

HE Mr Armen Muradyan
The Minister of Health
Ministry of Health
Government Building NO.3
375001 Yerevan
Armenia

28 May 2015

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

Your Excellency Mr Muradyan,

I am writing in relation to Armenia's proposal to Gavi for New Vaccines Support (NVS) for Inactivated Polio Vaccine (IPV) which was submitted to the Gavi Secretariat in January 2015.

In March 2015 your application was reviewed by the Gavi Independent Review Committee (IRC) which recommended "Approval" of your application. Based on Armenia's discussion with your Senior Country Manager to successfully address the IRC's issues as communicated in the Information Letter dated 14 April 2015, Gavi has approved Armenia 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 Armenia'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.

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 Armenia

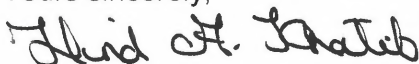
Appendix B: Financial and programmatic information per type of support

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 Ekaterina Rykovanova (erykovanova@gavi.org) if you have any questions or concerns.

Yours sincerely,



Hind Khatib-Othman
Managing Director, Country Programmes

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

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

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, Armenia is encouraged to contribute to vaccine and/or supply costs for IPV.****

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.

Armenia Support for Inactivated Polio Vaccine (IPV)

This Decision Letter sets out the Terms of a Programme

1. Country: Armenia				
2. Grant Number: 1518-ARM-25d-X / 15-ARM-08h-Y				
3. Date of Decision Letter: 28 May 2015				
4. Date of the Partnership Framework Agreement: Not applicable				
5. Programme Title: NVS, 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	Total⁴
Programme Budget (US\$)	US\$ 36,000	US\$ 133,000	US\$ 109,500	US\$ 278,500
10. Vaccine Introduction Grant: US\$ 100,000				
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	12,100	45,000		
Number of AD syringes	12,800	47,500		
Number of safety boxes	150	525		
Annual Amounts (US\$)	US\$36,000	US\$133,000		
12. Procurement agency: UNICEF				
13. Self-procurement: Not applicable				
14. Co-financing obligations: Not applicable Gavi's usual co-financing requirements do not apply to IPV. However, Armenia is encouraged to contribute to vaccine and/or supply costs for IPV.				

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.

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:

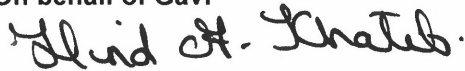
Reports, documents and other deliverables	Due dates
Annual Progress Report or equivalent	To be agreed with Gavi Secretariat

17. Financial Clarifications: Not applicable

18. Other conditions:

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

Signed by,
On behalf of Gavi



Hind Khatib-Othman
Managing Director, Country Programmes
28 May 2015

IRC NVS COUNTRY REPORT
Geneva, 16 to 27 March 2015

1. Type of support requested: IPV

Table 1

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 st and 2 nd choice, if applicable)
October 2015	2015 - 2018	1 st - 1 dose vial; 2 nd - 2 dose vial; 3 rd - 5 dose vial.

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

Introduction of one dose of IPV in routine immunisation has been widely discussed in the Country and finally endorsed by the Inter-Agency Coordination Committee on Immunisation (ICC) on 5 December 2014.

Armenia ICC consists mostly of government units. The ICC is well informed and the EPI manager is strong and effective. CSO participation is limited in Armenia as there are not many organizations working in the field of immunisation. Regular meetings with the Prime Minister's Chief of Staff, creates high level of political commitment. NITAG is relatively well functioning. Gavi provides support for capacity building for NITAG through its business plan.

3. Situation analysis – Status of the National Immunisation Programme

The country remains a high performing country for all antigens. There is a positive trend of increased coverage since 2008 with introduction of new vaccines. The country had no outbreaks in the 2013, which is a good indication of the immunity levels. Armenia was not affected by the measles outbreaks experienced in the neighboring countries and in the European region.

The overall vaccination coverage improved from 2008 to 2012, increasing from 86% to 95% for full vaccination coverage. In 2013, full vaccination coverage decreased by 2% due to Rota vaccine introduction in November 2012. Supervisory quarterly visits, a National Immunisation Program policy adopted in 2010 by the government, and yearly monitoring activities have all contributed to successful performance. There were no significant discrepancies between immunisation coverage data during last five years.

Despite severe economic crisis since the early years of transition the Government has not cut back on social spending despite a sharp fall in tax revenues resulting from the on-going economic recession. Immunisation

services are delivered by 850 health facilities under the jurisdiction of 225 Medical Service Providers in marzes and 36 in Yerevan. Armenia was certified polio-free in 2002 (last case in 1996). However, the Caucasus Region remains a geographical high-risk area, being a population transit zone with direct links to polio-endemic countries (www.unicef.org/newsline/poliopkabout-printer.htm - accessed 20/03/2015).

To prevent wild poliovirus importation and spread in republic of Armenia in 2008 supplementary polio vaccination activities were implemented among children under 5, with very high immunisation coverage. The last major events in the National Immunisation Programme were successful introduction of pentavalent vaccine in routine immunisation in 2009, Rotavirus vaccine in 2012, and Pneumococcal vaccine in 2014.

Armenia is a Gavi graduating country. A graduation assessment was conducted in 2013 with participation of partners; a new graduation assessment will be conducted to develop a costed graduation plan in 2015 following the 2014 Gavi Board decision on graduation support.

In accordance with WHO recommendations Armenia is preparing to proceed with the recommended process of introduction of one dose of inactivated polio vaccine (IPV) in routine immunisation schedule by the end of 2015.

4. Overview of national health documents

Planning of the National Immunisation Program is done through development of comprehensive Multi-Year Plans covering 5 years period. These multi-year plans, based on global and regional goals and national objectives and priorities, provide implementation strategies and key activities for the immunisation program. The cMYPs also have a costing component, which assists the MOH and MOF when deciding the NIP budget. The current cMYP, 2011-2015, is aligned to the NHP and routine immunisation strategy. The next version of the cMYP, scheduled for 2016-2020, will include IPV.

5. Gender and Equity

Gender Inequality Index for Armenia⁶

32.5%

Female adolescents currently married^{7/} in union (%)

7.9%

⁶ The Gender Inequality Index (GII) is a composite measure which captures the loss of achievement within a country due to gender inequality. The GII is interpreted as a percentage and indicates the percentage of potential human development lost due to gender inequality.

⁷ Generally early marriage indicates that girls are being taken out of school and married to significantly older men. This raises questions around inequality within these relationships and the ability of young women to make decisions about their own and their children's wellbeing.

The 2012 DHS for Armenia demonstrates the high performance of the country's EPI program. With regard to all basic vaccinations, coverage was 91.3% for boys, 91.7% for girls. Coverage was higher in rural areas (92.3%) than for urban (90.0%) and in the highest wealth quintile (90.8%) than in the lowest (88.3%). Despite high early marriage, the country does not anticipate the need to address equity barriers in the roll out of this IPV vaccine.

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

Despite the economic downturn the country provides all of the financing for its routine vaccines. A total estimated budget for introduction of IPV is US\$ 422,850 of which US\$ 100,000 is requested from Gavi as Vaccine Introduction Grant (VIG). The rest will be provided through the Government and partners. The vaccine cost is not reflected in the budget and the country is not co-financing IPV.

The activity plans and budgets are well aligned but 63% is earmarked for cold chain procurement. The use of the VIG is 100% for cold chain. The cold chain equipment budgeted totals USD 265,000. Country indicated that they will use the US\$ 100,000 for procurement of 100x200 liters WHO prequalified refrigerators. An additional 50 refrigerators are financed by Government. The procurement of WHO prequalified refrigerators will be done via UNICEF Supply Division. The IRC notes that the price of these refrigerators might lead to a tight budget if estimated cost per unit is higher (USD 1,000) and resulting procuring less refrigerators than originally planned.

7. Specific comments related to requested support

New vaccine introduction plan

At the national level the IPV introduction process will be overseen by the IPV introduction task force, which has prepared the IPV introduction plan, operationalized it with realistic timeline and budget. This is a nationwide introduction with government leadership and wider partnership.

Vaccine management and cold chain capacity

The last EVM assessment conducted in July 2014 revealed that progress has occurred, mainly on the primary store level, following the previous (2011) EVM assessment and 2013 follow up visit. However, further improvement is needed, especially at the lower levels of the vaccine supply chain.

A systematic sample of vaccine storage facilities was conducted, the data collated and assessed, for the three supply chain levels: primary, regional stores, and health facilities. Thirty-three sites including the central store (PR), all 10 regional (marz) stores (LD), and 22 health facilities (SP) were visited during the assessment. The assessment resulted in 6 global (applicable to all levels) and 41 detailed recommendations.

The EVM improvement plan version (dated 10 January 2015) is provided. A concern is the limited action in relation to the E5 Maintenance findings: “All stores should have preventive maintenance plans for their buildings, vaccine delivery vehicles, and cold chain equipment. All maintenance activities should be clearly documented and archived by store manager”.

At the time of EVM assessment required cold chain capacity was estimated considering planned introduction of PCV (September 2014) and IPV (September 2015). The assessment revealed deficit in net refrigerating capacities in some regions. In order to address these issues the MoH has already procured additional 40 m³ cold room for the National Warehouse (expected arrival in March 2015); and has planned to procure 10 (10 m³ each) cold rooms for the regional stores. Gavi's VIG will assist to replace and upgrade the cold chain equipment at the health care facility level. It is expected that the cold chain system will have enough capacity to accommodate the current and new vaccines.

Temperature mapping and monitoring studies are part of the improvement plan. The temperature monitoring and mapping work is also scheduled under the business plan support for early Q3. There is also further work planned for 2015 to strengthen the SOPs for vaccine management.

The IPV introduction task force has prepared the IPV introduction plan, operationalized it with realistic timeline and budget. It will also prepare an IPV distribution plan and monitor its timely distribution. Taking the above into consideration, it is technically and operationally feasible to introduce IPV in the national immunisation programme of Armenia (Introduction date: October 2015).

The country does not need to apply the WHO multi-dose vial policy (MDVP) for IPV because it is expected to use the one dose vial. However, the country has provided the following wastage rates:

- First preference (1-dose): 2% instead of 5% (indicative wastage rate)
- Second preference (5-dose): 15-25% instead of 15% (indicative wastage rate applying MDVP)
- Third preference (10-dose): 30-50% instead of 30% (indicative wastage rate applying MDVP)

Because of the least wastage rate (low birth cohort - 41,000), easier to train the vaccinators on usage and the least expected adverse events following immunisation, preferred presentation of IPV is stand-alone single dose vial.

Waste management

The current policy in Armenia on injection safety and waste management is sufficient for this IPV introduction. Under the existing injection safety and waste management policies and practice in the immunisation programme, the vaccination is carried out solely with auto-disable (AD) syringes, and the waste is stored temporarily in safety-boxes. The main method of

disposal of the sharp waste is incineration. However, open burning of safety boxes still exists in remote rural areas. During planned trainings this component will be emphasized once more to ensure compliance with injection safety requirements.

Training, Community Sensitisation & Mobilisation Plans

There is some misperception among health workers and families concerning multiple injections. For this, there is additional support through Gavi business plan for vaccine safety and communication training targeting particularly the health workers as they are the main influencers of parents' decision making on vaccines. The majority of concerns are around communication activities for vaccine resistance and AEFIs. To avoid multiple injections the IPV will be administered at 6 months.

A comprehensive strategy of communication and social mobilization has been developed with objectives, strategies and education, communication, and advocacy activities to promote parents' and medical professionals. Guidelines on reporting of mild AEFI has been developed, printed and distributed to HCWs involved in immunisation. There are small NGOs working on child health but their projects are very limited, and do not have particular capacity for immunisation and child health programs. The country is making effort to involve civil society, and patient rights groups to deal with the anti-vaccine movement especially when there are AEFIs.

Monitoring and Evaluation

A post introduction evaluation was not mentioned. AEFI concerns are also valid based on past experience and presence of anti-vaccine movement. This needs to be addressed through EPI training programs to ensure that health workers are fully engaged and on board. Starting from 2007 active and effective AFP surveillance has been in place.

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

- The cMYP is aligned with National Health Plan and Immunisation Strategic Plan
- Vaccine introduction plan is good.
- EVM Improvement Plan is in place.
- No discrepancy between figures presented in different sections of the proposal.

9. Overview of the proposal

Strengths:

Political commitment; strong partnerships and good immunisation system.
Good introduction plan.
Separate budget line and accounting system.

Weaknesses:

Misperceptions on quality of vaccines among health care professionals and public leading could jeopardize coverage.

Immunisation programme budgeting.

Lack of spare parts for cold chain maintenance.

The NIP is receiving decreasing donor support (i.e., training, supervision, monitoring, surveillance) so there is a need for increased domestic funding.

Risks:

Sustainable immunisation financing issues.

Mitigating strategies:

Financial Sustainable Plan with updated cMYP.

IRC comments for consideration:

Table 2

Comments for consideration
1. Country and Gavi to work in cooperation on overall Financial sustainability for the EPI programme as more and more vaccines are introduced and Armenia is graduating from Gavi support.
2. Armenia should review and place an improved cold chain maintenance activities and support for both IPV introduction and the EPI programme to maximise the utilisation and duration of the cold chain equipment. Gavi and partners (UNICEF) to assist with the review of the overall budget allocation within the cold chain renewal and in the overall EVM follow up plan by the country.

10. Conclusions

The strong health system, especially strong national immunization program prevailing in Armenia, makes IPV introduction very much feasible and major challenges are not foreseen.

11. Recommendation

Approval

Table 3a

Issues to be addressed	Action points
1. Cold chain maintenance for IPV introduction	1. Country and partners (UNICEF) to address the spare parts needed for the 100 cold chain equipment in relation to the VIG budget before the procurement.
2. There is no plan to evaluate the introduction	2. Post introduction evaluation, or alternative evaluation approach, to be included in the IPV Introduction work plan for

of IPV within 6-12 months period.

learning and documentation; and as provided in the guideline *“it is strongly recommended that countries conduct a Post Introduction Evaluation (PIE) 6-12 months after vaccine introduction. Countries should include their plans for conducting a PIE, or alternative evaluation approach, as part of their M&E plan.”*

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.

