



The Minister of Health and Family Welfare
Ministry of Health and Family Welfare
Ulaanbaatar
Mongolia

4 March 2015

Dear Minister,

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

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

In November 2014 your application was reviewed by the Gavi Independent Review Committee (IRC) which recommended "Approval with Recommendations" of your application.

We have since received a satisfactory response to these clarifications and/or your commitment to follow up on any outstanding clarifications according to an agreed timeframe. I am now pleased to inform you that the GAVI Alliance approved Mongolia for GAVI support as specified in the Appendices to this letter.

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 30% to 15% for the 5-dose vial. The change in guidance will apply from May 2015 once the manufacturers have moved the Vaccine Vial Monitor (VVM) from the cap to the label. As Mongolia is expected to receive its first shipment with the VVM on the label, the lower indicative wastage rate has been applied to calculate the approved doses in all years.

In order to ensure sufficient funding for all Gavi countries applying for IPV support, please note that Mongolia'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

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



funding for IPV.

Mongolia received a Partnership Framework Agreement (PFA) in December 2013. To date, we have not received the signatures of the Ministry of Health and Ministry of Finance on the PFA. Please be advised that until that Agreement has been signed between Gavi and Mongolia, Gavi will not process any further applications (for HSS and new vaccine support) that the Independent Review Committee has recommended for approval and will no longer disburse subsequent tranches of Health System Strengthening and/or Immunisation Services Support funds that were approved earlier.

The Appendices include the following important information:

Appendix A: Description of approved Gavi support to Mongolia

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 raj कुमार@gavi.org if you have any questions or concerns.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Hind Khatib-Othman".

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 *Mongolia* (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 Mongolia’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, Mongolia 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.

**MONGOLIA SUPPORT for
INACTIVATED POLIO VACCINE (IPV)**

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

1. Country: Mongolia				
2. Grant Number: 1518-MNG-25b-X / 15-MNG-08h-Y				
3. Date of Decision Letter: 4 March 2015				
4. Date of the Partnership Framework Agreement: Not yet signed				
5. Programme Title: NVS, IPV Routine				
6. Vaccine type: Inactivated Polio Vaccine (IPV)				
7. Requested product presentation and formulation of vaccine²: Inactivated Polio Vaccine, 5 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\$47,000	US\$176,000	US\$124,500	US\$347,500
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	22,800	85,700		
Number of AD syringes	22,000	82,100		
Number of re-constitution syringes				
Number of safety boxes	250	925		
Annual Amounts (US\$)	US\$47,000	US\$176,000		
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: Not applicable Gavi's usual co-financing requirements do not apply to IPV. However, Mongolia 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	15 May 2015
17. Financial Clarifications: Not applicable	
18. Other conditions: If Mongolia 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 Mongolia.	

Signed by,
On behalf of Gavi

Hind Khatib-Othman
Managing Director, Country Programmes
4 March 2015

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

1. Type of support requested: IPV

Planned start date	Duration of support	Vaccine presentation(s)
October 2015	2015 - 2018	5 dose, 10 dose, 1 or dose*

*3rd choice: 1 dose in annex A and 2 dose in annex B

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

Mongolia has been considering the inclusion of IPV in the immunisation programme since 2010. It was recommended in the document: *"Preparedness, response measures and prevention of importation of wild poliovirus during 2011-2015"* and in 2012 by the National Verification Committee. In May 2014, considering the WHO SAGE recommendations and the opportunity of Gavi support, the country decided to proceed toward the introduction of IPV.

The national center for communicable diseases (NCCD) is responsible for immunisation services. Mongolia has an ICC and a NITAG. The NITAG recommends new vaccines introduction and it endorsed the IPV introduction. The ICC coordinates partner support. WHO and UNICEF also support the program technically and financially. The NITAG recommendation was presented to the ICC along with the proposed introduction plan and application to Gavi and these were approved on 8th September 2014. The MOH and MOF signed the introduction plan.

3. Situation analysis – Status of the National Immunisation Programme

As of August 2014, the total population of Mongolia is estimated to be 2,969,098 (National Statistical Office of Mongolia). Mongolia is the least dense country in the world. Since 2006, the number of births per year has increased and is greater than was previously estimated. The number of births in 2013 was 79,371 compared to 45,326 in 2005 (National statistical office of Mongolia). The government wishes to increase the total population to 5 million in 20 years.

Mongolia reported greater than 95% DPT3 coverage for more than two decades. These administrative estimates have been validated by MICS surveys in 2005 and 2010, both of which found DPT3 coverage of greater than 90%. WUENIC estimates have thus mirrored Mongolia's administrative estimates. According to the Joint Reporting Form (JRF) for the year 2013, only one out of 339 districts had coverage of less than 80%; and another one district had the coverage between 80-90%.

Catch up campaigns (National Immunisation *Ten Days Campaign*) have taken place twice a year since 1993. In addition, since 2009, the RED strategy has been implemented in 8 provinces, in 6 districts with support of different health partners such as UNICEF, WHO,

Gavi and UNFPA. This has contributed to retaining high coverage as well as maintaining quality of services.

The country introduced pentavalent vaccine in 2005 and MMR in 2009. In 2012-2013, Mongolia introduced the Hepatitis A vaccine into the routine immunisation schedule in a phased manner. The joint appraisal report indicated that Mongolia plans to introduce PCV in January 2016.

According to the proposal all the new vaccines introductions were successful and the lessons have been incorporated into the IPV introduction plan. There was no program review in the previous five years, however the different advisory bodies conducted evaluations and have taken corrective actions.

In 2014, the government supported 93% of the cost of immunisations in Mongolia compared to only 7% in 2003. Now all routine vaccines (7 types of vaccine) and the associated transportation budget (to the districts and provinces) are paid by the Government. The only external support for the procurement of routine vaccines is the Gavi support for a percentage of the pentavalent vaccine according to the co-financing agreement.

The last polio case was reported in 1993 and Mongolia was declared polio free in 2000.

4. Overview of national health documents

The current cMYP is from 2011 to 2015 and IPV is not included. Mongolia will include IPV in the cMYP to be developed in 2015.

5. Gender and Equity

G.I.I. = 0.320; G.I.I. rank = 54; MMR = 63/100,000. The 2010 MICS did not show any gender disparity in coverage (93 and 92 per cent respectively for males and females).

Similarly, the coverage varied from 91% to 96% among different wealth quintiles. Geographically the variation was from 89% to 95%, the least being in the Western region. The country has high vaccination coverage rates for all routine antigens. However, due to remoteness, internal migration, poverty, and natural disaster such as heavy snows, the most disadvantaged population occasionally miss routine vaccination doses. Hard to reach populations including unregistered or mobile groups are being detected by the RED strategy. For IPV introduction, UNICEF is supporting a communication strategy to reach hard-to-reach populations.

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

There is a detailed list of activities for pre-introduction, introduction and post introduction periods and the IPV launch will be in October 2015.

A detailed introduction budget is presented. The total estimated budget for IPV Introduction in Mongolia is US\$ 410,819. It is proposed that US\$ 81,530 will be provided by the government, \$159,290 will be requested from WHO (for general cold chain support), \$70,000 will be requested from UNICEF, and US\$ 100,000 will be requested from Gavi as the vaccine introduction grant.

No co-financing for IPV is proposed. The NCCD in collaboration with the immunisation advisory bodies and international organizations (NITAG, ICC, MOH, WHO, UNICEF, and



JICA) will immediately begin discussions with the government to include IPV in future annual budgets. It is anticipated that once Gavi support for IPV has concluded, the Government of Mongolia will assume all costs related to IPV.

7. Specific comments related to requested support

New vaccine introduction plan

DPT is administered at 2, 3 and 4 months. IPV will be introduced at 4 months with DPT3. There will be no IPV catch up efforts.

Mongolia will develop detailed IPV introduction guidelines, adapt training materials and train all levels. They will also update their supervision guidelines and install cold chain equipment. IPV will be introduced at 4 months in line with GPEI's recommendation. The vaccine formulation of 1st choice is the 5 dose vial. The reason given for this preference is to minimize wastage in comparison with a 10 dose vial and to save storage space when compared to a 1 dose vial. Note: based on WHO's recent approval, the 10 dose vial is now MDVP compliant and could be used in the country.

Mongolia has a regulatory approval process, which involves three agencies, and according to the proposal this may take up to seven months to complete. IPV will be introduced nationwide and the country partners support the process. WHO and UNICEF will make financial and technical contributions. The vaccine will be procured through UNICEF supply division.

No other new vaccine is being introduced at the same time. The introduction timeline is detailed but it does not include the registration process. The vaccine is expected to arrive in Mongolia in July 2015 and for that to happen the registration process should be started in January 2015 or earlier.

Vaccine management and cold chain capacity

MoH has strongly supported the strengthening of the cold chain and vaccine management. It has taken effective steps for implementation of the EVMA recommendations. Out of a total of 18 recommendations, 10 (55%) have been fully implemented and 7 (40%) are in progress. Most activities have been successfully implemented by issuing government orders. This includes efforts to strengthen the cold chain strengthening with funds from the IPV VIG and WHO.

For stock management, the VSSM is implemented at national level. A refrigerated truck assures proper transport from the airport to the central store and from there to the provinces and districts. The HCs then come to collect the vaccines from the provinces and districts.

Mongolia has adopted the standards defined in the WHO module on "Injection surveillance and safety" and efforts are ongoing to implement these guidelines. Based on a government order, all waste from vaccine and vials are to be collected and disinfected before being destroyed (burying). Each HF is to have a team to take care of this. A report of each waste destruction is to be sent to the central level. Further training for this will be part of IPV introduction.

Training, Community Sensitisation & Mobilisation Plans

Mongolia will develop a training plan and training will be conducted at national, district/province and local levels. ICC and NITAG members will sensitise political leaders and decision makers and sensitisation materials including posters, TV spots, live interviews and newspaper articles will be developed and distributed.

Mongolia will conduct national and provincial launching ceremonies and this will be done at the anniversary of the 15th Mongolia polio free status. Mongolia plans to conduct a survey to find out the reasons for hesitancy and take corrective actions. UNICEF will support the development and implementation of the communication strategy that would help to reach all parts of the districts equitably including the poorer geographic areas.

Monitoring and evaluation plans

Monitoring tools and supportive supervision checklists will be updated. The EPI managers and inspectors will conduct supportive supervision visits to the local level. Mongolia will also conduct a post introduction evaluation (PIE) for IPV. The country has an AEFI monitoring system and IPV will be part of that monitoring system.

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

The IPV proposal is comprehensive and complete; there is consistency in the plan except for the introduction budget: in annex A the total budget is \$410,000, however in annex D it is US\$ 280,530. In both cases the VIG from Gavi is US\$ 100,000.

9. Overview of the proposal

Strengths:

- Mongolia has a very strong immunisation programme, with solid capacities, ready to take on new vaccines and also ready for graduation.
- High immunisation coverage for many years and no discrepancy between administrative estimates, survey estimate and WHO/UNICEF estimates.
- The monitoring and follow up system is strong.
- The country has been polio free for 15 years
- A very strong MoH support with clear orders for implementation of EVM recommendations.
- Government leadership in the health sector is strong, with use of governance, coordination and legal instruments to promote and sustain health programmes.

Weaknesses:

- No major weakness
- The 30 DTR (Fridge tags) are mostly expired and should be replaced.

Risks:

- The anti-vaccination lobby is growing and some communities/families may hesitate and/or refuse to get injection of IPV since Mongolia has been declared polio free.

Mitigating strategies:

- Assess the reason for any hesitancy through a survey and develop a suitable communication strategy.
- Organise expanded IEC and advocacy.

10. Conclusions

Mongolia presented a comprehensive plan to introduce IPV into its routine immunisation program following the GPEI guidelines. The country has been polio free for 15 years and as part of its effort to sustain its polio free status, the country plans to introduce IPV.

The application submitted is technically sound and provides all elements for a successful IPV introduction. Gavi support is valued as a very good investment and the country is committed to increasingly take responsibility for the whole immunisation programme.

11. Recommendations:

Approval with Recommendations

Recommendations to the Country:

1. Ensure the IPV registration process is initiated in a timely manner since this process may take up to 7 months.
2. Clarify the following about the implementation of the EVMA recommendations:
 - a. Confirm whether the first cold room planned for installation in 2014 has been installed.
 - b. Indicate when the second cold room will be installed
 - c. Provide and update on is status of the 4 activities not yet initiated

Recommendations to the Gavi Secretariat:

1. Clarify with the country the expected duration of Gavi IPV support.