

#### Gavi/14/513/mk/at/hk

H.E Dr Nafsiah Mboi The Ministry of Health J1. H.R. Rasuna Said Blok X.5 Kav. 4-9 Blok A Kuningan - Jakarta 12950 Indonesia

21 October 2014

Dear Ibu Nafsiah,

# INDONESIA's Proposal to the GAVI Alliance

I am writing in relation to INDONESIA's proposal to the GAVI Alliance for New Vaccines Support (NVS) for Inactivated Polio Vaccine (IPV) which was reviewed by the Gavi Independent Review Committee (IRC) on the 1st of July 2014.

The IRC recommended an approval of the Inactivated Polio Vaccine (IPV) support for Indonesia <u>subject to a number of recommendations</u>.

We have since received satisfactory responses to these recommendations and based on Indonesia's agreement with me to address any outstanding recommendations within the deadlines stated below, I am now pleased to inform you that Gavi <u>approved</u> Indonesia for Inactivated Polio Vaccine (IPV) as specified in the Appendices to this letter.

Recommendations	Way forward	Gavi Alliance Comments
Although the country has had experience in the introduction of IPV, the timeline proposed is tight and preparation should be carefully planned and monitoring closely	The country has submitted a revised - Annex C relating to the timelines of the introduction	sufficient response
CSO participation should be encouraged and shown in the introduction plan	CSO will participate with Socialization and Mobilization and empowering communities, develop information, education	sufficient response



Provide a detailed breakdown of the budget including detailed assumptions and unit costs for all line items	and communication (IEC) communities involving Scout Movement, Consortium (through religious leader), PKK, Midwives Associations Management and coordination cost will be used for: coordination meeting, monitoring and evaluation, external audit process and allowances for committee of procurement and secretariat for support of VIG activities. The country has re calculated the budget for management and coordination cost.	sufficient response
The country should confirm that budget in Annex D of the proposal is the correct budget	The country has resubmitted Annex D	sufficient response

This decision letter is only for the vaccine introduction grant and not for the doses. The Government of Indonesia had identified a preference for using a Biofarma 5 dose vial standalone IPV but is yet to clarify which supplier they will use. Once the Government clarifies appropriate supply arrangements for IPV vaccines Gavi will send an updated decision letter for the doses.

Indonesia received a Partnership Framework Agreement (PFA) in September 2012. We have still not received the signatures of the Ministry of Health and Ministry of Finance on the Partnership Framework Agreement. Please be advised that until that Agreement has been signed between the GAVI Alliance and Indonesia, the GAVI Alliance will no longer disburse the subsequent tranches of HSS funds and will also not be in a position to consider applications for the introduction of new vaccines from Indonesia. The PFA is a template document that formalizes the funding procedures that GAVI and Indonesia have largely been following since 2001. GAVI looks forward to Indonesia signing the PFA shortly, and remains available to solve high level issues that pose difficulties in terms of Indonesian law.



The Appendices includes the following important information: Appendix A: Description of approved Gavi support to Indonesia

Appendix B: Financial and programmatic information per type of support

Appendix C: Internal Appraisal Report

Appendix D: The terms and conditions of Gavi support.

Please do not hesitate to contact my colleague <u>athomson@gavi.org</u> if you have any questions or concerns.

Yours sincerely,

Hind Khatib-Othman

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Managing Director, Country Programmes

cc: WHO Country Representative

**UNICEF** Country Representative



# Description of GAVI support to Indonesia (the "Country")

## **New Vaccines Support (NVS)**

The GAVI Alliance 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:

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

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 immunization provided with these vaccines.

Item number 11 of Appendix B summarizes 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 cannot 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

\*\*\*Note: GAVI's usual co-financing requirements do not apply to IPV. However, INDONESIA is encouraged to contribute to vaccine and/or supply costs for IPV. \*\*\*

In accordance with the GAVI Co-financing Policy, the Country has agreed to make the required contribution to co-financing vaccine doses as indicated in Appendix B. Item number 14 of Appendix B summarizes the budget and the quantity of supply that will be procured with country's funds in the corresponding timeframe. The total co-financing amount indicates costs for the vaccines, related injection safety devices (only applicable to intermediate and graduating countries) and freight.



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 the GAVI Alliance. 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.

The total co-financing amount expressed in item number 14 of Appendix B does not contain costs and fees of the relevant Procurement Agency, such as contingency buffer and handling fees.

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. In accordance with the GAVI Co-financing Policy (<a href="http://www.gavialliance.org/about/governance/programme-policies/co-financing/">http://www.gavialliance.org/about/governance/programme-policies/co-financing/</a>), the co-financing contribution is payable annually to UNICEF/PAHO.

If the purchase of the 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 must 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:

<u>Transparency and Accountability Policy (TAP)</u>: Compliance with any TAP requirements pursuant to the GAVI TAP Policy and the requirements under any Aide Memoire concluded between GAVI and the country.



<u>Financial Statements & External Audits</u>: Compliance with the GAVI requirements relating to financial statements and external audits.

<u>Grant Terms and Conditions:</u> Compliance with GAVI's standard grant terms and conditions (attached in Appendix D).

<u>Country Co-financing:</u> GAVI must receive proof of country co-payment from the Country such as invoices or shipment receipts if neither UNICEF nor PAHO is the procurement agent for country co-financed vaccine for the prior calendar year.

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. The GAVI Alliance uses country systems for monitoring and auditing performance and other data sources including WHO/UNICEF immunization coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunized and on co-financing of the vaccine.

Country will report on the achievements and request support for the following year 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 Immunization Coordination Committee (ICC), and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). The APRs or equivalent will also contain information on country's compliance with the co-financing arrangements outlined in this letter. APRs or equivalent endorsed by the ICC should be sent to the GAVI Secretariat no later than 15 May every year. Continued funding beyond what is being approved in this letter is conditional upon receipt of satisfactory Annual Progress Reports or equivalent and availability of funds.



#### Indonesia

# SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

- Country: Indonesia
   Grant Number: 15-IDN-8h-Y
   Date of Decision Letter: 21 October 2014
   Date of the Partnership Framework Agreement: Not yet signed
   Programme Title: NVS, IPV Routine
   Vaccine type: Inactivated Polio Vaccine (IPV)
  - 7. Requested product presentation and formulation of vaccine<sup>1</sup>: Manufacturer to be confirmed
  - 8. Programme Duration<sup>2</sup>: 2015
  - 9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):

Please note that endorsed or approved amounts for 2017 and 2018 will be communicated in due course, taking into account updated information on country requirements and following GAVI's review and approval processes.

	2015	2016	2017	Total <sup>3</sup>
Programme	To be	TBD	TBD	TBD
Budget (US\$)	determined (TBD)			

10. Vaccine Introduction Grant: US\$3,688,500

<sup>&</sup>lt;sup>1</sup> Please refer to section 18 for additional information on IPV presentation.

<sup>&</sup>lt;sup>2</sup> This is the entire duration of the programme.

<sup>&</sup>lt;sup>3</sup> Once determined, this will be the total amount endorsed by GAVI for 2014 to 2016.



## 11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement): 4 Not Applicable

Type of supplies to be purchased with GAVI funds in each year	2015	2016
Number of vaccines doses	TBD	TBD
Number of AD syringes	TBD	TBD
Number of re-constitution syringes	TBD	TBD
Number of safety boxes	TBD	TBD
Annual Amounts (US\$)	TBD	TBD

12. Procurement agency: TBD

13. Self-procurement: TBD

#### 14. Co-financing obligations: N/A

GAVI's usual co-financing requirements do not apply to IPV. However, Indonesia is encouraged to contribute to vaccine and/or supply costs for IPV.

- 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: Not Applicable.

#### 18. Other conditions:

We have still not received the signature of the Ministry of Health on the Partnership Framework Agreement. Please be advised that until that Agreement has been signed between the GAVI Alliance and Indonesia, the GAVI Alliance will no longer disburse subsequent tranches of HSS funds and will also not be in a position to consider applications for the introduction of new vaccines from Indonesia. The PFA is a template document that formalizes the funding procedures that GAVI and Indonesia have largely been following since 2001. GAVI looks forward to Indonesia signing the PFA shortly, and remains available to solve high level issues that pose difficulties in terms of Indonesian law.

2 Chemin des Mines 1202 Geneva. Switzerland Tel. + 41 22 909 65 00

<sup>&</sup>lt;sup>4</sup> This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.



Indonesia understands that Gavi disburses the VIG on the assumption that its application of the doses of IPV vaccine will be approved.

If Indonesia envisages a switch in product presentation, it is encouraged to incorporate elements for both IPV presentations in its 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 Indonesia.

Signed by,

On behalf of the GAVI Alliance

Hind Khatib-Othman Managing Director, Country Programmes 21 October 2014

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# Independent Review Committee (IRC) Country Report GAVI Secretariat, Geneva • 23 June – 4 July 2014 Country: INDONESIA

#### 1. Type of support requested: IPV

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> choice)
June 2015	2015-2018	Biofarma 5-dose vial
		Bilthoven 5-dose vial

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

The ICC merged with HSCC in 2011; participation is inclusive: MoF, MoH EPI and MCH, Ministry of Foreign Affairs, BPKP (Government Auditor), DG of Pharmaceutical and Medical Devices, CSOs and International Agencies WHO and UNICEF. The GAVI application for IPV introduction was fully endorsed by the ICC/HSCC during a meeting held on May 8, 2014. Both the Minister of Health and the Minister of Finance provided signatures endorsing the application. Indonesia Technical Advisory Group of Immunisation in 2014 has recommended the introduction of IPV into routine schedule and by 2016 tOPV should be replaced by bOPV.

#### 3. Situation analysis - Status of the National Immunisation Programme

Indonesia has had a significant improvement of its economy. Between 2002-2008, the GDP increased by 17%-20% per year and the economic growth was 30%. Expenditure in health is 2% of GDP. Indonesia is a graduating country of 253 million inhabitants, with IMR 26 per 1,000 live births and GNI per capita US\$ 3,420. Indonesia has received 94 million since 2002, 48 million in vaccine and 46 million in non-vaccine support. Immunisation Programme started in 1977 and decentralisation and political reform affected sustainability of funds for the programme. The country has 33 provinces, 497 districts and 8,742 villages. Local governments are responsible for the operational cost of the EPI programme and the central government takes care of procurement of vaccines and supplies, technical assistance, development of guidelines, M&E, quality control and training.

The trend of DTP3 coverage provided by the country in this proposal indicates an increase in DPT3 coverage from 64% in 2012 to 76% in 2013. Indonesia had had last case of polio in 1995; however in 2005 the country had an imported outbreak. There were also measles and diphtheria outbreaks which



made EPI a strategic priority of the government in the MOH strategic plan 2010-2014.

Indonesia started to introduce IPV in a study carried out in 2004-2012 together with WHO in the province of Yogyakarta to assess the performance of the vaccine. There are lessons learned, well summarised in a table in the proposal, and actions to be taken into account for the introduction of the vaccine in the regular schedule of EPI. In addition, since the introduction of Penta in 2013, some recommendations are also considered to improve preparation and implementation of new vaccine introduction through training of health care staff and social mobilisation strategy.

#### 4. Overview of national health documents

The cMYP 2010-2014 is aligned with the National Strategic Plan and the new cMYP 2015-2019 will include the introduction of IPV in all provinces by 2015. The cMYP states that there should be universal child immunisation by 2014 and introduction of new vaccines as they become available. Penta 2013 is 20% and should reach 80% in 2014. No funding gap is identified for the cMYP 2010-2014 taking into account probable funding sources. Otherwise, the gap would be 25%. No funding gap is identified for the IPV introduction in 2015.

#### 5. Gender and Equity

Population	250 million
<5 mortality	31
MMR	220
GII	0.49
GII Rank	106/148

The gender disaggregated data is from a basic health survey, which indicated the same coverage rates for male and female. According to the UNICEF the infant mortality rates in various geographical locations vary widely (34 vs 57). Under-five and infant mortality rates amongst the poorest households are generally twice as high as those in the highest income families. There is a 22 per cent difference between the number of women in urban and rural areas who benefit from the attendance of a trained health worker during childbirth. More than 84 per cent of the lowest income mothers give birth at home, compared to just 15 per cent amongst the richest families. Low DTP3 coverage (DHS 2012) were observed among children whose mothers have low education (26%), living in certain geographic location (Papua Province 35%), belonging to high birth order of 6+ (36%), are from the household's lowest income quintile (52%) and those living in rural areas (67%).



Some of the barriers include lack of father's involvement in immunisation. Religious influences have been recognised in the proposal and a communication strategy is proposed to address these gender issues on low male involvement as decision makers and influencers for the programme. Examples of implementing equitable access to social basic services among the deprived populations include the Anti-Poverty Programs to increase utilisation of immunisation and other public health programmes such as targeted Conditional Cash Transfers, Community Grants, Social Health Insurance, and scholarships among the poor. Supply side health services that include immunisation in the targeted areas are mapped and strengthened.

It is known that a country like Indonesia with such geographical challenges (remote, difficult to reach) and diverse local culture that inhibit the immunisation service, may cause no or low coverage of immunisation in some areas. The Indonesian government is currently trying to implement equitable health services. For that purpose, the MoH formed a special unit whose task was to ensure that the implementation of health programmes including immunisation can take place in difficult to reach areas.

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

Indonesia has stated that there will be no co-financing for the new vaccine introduction. The birth cohort is 4,734,533. At US\$ 0.80 per child, the VIG is calculated at U\$ 3,787,627. The total cost of IPV VIG will be US\$ 16,590,444. 39.7% (US\$ 6,580,912) is requested from GAVI: US\$ 3,787,626 will be from the IPV introduction grant and US\$ 2,793,286 from the HSS grant. The Government will allocate US\$ 9,824,531 (59.2%), and US\$ 185,000 will be sourced from other partners.

However, the application states that for 2015 the requested amount for vaccines (Population 2,159,886), including 25% buffer stock and 30% waste management, is US\$ 8,128,913 and for 2016 US\$ 11,784,176. In addition, the VIG request is US\$ 3,787,626.

Also, in the application it is mentioned that total annual cost for IPV introduction is US\$ 12,975,951 and around US\$ 3,787,626 is requested to GAVI. Remaining cost is funded by the government (US\$ 8,493,325), existing GAVI HSS/VIG fund (US\$ 510,000) and partners contribution (US\$ 185,000).

Only lump sum amounts have been provided for certain major cost categories including those representing substantial amounts as detailed below. No assumptions and unit costs for these large amounts were provided.



- Management and coordination of US\$ 635,090 (which accounts for 17% of the total IPV VIG requested from GAVI)
- Social mobilisation, IEC, advocacy:
  - Public Service Announcement US\$ 554,405
  - o AEFI Socialisation meeting US\$ 486,370
  - Socialisation and advocacy meeting US\$ 748,426

Financial audit issues from FMA and CPA in 2013 are resolved. The government has requested that the VIG be transferred according to the financial management modalities agreed upon with GAVI, which are still applicable.

### 7. Specific comments related to requested support

#### New vaccine introduction plan

IPV will be produced by Biofarma/Sanofi Pasteur, which is the requested presentation of the vaccine. Biofarma/SP are currently finalising the partnership and the establishment of manufacturing processes, and regulatory approvals should be ready by June 2015, at the time of the proposed introduction. The National Regulatory Agency is the National Agency of Drug and Food Control (NADFC). Indonesia exports vaccines through the UNICEF procurement system. Therefore NADFC plays an important role globally and currently it is considering regulatory implications of Biofarma/SP alliance for IPV. It is expected to be licensed by March-April 2015 according to the timeline of the NVIP.

There will be a nation-wide introduction of the vaccine at 4 months of age at the time Penta3 or OPV4 is administered. 4 doses of OPV will be given regardless of IPV schedule.

Indonesia is aware that NVI may have important issues to deal with in relation to training and social mobilisation, particularly with regards to perceptions and attitudes towards multiple injections, vaccine hesitancy of certain groups, and the workload and communication of the frontline health workers and implementation of the multidose-vial policy.

MR will be introduced in 2016 and the country is planning the introduction of Rota in 2017, PCV in 2018, and JE in 2019. IPV introduction will strengthen the MR campaign and the training and preparedness of future introduction of the other vaccines in the next 3-5 years.

# Vaccine management and cold chain capacity

EVM June 2011-May 2012 states that there is enough cold chain capacity in the country. National level is sufficient for the introduction of IPV. For district



level 78% of districts have enough capacity. HSS may be used for gaps at district capacity, if required. The storage capacity at national store is sufficient.

Most of the province stores have spare cold chain capacity in excess of 30% (as per EVM report 2012). However, there are specific provinces that will have capacity gaps. The District EVM report indicated that 78% of districts have sufficient capacity for routine immunisation. The Country is planning for a cold chain inventory updating (or assessment) in July 2014 which should reflect gaps at this level for IPV and other new vaccines for the next 5 years. IPV introduction will have minimal impact on district cold chain and as per the EVM results, the space will be sufficient for most districts. The assessment (inventory update) will result in recommendation of most appropriate quantities and type of equipment to address gaps in storage and other related issues. A portion of the existing GAVI HSS funds may be utilised to fill any gaps in the country's cold storage and thus, IPV introduction should not be limited by cold storage issues.

The capacity at HC level is sufficient to introduce IPV using 5 weeks maximum stock levels except for Puskesmas without operational refrigerator. The gaps would be reflected through the July 2014 assessment, which results would be available by September 2014. Under circumstances where there are health centres that have storage capacity gaps, a 4 week maximum stock level maybe applied, that will mean more frequent delivery requests of the vaccine to the district level.

Over a period of twelve months between June 2011 and May 2012 Indonesia has conducted two EVM Assessments to represent the total country and it showed that the country has enough cold chain capacity at all level. Indonesia preference is 5-dose vial, which assumes 30% wastage rates.

#### Waste management

It is expected that the introduction of IPV will not impact the waste management, a system already in place and the waste management and injection safety will be incorporated appropriately in the technical guidelines.

#### Training, Community Sensitisation & Mobilisation Plans

The introduction of a new vaccine such as IPV will be the opportunity for the health workers training with respect to specific aspects of this vaccine. These activities will continue to be on top of the agenda placing the focus on providing health workers with the adequate information and communication skills, training on injection technique and safety, adverse events following immunisation, interpersonal communication strategy at all level. Training on



social mobilization and advocacy will be a collaboration of Health Promotion-MOH.

Staff training will focus on injection safety and health workers skills in relation to multiple injections. Other activities to introduce new vaccine such as social mobilisation, IEC materials, AEFI surveillance were provided by GAVI and cofinanced by Gol. Donors (WHO, UNICEF and others) will also contribute to this. Training of trainers will be organised in a cascade manner from central to provinces, districts and training of health workers at the health facility level. Aside from classroom trainings, on site follow up training and supportive supervision by central, provincial, district teams to health center midwives will be done to ensure greater understanding as well as assure the adaption of multiple injections. Globally available training materials will be reviewed by a core team for Indonesia adaptation and translation. This will also include development of materials such as a handbook for health workers, FAQs, fact sheets, training video, posters, pre-and post-knowledge tests, etc.

The new IPV introduction can be integrated in each component of the communication strategy. The communication strategy to improve routine immunisation has recognised some risks based on some studies conducted to understand perceptions on immunisation and from experts opinions. The communication-related risks are: health workers concerns about administration of at least 2 injections during one visit by the child, false contraindications, fever after DTP injections, and misconceptions by some religious groups on non-purity of Oral Polio vaccine. Key messages, communication materials are currently developed to address these various concern e.g advocacy brochures for community leaders (informal, religious), video, flip charts, leaflets, brochures for health workers and kaders. Improving face to face or interpersonal communication skills of midwives and kaders through trainings and supportive onsite coachings to better respond to these challenges needs to be the strategic focus and as priority strategy combined with public awareness, community leaders engagements and advocacy/mobilisation as well as organisation of support groups. The IPV introduction will be an opportunity to address these risks and strengthen the programme. Real time communication monitoring from various channels needs to be activated to anticipate whatever concerns the community will raise once the IPV vaccinations start in health facilities.

# Monitoring and evaluation plans

A post introduction evaluation (PIE) is planned for end 2015 and beginning of 2016. The AEFI system will be updated for the IPV introduction. Supervision will be conducted every 2 months. The monitoring check list has been updated with IPV information. 14% of the budget will be allocated for evaluation.



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

The MOH strategic plan (2010-2014) has the goal to enhance health and nutritional status of the population, decrease morbidity of common diseases and increase public budget for health. In both cMYP 2015-2019 and in the Indonesian Medium Term Development Plan (RPJMN) the IPV introduction and the Annual EPI plan are included.

#### 9. Overview of the proposal

# Strengths

- Very well prepared proposal. A coherent, solid and detailed introduction plan is presented;
- Indonesia has the experience of an early introduction of IPV in the study carried out with WHO in 2004-2012;
- cMYP 2015-2019 and MOH strategic plan have considered the IPV introduction in the EPI programme;
- The country has enough cold chain capacity at all levels for the planned vaccine introductions, including the IPV introduction;
- The EPI programme has a proven track record of new vaccine introduction (Penta) and has the experience and capacity to introduce IPV;
- Functioning AEFI system and good AFP surveillance.

#### Weaknesses

- In some new districts, cold chain equipment at district level and health centres is inadequate;
- Active involvement of key stakeholders must be strengthened;
- The introduction budget is not clearly stated because there are three different budgets and it is not known which one is the correct one;
- The Post-Introduction Evaluation was not detailed in the Introduction Plan;
- Over estimation of indicative wastage rates;
- Detailed line items were not provided in the budget.



#### Risks

- Protracted negotiations between GAVI and Country on PFA signing are ongoing, which may result in problems for future disbursements;
- Health workers may have concerns regarding two injections in one visit;
- Short 3 month timeline;
- Anti-vaccine or religious groups.

# Mitigating strategies

- Financial audit issues from FMA and CPA in 2013 were resolved;
- Training to health workers is anticipated and new IEC materials will be prepared;
- Social communication strategy researched;
- Planning and detailed preparation, including training as well as proper management of supply and delivery mechanisms.

#### 10. Conclusions

This is a sound proposal with VIP well defined. EPI programme of the country has political and budget support. Immunisation for children and children's health are considered priorities for the country. The country has taken careful steps for the introduction of IPV including development of new IEC materials, training of personnel and social mobilisation to reactivate commitment of stakeholders. IPV introduction will strengthen EPI programme and prepare the country for the introduction of new vaccines. HSS will enhance the introduction of IPV in the country. The budget will need to be clarified.

#### Recommendations

Approval with Comments

#### Comments:

- Although the country has had experience in the introduction of IPV, the timeline proposed is tight and preparation should be carefully planned and monitoring closely;
- CSO participation should be encouraged and shown in the introduction plan;
- Provide a detailed breakdown of the budget including detailed assumptions and unit costs for all line items;

The country should confirm that budget in Annex D of the





#### **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 accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

#### **CONFIRMATION OF LEGAL VALIDITY**

The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

# CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARANCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

#### **ARBITRATION**

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.



The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

#### **USE OF COMMERCIAL BANK ACCOUNTS**

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.