

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

24 June 2015

Dear Minister,

Decision Letter: Pakistan's support for IPV

I am writing in relation to Pakistan's support for Inactivated Polio Vaccine (IPV), which was approved by Gavi in July 2014, to inform you that Gavi has now approved the 2016 programme year.

Please note that a number of programmatic changes have led to a revision in the total number of doses and devices needed by Pakistan. These programmatic changes may have required revisions to target population, indicative wastage rate and/or introduction date, and will apply differently to each country. Additional details on these programmatic changes are provided in the table below. Guidance on the application of the WHO Multi Dose Vial Policy for IPV is available in a separate PDF document.

The programmatic changes will have the following impact:

- The number of approved doses and devices for years 2015 and 2016 has been amended from what was communicated in your previous Decision Letter (dated 6 August 2014), the changes are reflected in the attached new Decision Letter.

In order for Pakistan to ensure continuous availability of doses throughout the programme, UNICEF SD will work with you to ensure that the shipment plan is in line with Pakistan's needs. (i.e. some doses scheduled for 2015 can be shipped in 2016)

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: The terms and conditions of GAVI Alliance support.

Please do not hesitate to contact my colleague Dr Hamidreza Setayesh «hsetayesh@gavi.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

<p>Programmatic changes requiring adjustments of doses and devices total figures: <u><i>These changes may or may not apply depending on each country situation.</i></u></p>	
Target population:	<p>Pakistan's target population were initially set by WUENIC 2012 estimates of DPT3 coverage data and the 2012 Revision of the UN World Population Prospects. WUENIC has since released the 2013 estimates, which were used to revise the annual target population for the allocation of doses.</p>
Indicative wastage rate:	<p>In November 2014, WHO revised its guidance on the application of the WHO Multi-Dose Vial Policy for IPV (attached note). This revision means that indicative wastage rates are reduced from 50% to 20% for the 10-dose vial and from 30% to 15% for the 5-dose vial.</p>
Introduction date:	<p>In case the introduction of IPV has been delayed, the number of doses required has also been reduced proportionally.</p>

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 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 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

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.

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.

**Pakistan Support for
Inactivated Polio Vaccine (IPV)**

This Decision Letter sets out the Terms of a Programme.

1. Country: Pakistan				
2. Grant Number: 1518-PAK-25c-X / 15-PAK-08h-Y				
3. Date of Decision Letter: 23 June 2015 (this Decision Letter replaces the previous Decision Letter for IPV dated 6 August 2014)				
4. Date of the Partnership Framework Agreement: 19 May 2015				
5. Programme Title: NVS, IPV Routine				
6. Vaccine type: Inactivated Polio Vaccine (IPV)				
7. Requested product presentation and formulation of vaccine¹: Inactivated Polio Vaccine, 10 dose(s) per vial, LIQUID				
8. Programme Duration²: 2015 - 2018				
9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement): <i>Please note that endorsed or approved amounts for 2018 will be communicated in due course, taking into account updated information on country requirements and following Gavi's review and approval processes.</i>				
	2015	2016	2017	Total ³
Programme Budget (US\$)	USD 5,764,500	USD 1,645,000	US\$4,328,000	US\$11,737,500
10. Vaccine Introduction Grant: US\$ 3,678,500 was approved as per the Decision Letter dated 6 August 2014, of which US\$ 3,420,894 was disbursed to Pakistan by 24 June 2015.				

¹ Please refer to section 18 for additional information on IPV presentation.

² This is the entire duration of the programme.

³ This is the total amount endorsed by Gavi for 2015 to 2017. The total amount has been revised and reduced from the previous endorsed amount based on changes to target populations, indicative wastage rates and introduction dates (where applicable). These reductions have been applied from 2016.

<p>11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):⁴ The Annual Amount for 2015 and 2016 has been amended.</p>						
Type of supplies to be purchased with Gavi funds in each year	2015	2016				
Number of vaccines doses	5,435,100	1,624,300				
Number of AD syringes	5,978,600	373,000				
Number of safety boxes	65,775	4,125				
Annual Amounts (US\$)	US\$ 5,764,500	US\$1,645,000				
<p>12. Procurement agency: UNICEF</p>						
<p>13. Self-procurement: Not applicable</p>						
<p>14. Co-financing obligations: Not applicable 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.</p>						
<p>15. Operational support for campaigns: Not applicable</p>						
<p>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:</p> <table border="1" data-bbox="295 1243 1332 1355"> <thead> <tr> <th>Reports, documents and other deliverables</th> <th>Due dates</th> </tr> </thead> <tbody> <tr> <td>Annual Progress Report or equivalent</td> <td>To be agreed with Gavi Secretariat</td> </tr> </tbody> </table>			Reports, documents and other deliverables	Due dates	Annual Progress Report or equivalent	To be agreed with Gavi Secretariat
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Annual Progress Report or equivalent	To be agreed with Gavi Secretariat					
<p>Financial Clarifications: Not applicable</p>						
<p>17. Other conditions:</p> <p>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.</p>						

Signed by,
On behalf of Gavi



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

⁴ This is the amount that Gavi has approved.

Appendix C

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 TRANSPARENCY 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.

November 2014

Application of WHO Multi-Dose Vial Policy for Inactivated Polio Vaccine

Multi-dose vials of IPV produced by Sanofi Pasteur and Bilthoven Biologicals are approved for use for up to 28 days after opening

New preservative efficacy data from studies conducted by Bilthoven Biologicals and Sanofi Pasteur on their Inactivated Polio Vaccines (IPV) presented in 5 and 10 dose-vials has shown that **both multi-dose vaccine presentations may be used up to 28 days after opening**, provided that the product is appropriately handled and stored.

The [WHO Policy Statement: Multi-dose Vial Policy \(MDVP\)](#), Revision 2014, on the use of opened multi-dose vaccine vials specifies the criteria under which opened multi-dose vials can be kept and used for up to 28 days after opening. If the criteria are not met, the multi-dose vials must be discarded at the end of the immunization session, or within six hours of opening, whichever comes first.

Based on the data submitted by the manufacturers and validated by their national regulatory authorities, and in line with the European pharmacopeia guidelines¹, the WHO Prequalification team has confirmed that the data supports the use of opened multi-dose vials of IPV in subsequent immunisation sessions (up to 28 days), in accordance with the [WHO Policy Statement: Multi-dose vial Policy \(MDVP\)](#), Revision 2014.

Placement of Vaccine Vial Monitors (VVMs) on IPV vials

The VVM is an important visual trigger for the implementation of the multi-dose vial policy.

Presently, the multi-dose vials of IPV are manufactured with the VVM on the flip-off cap, signalling that the vial must be discarded at the end of the immunization session, or within 6 hours, whichever comes first.

With the new approval of use for up to 28 days after opening, the VVM placement will now be changed. Future production of vials will ensure VVM placement on the label of the vaccine vial, so that after opening, the exposure of the vial to temperature over time can be monitored by the VVM, to help ensure that the vaccine has not been damaged by excessive heat exposure.

Availability of IPV multi-dose vials with VVMs on the vaccine label will start from Q2 2015.

WHO strongly recommends that countries start using the IPV multi-dose vials for up to 28 days only after the VVM placement appears on the vaccine labels, expected from May 2015.

¹ European Pharmacopoeia, Supplement 7.6 (reference 01/2013:0153)

Programmatic implications

The delay of shifting the VVM placement from the flip-off cap to the vaccine label, which is anticipated to appear on vaccine shipments around May 2015, suggests two pathways for EPI programmes. Specifically:

<p><i>For countries with plans to introduce IPV <u>before</u> May 2015</i></p>	<p>Countries will receive IPV shipments with the VVM on the cap, indicating that the opened multi-dose vial must be discarded at the end of the session or after 6 hours, whichever comes first.</p> <p>It is recommended that health workers are trained on handling multi-dose vials under both conditions (a 6 hour discard and 28 day discard), and are also informed of what to expect in the future in terms of vaccine presentation changes and anticipated timeline.</p> <p><u>Once supplies of IPV vials with the VVM on the label are received in-country, a memo should be sent to health workers with information on when to implement the 28 day discard to multi-dose vials of IPV and to reinforce the training health workers have received previously.</u> The timing of this transition will be agreed per country, based on their preferences and supply availabilities.</p>
<p><i>For countries with plans to introduce IPV <u>after</u> May 2015</i></p>	<p>Countries will receive IPV vials with the VVM on the label, indicating that the vaccine must be discarded within 28 days after opening. Generic health worker training materials will be adapted soon and available for customization per country.</p>

Projected vaccine wastage

A proper application of the MDVP can decrease wastage while ensuring safety. Taking advantage of using a 28-day discard on opened multi-dose vials, the indicative maximum wastage rate of **20% for 10-dose vials, and 15% for 5-dose vials**, can be used in forecasting the estimated vaccine needs.

Supply allocation principles during this transition

To support countries to successfully introduce IPV, WHO and UNICEF Supply Division are working closely with regions and countries to understand national policies related to the application of the MDVP, and to allocate the available supplies to best support the programmatic objectives.

For further information on IPV introduction as related to the *Polio Endgame Plan*:

http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en/