

#### GAVI/13/688/kh/dlc

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

14 November 2013

Dear Minister

#### Pakistan's Proposal for Measles SIA support

I am writing in relation to Pakistan's letter to GAVI dated 2 September 2013 requesting a review of the decision on the allocation of resources for devices for the forthcoming measles SIA..

As communicated to you by letter dated 24 October 2013 (ref. GAVI/13/662/ac), GAVI has granted an approval to issue this revised decision letter adjusting for a shortfall for the procurement of devices for children 9 months to 5 years. This decision letter therefore replaces and supplants the decision letter dated 5 August 2013 on the Measles SIA support (ref. GAVI/13/282/da/dlc).

Measles SIA campaigns are exempt from co-financing, however the country will cover the cost of the vaccines when the GAVI-supported campaign has reached its completion.

For your information, this document contains the following important attachments:

Appendix A: Description of approved GAVI support Appendix B: Financial and programmatic information

Appendix C: The IRC Report

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Appendix D: GAVI Secretariat Review of the Revised Measles SIA Plan of Action

Appendix E: The terms and conditions of GAVI Alliance support

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

Yours sincerely,

Hind Khatib-Othman

Managing Director, Country Programmes



CC:

Minister of Finance

Director of Medical Services Director Planning Unit, MoH

EPI Manager WHO Country Rep. UNICEF Country Rep. 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 the country'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 to vaccinate children aged 9 months to <5 years 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.

GAVI is not responsible for any liability that may arise in connection with the distribution or use of vaccines and related supplies after title to such vaccines and related supplies has passed to the country, excluding liability for any defect in vaccines and related supplies, which remain the responsibility of the applicable manufacturer.

# 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.

<u>Monitoring and Annual Progress Reports:</u> The 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 coverage estimates.



As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and the delivery of funds to co-finance the vaccine.

The country will report on the achievements and request support for the following year in the Annual Progress Report (APR) and a technical report. The APR 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 will also contain information on country's compliance with the co-financing arrangements outlined in this letter. APRs 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 and availability of funds.



# Appendix B

#### Measles VACCINE SUPPORT

This sets out the terms of a Programme.

2.	Grant Number: 13-PAK-09a-X / 13-PAK-23a-Y
3.	Decision Letter date: 14/11/2013
4.	Date of the Partnership Framework Agreement: n/a
5.	Programme Title: New Vaccines Support (NVS)
6	Vaccine type: Maggles

Vaccine type: Measles

1. Country: Pakistan

 Requested product presentation and formulation of vaccine: Measles, 10 dose(s) per vial, LYOPHILISED

8. Programme Duration<sup>1</sup>: 2013

9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)

	2013	Total <sup>2</sup>
Programme Budget (US\$)	US\$12,389,500	US\$12,389,500

10. Vaccine Introduction Grant: Not applicable

11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):3

Type of supplies to be purchased with GAVI funds in each year	2013	2014
Number of Measles vaccines doses	36,996,100	
Number of AD syringes	16,300,200	
Number of re-constitution syringes	1,809,400	
Number of safety boxes	201,025	
Annual Amounts (US\$)	US\$12,389,500	

12. Procurement agency: : UNICEF

13. Self-procurement: Not applicable

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

According to the Co-Financing Policy, the Country falls within the Intermediate group. The following

<sup>&</sup>lt;sup>1</sup> This is the entire duration of the programme.

<sup>&</sup>lt;sup>2</sup> This is the total amount endorsed by GAVI for the entire duration of the programme. This should be equal to the total of all sums in the table.

<sup>&</sup>lt;sup>3</sup> This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.



Number of vaccines doses  Number of AD syringes  Number of re-constitution syringes  Number of safety boxes  Value of vaccine doses (US\$)  Total Co-Financing Payments (US\$) (Including freight)  15. Operational support for campaigns: The support for operational costs for campaign has been disburse in cash through WHO and UNICEF.  2013  Grant amount (US\$)  US\$21,664, 500  16. Additional documents to be delivered for future disbursements:  Reports, documents and other deliverables  Due dates  APR: May 15, 2014  Technical report: to be submitted within 2 months of completion of the campaign, and	Type of supplies to be purchased with Country funds in each	year	2013	2014	2015	2016	
Number of re-constitution syringes  Number of safety boxes  Value of vaccine doses (US\$)  Total Co-Financing Payments (US\$) (Including freight)  15. Operational support for campaigns: The support for operational costs for campaign has been disburse in cash through WHO and UNICEF.  2013  Grant amount (US\$)  US\$21,664, 500  16. Additional documents to be delivered for future disbursements:  Reports, documents and other deliverables  The country will report on the achievements and request support for the following year in the Annual Progress Report (APR) and a technical report. The technical report should be submitted within 2 months of completion of the campaign, and the post campaign coverage survey report to be submitted as		,					
Number of safety boxes  Value of vaccine doses (US\$)  Total Co-Financing Payments (US\$) (Including freight)  15. Operational support for campaigns: The support for operational costs for campaign has been disbursed in cash through WHO and UNICEF.  2013  Grant amount (US\$)  US\$21,664, 500  16. Additional documents to be delivered for future disbursements:  Reports, documents and other deliverables  The country will report on the achievements and request support for the following year in the Annual Progress Report (APR) and a technical report. The technical report should be submitted within 2 months of completion of the campaign, and the post campaign coverage survey report to be submitted as	Number of AD syringes						
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	support for the following year in the Annual Progress Report (APR) and a technical report. The technical report should be submitted within 2 months of completion of the campaign, and the post campaign coverage survey report to be submitted as	d To	Technical report: to be submitted within 2 months of completion of the campaign.				

Signed by On behalf of the GAVI Alliance

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Hind Khatib-Othman

Managing Director, Country Programmes 14 November 2013





# IRC NVS COUNTRY REPORT Geneva, April 2013

#### IRC COUNTRY REPORT

Country name: Pakistan

Type of support requested: Measles SIA Support

Vaccines requested: Measles, 10 dose/vial, Lyophilized

Country Profile/Basic Data

Population (GAVI -2012)	179,951,1 40
Birth cohort (GAVI-2012)	4,778,735
Surviving Infants (GAVI- 2012)	4,462,398
JRF Country Estimate	80% 89% 93%

Infant mortality rate (GAVI- 2012)	59.20/100 0
Co-financing country group (2012)	Intermedia te
GNI/capita (2011)	\$1120
Government Health Expenditure, % Total Gov Expenditure (WHO, 2010)	3.6%
Total Health Expenditure, % GDP (WB, 2010)	2.2%

Source: GAVI Country Hub Data, JRF forms, WHO, World Bank

## 1. Type of support requested/Total funding/Implementation period

Pakistan is requesting support to conduct a phased nationwide measles SIA (10 dose/vial, lyophilized) targeting 62,493,411 children 9mo - 9yrs. The first phase of the SIA is planned for the second week of June 2013, targeting areas at high risk for flooding during the monsoons (66% of target population), and the second phase is planned for Oct 2013 and will cover all remaining areas (34% of target population). The country is requesting GAVI support of US\$13,318,600 for vaccine and supplies and US\$21,664,382 for operational costs for a total of US\$34,982,982. The country's request for support has been limited to the less than five age group; the funds for the 5-9 year age group will be mobilized from the government and partners. The planned measles SIA will be integrated with OPV provision for children less than five years.

#### 2. History of GAVI support

Table 1. NVS and INS Support

NVS and INS support	Approval Period
Hep B Mono	2001-2006
DTP-HepB-Hib	2008-2015



Pneumococcal (PCV10)	2011-2015
INS	2003-2005

Table 2. Cash Support

Cash support	Approval Period
ISS	2001-2011
INS	2003-2005
HSS	2008-2011
CSO Type A	2008
CSO Type B	2009 - 2012

# 3. Composition & Functioning of the ICC

The application was complied by the WHO EPI Medical Officer and the EPI focal point for measles at the Ministry of Inter Provincial Coordination (MoIPC). The Secretary of Finance and the Minister of IPC provided signatures in support of the application. The ICC discussed endorsement of the GAVI Measles SIA proposal at a meeting held on March 11, 2013. The MoIPC Secretary chaired the meeting and the EPI National Program Manager presented the salient features of the application. Meeting participants from DfID and USAID expressed reservations on the proposed nationwide measles SIA due to the poor performance of the measles SIAs conducted in 2010/11, resulting largely from the absence of appropriate monitoring and oversight by the government.

The ICC TORs and official membership along with a list of attendees at the March 11<sup>th</sup> session was provided with the application materials. There are currently ten official ICC members and five of these members (GoP, WHO, UNICEF, USAID, JICA) attended the March 11<sup>th</sup> session. Signatures endorsing the proposal were obtained from key government representatives, WHO, UNICEF, and JICA; USAID did not endorse the application, WB did not attend the session, and DfID is not a formal ICC member. Since four out of the five formal members attending the March 11<sup>th</sup> meeting endorsed the proposal, the proposal was formally endorsed. The ICC does not have written statutes outlining quorum, voting, and decision-making policies.

Subsequent to the March 11<sup>th</sup> meeting, USAID, DfID and the WB drafted a joint response to the MoIPC clarifying their lack of endorsement for the GAVI Measles SIA application. The letter expressed major concerns with weak leadership and program management, lack of technical skills and trained personnel, inadequate monitoring and oversight, and lack of accountability mechanisms of Pakistan's EPI program. Responses to the joint letter from WHO and the GoP were included in the application materials for IRC review. The response from the GoP attempted to address some of the key concerns outlined in the joint donor letter including: transparency in vaccine procurement by using the UNICEF SD; independent monitoring and evaluation through use of the existing monitoring structure of the Polio Program and engaging an independent organization/institution for the evaluation of the SIA; and government commitment to strengthening routine immunization evidenced through the recent development of updated provincial POAs in concert with key partners and the donors (including USAID, WB and DfID).

#### 4. Status of the National Immunisation Programme

#### a) Overview

The Expanded Programme on Immunization was launched in Pakistan in 1978, providing the six traditional vaccines, including routine measles vaccine at 9 months of age. With support from GAVI and other partners, Hepatitis B vaccine was introduced in 2002, followed by Hib in 2008. In 2009, following recommendations from the NITAG, a second dose of measles vaccine was introduced into the routine schedule, initially at 18 months of age and later revised to 15 months of age. In addition, the country obtained GAVI support for PCV10 introduction in 2012; PCV10 was introduced in Punjab in Oct 2012 and AJK in Jan 2013 with expected roll out in the rest of the country by mid 2013. The EPI also vaccinates pregnant women with Tetanus Toxoid vaccine to protect newborns from neonatal



tetanus. The country applied for the introduction of rotavirus vaccine (RV) in 2011; the IRC recommended resubmission due to the lack of an introduction plan and concerns around implementation given the recent devolution to the provinces.

The MoIPC was designated as the executor of GAVI support in Jan 2013. This decision will allow continuation of GAVI cash based support activities, largely directed towards strengthening the routine immunization system (ISS and HSS funding). There is strong agreement within the GoP and its health partners that routine EPI needs to be strengthened and the World Bank is currently spearheading a National Immunization Support Project (NISP) focused on achieving key results in access to routine immunization in Pakistan along three dimensions of service coverage, equity and quality.

Pakistan supports the WHO/UNICEF global measles mortality reduction and the EMRO measles elimination goals. The country does not have a formal national measles elimination plan but provided targets for measles elimination in the application form. Administrative coverage of MCV1 increased from 68% in 2002 to 97% in 2012, however, the 2006-07 DHS survey found MCV1 coverage to be substantially lower at 50.2% (card or history), as did the 2011 Pakistan Social & Living Standard Measurement Survey (53% card or history) and the 2011 National Nutrition Survey (64.6%, history). This discrepancy between administrative and survey coverage estimates resulted in an official 2011 WHO/UNICEF MCV1 coverage estimate of 80%. The 2011 administrative coverage for MCV2 was 56% (increased from 30% in 2009), while the official 2011 country estimate was 53% (there is no official WHO/UNICEF estimate for MCV2).

Pakistan conducted a phased nationwide measles catch-up SIA in 2007/08 vaccinating more than 66 million children aged 9 mo-12 yrs in five phases. The average administrative coverage over all phases was 101% (range: 97%-105%). A post-SIA coverage survey to validate administrative coverage in all districts/divisions was not done, but an independent coverage assessment in 20 districts of Punjab following standard WHO methodology found 96% coverage. Given the high coverage achieved during the catch-up SIA, the NITAG made the recommendation to introduce second dose measles vaccine to the routine vaccination schedule, with the aim to maintain the high population immunity gained through the catch-up SIA through 2 doses of routine vaccination. However, routine coverage of MCV1 and MCV2 following the 2007/08 measles catch-up SIA did not reach the desired levels and signs of gradual accumulation of suceptibles due to this low coverage was first detected in 2009, when a gradual and steady rise in the number of suspected cases was seen. In response, the government decided in consultation with WHO, UNICEF and other partners, to conduct a nationwide follow-up measles SIA in 2010/11 targeting children aged 9-59 months. Due to the massive flood that hit Pakistan in 2010, the SIA ended up being adjusted to focus on flood affected districts as an emergency response in two phases, and in the non-flood affected districts in a 3<sup>rd</sup> phase. Lack of monitoring and oversight by the MoH was largely blamed for the poor performance of the 2010/11 SIA.

No mention was made if lessons learned from the problematic follow-up measles SIA in 2010/11 and the more successful catch-up measles SIA in 2007/08 were used when planning the 2013 SIA. The POA does mention that critical programmatic information and lessons learned from the experiences with both polio SIAs and the routine immunization program will be used in the detailed planning of the SIA.

#### b) Gender & Equity Issues

The application does not specifically address gender issues and Pakistan does not collect gender-disaggregated data. The cMYP notes wide variations in immunization coverage between provinces and districts that is partially related to the diverse geographical and demographic conditions but is also due to variations in management capacity and commitment, and absence of accountability of EPI performance. The Measles SIA POA section on microplanning indicates that individual union council microplans will be developed, that identify and address hard to reach populations and other special challenges in the particular area/population.



## 5. Comprehensive Multi Year Plan (cMYP) overview

The cMYP covers the period from 2011-2015. The cMYP has not been updated with the specifics of the 2013 planned Measles SIA. The cMYP mentions the need for a nationwide follow-up Measles SIAs and mentions the follow-up SIA conducted in 2010/11. The Measles SIA POA indicates that the cMYP will be updated to include the details of the planned 2013 SIA "in coming months".

## 6. Measles SIA Plan of Action

In 2011, the number of reported measles cases increased seven fold (3,890 cases) as compared to 2010. In 2012, an even greater increase was seen with an approximate 15,000 cases and more than three hundred deaths reported. The cases were not confined to any particular geographic area; a high incidence of measles is reported in all provinces/federating units. An analysis of over 7000 lab confirmed measles cases in 2012 found that 68% of cases were less 5 years of age and 92% of cases were less than ten years of age; 60% of the cases in 2012 were never vaccinated against measles and 20% were vaccinated with only one dose. This increase in measles cases has persisted in 2013; in Sindh province alone, 500 deaths due to post-measles complications have occurred between Oct 2012 and Feb 2013. To address the outbreaks of measles, provincial health departments attempted to curb the situation through patchy outbreak response immunization activities targeting different age groups with vaccines available through the routine program. The POA states "selection of the area and age group was not always done on the basis of local epidemiology and hence had little impact in controlling the situation".

The GoP requested technical support from the WHO to identify key causes of the increase in measles cases and recommendations to deal with the situation. In a response a joint WHO/UNICEF/GAVI mission visited Pakistan in Feb 2013 to review the measles situation. Through review of the epidemiology, the mission had two main recommendations: 1) Strengthen routine immunization to raise MCV coverage and; 2) Conduct a nationwide measles SIA targeting all children 9mo-9yrs in two phases. The joint mission recommended a nationwide SIA given the high incidence rate of measles in all provinces/federating units and targeting of a wider age range to cut the ongoing transmission. In addition, it was recommended that the flood prone districts be prioritized prior to the monsoons (by June 2013), since the floods have potential to cause displacement of a significant proportion of the population, compounded by prevailing low immunity that could result in devastating outbreaks. The recommendations from the joint mission were presented and endorsed at a joint NITAG-ICC meeting held on February 15, triggering the government to initiate the planning and resource mobilization process. Review of the list of participants at the February 15 meeting revealed that representatives from USAID, WB and DfID did not attend and only 5 of the 10 official ICC members were present (GoP, WHO, UNICEF, JICA, Rotary International).

The phased nationwide SIA will target 62,493,411 children 9mo–9yrs, with a goal to reach at least 95% of the targeted children. The first phase will target 41,378,728 children and is planned for the 2<sup>nd</sup> week of June in flood prone areas that include the entire Sind, Khyber Pakhtunkhwa, Balochistan provinces, 8 southern districts of Lahore and Faisalabad districts of Punjab, and the FATA. The second phase is planned for October 2013 and will target 21,114,683 children in the remaining areas of the country. The IRC is concerned that this schedule may be difficult to adhere to given the cumulative lead time required by GAVI to disburse funds and UNICEF to supply vaccine is typically 4-6 months. A more realistic start date for initiation of the SIA (with GAVI support) is Sept-Oct 2013, provided that the remaining part of the budget is identified. However, this delay may risk escalation of the epidemic during the monsoons and consequent major implementation barriers for outbreak response immunization in the flood prone regions.

Measles vaccines and supplies will be procured through UNICEF, and a reasonable estimated wastage rate of 11% has been used. The SIA will be conducted as a rolling SIA over 6-9 working days and vaccination will be provided through fixed EPI centres, outreach vaccination sessions (areas outside catchment area of fixed centres) and by mobile vaccination teams



(remote areas with scattered populations). In addition to measles vaccine, polio vaccine will be provided for all children less than five years. The Measles SIA provides appropriate activities related to: how measles and OPV will be offered; orientation & training; microplanning; advocacy, social mobilization and communication; cold chain and logistics management; waste management; recording and reporting; AEFI surveillance and management; supervision and monitoring; and post SIA coverage evaluation. However, the POA contained no analysis of the security situation and threats to health workers, despite the recent killings of several polio workers and the growing insecurity in high-risk regions of the country.

The POA has provided examples of where the technical, logistical and financial inputs in different SIA programmatic areas including microplanning, training, partnership and program coordination, advocacy and social mobilization, cold chain infrastructure and management, vaccine safety, resource mobilization, supervision, and monitoring and evaluation will have potential impacts on strengthening the capacity of routine immunization service beyond the SIA. The target provided in the application form for MCV1 coverage in 2013 is 80%, increasing to 95% by 2016, and for MCV2 coverage the target in 2013 is 60%, increasing to 90% by 2016. In addition, in Feb 2013 all provinces and federating units developed comprehensive POAs for 2013-14 for strengthening routine immunization linking with the cMYP. The plans were developed using 14 broad thematic areas, and experts from WHO HQ, EMRO and CO and other partners (UNCEF, JICA, USAID, WB) facilitated this process. Specific indicators and processes to measure these indicators were identified for each activity and a budget for the activities was created.

The existing oversight mechanism for the Polio Eradication will be used to ensure proper monitoring of the SIA preparation and implementation. Specific indicators have been provided in the POA that will be used to assess both the preparation and implementation of the SIA (process indicators). In addition, rapid convenience assessments (RCAs) will be conducted in areas where the SIA vaccination has been completed to guide mop-up vaccination activities. RCAs will be done in purposefully chosen areas where children are more likely to be missed (i.e. marginalized and hard to reach populations, border areas, etc). A post-SIA coverage survey will be conducted to monitor the outcome of the SIA. The country aims to conduct the post-SIA coverage survey in every district, and if this is not possible at least in every division, using standard WHO cluster coverage survey methodology. A third party will conduct the survey within one month of SIA completion and the report from the evaluation will be published within one month of conducting the survey.

Based on the current routine coverage levels and the expected coverage level for the upcoming SIA, the country has projected the next follow-up SIA for 2016 targeted towards children 9months to <4 years. The ultimate aim is to replace the current second dose measles vaccine with MR vaccine to reduce rubella related morbidity and mortality associated with CRS.

#### 7. Improvement plan

There are major weaknesses within the vaccine supply chain, primarily in relation to vaccine management, stock management, and data management. A prime example of this is the more than 48 million doses of OPV unaccounted for in 2012 (OPV Management Assessment Report). Deficiencies in these areas can be addressed in the short term through improved management and quality control mechanisms. The WHO tool for vaccine and stock management (VSSM) has been introduced and personnel should be assigned to ensure its use. Introduction of this tool along with other management and quality control mechanisms will go a long way to assuring successful implementation of the measles SIA and will also directly benefit the routine program.

Significant issues with cold chain equipment are also evident, but these equipment shortcomings are not seen as critical to the implementation of the measles SIA. They are critical, however, for the storage of routine vaccines and the introduction of new vaccines. Good progress has been made in replacing and adding new equipment at all levels of the supply chain, but much remains to be achieved, particularly with the planned RV introduction; quality of stock management and the management of wastage must be significantly improved.



A strong recommendation was made in the fall of 2012 to establish a Vaccine Management Committee at the national level, which would be supported by vaccine management committees in each province. This process is critical to the success of the SIA; however, these committees should address all aspects of vaccine and data management for ALL vaccines. For the proposed measles SIA, there are plans to establish technical sub-committees for operational management, but there is no mention of the apex vaccine management committee; the concern being that these sub-committees would not have decision-making powers to strengthen systems, although involvement of a UNICEF designated CCL expert should help.

The country reports that most of the recommendations of the Improvement Plan have been completed (as of May 2011). An assessment of storage needs in Punjab and Sindh Provinces suggest that with good shipping and distribution planning for the SIA, routine vaccines would not be at additional risk in terms of available cold room/refrigerator capacity for storage. In addition, Pakistan regularly conducts polio SIAs and the program is very experienced in managing large volumes of vaccine for storage and distribution. While volumes for the measles SIA will be substantially greater (2x), measles vaccine is more stable (VVM7 or VVM14 temperature/time sensors rather than the VVM2 on the highly temperature sensitive OPV vaccine). Other measures the country could consider for the measles SIA, includes use of vaccines with VVM14 vaccine vial monitors rather than VVM7 and use of the 20-dose/vial presentations rather than 10-dose/vial presentations, as this would reduce the required storage volume by 50%-100%.

# 8. Cold chain capacity

The 2012 OPV Management Assessment report indicates that since the 2009 EVM the Federal store has undergone a major refit and now has five cold rooms of 50m³ at +4°C, four 25m³ rooms at +4°C, one 50m³ room at - 20°C, and four 15m³ rooms at -20°C. The quality of Provincial stores in Punjab, Sindh, KPK and Balochistan vary. The Punjab store is old but functioning well and is regularly maintained. In contrast, the Sindh provincial store in Karachi has four +4°C cold rooms and one -20°C cold room, both of which have been very poorly maintained. Peshawar has five cold rooms, two of these are broken and when there is a power failure, available generators have insufficient capacity to run all the cold rooms at the same time. The quality of vaccine and stock management at District level is generally weak.

There was reference to a 5-year plan for cold chain capacity expansion at all levels "which incorporates requirements for PCV10 and RV" but the plan itself was not included. It is not clear why the expansion is needed for PCV10 and RV if the current system can accommodate these vaccines. UNICEF pre-assessment confirms the country's cold chain readiness. However, it points at another issue that requires further clarification: the "Government is in the process of transferring funding to UNICEF for 38 cold rooms of 10 m3 with 38 voltage stabilizers. Due to problems in the MOH and some prerequisites for the GAVI funds this has still not happened. According to the UNICEF country office the problem is that even the installation of all cold rooms needs to be covered under GAVI funds, the MoH expects UNICEF to calculate what it would cost them to send their technicians to do the installations of the rooms, except 1 or 2 that UNCIEF could do in an installation project. The order for the equipment cannot be released until the way ahead for the installation, with estimation of the costs, has been figured out.

The country plans to depute a vaccine and logistics management expert with support of UNICEF to provide technical guidance in to handling the large volumes of vaccine and logistics during the preparation and implementation of the measles SIA. In addition, cold chain and logistics management committees will be formed at central, provincial, and district levels. District management committees will assess their own cold chain capacity at district stores and in health facilities and will identify and communicate with the province the need for replacement or addition of equipment in the district in advance of the SIA. Out of order but repairable equipments will be repaired with local initiative if possible. Provincial vaccine and logistics management committees will gather data from districts on their cold chain status and plan accordingly for vaccine and logistics distribution to the districts. Appropriate supply cycle with specific quantity, volume, timing and mode of transportation will be



developed for each district and monitoring of the supply chain according to the plan will be followed. However, the IRC expresses concern that these activities may not be completed in time to ensure a high-quality SIA for Phase 1 scheduled in June 2013.

## 9. Financial Analysis

Pakistan fully covered the costs for routine measles vaccine and injection supplies in 2008-2010 and 2012; in 2011, 33% of the funding for routine measles vaccines and supplies came from partners. The country has secured funding for routine measles vaccine for 2013 (US\$6.5 million) and has also committed to procuring measles vaccine for routine immunization for 2014 and 2015. The application also specifies that the government is committed to bear all recurrent operating costs for routine vaccines for all children in coming years, amounting to approximately US\$40 million/year. Data from the final budget for the 2007/08 catch-up measles SIA indicates that the government contributed 1.9% of the total costs in the form of vaccines and injection supplies; the remainder of the SIA budget was received through support from partners.

The estimated total cost for vaccine and injection supplies is U\$\$24,972,376. The country has requested a total of U\$\$13,318,600 GAVI funding for vaccines for the under-five age group during phase 1 (U\$\$8,818,636), and vaccines and injection supplies for the under-five age group during phase 2 (U\$\$4,499,964). The injection equipment for all age groups during phase 1 (U\$\$2,640,000) will be covered by the MR initiative. In addition, the Sindh provincial government has committed U\$\$4 million for vaccine procurement. This leaves a funding deficit for vaccine and injection supplies of approximately U\$\$5 million. The government has noted that the other provincial governments are in the process of mobilizing resources for vaccines and injection supplies and that further support will be solicited from partners, including the MR initiative.

The country estimated total operational costs for the planned measles SIA at US\$40,620,717 (Table 6.3b). GAVI is requested to fund 100% of the operational costs for the under-five age group, which translates to approximately 53% of the total operational costs. There are some concerns with respect to several line items in the operating budget for which clarifications are requested. The country has estimated that the government will cover 23% of the operational costs and that other partners will cover the remaining 23%, although these funds had not been secured at the time of application. Part of the operational costs will be covered by the Polio Eradication initiative, however, details were not provided on how the operational costs will be shared & attributed for the measles and OPV SIAs. Unless USAID, the WB and DfiD revise their stance and decide to support the Measles SIA, the IRC is concerned regarding Pakistan's ability to mobilize the outstanding operational funds for vaccinating the 5-9 year age group.

#### 10. Co-financing arrangements

The GAVI measles SIA guidelines require countries to contribute towards the costs of immunizing its children against measles, using the past government contributions towards measles SIAs as the minimum reference point. The committed US\$4 million in funding for vaccines from Sindh province equates to 6% of the total SIA cost (and is above the 1.9% government contribution during the 2007/08 SIA). The remaining funding gap for the 5-9 year age group is to be raised from the provinces and other donors; therefore the final proportion contributed by the government is likely to be considerably higher than 6%.

Pakistan is presently in partial default for its co-procurement of Pentavalent vaccine; a tender has been issued and the country intends to place the order after March 22, 2013. Pakistan has fully co-financed procurement of PCV10.

#### 11. Consistency across proposal documents



There is reasonable consistency between the various proposal documents, however, as indicated in previous sections, the cMYP does not included the details on the 2013 Measles SIA. Information provided on costs, quantities, volumes co-financing etc are consistent across proposal documents.

#### 12. Overview of the proposal: Strengths & weaknesses

#### Strengths:

- The country has developed a comprehensive and well-written Measles POA (within a very short time interval) that includes indicators to monitor progress during the planning and implementation of the SIA
- Use of the successful existing oversight mechanism from the Polio Eradication Initiative to provide oversight and monitoring of the measles SIA.
- A post-SIA coverage survey in all districts/divisions using accepted methodology will be conducted by a "third party" to monitor the outcome of the SIA
- A fairly successful catch-up measles SIA was conducted in 2007/08 and the country has demonstrated the ability to successfully conduct large, frequent polio SIAs
- Strong commitment from government and partners to strengthen routine immunization, evidenced by the recent provincial POAs for 2013-2014 and the World Bank led NISP
- An apparent strong level of support from provinces to raise funds to contribute towards the measles SIA in the 5-9 year age group

#### Weaknesses:

- A deteriorating routine immunization system due to weak program management, inadequate monitoring and lack of accountability mechanisms
- Very short (and seemingly unrealistic) interval to initiate Phase 1 of the SIA, threatening the ability to plan and execute a high-quality SIA
- Substantial funding gap (47% of operating funds, 20% of vaccines and supplies) for the 5-9 year age group that is yet to be mobilized from the GoP and partners. The lack of support from key development partners for the SIA threatens the ability to raise these outstanding funds.
- The most recent follow-up SIA in 2010/11 was very poorly managed with a complete lack of accountability and therefore did not manage to achieve targets
- The application contained no analysis of the security situation and threats to health workers, despite the recent killings of polio workers and the growing insecurity in high-risk regions of the country.
- The cMYP has not been updated to include details on the planned measles SIA, though the application indicates that the document will be updated in the coming months
- Details on how operational costs will be shared & attributed for the measles and OPV SIAs
  are not provided despite indicating that the Global Polio Eradication Initiative will
  contribute towards the operational costs of the joint SIA.

#### Risks:

- The GoP may not be able to raise the required funds to cover the 5-9 year age group, resulting in continued transmission and outbreaks of measles
- An assessment of OPV management during polio SIAs indicates serious problems with vaccine management
- Possible reduced focus on routine immunization and primary care as a result of SIAs.
- Inability to carry out the first phase of the SIA by June 2013, given the typical 4-6 month period required for release of funds and purchasing and shipment of vaccines.
- Threats to safety of Measles SIA workers given the devastating recent attacks on polio SIA workers



# Mitigating Factors:

- Recent efforts to strengthen routine immunization by the GoP in concert with key partners
- The MoIPC has been designated as the executing partner for GAVI support. This decision will allow continuation of GAVI cash based support activities, largely directed towards strengthening the routine immunization system (ISS and HSS funding)

#### 13. Recommendations

**Vaccine: Measles SIA Support** 

**Recommendation:** Approval with Clarifications

#### Clarifications:

- Submit to GAVI the plans and progress for raising funds for the 5-9 year age group and demonstrate how operational costs will be shared & attributed for the measles and OPV SIAs.
- 2. Provide details on the vaccine management committees and sub-committees proposed to strengthen vaccine, stock, and data management along with a clear delineation between the decision-making powers and operational roles of these committees and their respective roles for the measles SIA and routine immunisation program.
- 3. Justify the following operating cost line item expenditures:
  - a) Vaccine and logistics transportation from port of entry to central level and to provinces and districts
  - b) Transportation costs for vaccinators and supervisors
  - c) Refreshments for volunteers and vaccinators
- 4. Provide an alternative implementation schedule should the country be unable to initiate Phase 1 of the SIA as per the proposed schedule, given the typical 4-6 months period required to release funds and purchase and ship vaccines.

#### Note to Pakistan

The measles SIA POA made no mention of the security situation and threats to health workers, despite the recent killings of several polio workers and the growing insecurity in high-risk regions of the country. The country should conduct an analysis of the current security situation and resultant risks to health workers to create plans to improve the security of SIA workers.



# Appendix D

# GAVI Secretariat Review of the Revised Measles SIA Plan of Action 3 June 2013

#### **Background**

The GAVI Alliance Executive Committee (EC) deferred its decision on the application by the Government of Pakistan (GoP) for support to undertake a nationwide measles SIA, because of concerns that the issues raised by in-country development partners were not adequately addressed in the original application and Plan of Action (PoA). The GAVI Secretariat conveyed these concerns to the Ministry of National Health Services, Regulations and Coordination in a letter dated 13 May 2013<sup>4</sup>. Resubmission of the revised PoA was requested by 29 May 2013. The Secretariat team assessed the revised PoA, paying particular attention to the main concerns raised by the in-country development partners, from 29-31 May 2013<sup>5</sup>.

#### Review team findings on the issues raised by the in-country development partners.

How the Plan of Action (PoA) demonstrates measles SIA is embedded in routine immunization?

Secretariat Findings: The revised PoA goes in to much more detail in describing how the measles SIA will be incorporated into routine immunization. A number of strategies in the SIA are designed to reinforce routine immunization including social mobilization messaging for routine immunization; interpersonal training for vaccinators that will enable them to positively communicate before and during the campaign on the benefits of routine immunization; and making the Union Council supervisors being accountable for establishing and following up on defaulter lists for routine immunization. SIA activities that will contribute to routine immunization include the following: i) training on vaccine management, cold chain and logistics will focus on all vaccines in the routine immunization program; ii) information and social mobilization activities will be undertaken to create demand for all antigens; iii) advocacy for routine immunization and dissemination of information schedules on the availability of routine immunization; iv) and strengthening recording, data management and reporting of routine immunization will be incorporated in the training. The revised PoA emphasizes that routine immunization services will continue un-interrupted throughout the SIA. The revised PoA is acceptable.

How well the PoA demonstrates the assurance of systemic accountability for measles SIA down to the Union Council level?

Findings: The revised PoA does not include much additional information than what was described in the original PoA. Immunisation Task Forces will be established at National, Provincial and District level. The revised PoA again outlines the responsibilities at each level from Federal, to Provincial, to district and down to the Union Council level. At the Union Council level, the Union Council Supervisor is in charge for planning and implementation of the activity. A series of indicators are included, reflecting accountability. Reporting is designed to be bottom up from Union Council, to District, to Province and up to the Federal Level. The revised PoA is acceptable.

<sup>&</sup>lt;sup>4</sup> The letter conveying specific concerns of the development partners to the Ministry of National Health Services, Regulation and Coordination, dated 13 May 2013; is available upon request from the GAVI Secretariat.

<sup>&</sup>lt;sup>5</sup> The Terms of Reference for the Secretariat Review is available upon request from the GAVI Secretariat.



How well the PoA demonstrates how the monitoring and evaluation of the SIA will strengthen routine EPI information management?

Findings: The revised PoA does not clearly demonstrate how the M&E of the SIA will strengthen routine EPI information management. Information provided is in accordance with the information requested under the GAVI application guidelines and is consistent with the level of information provided by other applications for measles SIA support. However, programmatic information such as target population, socio-cultural and geographical factors, low coverage areas, and cold chain status, generated in the course of preparation and implementation of the campaign, including those generated from polio programmes, can be used in routine immunisation programme planning and implementation. Also, the person responsible at the UC level, the UC supervisor will be responsible for updating the Master Tour Plan for Routine Immunisation. The revised PoA is acceptable.

Request for clarification on the tendering modalities of the independent evaluation of the SIA and the terms of reference.

The tendering modalities of the independent evaluation will be managed by WHO. Two tendering options are given either through awarding an "Agreement for Performance of Work (APW)" or through awarding a "Letter of Agreement (LOA)". No preference was mentioned. The timeline for the tendering modalities were not outlined and it is important to recognise that this will have to be undertaken several months in advance. The tendering modalities are transparent, but the development partners need to remain involved.

The TOR of the independent evaluation has not been submitted, but the timing of the evaluation and report due date are provided. This information is consistent with the depth of information provided in other measles SIA application. The revised PoA is acceptable.

#### **Overall findings:**

The revised PoA is much more detailed than the previous one and takes routine immunization strengthening into consideration in various aspects of planning, implementation and M&E of SIAs. Furthermore, there is more integration with the polio work-stream in that two SIA (measles and polio) are undertaken simultaneously in November. The timing of the campaign is much more feasible allowing adequate time for preparation. Key development partners and provincial offices were also involved in the revision of the PoA, which leads to stronger ownership and confidence that the campaign will get the support it needs.

# **Recommendation:**

The revised PoA is acceptable by the Secretariat Review team.

# Follow up

The GAVI Secretariat will proactively remain engaged with the Federal EPI Cell and the Inter Agency Coordination Committee to ensure that the concerns of the development partners i.e. that the SIA is embedded in routine immunization; assurance of systemic accountability down to Union Council level; that the monitoring and evaluation activities of the SIA will strengthen routine immunization and that the tendering modalities of the independent evaluation is transparent, are addressed in the planning, implementation and evaluation of the measles SIA.



# The following are additional technical considerations highlighted by the Secretariat review team:

#### Micro planning considerations:

- The Master Tour Plan for routine immunization is a new positive inclusion. It is outlined that this will be used to feed into the micro plan and micro plan will be used to update the Master Tour Plan. However the 6-9 yrs. age group is not included in this design. Special plans will need to be developed to accurately capture this segment of the population.
- Presumably polio has the most detailed micro plans of population locations; however
  this does not appear as the starting point for the development of the routine
  immunization and campaign micro plans described in the revised PoA. Polio micro plans
  should be among the resources included in the training sessions and a training strategy
  for micro planning to build upon polio micro plans is encouraged.
- The micro plans should include a list of when the routine immunization sessions are held and in which catchment areas. During the campaign each child's vaccination card should be reviewed and the parent should be advised when and where to take the child for routine immunization. This information would be part of the ley messages that vaccinators provide to caretakers and families.

#### Management considerations:

- Operational guidelines will need to be developed in an iterative and inclusive manner to draw on the experience of immunization partners.
- The revised PoA indicates monitoring and oversight structures will continue to function
  after the campaign. In- country development partners should follow up with the
  government what is intended and how this will be sustained in the overall accountability
  systems.
- It is necessary to monitor other routine immunization antigen stock levels during this time as greater quantities will be required.
- Performance based payment of frontline immunization staff does "lock-in" plans to conduct coverage evaluation surveys (CES) in all districts. This will be very expensive and difficult to implement and may not be required to assess the quality/coverage of the campaign. Furthermore, it is unclear whether this will be acceptable to the health workers and how it would be implemented.

#### Advocacy, Communication and Social Mobilization considerations:

• Three or four key messages at minimum should be incorporated into the training program of the vaccinators to inform every parent/ caregiver at time of vaccination. For example messages can include what vaccines were given. What side effects might be expected and what to do. After reviewing the immunization card when to come back for next vaccination and where to come back to. These messages should be established prior to the TOT and be actively monitored by vaccination team supervisors dueing the SIA..

#### Supervision monitoring and evaluation considerations:

• Pre and during campaign monitoring indicators should ensure accountability of preparatory and implementation activities.



- Performance bases remuneration:
  - o If performance based remuneration is based on administrative coverage figures, manipulation of data will likely occur.
  - Consideration should be given to managing specific scenarios, such as if coverage evaluation survey results <95%. Would field workers are not paid until mop-up activities are conducted? Would there be a second assessment to validate coverage?
     More mop-up activities, would additional resources be required and provided?
- Carry out robust post campaign coverage evaluation surveys in more than 140 districts is by all accounts a major undertaking in terms of time and resources and should be carefully considered in terms of practicality and necessity.
- Government and partners may want to consider if the DITFs are a long-term mechanism
  for reinforcing accountability, particularly after the investment of establishing them.
  Having a mechanism for reviewing and acting upon monitoring data reinforces the
  longevity of the monitoring systems.



# Appendix E

#### **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.

