support to *India* (the "Country")

New Vaccines Support (NVS)

Gavi has approved the Country's request for supply of vaccine doses and related injection safety material which are estimated to be required for the immunization programme as set out in Appendix B. Financing provided by Gavi for vaccines will be in accordance with:

- Gavi Alliance Guidelines governing India's proposal application; and
- The final proposal as approved by the the Independent Review Committee (IRC), including any subsequent recommendations.

The vaccines provided will be used as the country has proposed. The principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO/V&B/99.25) shall apply to all immunisation provided with these vaccines.

Item number 11 of Appendix B summarises the details of the approved Gavi support for vaccines in the years indicated.

Any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies can not be paid for using Gavi funds.

The Country shall be solely responsible for any liability that may arise in connection with: (i) the implementation of any programmes in the Country; and (ii) the use or distribution of vaccines and related supplies after title to such supplies has passed to the Country. Gavi shall not be responsible for providing any additional funding to replace any vaccines and related supplies that are, or became, defective or disqualified for whatever reason.

Country Co-financing (Not applicable to India)
****Note:Gavi's usual co-financing requirements do not apply to IPV. However, the country is encouraged to contribute to vaccine and/or supply costs for IPV.****

Countries may select to co-finance through UNICEF Supply Division, PAHO's Revolving Fund, or self-procure their co-financing requirement following their own procedures, except for the Pneumococcal vaccine that needs to be procured through UNICEF.

If the purchase of the co-financed supply is carried out through UNICEF or PAHO, the payment is to be made to UNICEF or PAHO (whichever is applicable) as agreed in the Procurement Services Memorandum of Understanding between UNICEF or agreements between PAHO (whichever is applicable) and the country, and not to Gavi. Please keep in contact with UNICEF or PAHO (whichever is applicable) to understand the availability of the relevant vaccine(s) and to prepare the schedule of deliveries.

Information on these extra costs and fees will be provided by the relevant Procurement Agency as part of the cost estimate to be requested by the country. UNICEF/PAHO will share information with Gavi on the status of purchase of the co-financed supply.

If the purchase of any co-financed supply is carried out by the Government, following its own procurement procedures and not procuring from UNICEF Supply Division or PAHO's Revolving Fund, the Government will submit to Gavi satisfactory evidence that it has purchased its co-financed portion of the vaccines and related supplies, including by submitting purchase orders, invoices, and receipts to Gavi. Gavi encourages that countries self-procuring co-financed products (i.e.auto-disable syringes and syringe and needle disposal boxes) ensure that products appear on the applicable WHO list of pre-qualified products or, for syringe and needle disposal boxes, that they have obtained a certificate of quality issued by a relevant national authority.

Gavi support will only be provided if the Country complies with the following requirements:

Transparency and Accountability Policy(TAP): Compliance with any TAP requirements pursuant to the Gavi TAP Policy and the requirements under any Aide Memoire concluded between Gavi and the country.

Financial Statements & External Audits: Compliance with the Gavi requirements relating to financial statements and external audits.

Grant Terms and Conditions: Compliance with Gavi's standard grant terms and conditions (attached in Appendix D).

Monitoring and Annual Progress Reports or equivalent: Country's use of financial support for the introduction of new vaccinations with the vaccine(s) specified in Appendix B is subject to strict performance monitoring. Gavi uses country systems for monitoring and auditing performance and other data sources including WHO/UNICEF immunisation coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and on co-financing of the vaccine.

Country will report on the achievements in the Annual Progress Report (APR) or equivalent. The APR or equivalent must contain information on the number of children reported to have been vaccinated with DTP3 and 3 doses of pentavalent vaccine by age 12 months, based on district monthly reports reviewed by the Immunisation Coordination Committee (ICC), and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). APRs or equivalent endorsed by the ICC, should be sent to the Gavi Secretariat no later than 15 May every year.

Appendix B1

India Support for Inactivated Polio Vaccine (IPV)

This Decision Letter sets out the Programme Terms of a Programme.

1. **Country:** India
2. **Grant Number:** 1516-IND-25b-X
3. **Date of Decision Letter:** 5 June 2015
4. **Date of the Partnership Framework Agreement:** Not yet signed
5. **Programme Title:** NVS, IPV Routine
6. **Vaccine type:** Inactivated Polio Vaccine (IPV)
7. **Requested product presentation and formulation of vaccine**[1]**:** Inactivated Polio Vaccine, 5 dose(s) per vial, LIQUID
8. **Programme Duration**[2]**:** 2015 - 2016
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

	2015	2016	Total[3]
Programme Budget (US$)	US$3,990,000	US$3,990,000	US$7,980,000

10. **Vaccine Introduction Grant:** Not applicable
11. **Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):**[4]

Type of supplies to be purchased with Gavi funds in each year	2015	2016
Number of IPV vaccines doses	2,000,000	2,000,000
Number of AD syringes		
Number of re-constitution syringes		
Number of safety boxes		
Annual Amounts (US$)	US$3,990,000	US$3,990,000

[1] Please refer to section 18 for additional information on IPV presentation.
[2] This is the entire duration of the programme.
[3] This is the total amount endorsed by Gavi for 2015 to 2016.
[4] This is the amount that Gavi has approved.

12. Procurement agency: UNICEF

13. Self-procurement: Not applicable

14. Co-financing obligations: Not applicable

15. Operational support for campaigns: Not applicable

16. The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:

Reports, documents and other deliverables	Due dates
Annual Progress Report or equivalent	To be agreed with Gavi Secretariat

17. Financial Clarifications: The Country shall provide the following clarifications to Gavi*: Not applicable

**Failure to provide the financial clarifications requested may result in Gavi withholding further disbursements*

18. Other conditions:

If India envisages a switch in product presentation, it is encouraged to incorporate elements for both IPV presentations in your initial introduction preparations, in order to minimise the need for later interventions and facilitate the switch. In those circumstances, in principle, no product switch grant will be provided to India.

Signed by,
On behalf of Gavi

Hind Khatib-Othman
Managing Director, Country Programmes
5 June 2015

Annex B2

India Support for Inactivated Polio Vaccine (IPV)

This Decision Letter sets out the Programme Terms of a Programme.

1. **Country:** India
2. **Grant Number:** 1516-IND-25c-X
3. **Date of Decision Letter:** 5 June 2015
4. **Date of the Partnership Framework Agreement:** Not yet signed
5. **Programme Title:** NVS, IPV Routine
6. **Vaccine type:** Inactivated Polio Vaccine (IPV)
7. **Requested product presentation and formulation of vaccine[5]:** Inactivated Polio Vaccine, 10 dose(s) per vial, LIQUID
8. **Programme Duration[6]:** 2015 - 2016
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

	2015	2016	Total[7]
Programme Budget (US$)	US$5,794,500	US$16,800,000	US$22,594,500

10. **Vaccine Introduction Grant:** Not applicable

[5] Please refer to section 18 for additional information on IPV presentation.
[6] This is the entire duration of the programme.
[7] This is the total amount endorsed by Gavi for 2015 to 2016.

11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):[8]

Type of supplies to be purchased with Gavi funds in each year	2015	2016
Number of IPV vaccines doses	4,939,500	19,207,300
Number of AD syringes		
Number of re-constitution syringes		
Number of safety boxes		
Annual Amounts (US$)	US$5,794,500	US$16,800,000

12. Procurement agency: UNICEF

13. Self-procurement: Not applicable

14. Co-financing obligations: Not applicable

15. Operational support for campaigns: Not applicable

16. The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:

Reports, documents and other deliverables	Due dates
Annual Progress Report or equivalent	To be agreed with Gavi Secretariat

17. Financial Clarifications: The Country shall provide the following clarifications to Gavi*:

**Failure to provide the financial clarifications requested may result in Gavi withholding further disbursements*

18. Other conditions:

If India envisages a switch in product presentation, it is encouraged to incorporate elements for both IPV presentations in your initial introduction preparations, in order to minimise the need for later interventions and facilitate the switch. In those circumstances, in principle, no product switch grant will be provided to India.

Signed by,
On behalf of Gavi

Hind Khatib-Othman
Managing Director, Country Programmes
5 June 2015

[8] This is the amount that Gavi has approved.

Appendix C

Independent Review Committee (IRC) Country Report
GAVI Secretariat, Geneva • 10 -24 November 2014
Country: INDIA

The IRC was requested to review India's application for IPV support on technical grounds only as Gavi's IPV programme budget does not currently include funding for India. According to the Gavi Board decisions of November 2013, any support for IPV introduction in India would need to be considered by the Gavi Board.

1. Type of support requested: IPV

Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st, 2nd, and 3rd choice)*
August – September 2015	2015-2018	5 dose
		10 dose

2. In-country governance mechanisms (ICC/HSCC) and participatory proposal development process

A meeting was chaired by the Secretary on July 2014 with participation of stakeholders including government, international organisations and vaccine manufacturers. According to a recent Joint Appraisal, the equivalent of an ICC in India is the Immunisation Action Group (IAG). Clarification may need to be sought with the country on whether this application has been reviewed and endorsed by the IAG.

The NTAGI (Indian equivalent of NITAG) met in June 2014 and recommended the introduction of IPV tentatively in mid-2015 and based on a comprehensive introduction plan. The NTAGI decision follows a recommendation of its Technical Sub-Committee of March 2014 and an Indian Expert Advisory Group discussion in 2013, which also recommended introduction of IPV.

The NTAGI meeting of June 2014 also endorsed a strategy for increasing the coverage of all routine vaccines and introduction of other vaccines (Rota, JE, MR).

3. Situation analysis – Status of the National Immunisation Programme

The most recent EPI coverage survey indicates DPT3 coverage of 71.5% (CES 2009). The most recent JRF data reports a coverage rate of 76% (a decline from 85% in the previous year). WHO UNICEF estimates indicate that there has been a 72% coverage rate (DPT3) for the last 6 years (2007 – 2013). There are significant inter-State coverage differences, and the national program has identified a set of high priority districts for routine immunisation strengthening. India accounts for about 30% of the worlds unimmunised children.

The cMYP indicates that 2012 and 2013 will be the year of strengthening routine immunisation, with proposed strategies including introduction of village health and child health days, improved strategies for delivering vaccines to outreach sessions.

The MoHFW is also supported by an Immunisation Technical Support Unit (ITSU). The cMYP indicates that rotavirus, JE, rubella, Pneumococcal and Pentavalent vaccines, are expected to be introduced and expanded in the schedule. Pentavalent vaccine introduction (first introduced in 2011) has been conducted in two stages to date. The first stage included two States (Kerala and Tamil Nadu). By the second stage, the introduction had expanded to 6 States by 2013. By 2015, it is planned that Pentavalent will be scaled up nationally, with Government assuming financing of the vaccine from 2016.

The PIE documents clarify lessons learned for the upcoming IPV introduction including the need for updated micro-plans for high risk areas, long lead times for preparation, careful assessment of cold chain capacities and filling of staff vacancies in high risk areas, and careful monitoring of immunisation data by State and District task forces for immunisation.

The proposal is in line with WHO eligibility criteria, with plans for introduction of a single dose of IPV nationally into the routine immunisation schedule at 14 weeks of age.

There has been no reported polio case since 11 January 2011. India has been declared polio non-endemic country by World Health Organization in early 2012. India is in the Tier 1 group of countries for cVDPV2 outbreak and importations. The cMYP indicates that since 2012, the substantial number of polio focused staff is being reoriented towards routine immunisation strengthening, although the introduction plan has no further explanation of this. Other polio eradication initiatives include conducting of SIAs in 2014 and 2015, and enhanced disease and environmental surveillance in high risk areas. Other strategies include State emergency preparedness and response plans, maintenance of stockpiles of OPV and introduction of IPV.

4. Overview of national health documents

The introduction plan mentions most of the main elements of the strategy, but is light on detail. The cMYP documents a polio eradication strategy and the plan is stated for introduction of IPV. Required documents for timeline (attachment C) and costing (attachment B) are attached.

5. Gender and Equity

Human Development Index 2014:	135/186
Gender Inequality Index:	0.617
% of Women Married/In Union before age 18*:	47%

* Generally early marriage indicates that girls are being taken out of school and married to significantly older men. This raises questions around inequality within these relationships and the ability of young women to make decisions about their own and their children's wellbeing.

There is no information on gender and equity issues in the IPV proposal. Although there is a detailed plan for reaching the difficult to reach documented in the proposal, the proposal nonetheless identifies that a set of lower performing districts will be prioritised for additional monitoring and supervision support.

However, the latest cMYP 2013-2017 notes 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." Therefore India is committed to making special efforts to reach out "to targeted beneficiaries belonging to the lower socio-economic strata, those living in urban slums, rural areas, tribal and other hard-to reach areas."

Micro planning will be revised to include high-risk areas including migratory settlements. According to the Joint Appraisal, UNICEF is supporting the transition of the entire Polio Social Mobilisation Network towards boosting Routine Immunisation coverage but no information is provided. No information is provided on civil society involvement.

6. Proposed activities, budgets, financial planning and financial sustainability

The attached introduction timeline documents a 5 month program of introduction, with preparatory programs of securing financing, preparing communication and training materials and assessing cold chain space conducted 3 months before the introduction. There is largely a logical sequence with the timeline of activities, although there are some inconsistencies. For example, IEC production is proposed before conducting of a needs assessment. The timeline (commencement date and sequencing) may need to be reviewed and updated.

The timeline and introduction plan does not suggest any plan for a phased introduction, but rather a nationwide introduction across all the States of India. It would be helpful to provide further clarification on the feasibility of a nationwide introduction.

There is minimal financial sustainability risk for the program, with costing of financing included within the cMYP including a proposal to finance IPV by the government. This is contrary to the GoI's subsequent proposal to Gavi to request the funding (cMYP developed before the IPV application). The introductory grant will be managed through WHO and UNICEF channels. GoI will fully finance pentavalent vaccine from 2016.

The ICC minutes (minutes of the group meeting discussing IPV introduction in India as submitted with the application) indicate that India was requesting production capacity through local manufacturers, although a request has now come to Gavi for financing. This may need to be clarified.

Financial Management of VIG Grant: India has applied for a VIG to the amount of US$ 5,083,000. The VIG is supposed to be transferred to WHO and UNICEF: The WHO Country Office (WCO) would receive US$ 3,613,000 and UNICEF would receive US$ 1,470,000. The activities have been properly outlined in the Application. Funds will be managed and disbursed through WHO and UNICEF channels. 6% of the budget have been allocated to document production (development, procurement

and printing of training materials); 8% for cold chain assessments, follow up and monitoring (UNICEF); 4% for data management (state level training); 3% for post introduction evaluation in all states; and 5% have been earmarked as programme support costs. The VIG budget request is much lower than the maximum possible VIG amount for a country with India's birth cohort. This may need to be clarified.

Annex D of the Application provides a sufficiently detailed overview of budgeted costs for the activity areas described above. Co-financing of the introduction costs has not been indicated in the VIG budget. Further costing detail is provided in India's cMYP 2013-2017, which indicates that the Government of India will seek financing for IPV for the envisaged time period of Gavi support. No Gavi/GPEI funding support is indicated in the cMYP. No funding gap or government or development partner co finance is specified.

7. Specific comments related to requested support

New vaccine introduction plan

The planned introduction is for the third quarter in 2015 (as stated in the introduction plan) and in August according to the proposal document. The introduction month should be clarified.

The proposal is for administration at the age of 14 weeks according to the routine immunisation schedule. IPV will be administered with pentavalent vaccine, although no details are given of what advice will be given to health workers regarding injection site (i.e. left or right).

The introduction is nationwide. The IPV introduction will take place at the same time as nationwide expansion of introduction of the pentavalent vaccine. The proposal discusses synergies between the two introductions in terms of expansion of cold chain space. Cold chain space availability has expanded due to no longer requiring space for separate DPT and hepatitis vaccines. Otherwise, no synergies are described in terms of communication, training or monitoring and supervision. There is limited information on the process or content areas of State level Introduction Plans, besides mentioning of preparation of checklists for States and Districts.

The total target population (excluding infant deaths) is 78,319,446 for the 2015-2018 period. India has the highest birth cohort (26.6 million) amongst Gavi-eligible countries and accounts for the largest number of unimmunised children (6.9 million) globally (Gavi Board paper and documents). The introduction will be led by the Immunisation Division at the MoHFW. The introduction plan summarizes the overall introduction strategy that includes training, supervision, and delegation to States for engaging local partners in implementation. High risk districts have been prioritized for routine immunisaton strengthening. The national level will develop the guidelines, conduct national workshops and trainings to ensure success with nationwide efforts. At this level, there will be a team of observers to monitor program roll out nationally to ensure smooth introduction, particularly in high risk areas. Training and communication planning will be conducted before the vaccine is introduced and cold chain capacity and logistics at State, District and block level will be assessed before introduction, although it is not clear how this will be done and who will do it. This may require clarification.

First preference is for a 5 dose vial, and second preference for a 10 dose vial. There is a National Regulatory and Licensing Authority in India (DCDI). The one and 10 dose vials have already been licensed. The 5 dose presentation may take up to 4-6 months for licensing approval but the plan states this would not affect the timing of the delivery of the vaccines. The "ICC minutes" indicate that the DCDI could license the vaccine within 2 months

Procurement will be through UNICEF utilizing Gavi resources. According to ICC minutes, an estimated 60 million doses would be required by 2016.

Vaccine management and cold chain capacity

EVM assessment findings and recommendations in EVM draft from 2013 (draft 3.5) are documented. There is alignment with the cMYP 2013-17, particularly in relation to HR issues (e.g. dedicated staffs for CCL at all level), Monitoring and management information issues (e.g. issues such as lack of real time vaccine stock status, temperature monitoring system). The EVM is used well as a diagnostic tool. The conclusion of EVM was that the cold chain and vaccine management, and the immunisation programme as a whole needs to be revitalized in order to improve the current coverage and performance.

Highlights of the EVM included the following. The consolidated EVM category scores were as follows: (WHO recommends a minimum of 80% performance for each criterion): Management (47%), Repair & Maintenance (54%) and Vehicles (29%) implying immediate action especially related to management, repair & maintenance and vehicles at all levels. The consolidated EVM indicator score indicated that no scores are up to 80% at any level of the cold chain. Similarly low scores were reached for Vaccine Storage Temperature (37%), Distribution (24%), and Vaccine Management Practices (29%).

A comprehensive list of recommendations has been provided to address the different weaknesses that are responsible for the current performance of the immunisation programme. These recommendations, segregated according to categories and priorities are used to develop an improvement plan and action plan. However, there is no update of the status of implementation of recommendations which is a critical area that should be clarified.

In terms of cold chain capacity at district, regional and central levels, the cold chain infrastructure has a network of cold chain stores (5 levels) consisting of Government Medical Supply Depots (GMSD), State, Regional/Divisional Vaccine stores, District and PHC/CHC vaccine storage points. According to the National EVM conducted by UNICEF in 2013 and the data from national cold-chain MIS, India has sufficient cold chain space at district level (and levels below) and IPV introduction will not be a challenge. A major risk is that the majority of the WICs of GMSDs, State Vaccine Stores and Divisional VS are more than 20 years old and some even more than 28 years old with concrete cold rooms in GMSD.

Considering national data and as per a study conducted by Immunisation Technical Support Unit (ITSU) 10 dose vial will result in considerable vaccine wastage of 70%, with 30% wastage for 5-dose vials in India. The reason given for this is that there is no open vial policy for IPV and the average session size in India is three. Lack of open vial policy is based on the recommendation of the Expert Advisory Group appointed by the Indian Council of Medical Research. The country indicates it will

implement wastage reduction activities, with refresher trainings on this topic proposed, but the reasons for the high wastage rate for the 10 dose vial (70%) may need to be further clarified (particularly given the size of this investment).

Waste management

In terms of waste management and injection safety, injection safety protocols are incorporated into existing routine immunisation guidelines. All health staff dealing with injections including routine immunisation injectable vaccines are regularly trained on these protocols. Information from monitoring of sites is shared with districts and states for appropriate response. During training for IPV introduction, injection safety and its benefits for the health worker, beneficiary and community will be reemphasized. Waste sharps generated from immunisation with IPV will be handled as per guidelines prescribed by the Biomedical Waste Management and Handling Rules.

Training, Community Sensitisation & Mobilisation Plans

The proposal (introduction plan) outlines detailed plans for training including preparation of training packages for various levels and for various cadres including at State, District and Block levels. The trainings will include "'sensitisation"" training for community level workers and for professional associations.

The communication plan is well documented, with proposals to develop strategies for influential persons, mass media, and the general population. Activities will include material preparation, advocacy meetings and social mobilisation, with materials prepared in local languages. The communication plan will be prepared 6 months in advance of the introduction. There is no mention of a risk communication strategy in the context of multiple polio vaccines as well as co-administration of IPV with pentavalent vaccine. A risk communication strategy should document the coordinated response to AEFI as well as to media generated rumor.

Monitoring and evaluation plans

As stated above, PIE assessments have been conducted for pentavalent vaccine introductions, and lessons learned have been applied for the development of the IPV introduction plan.

The introduction plan provides description of a system of monitoring at national, State and Block levels. In addition, these monitoring activities have detailed costing for monitoring by surveillance medical officers, administrative officers and drivers for WCO India. Elsewhere in the introduction plan, it is stated that there will be a system of National Observers monitoring preparedness, vaccine distribution and cold chain capacity, and checklists will be prepared for use by State and District officers. At National State and District levels, managers will be encouraged to monitor both IPV and routine immunisation strengthening.

Standard procedures for responding to AEFI were updated in 2011 and there will be a further update in 2014 and communication guidelines for response to AEFI have also been updated. These guidelines will be reinforced during the introduction training.

8. Country document quality, completeness, consistency and data accuracy

The introduction plan and attachments are limited in detail but overall meet the basic requirements. A mandatory requirement (EVM implementation plan) is not attached to the submission. Overall the information and data presented is consistent.

9. Overview of the proposal

Strengths

- The proposal is in line with WHO, SAGE and GPEI recommendations;
- The country has a demonstrated track record with new and underutilized vaccine introduction. Lessons learned from the introduction have been built into the situation analysis and proposal;
- There is a logical timeline of activities, and the description of costs is logically linked with the proposal and timeline;
- There is limited sustainability risk due to high levels of political commitment to immunisation financing and polio eradication;
- There is a strong emphasis on strengthening of routine immunisation;
- India is a Tier 1 country for polio eradication.

Weaknesses

- It is unclear how the pentavalent scale up and IPV roll out are linked in terms of training, communication or supervision;
- There is no EVM progress report of the plan attached, despite supply chain management being identified as a significant system problem;
- The introductory plan, though comprehensive, lacks detail, and no sub national plans are provided that would guide the RI strengthening strategy and monitoring and supervision approach.

Risks

The main risks include the following:

- That States may lack adequate preparation for a national roll out within the specified timelines;
- Global IPV supply may be inadequate to meet supply needs of India in such a short time frame (although as India is a Tier 1 country it may well be prioritised for vaccine supply).

Mitigating strategies

- Development of checklists to guide introductions at State and District level;
- That supply chain assessments are undertaken on a State wide basis prior to vaccine shipments;
- Communication by Gavi and UNICEF Supply Division with the country and vaccine manufacturers to potentially adjust the introduction timeline to the availability of supply, if required.

10. Conclusions

The Government of India has demonstrated the capacity to roll out new vaccine introductions in recent years. The country has also undertaken significant strides in supporting the global polio eradication effort, and has demonstrated the capability to mobilise political, stakeholder and financial commitment for polio eradication. The eradication strategy is well documented in the latest cMYP, and the proposed IPV

introduction is consistent with both this strategy as well as GPEI, WHO eligibility requirements. As a tier 1 country, India is a high priority for IPV introduction and for acceleration and consolidation of eradication and routine immunisation strengthening efforts. There are a number of areas where additional clarification is required in such areas as financial planning, target setting, wastage rates, supply chain and state introduction planning and the Gavi Board's endorsement of any potential funding. To enable the fairest assessment possible of additional budget support for India, these clarifications should ideally be addressed prior to submission of a Board request.

11. Recommendations

Approval with Recommendations

Recommendations and clarifications are listed below. These should ideally be addressed prior to submission for Board request. Board approval would also be needed before any vaccine is shipped.

1. Introduction Planning and Timelines

(a) Although the preparation of State and District level checklists are mentioned, more clarity is sought in general terms on the timeline and the process by which State Introduction plans will be developed, reviewed and implemented. More description is also needed from the country on the feasibility of a nationwide introduction.

(b) The timeline may need to be readjusted taking into account supply availability, State introduction planning and preparedness and the logical sequencing of activities.

(c) The country is commended for its approach in focusing on priority districts with lower coverage which has overall higher risks. Clarification is sought on how this approach will integrate equity issues into State and District introduction planning (or into introduction checklists).

(d) Please clarify the introduction month (indicated as August 2015 in the application form and September 2015 in the introduction plan).

2. ICC Endorsement

(a) Consideration may need to be given to formal endorsement by the ICC (IAG in India) of this proposal.

3. Guidelines on Injection Sites

(a) The country should clarify how guidance and communication will be provided to health workers in relation to site of vaccine administration (in the context of co-administration with pentavalent vaccine).

4. Supply Chain

(a) The progress report on the implementation of the improvement plan from an EVM conducted within the preceding 36 months is not included (as per the mandatory requirements listed in section 2.1 of the guidelines). A status report

on the implementation of the Improvement Plan should be provided. This is a critical issue.

(b) It is recommended that an investment plan be developed to replace WIC's older than 20 years and strengthen cold store capacity including monitoring systems.

5. Vaccine Wastage

(a) The Government of India is proposing a 70% wastage rate for the 10 dose vial. As this is above the Gavi recommended threshold of 50% for this vaccine, further clarification is required as to how the additional wastage rate will be financed. Alternatively, GoI should indicate what the wastage rate will be for the 10 dose and 5 dose vials, given that WHO has recently updated its guidance in relation to an open vial policy for IPV.

6. Targets

(a) Targets for 100% are proposed for IPV introduction for the first year, when most recent WUENIC estimates demonstrate a 72% coverage rate. Also it is noted that across three years, the same numbers of cohort are nominated to be vaccinated. The target will need to be re-negotiated with the country, taking into account latest estimates and intended implementation of coverage improvement plans.

7. VIG Grant

(a) The VIG budget is much lower than what would have been expected based on the relevant birth cohort. The country should clarify if it was the intent to request a much smaller amount. The total budget calculation also needs to be checked against the exchange rate and sub totals. The GoI is requested to specify what its financial contribution to the introduction operational costs will be.

8. Vaccine Procurement and Request

(a) Clarification is required on the duration of the support requested by Gavi, and on the intent of the GoI to self-procure through local manufacturers.

9. Communication Strategy

(a) Although the communication strategy is well documented, there is no mention of development and implementation of a risk communication strategy in the context of multiple vaccine introductions (IPV and pentavalent). It should be clarified as to how the country will develop and implement such a risk communication strategy, particularly given the risk associated with a nationwide introduction.

10. Financing

(a) Given the special category of India for Gavi financing, the requested support for IPV vaccine introduction will need to be considered by the Gavi Board.

Appendix D

Gavi Alliance Terms and Conditions

Countries will be expected to sign and agree to the following Gavi Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between Gavi and the country:

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by the Gavi Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the Gavi Alliance. All funding decisions for this application are made at the discretion of the Gavi Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

The Country will notify the Gavi Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The Gavi Alliance will document any change approved by the Gavi Alliance, and this application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the Gavi Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the Gavi Alliance, within sixty (60) days after the Country receives the Gavi Alliance's request for a reimbursement and be paid to the account or accounts as directed by the Gavi Alliance.

SUSPENSION/ TERMINATION

The Gavi Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any Gavi Alliance-approved amendment to this application. The Gavi Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of Gavi Alliance funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the Gavi Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the Gavi Alliance, as requested. The Gavi Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how Gavi Alliance funds are used. The Country will maintain its accounting records in