

The Minister of Health
Ministry of Health
Kichik Deniz Kuc.4
370014 Baku
Azerbaijan

9 February 2015

Dear Minister,

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

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

In November 2014 your application was reviewed by the Gavi Independent Review Committee (IRC) which recommended "**Approval with Recommendations**" of your application. Based on Azerbaijan's successful response to the Senior Country Manager to address the IRC's comments, Gavi has approved Azerbaijan for Gavi support for IPV, as specified in the Appendices to this letter.

In order to ensure sufficient funding for all Gavi countries applying for IPV support, please note that Azerbaijan's initial allocation of IPV doses and associated supplies have been adjusted using UN population data¹ and WHO UNICEF estimates of DTP3 coverage in 2013, 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 the availability of supply and sufficient Gavi funding for IPV.

The Appendices include the following important information:

Appendix A: Description of approved Gavi support to Azerbaijan

Appendix B: Financial and programmatic information per type of support

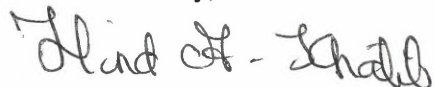
Appendix C: A summary of the IRC Report

Appendix D: The terms and conditions of Gavi support

Please do not hesitate to contact my colleague Nilgun Aydogan (naydogan@gavi.org) if you have any questions or concerns.

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

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

Description of Gavi support to Azerbaijan (the “Country”)

New Vaccines Support (NVS)

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

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

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

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

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

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

Country Co-financing

****Note:Gavi’s usual co-financing requirements do not apply to IPV. However, Azerbaijan is encouraged to contribute to vaccine and/or supply costs for IPV.****

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

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

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

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

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

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

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

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

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

Country will report on the achievements 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 APRs or equivalent and availability of funds.

Appendix B

Azerbaijan SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

1. Country: Azerbaijan				
2. Grant Number: 1518-AZE-25d-X / 15-AZE-08h-Y				
3. Date of Decision Letter: 9 February 2015				
4. Date of the Partnership Framework Agreement: Not applicable				
5. Programme Title: New Vaccine Support, IPV Routine				
6. Vaccine type: Inactivated Polio Vaccine (IPV)				
7. Requested product presentation and formulation of vaccine²: Inactivated Polio Vaccine, 1 dose(s) per vial, LIQUID				
8. Programme Duration³: 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 ⁴
Programme Budget (US\$)	US\$284,000	US\$500,500	US\$434,000	US\$1,218,500
10. Vaccine Introduction Grant: US\$131,000				
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	2016		
Number of IPV vaccines doses	95,900	169,200		
Number of AD syringes	101,500	178,200		
Number of safety boxes	1,125	1,975		
Annual Amounts (US\$)	US\$284,000	US\$500,500		
12. Procurement agency: UNICEF				

² Please refer to section 18 for additional information on IPV presentation.

³ This is the entire duration of the programme.

⁴ This is the total amount endorsed by Gavi for 2015 to 2017.

⁵ This is the amount that Gavi has approved.

13. Self-procurement: Not applicable	
14. Co-financing obligations: Gavi's usual co-financing requirements do not apply to IPV. However, Azerbaijan is encouraged to contribute to vaccine and/or supply costs for IPV.	
15. Operational support for campaigns: Not applicable	
16. The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:	
Reports, documents and other deliverables	Due dates
Annual Progress Report or equivalent	To be agreed with Gavi Secretariat
17. Financial Clarifications: not applicable	
18. Other conditions: If Azerbaijan 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 Azerbaijan.	

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

1. Type of support requested: IPV

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 st , 2 nd , and 3 rd choice)
July 2015	2015-2018	1 dose, others not specified

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

The ICC appears to be active. In addition to representatives of units of the Ministry of Health, it includes UNICEF, WHO and RVF, a local foundation which supports immunisation. A NITAG was recently formed. The NITAG recommended to the Ministry of Health (MoH) to initially introduce IPV as a single dose at 6 months of age with a subsequent switch to a 3 dose schedule with an IPV-containing combined vaccine, starting from 2018 (upon WHO prequalification of IPV-containing combined vaccines and an updated WHO position paper on pertussis vaccine). This recommendation was then approved by the MoH.

3. Situation analysis – Status of the National Immunisation Programme

Prior to this year, WHO and UNICEF estimates demonstrated discrepancies compared with Azerbaijan's administrative estimates of DPT3 coverage greater than 90%. The WUENIC estimates were based on the 2006 DHS, which found DPT3 coverage of only 70%. This year WUENIC acknowledged the results of a 2011 DHS which found DPT3 coverage of 81% and for reasons not explained in the WUENIC report (the proposal notes that the data quality issues are being addressed with technical support from WHO) they finally decided to endorse the country's administrative DPT3 estimate of 93% in 2013. As a result, the graph in this year's WUENIC report suggests a major, steady climb in coverage of 15 percentage points over the last 8 years. Without a high quality coverage survey, present coverage may also be uncertain. Of note, in 2013, the country experienced measles outbreaks similar to other neighboring countries (Georgia and Turkey).

The proposal notes that the main challenges to high coverage in some areas are population migration, lack of refrigerators at some health facilities, reliance on outreach immunisation for some remote areas, and over-use of contraindications.

Azerbaijan has experienced rapid economic growth due to oil production and is graduating from Gavi support. Hence Azerbaijan currently does not receive any cash support apart from HSS funds remaining from a previous Gavi grant. The country was visited in August 2013 for a graduation assessment which concluded that Azerbaijan was expected to sustain investments in immunisation without much threat to financial sustainability. A major issue was identified as vaccine procurement at affordable prices. Since then, the country has shifted vaccine procurement to

UNICEF Supply Division, including for traditional vaccines. This has resulted in major savings. Currently the only vaccine support received from donors is Gavi Hib containing Pentavalent and PCV10 support. All other vaccines in the schedule (82% of all vaccine costs) are covered from the state budget.

No polio case has been registered in the country since 1996 and in 2002, Azerbaijan was certified as polio free.

4. Overview of national health documents

The cMYP, 2011-2015 mentions introduction of IPV only as possibility. It had not yet been recommended by a local advisory committee at the time the document was written.

5. Gender and Equity

G.I.I. = 0.34; G.I.I. rank = 62; MMR 43 / 100,000. The 2006 DHS found a major disparity in DPT3 coverage between boys (74%) and girls (49%). The proposal does not provide any information related to gender and equity barriers.

The 2006 DHS also found major disparity in coverage by wealth (74% among the wealthiest quintile vs 49% among the poorest quintile) and urban (68%) vs rural (52%).

Azerbaijan continues to be affected by an unresolved conflict with Armenia over the Nagorno-Karabakh region. There are 1 million refugees and internally displaced persons (IDPs) in Azerbaijan. The proposal does not outline a plan to reach these communities.

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

Azerbaijan has some experience with new vaccine introduction: HepB in 2001, MMR in 2003, Hib-Penta in 2011 and PCV in 2013. IPV introduction was initially planned for April 2014 but subsequently postponed to July 2015.

The proposal seeks USD 131,000 support from Gavi out of a total budget of USD 166,000. The remaining USD 35,000 will come from WHO sources. The itemized budget seems reasonable and relevant.

7. Specific comments related to requested support

New vaccine introduction plan

The timeline for nationwide IPV introduction in the country appears reasonable.

Both the general public and HCWs are very concerned about contraindications to immunisation. National guidelines are not well aligned with WHO policies on vaccine contraindications and are cautious to the point of limiting the delivery of immunisation services. This cautious approach includes a policy to give no more than two injections at the same time for fear of "overloading a child's immune system."

At the time of the application development, WHO had not yet released the updated WHO Multi-Dose Vial Policy for IPV. In any case, Azerbaijan has not adopted the WHO open vial policy at this time for any vaccines. The ramifications of this are that an open vial must be discarded after 6 hours of having been opened. This greatly increases wastage rates and has influenced the decision to procure single-dose vials. If the country subsequently decides that an open vial can be kept for 28 days, the decision as to vial size could be revisited.

IPV will be provided to all children at 6 months of age jointly with the third dose of PC, thus an extra visit will not be needed. This is in line with WHO recommendations. Administering IPV at 6 months of age will avoid three injections at a single visit. The number of OPV doses administered will appropriately remain the same. IPV will be administered intramuscularly in the outer part of the right thigh, with PCV injected afterwards in the left thigh.

At the present time, a standalone IPV vaccine is not registered by the NRA. However, the law provides for approval of WHO prequalified vaccines without registration.

Vaccine management and cold chain capacity

An EVMA was conducted in 2014. It shows improvement in a number of areas since the earlier 2011 EVMA. But there is still opportunity for improvement, especially in vaccine temperature monitoring and vaccine storage capacity at district and health facility level. The EVMA also mentions very large variations in cold chain equipment, vaccine management, stock management, knowledge, adequacy of buildings at service provider level, meaning that adequate support is needed in some specific areas.

The EPI will not implement the multidose vial policy until the NRA specifically allows it. Thus the 1 dose vial is the preferred presentation; any other presentation will lead to high wastage since the policy will not be applied.

Shipment and distribution of IPV vaccine is very well described. There is sufficient vaccine storage capacity at central and district level to accommodate IPV introduction. The country plans to purchase additional fridges to replace non-PQ equipment. At service provider level, only 1179 out of 2265 posts have vaccine storage facilities. The remaining vaccination points are outreach points from "doctors points". Through the Gavi IPV VIG grant, the country plans to procure 1600160 30DTR freezers for the largest health facilities, in addition to 24 fridges.

Waste management

Azerbaijan lacks enough incinerators, and at local level the incineration of medical wastes is conducted in incinerators of donor organisations, but frequently also in improvised incinerators (tanks) or just in holes.

Training, Community Sensitisation & Mobilisation Plans

One of the main impediments to better coverage is the reluctance of staff to immunize due to misinformation on contraindications. Training will be provided to attempt to overcome this. As an EPI requirement, prior to introduction of IPV, all vaccinators should be certified for IPV administration. Results of PCV monitoring and EVM

assessment conducted in 2014 suggest that, in general, staff involved in the immunisation programme had good knowledge and skills in terms of cold chain, vaccine handling and injection safety. Adaptation of trainings materials on IPV introduction will be submitted to medical colleges for further incorporation into an immunisation pre-service curriculum.

The MoH plans to use a website as the main platform for IPV introduction, social mobilisation and advocacy activities. It targets media, health workers, general population and policy makers. On the other hand, the proposal mentioned that there is no comprehensive communication strategy for the immunisation programme, including crisis communication. All activities in this area are planned and implemented on an *ad hoc* basis. However, NIP does not appear to have suffered unduly from insufficient communication/social mobilisation planning, mainly due to strong political commitment to immunisation at government level and the absence of an active anti-vaccination lobby at country level.

Monitoring and evaluation plans

The country has significant experience in monitoring of new vaccine implementation. Monitoring of new vaccine implementation is conducted by staff of the Republican Center for Hygiene and Epidemiology, with WHO support. The same practice was used for PCV introduction in 2013. The national staff is familiar with and skilled in conducting Post Introduction Evaluations, particularly for Hib pentavalent vaccine. A PCV PIE is scheduled for Q1 2015 and an IPV PIE for 2016.

In 2005, EPI began strengthening its AEFI surveillance system and gradually improved AEFI reporting at health centre level. A revision of the AEFI surveillance system is needed to integrate EPI with NRA efforts.

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

Documents presented for this application are consistent.

9. Overview of the proposal

The proposal is full of interesting but unrequested information. The details provided suggest that vaccine introduction will be accomplished successfully.

Strengths:

- WHO and UNICEF now endorse administrative coverage estimates.
- The country's oil revenues are helping to sustain an adequate for the NIP and the government is funding an increasing proportion of vaccine-related costs.
- Plans for the introduction are in line with WHO guidelines
- The licensure of the vaccine into the country could have been a problem, but a special waiver has been set up.
- Storage capacity is adequate.

Weaknesses:

- A high quality immunisation coverage survey is needed to validate administrative coverage estimates that were previously discounted by WHO and UNICEF.
- HCWs are worried about giving too many antigens simultaneously and possible reactions to DTP. They apply too many false contraindications to immunisation.
- A lack of waste disposal policy.
- Variations in cold chain equipment in different locations.

- Existence of high risk groups from poverty, internal conflict, population displacement and migration.
- No preparation for communication crisis.

10. Conclusions

Azerbaijan submitted a clear proposal to introduce one dose of IPV into their routine immunisation system in-line with the GPEI Endgame Strategic Plan and recent WHO SAGE recommendations. The country has had good experiences with previous vaccine introductions and is proactive in capitalizing on the introduction of IPV to support the wider immunisation programme. The programme is aware of the weak areas (especially the issue of data quality) and is taking appropriate steps to deal with it. Based on the past performance and track record of new vaccine introduction, Azerbaijan is capable of smoothly introducing an IPV dose to the routine EPI system. The country has provided adequate justification and documentation for the IRC to recommend approval of their proposal with recommendations as outlined below.

11. Recommendations

Approval with Recommendations

Recommendations to the Country:

1. A high quality coverage survey may be a priority in order to validate administrative estimates of coverage.
2. As part of its overall advocacy plan, the NIP should consider including a clear explanation of the well-established safety of IPV vaccine, and thus severe illness or reactions are not anticipated.
3. Use IPV introduction as a stimulus to make energetic attempts to reach high-risk groups and individuals e.g. the poor, girls, displaced persons/refugees.
4. Suggest using IPV introduction as a good opportunity to develop a national medical waste disposal policy. Some of the savings made from vaccine procurement can be utilized for waste disposal for the immunisation program.
5. Consider acceleration of efforts to install continuous temperature recorders at service provider level.

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.