



Mr. Andrei Usatii
The Minister of Health and Social Protection
Ministry of Health and Social Protection
2, Alexandri Str.
MD-2009 Chisinau
Republic of Moldova

11 February 2015

Dear Minister,

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

I am writing in relation to Moldova'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 Moldova's successful response to the Senior Country Manager to address the IRC's comments, Gavi has approved Moldova for Gavi support for IPV, as specified in the attachments to this letter.

In order to ensure sufficient funding for all Gavi countries applying for IPV support, please note that [COUNTRY]'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.

Please do not hesitate to contact me 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 Programs

Attachments: Decision Letter
IRC report

¹ UN World Population Prospects, Revision 2012 ([http://www.un.org/en/development/desa/pop/](#))

Moldova SUPPORT for INACTIVATED POLIO VACCINE (IPV)

This Decision Letter sets out the Terms of a Programme

1. Country: Moldova				
2. Grant Number: 1518-MDA-25d-X / 15-MDA-08h-Y				
3. Date of Decision Letter: 11 February 2015				
4. Date of the Partnership Framework Agreement: 5 February 2015				
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	Total ⁴
Programme Budget (US\$)	US\$36,000	US\$135,000	US\$112,000	US\$283,000
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	12,200	45,600		
Number of AD syringes	12,900	48,200		
Number of safety boxes	150	550		
Annual Amounts (US\$)	US\$36,000	US\$135,000		
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: Gavi's usual co-financing requirements do not apply to IPV. However, Moldova 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:					
<table border="1"> <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				
17. Financial Clarifications: not applicable					
18. Other conditions: If Moldova 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 Moldova.					

Signed by,
On behalf of Gavi



Hind Khatib-Othman
Managing Director, Country Programmes
11 February 2015

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

1. Type of support requested: IPV

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1st, 2nd, and 3rd choice)
October 2015	2015 - 2018	One dose presentation (no 2nd choice)

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

Moldova is planning to introduce IPV nationwide, starting on 1st October 2015. All relevant stakeholders participated in the decision making process for the introduction of IPV. The NITAG (established in 2013; with written terms of reference) held a meeting in September 2014 to discuss and endorse the introduction. The application was endorsed by the Minister of Health and the Minister of Finance. The IPV proposal was discussed and endorsed by the ICC members in September 2014.

The ICC is functioning with a clear TOR and met 3 times in 2013. CSOs are not represented at the ICC.

3. Situation analysis – Status of the National Immunisation Programme

Moldova is a high performing Gavi graduating country (GNI/capita is US\$2,070). The population is 3.4 million and the birth cohort about 41,594. The country is divided into 44 administrative-territorial units with a large number of scattered villages.

Moldova has achieved a high level (over 90%) of DPT3 dose coverage nationwide. There have been no differences between administrative and WUENIC data. However, over the last decade a small drop has been observed (from 97% in 2006 to 90%-92% since). The main factor behind the lower coverage rates is the increased refusal of vaccination by families especially in Chisinau (DPT3 = 71%) and in Transnistria Region. Due to lack of financial resources and different governance mechanisms, new vaccine introductions such as PCV and rota vaccines are on hold in Transnistria.

There are difficulties in determining the accuracy of the denominator due to the intense internal and external migration, a computerized database was introduced in 2013, with the aim to improve the data collection procedure and the data quality.

Effective implementation of the NIP is based on intense cooperation and interaction between many in-country partners. Moldova has successfully

introduced three new vaccines: Pentavalent in 2011, RCV in 2012, and PCV in 2013. A post introduction evaluation (PIE) for rotavirus vaccine was conducted in April 2013. The general findings were satisfactory giving indications of a well managed immunization program. Weaknesses and some challenges were also identified within the program.

The country was visited for a graduation assessment in February 2014 and a graduation plan was developed to be partially supported by Gavi. The plan is mainly to support the capacity building of the NRA, NITAG and other governance institutions for improved immunization financing and program sustainability.

4. Overview of national health documents

The cMYP 2011-2015 is aligned with national health and development policies and addresses the GIVS strategic areas. It explores costing and financing scenarios and highlights Gavi co-financing to introduce rotavirus vaccine, and pneumococcal vaccine

The IPV introduction is not included in the current cMYP as the decision was taken within the framework of the Polio End Game Strategy to mitigate risks associated with the withdrawal of type 2 OPV. There is a plan to update the cMYP in 2015 to cover the period 2016-2020 in collaboration with WHO, UNICEF & Gavi.

5. Gender and Equity

GII	0.302 (medium)
GII rank	51
MMR	41 /100,000
Adolescent birth rate	29.3
Female literacy	99%

It is stated in the proposal that there are no political, ethnic, cultural, gender or social gaps in access to immunization services. However there is no supporting data to validate this information. In the section outlining the problems related to immunization, it is stated that lack of staff and resources in some remote health facilities is an issue. However it is not specified how these remote areas will be made more functional for immunization. The MICS 2012 found DPT3 of 82% for urban areas and 93% for rural areas. Coverage rates were slightly higher for girls than boys. The proposal notes that there are no gender barriers in access to immunization. Sex disaggregated data were reported in the 2013 APR.

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

The government procures all traditional vaccines and is co-financing pentavalent, Rota and PCV vaccines. The government has no plans for co-financing of IPV.

The total operational costs for IPV implementation have been estimated at US\$ 303,400. The country is eligible for US\$ 100,000 for vaccine introduction grant (VIG). The Gavi VIG will cover about 33% of the operational costs. The major line items in the VIG budget are communication and social mobilization activities (60%) and training and capacity building activities (30%). Funds have been earmarked for the PIE. Gavi Partners (WHO & UNICEF) will cover (28%) of the required budget, and the Government will contribute to the outstanding (39%). A detailed budget was provided in Annex D of the application. There is a logical flow of activities in the timeline provided and the unit costs in the budget appear reasonable.

Financial sustainability strategies are reflected in the proposal and seem feasible given country's past performance. The country has not received other cash grants from Gavi to-date such as HSS or ISS.

Fiduciary management arrangements had been submitted to Gavi. The government has requested that the VIG be transferred according to the financial management modalities previously agreed upon with Gavi. The funds will be transferred to the government account as with other VIGs. The country is not prioritised for an FMA as there has not been any substantial cash grant to country such as HSS.

7. Specific comments related to requested support

New vaccine introduction plan

The New Vaccine Introduction Plan for IPV clearly outlines the justification for the introduction of one dose of IPV into the routine immunisation programme. WHO certified Moldova as a polio-free country in 2000. Despite the overall satisfactory performance of the AFP surveillance system, some rayons (20%) do not provide timely zero reports and some areas have been silent areas for many years.

Moldova has planned a nationwide IPV introduction for October 2015. In line with WHO/SAGE recommendations the IPV will be administered at 6 months of age jointly with the 3rd dose of pentavalent, intramuscularly in the outer part of right thigh (one vaccine in each thigh).

The one dose presentation of IPV is requested. This seems suitable given the size of the target population and its geographical distribution. According to Moldova's laws, WHO-pre-qualified vaccines delivered to the country via UNICEF do not require licensing in the country. The country will use UNICEF as procurement agent.

IPV introduction is not affecting or displacing other new vaccine introduction plans.

Vaccine management and cold chain capacity

The last Effective Vaccine Management (EVM) assessment was carried out in April 2011. The country introduced Rota on 1st July 2012 and PCV on 1st Oct 2013. The past EVM considered the capacity requirement for these 2 vaccines. According to the assessment most of the indicators at all levels have scored more than 80%, with just a couple of them being a little less. Temperature monitoring, maintenance and stock management have been the lower performing indicators. The country has developed its EVM improvement plan and has taken a series of actions to address problems identified.

The national vaccine warehouse, as well as refrigerating equipment, was repaired. Cold storage capacity was increased and computerized data management was introduced. By mid 2014, 19 out of 22 recommendations were implemented. Further details of the actions accomplished have been submitted along with the proposal.

The new EVM is reported as having been completed on 31 October 2014.

Waste management

Policies, standards/guidelines related to immunization waste management are available. Ecological services are imposing fines for burning of syringes with open fires. The country is aiming to introduce new technologies but there is shortage of funding.

Training, Community Sensitisation & Mobilisation Plans

Training of health workers on IPV will be integrated into NIP training courses and educational materials. The materials developed for IPV introduction by GPEI/WHO will be used. A thorough training will be conducted to reinforce the communication capacities of health workers to raise community awareness.

With certain communities, a trend of increasing vaccine refusals and hesitancy among the parents has been observed. However, no specific measures to address this problem have been implemented due to limited resources and capacity for developing and promoting social mobilization tools and activities. According to the proposal a comprehensive communication plan for introduction of IPV will be developed based on WHO recommendations and tailored for various target groups. Thus, the Gavi vaccine introduction grant would represent an important contribution to implementation of previously planned communication and advocacy activities.

Monitoring and evaluation plans

The existing NIP monitoring and evaluation system will monitor the different aspects of programme implementation (stock data, vaccination coverage, vaccine wastage, adverse events following immunization, and population perceptions). Monitoring tools will be updated to include IPV then printed and distributed. All health workers will be trained on the updated data collection tools to ensure the quality of data collected. Supportive supervision is planned at all levels. A PIE is planned.

Little information is provided about the existing AEFI surveillance system. As per the country appraisal conducted in July 2014 there is no standardized protocol for case investigations nor is there a case report form. The country does plan to update the AEFI reporting tools and train health workers on AEFI monitoring.

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

There was relatively good consistency between proposal documents and the required documents submitted with the application. No data inconsistency is observed. As outlined in the situation analysis section of the report, there are on-going challenges to universal immunization coverage. Steps have been put in place by the country and partners to start dealing with this issue.

9. Overview of the proposal

Strengths:

- Well established EPI system with sustained high coverage;
- All traditional vaccines are funded by the government which has met the co-financing requirements for Gavi supported new vaccines;
- In- country support and coordination with different stakeholders.
- Financial sustainability plan and modalities are in place.

Weaknesses:

- No clear plan or strategies to address the low coverage areas (urban& remote)
- Weak capacity for promoting social mobilization tools and activities
- Functionality of the AEFI system is not clear
- Weak AFP surveillance in some remote areas.
- CSOs are not represented on the ICC

Risks:

- Transnistrian region might have problems paying for IPV in the event Gavi support does not cover the IPV costs beyond 2018.
- Increasing trend of vaccine hesitancy among population especially in urban areas, which could be influenced by the anti-vaccine movement

Mitigating strategies:

- Capitalize on IPV introduction to penetrate the hard to reach population
- As IPV is fully supported by Gavi with no co-financing obligation, the Transnistria region is to take on IPV introduction.
- Strong determination of country partners to address the vaccine hesitancy.

10. Conclusions

Moldova has requested support to introduce one dose of IPV into their routine immunization system in-line with the GPEI Endgame Strategic Plan and recent WHO SAGE recommendations. The country has good experience with previous vaccine introductions and is attempting to deal with the ongoing issues on the immunization services and coverage. Based on the past performance and track record of new vaccine introduction, Moldova is unlikely to face serious bottlenecks to IPV introduction. 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. Revise the AEFI plan and include additional required activities to strengthen the AEFI surveillance system.
2. Outline and implement clear communication strategies /approaches to address vaccine hesitancy/ refusal. Technical assistance may be considered.
3. Prepare and implement a plan to reach remote & marginalized populations.
4. Consider inclusion of one or more CSO representative in the ICC.

Recommendations to the Gavi Secretariat:

1. Follow up on efforts to strengthen AEFI surveillance and response
2. Clarify how the IPV vaccines and financial support will be delivered and monitored in the autonomous region.
3. Considering the fragile situation and the financial challenges in Transnistria Region, Gavi Secretariat should work with partners to identify the bottlenecks to immunization in the Transnistria Region and work with the country to outline clear agreed upon strategies to address them. Sustainability of IPV immunization beyond Gavi support and the polio end game strategy should be considered by Gavi and partners.