GAVI/14/400/dlc/ac

The Minister of National Health Regulation and Services.
Ministry of National Health regulation and Services
Government of Pakistan
Islamabad
Pakistan

6 August 2014

Dear Minister,

Pakistan's Proposal to the GAVI Alliance

I am writing in relation to Pakistan's proposal to the GAVI Alliance for New Vaccines Support (NVS) for Inactivated Polio Vaccine (IPV) which was submitted to the GAVI Secretariat in May 2014.

In July 2014 your application was reviewed by the GAVI Independent Review Committee (IRC) which recommended "Approval with Comments" of your application. Based on Pakistan's agreement with your Senior Country Manager to address the IRC's comments within the deadlines stated below, the GAVI Alliance has approved Pakistan for GAVI support for IPV, as specified in the Appendices to this letter.

Comment	Suggested way forward	Timeframe
Consider making a financial provision for a PIE;	*A provision of USD 76,468 is being included in the revised budget for a PIE. .*	21st August 2014
Timeline covers the period from March 2014 to Feb 2015. It should be extended through Dec 2015,	*It will be extended until Dec 2015, the following activities will be added accordingly* - *Vaccine distribution schedule* - *Post Introduction Evaluation* - *Communication and Social Mobilization activities* - *Amendment of the Introduction Plan according to the IPV procurement standard lead times* - *Plan for effective implementation in Reaching Every Child including children in the security compromised, difficult to reach areas shall be developed and shared;* - *DQS (Data Quality Survey) will be included in the work plan.*	21st August 2014
Country to provide a justification and details of cold chain equipment procurement plans for the amount of US$ 1.529 million to support the introduction of IPV as requested.	The cold chain inventory using CCEM-II tool has been completed with the support of UNICEF for the National, all the four provincial (Balochistan, Punjab, KP and Sindh) and 56 district/town/agency EPI stores as well as the distribution points and service delivery points in these 56 districts/towns/agencies. The assessment report shows the need for expansion of the	21st August 2014

Comment	Suggested way forward	Timeframe
	cold chain capacity at the National, one Provincial and in 35 districts (4 in Balochistan, 7 in FATA, 4 in KPK, 2 in Punjab and 2 districts & 12 towns in Sindh) out of 56 assessed. The cold chain equipment planned to be procured include the cold rooms for the provincial / divisional stores, ILRs for the district and sub-district level EPI stores and service delivery points as well as the solar refrigerators for the areas with no electricity. As the total VIG has been reduced from US$5.2 million to US$3.8, the detail of the equipment to be procured needs to be reviewed and revised.	
To consider planning to conduct EPI review in the near future;	EPI review is planned for Sindh and Balochistan before the end of 2014	*Dec 2014*
The National EPI policy to be revisited to include introduction of IPV vaccine;	The National EPI Policy will be revisited and updated in the 3rd quarter of 2014 jointly with all the partners and stakeholders and inclusion of IPV in the National EPI Schedule will be addressed and endorsed by NITAG.	*21st August 2014*
Revision of budget and work plan according to revised figures.	*Any revision needed will be submitted*	21st August 2014

Please be advised that if comments are not addressed in a manner satisfactory to GAVI within the agreed timeframe, Pakistan may be requested to reapply for IPV support.

In order to ensure sufficient funding for all GAVI countries applying for IPV support, please note that Pakistan's initial allocation of IPV doses and associated supplies have been adjusted using UN population data[1] and WHO UNICEF estimates of DTP3 coverage in 2012, consistent with the calculation underlying the IPV budget approved by the GAVI Board in November 2013. Reflecting these adjustments, the Vaccine Introduction Grant (VIG) has been revised in line with UN population estimates of the birth cohort.

Following a country's introduction of IPV, in exceptional circumstances with clear supporting evidence of an additional need and in consultation with the country and partners, doses may be revised upwards to meet that need. Any such revision would be subject to GAVI's approval and reporting processes, and subject to sufficient GAVI funding for IPV being available.

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 Pakistan the GAVI Alliance will no longer disburse subsequent tranches of HSS funds and will also not consider Pakistan eligible to apply for the introduction of new vaccines.

[1] UN World Population Prospects, Revision 2012 (http://esa.un.org/wpp/)

The Appendices includes the following important information:
Appendix A: Description of approved GAVI support to Pakistan
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 Alliance support

Please do not hesitate to contact my colleague Anne Cronin (acronin@gavialliance.org) if you have any questions or concerns.

Yours sincerely,

Hind Khatib-Othman
Managing Director, Country Programmes

cc: The Minister of Finance
The Director of Medical Services
Director Planning Unit, MoH
The EPI Manager
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division
The World Bank

Appendix A

Description of GAVI support to *Pakistan* (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 Pakistan's proposal application; and
- The final proposal as approved by the the Independent Review Committee (IRC), including any subsequent comments.

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
****Note:GAVI's usual co-financing requirements do not apply to IPV. However, Pakistan 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 summarises 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 (http://www.gavialliance.org/about/governance/programme-policies/co-financing/), 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:

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).

For all vaccines except IPV: Country Co-financing: 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 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 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 Immunisation 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.

Appendix B

Pakistan SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

1. **Country:** Pakistan
2. **Grant Number:** 1518-PAK-25c-X / 15-PAK-08h-Y
3. **Date of Decision Letter:** 06/08/2014
4. **Date of the Partnership Framework Agreement:** not applicable as of yet
5. **Programme Title:** NVS, IPV Routine
6. **Vaccine type:** Inactivated Polio Vaccine (IPV)
7. **Requested product presentation and formulation of vaccine[2]:** Inactivated Polio Vaccine, 10 dose(s) per vial, LIQUID
8. **Programme Duration[3]:** 2015 - 2018
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	Total[4]
Programme Budget (US$)	US$10,389,000	US$8,410,000	US$18,799,000

10. **Vaccine Introduction Grant:** US$3,678,500

[2] Please refer to section 18 for additional on IPV presentation.
[3] This is the entire duration of the programme.
[4] 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):[5]

Type of supplies to be purchased with GAVI funds in each year	2015
Number of IPV vaccines doses	9,058,500
Number of AD syringes	5,978,600
Number of re-constitution syringes	
Number of safety boxes	65,775
Annual Amounts (US$)	US$10,389,000

12. Procurement agency: UNICEF

13. Self-procurement: not applicable

14. Co-financing obligations: N/A

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

15. Operational support for campaigns: N/A

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 the 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:**

Comment	Suggested way forward	Timeframe
Consider making a financial provision for a PIE;	*A provision of USD 76,468 is being included in the revised budget for a PIE. .*	21st August 2014
Timeline covers the period from March 2014 to Feb 2015. It	*It will be extended until Dec 2015, the following activities will be added accordingly*	21st August 2014

[5] This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

should be extended through Dec 2015,	- *Vaccine distribution schedule* - *Post Introduction Evaluation* - *Communication and Social Mobilization activities* - *Amendment of the Introduction Plan according to the IPV procurement standard lead times* - *Plan for effective implementation in Reaching Every Child including children in the security compromised, difficult to reach areas shall be developed and shared;* - *DQS (Data Quality Survey) will be included in the work plan.*	
Country to provide a justification and details of cold chain equipment procurement plans for the amount of US$ 1.529 million to support the introduction of IPV as requested.	The cold chain inventory using CCEM-II tool has been completed with the support of UNICEF for the National, all the four provincial (Balochistan, Punjab, KP and Sindh) and 56 district/town/agency EPI stores as well as the distribution points and service delivery points in these 56 districts/towns/agencies. The assessment report shows the need for expansion of the cold chain capacity at the National, one Provincial and in 35 districts (4 in Balochistan, 7 in FATA, 4 in KPK, 2 in Punjab and 2 districts & 12 towns in Sindh) out of 56 assessed. The cold chain equipment planned to be procured include the cold rooms for the provincial / divisional stores, ILRs for the district and sub-district level EPI stores and service delivery points as well as the solar refrigerators for the areas with no electricity. As the total VIG has been reduced from US$5.2 million to US$3.8, the detail of the equipment to be procured needs to be reviewed and revised.	21st August 2014
To consider planning to conduct EPI review in the near future;	EPI review is planned for Sindh and Balochistan before the end of 2014	*Dec 2014*
The National EPI policy to be revisited to include introduction of IPV vaccine;	The National EPI Policy will be revisited and updated in the 3rd quarter of 2014 jointly with all the partners and stakeholders and inclusion of IPV in the National EPI Schedule will be addressed and endorsed by NITAG.	*21st August 2014*
Revision of budget and work plan according to revised figures.	*Any revision needed will be submitted*	21st August 2014

If Pakistan 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 Pakistan

Signed by,
On behalf of the GAVI Alliance

Hind Khatib-Othman
Managing Director, Country Programmes
6 August 2014

Appendix C

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

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1. Type of support requested: IPV

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

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

The application for the IPV introduction was compiled by Federal EPI with the support of the technical partners including WHO and UNICEF. The IPV application was presented to ICC and after the endorsement by the ICC members, the application was signed by the Ministry of NHSRC and Finance, before its submission to GAVI.

Signatures supporting the application were provided from both Ministers of Health and Finance.

The EPI is high in the political agenda and is considered one of the top health priorities and coordination with all stakeholders is always sought for decision making to improving immunisation performance in the country. IPV introduction in the country has been approved by both the National Steering Committee for Polio and ICC.

A meeting of the ICC was convened on 24st April 2014 to review the IPV proposal submission. Members from MoH, WHO, UNICEF, USAID, JAICA and civil society attended the meeting. The minutes indicated that the members unanimously approved the introduction of the IPV. Other issues related to introduction were also discussed including the schedule, dose and the time of introduction. The members also expressed their concerns for accepting 3 injections during the vaccination session and recommended advocacy and social mobilisation. Pakistan's National Steering Committee for Polio Eradication met on 21st March who approved the introduction of IPV, and the committee made a recommendation on when to submit the proposal to GAVI.

The ICC members' endorsement is provided through signatures. However, there is no indication of a functional National Immunisation Technical Advisory Group (NITAG).

3. Situation analysis – Status of the National Immunisation Programme

Pakistan is a country with complex operational dynamics, unstable socio-economic condition and deteriorating security situation in the country including natural and man-made disasters and is the sixth most populous country in the world with the current population of 179,160,000 growth rate of two percent, and with 64 percent of its

population living in rural areas. The health and sanitation infrastructure is adequate in urban areas but is generally poor in rural areas.

Pakistan has a mixed health system, with coexistence of public and private sectors. Private sector accounts for approximately 80% of all outpatient visits. The public sector was until June 2011 led by the Ministry of Health, however, the Ministry was abolished in June 2011 and all health responsibilities (mainly planning and fund allocation) were devolved to provincial Health departments which had until now been the main implementers of public sector health programmes.

The Expanded Programme on Immunisation in Pakistan was launched in 1976 on a pilot basis and was expanded country wide by 1978. Until 2001, the EPI programme provided six traditional antigens to children below one year of age. During 2002, monovalent Hepatitis B vaccine was added to the childhood immunisation schedule with GAVI support which was later changed to Tetravalent (DPT-HepB) in 2006. EPI Pakistan added Hib vaccine as pentavalent form (DPT-HepB-Hib) in its childhood immunisation schedule from 2008 with GAVI NVS support under a co-financing agreement. In 2012, Pakistan started introduction of PCV-10 in its routine immunisation (RI) schedule in a phased manner and it is now introduced in more than 95% of the country. As of now the EPI programme is offering immunisation services against **9** vaccine-preventable diseases.

The introduction plan for IPV will capitalise on the gains made in Polio but also contribute in RI strengthening with a strong emphasis on system strengthening. GAVI is the largest donor of EPI services in Pakistan since 2001.

As per overall policy of the Federal Ministry of National Health Services, Regulation and Coordination, EPI services are to be integrated and extended through primary health care. As such, the immunisation is delivered through Rural Health Centres, Basic Health Units, Maternal and Child Health's and hospitals. The services are also delivered through the static and outreach strategies.

The official country estimates of DTP3 coverage differ from WUENIC data. The administrative estimation of DTP3 coverage for 2013 was 89% while the WUENIC estimation was 81% and the house hold survey showed a drop in DTP3 coverage to 65%. The need to strengthen data management is one of the main priority interventions in the programme.

Introduction of multiple new vaccines in recent past had enriched the EPI programme with requisite technical expertise and experience for introduction of another new vaccine such as IPV. Furthermore, the presence of the technical partners including WHO and UNICEF, bilateral and multilateral partners and relevant stake holders provides an opportunity to the Government of Pakistan for smooth introduction of IPV in the country. These lessons learned are reflected in the IPV introduction plans.
No comprehensive EPI review was carried out for more than 3 years.

Major Concerns include the following:
Security compromised areas pose a threat to routine immunisation and jeopardise the gain toward interrupt polio transmission in Pakistan. The country will adopt strategies to overcome such problem i.e. IPV introduction would be leveraged to ensure adequate consideration of this important RI risk and include an Emergency preparedness and response plan and functional committees which ensure

collaboration with security agencies and local community leaders in security challenged areas.

Pakistan is one of the three countries with Polio reservoirs (both wild type-1 and 3 polio cases were reported). The number of polio cases decreased dramatically from 558 in 1999 down to 87 in 2014. Majority of polio cases were detected from inaccessible and security compromised areas.

The AFP surveillance is well established and showed robust surveillance indicators i.e. Non-polio rate >2/100,000 in children under 15 yrs of age across the country.

4. Overview of national health documents

The IPV introduction has been incorporated into the current cMYP (2014-2018) under the section on introduction of new vaccines. The application pointed out that the National Immunisation Policy is presently under review to incorporate IPV in the policy documents.

5. Gender and Equity

Pakistan has the sixth largest population in the world. Immunisation coverage surveys suggest that 1 in every 5 children is not immunised and in rural areas 2 out of 3 children are not immunised. Pakistan is therefore one of ten countries receiving GAVI Equity funding to implement a programme for equity in immunisation.

With the support of UNICEF, a national level Knowledge Attitude Practice and Behaviour (KAPB) study is underway to look at key drivers of inequities in immunisation and main barriers to access immunisation services. The study is scheduled for completion in June 2014 and the findings of the study will address different barriers to Routine Immunisation in Pakistan. Furthermore the findings of the barrier study 2014 will inform the formulation of the national communication strategy with provincial chapters. All these activities are reflected in the comprehensive Multi Year Plan (cMYP) 2014-2018. In addition, to further inform decision-makers there is a December 2013 DHS.

Based on a desk review of the latest surveys, Pakistan, with the support of UNICEF, undertook a situation analysis of the key drivers of immunisation inequities in ten districts of Pakistan. Out of ten pilot districts, six overlapped with Polio high risk districts where PEI-EPI convergence has taken place. This equity study 2013-14 across ten pilot districts does not reveal significant difference in the access to immunisation services by gender since 82% of boys and 79% of girls aged 12–23 months were fully immunised (although the DHS found lower rates: 56 percent boys versus 52 percent girls were fully immunised). However, significant deprivations were observed across geographic regions (urban–rural difference in immunisation coverage is 66% - 48%) and socio-economic quintiles (from 23% in lowest wealth quintile to 75% immunisation in highest wealth quintile).

With regard to the status of women, the DHS confirmed that women marry younger than men. For example, a higher proportion of teenage girls age 15-19 (14 percent) are married than teenage boys (2 percent). The DHS found that 12% of female school dropouts did so because they got married.

It is therefore significant that basic vaccination results by education of mother ranges from 40% for illiterate mothers to 76% for well educated mothers.

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

Pakistan is in the low-middle income group of GAVI country. The country does not plan to co-finance IPV since this is not a requirement for this window. The budget template has been adequately completed (Annex D). The budget line is appropriate.

The vaccine introduction grant (VIG) is in line with GAVI rules (US$ 0.80 per child in the birth cohort) amounting to US$ 5,260,521.

In summary, the introduction grant budget is generally well detailed and costs provided seem appropriate.

7. Specific comments related to requested support

a) New vaccine introduction plan

Pakistan has introduced multiple new vaccines in recent past years that enriched the programme with requisite technical expertise and experience for introduction of any new vaccine. The proposed plan activities are well laid out and appear feasible reflecting a good preparation and strong support from partners.

The proposal recognises the constraints facing the programme implementation including reaching children in the security compromised areas. IPV introduction would be leveraged to ensure adequate consideration of this important RI risk and include an Emergency preparedness and response plan and functional committees which ensure collaboration with security agencies and local community leaders in security challenged areas. Other constraints identified were timely and sufficient disbursements of social mobilisation resources and the absence of dedicated EPI communication staff at national and regional levels. However, the plan does not provide any information on how provinces with very poor coverage will be prioritised in terms of a specific targeted strategy and resources apart from accelerated early introduction.

The introduction timeline presented is quite challenging considering the above mentioned programme constraints, the size of the country and given the number of people to be undergoing training. The transfer of funds for advocacy and social mobilisation should be released at earliest, given that this is a critical activity.

The IPV introduction is in line with the Polio Eradication and SAGE recommendations. The introduction of IPV will be nationwide in January 2015 given at 14 weeks and co-administered intramuscularly with the third dose of OPV3, DTP-HepB-Hib3 (Penta) and PCV3.

The National EPI policy is currently under revision and will include introduction of a single IPV. The country vaccination policy indicated procedures for the administration of multiple vaccines. Both PCV and IPV would be given in the left thigh at the same site, while Penta will be given in the right thigh. The vaccine given in the same limb will be separated by at least 2cm using finger to determine the distance.

IPV vaccine procurement will occur through UNICEF. The EPI Programme has already submitted application for licensure of multi-dose (10 dose) IPV. The registration of the 10 dose vial is technically and commercially cleared through DRA and the registration letter is currently under process. It's advisable to register all types of IPV presentations.

The proposal provides insufficient information on plans demonstrating synergies related to on-going immunisation activates (i.e. trainings, supervisions, advocacy, communication packages etc) with proposed IPV introduction activities.

b) Vaccine management and cold chain capacity

Pakistan conducted its first EVM in April 2014 sampling 151 sites across all provinces. The improvement plan is in preparation and will be aligned with the 2014 Joint WHO/UNICEF Statement.
Overall EVM performance indicates that incoming vaccine management practices at the Central store is excellent, vaccine storage capacity, equipment and infrastructure status and vaccine management practices throughout the entire system are within 10% of the WHO recommended performance norms. Vaccine distribution practices, stock management and data reporting are notably weak on a national scale.

There are regional pockets of variance from these national patterns. Vaccine storage capacity in the Punjab Province is less than adequate at some locations for example, and general levels of performance in Provinces with compromised security are distinctly weaker.

The assessment has only been recently published so progress against any improvement plan cannot be determined.

Main recommendations emerging from the assessment other than those self evident from the findings are:

- To establish an EVM Secretariat within a broader steering committee framework of vaccine management;
- To adopt the comprehensive Effective Vaccine Management (cEVM) approach as defined in the WHO/UNICEF Joint Statement;
- Pakistan should examine the institutional and operational barriers and mechanisms required to improve vaccine supply chain efficiency and further streamline storage capacity.

Cold chain expansion plans are well described in the IPV plan. At the central store the current cold storage capacity is adequate to accommodate the current vaccines in the immunisation schedule according to the current frequency of shipments; also it is adequate to accommodate the planned IPV introduction in 2015 (10 dose vial presentation with quarterly shipments). The volume per supply period for all vaccines to be stored at the national store will occupy about 64% of the available storage volume. The capacity at the national store will be also enough to accommodate the introduction of Rota vaccine. Central store occupancy rate will increase to 90%.

Cold chain capacity at provincial levels is also adequate to accommodate the current vaccine in the schedule but there are variations in readiness to introduce new vaccines. There will be 100% occupancy of available storage space in the Punjab

Province with the introduction of IPV and a deficit of storage capacity of 44% when Rota vaccine is introduced. Other Provinces already have sufficient installed storage capacity for IPV and Rota.

Pakistan has recently conducted a cold chain inventory using a WHO/PATH Web-based tool (CCEM2) in 56 districts (30%) at over 2,000 health facilities. This process will be extended nationwide by the end of 2014. Funding for this is requested in the IPV VIG. This will permit an on line analysis, location by location nationwide to assess functionality of installed equipment and storage capacity. Cold chain equipment has been supplied through funding from the People's Republic of China and Japan to meet any deficits in storage capacity at specific locations.

Pakistan has also introduced a real time management information system (vLMIS) in early 2014 in more than 30% of the country. Funding support is to be mobilised to extend the vLMIS nationwide in 2014. This tool will facilitate real time monitoring of vaccine stock levels throughout the entire distribution system and storage capacity nationwide.

A 2012 survey indicated 5,684 (or 81% of all service delivery points), had appropriate and functional cold chain equipment. ILR's were available in 4,892 service delivery points. Most provinces experienced 1 or 2-month stock out of Polio and BCG in 2012 (cMYP 2014-2018).

The Health Facilities where storage equipment is not available collects vaccines on scheduled immunisation days using either cold boxes or vaccine carriers. In Health Facilities with cold storage capacity, vaccines are collected on a monthly basis and stored for use during sessions. Most Health Facilities use motorcycles for vaccines collection and in some cases bicycles are also used. Cold boxes and vaccine carriers are used for vaccine transportation at the various levels. Monitoring of temperatures during transport is not traditionally done as conditioned icepacks are used for vaccine transport. No issues with respect to IPV storage are anticipated.

c) Waste management

Country does not anticipate any need for changes in their waste management plans to accommodate IPV into the routine EPI. The current plans on waste management could easily accommodate the IPV introduction. The application notified that the national guidelines has addressed the injection safety procedures whereby the "bundling" principle is applied and the final disposal of used syringes and sharps is incinerated or by pit burning. Whatever method is adopted, it will be carried out under direct supervision of a responsible officer. All existing waste management and injection safety activities will be followed for IPV in line with national injection safety policies.

d) Training, Community Sensitisation & Mobilisation Plans

Training of health workers and all stakeholders for IPV introduction will be carried out prior to the introduction of IPV. The training material will be developed in line with the WHO guidelines. The guidelines will be developed on the vaccine administration, vaccine storage, delivery, injection safety, AEFI etc. The training will be conducted in cascade fashion starting from Training of master trainers (TOT) at

the federal level and going down to district and Union council level. Training materials will be developed covering technical and an operational manual that cover policy, scientific, and operational aspects related to introduction of IPV; a handbook for HWs; FAQs; fact sheets on operational aspects including application of the multi-dose vial policy and multiple injections; case-studies on introduction experience from other settings; training videos; and posters.

Training will be offered as an integrated package to combine material and better utilise training time, to re-train the frontline health workers on immunisation practices such as injection safety, AEFI communications, cold chain management, data collection, analysis, and use for action. The preparatory activities (Annex C) are well laid out.

Country foresees risks pertaining to the administration of three injections to the child during the vaccination session. Furthermore, in some parts of Pakistan, community acceptability for oral polio vaccine is an issue in contrast to routine immunisation which is well accepted in those areas.

Country will develop a strong advocacy and communication strategy in coordination with partners emphasising on the need of protecting children at a quicker pace with few vaccination visits required hence enhancing the efficiency of the health care providers. This strategy will be tailored based on survey conduction, to improve vaccine acceptance especially for poliomyelitis vaccines.
Communications strategies will be based on the acceptance of IPV immunisation. A clear rationale for OPV and IPV administration will be provided to the media, medical institutions and religious, traditional and political leaders. Public communication to caregivers will focus on the success of polio eradication, which opens the door for the provision of new vaccines such as IPV to complete the existing polio programme. Advocacy among technical experts for public support and endorsement of IPV and OPV will be critical in this area.

e) Monitoring and evaluation plans

The EPI programme will update the information systems to facilitate collection of core indicators related to IPV introduction. The reporting forms, registers and immunisation cards, request form, vaccine stock ledgers and other forms will be updated accordingly the electronic and web based computerised system used for reporting and recording of vaccine administration. This will allow monitoring the coverage of the new vaccine as done for other vaccines in the schedule. In addition, the main recording tools that are used for immunisation-related activities will be adapted to include IPV vaccine.

As per the document the routine monitoring is ineffective, partly because context-specific monitoring tools are not used and partly because supervision on monitoring is weak. Data also does not include information from private providers.

The quality of supervision and monitoring is variable in the provinces. Furthermore, supervisory visits are unstructured due to poor supervision by the higher level of managers and poor capacity of district managers to assess coverage reports through desk reviews.

No information is provided on independent DQS assessment. The introduction plan indicated that post-introduction evaluation assessment of the IPV introduction will be carried out 6 months after introduction of vaccine.

AEFI surveillance system is established and the national guidelines are developed. The AEFI and VPD reporting are integrated into the regular reporting system that will also include IPV. The AEFI system and response will be included in the training for introduction of IPV. Expert AEFI committee at different levels meets immediately to discuss an action plan.

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

There is fairly good consistency between different information presented in the proposal documents and cMYP.

9. Overview of the proposal

Strengths:

- Pakistan has demonstrated readiness and strong commitments towards introducing IPV into its routine immunisation. The proposal outlined a clear introduction plan including the main components and activity timelines were provided. There is adequate storage capacity at all levels for all presentation options and plans for social mobilisation are developed;
- A very well written proposal, with comprehensive detail of the Cold chain and logistics (CCL) situation. This permits an assessment of CCL readiness for IPV. The proposed investment of IPV VIG resources in inventory management provides comfort for the introduction of IPV and also prepares the country for the introduction of future vaccines and online monitoring of supply chain status.

Weaknesses:

- No information is provided about refugee and internally displacement communities in relation to introduction of IPV immunisation services;
- Private sector accounts for approximately 80% of all outpatient visits. No plans provided to engage this crucial sector;
- No details were provided on the plans for post-introduction evaluation of IPV; Potential synergies between introduction activities for IPV were not addressed in the application;
- No justification or details are provided for the US$ 1,529,364 proposed for procurement of cold chain equipment.

Risks:

- Ambitious plan considering ongoing polio transmission, instability and security risks;
- Anticipated limited acceptance by the parents in giving three injections and in some parts of Pakistan, community acceptability for oral polio vaccine is an issue in contrast to routine immunisation which is well accepted in those areas;

- Low commitment toward routine EPI in some districts;
- Low performing provinces and political interference in staffing;
- The CCEM and/or LMIS are not fully operational by the time IPV is introduced in January 2015;
- The status of funding for nationwide scale up of vLMIS is unknown.

Mitigating Factors:

- Strong political support as well as support from in country partners to the launch of IPV vaccines;
- GAVI commit to disburse VIG funds promptly, so that UNICEF can provide bridge funding to complete the CCEM nationwide.

10. Conclusions

Pakistan has provided adequate justification and documentations to recommend approval of their proposal. The country has a strong capacity and highly commendable integrated approach to introduction of IPV. The proposed approach to improve inventory and data management systems provides comfort of system readiness to introduce IPV and prepares the country for other new vaccines and continuous real time monitoring of supply chain readiness.

11. Recommendations: Approval with comments

Comments for the country:

- Country to consider planning to conduct EPI review in the near future;
- Country to consider registering all types of IPV presentations;
- The National EPI policy to be revisited to include introduction of IPV vaccine;
- Country to update the IPV introduction plan to outline how the private sector will be engaged;
- Consider to include plans to conduct regular independent DQS assessment;
- Consider making a financial provision for a PIE;
- Timeline covers the period from March 2014 to Feb 2015. It should be extended through Dec 2015, and indicate subsequent vaccine distribution schedules;
- Consider providing an annex reflecting a plan on how to deal with refugees and internally displaced communities in relation to introduction of IPV and routine immunisation services;
- Consider revisiting the timeline of the proposal to allow sufficient space for effective implementation in Reaching Every Child including children in the security compromised, difficult to reach areas;
- Country to provide a justification and details of cold chain equipment procurement plans for the amount of US$ 1.529 million to support the introduction of IPV as requested.

Comments to Secretariat:

- The Secretariat may wish to consider working with in-country partners to assist Pakistan with provision of strategies development on how to deal with

refugees and internally displaced communities in relation to IPV immunisation services;

- Secretariat to seek from country, the amount to be earmarked to meet storage capacity deficits in the Punjab and/or locations identified in the CCEM inventory as being short of storage capacity;
- The Secretariat to have a dialogue with USAID (Deliver) to understand the status of funding for national scale up of vLMIS in view of having this fully operational for the introduction of IPV and perhaps use of HSS resources for future operational and maintenance costs;
- Bearing in mind that Pakistan is one of ten countries receiving GAVI Equity funding to implement a programme for equity in immunisation, the IRC requests the Secretariat to support the extension of the equity study to the national level, its integration into the cMYP 2014-18 and into the national communications strategy with associated indicators: reductions in coverage gaps related to geographic inequity, socio-economic inequity, and level of mother's education. The introduction of IPV is an opportunity to further enhance and build upon the outcomes of these efforts.

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 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.