

5 February 2015

Dear Minister,

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

I am writing in relation to Uzbekistan'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 Uzbekistan's agreement with your Senior Country Manager to address the IRC's comments within the deadlines stated below, Gavi has approved Uzbekistan for Gavi support for IPV, 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 Uzbekistan 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 Uzbekistan's initial allocation of IPV doses and associated supplies have been adjusted using UN population data<sup>1</sup> 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,



Hind Khatib-Othman  
Managing Director, Country Programs

Attachments: Decision Letter  
IRC report  
IPV MDVP note

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

## Uzbekistan SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

<b>1. Country:</b> Uzbekistan				
<b>2. Grant Number:</b> 1518-UZB-25b-X / 15-UZB-08h-Y				
<b>3. Date of Decision Letter:</b> 5 February 2015				
<b>4. Date of the Partnership Framework Agreement:</b> 07/02/2014				
<b>5. Programme Title:</b> NVS, IPV Routine				
<b>6. Vaccine type:</b> Inactivated Polio Vaccine (IPV)				
<b>7. Requested product presentation and formulation of vaccine<sup>2</sup>:</b> Inactivated Polio Vaccine, 5 dose(s) per vial, LIQUID				
<b>8. Programme Duration<sup>3</sup>:</b> 2015 - 2018				
<b>9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):</b> <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 <sup>4</sup>
Programme Budget (US\$)	US\$886,500	US\$1,586,000	US\$1,190,500	US\$3,663,000
<b>10. Vaccine Introduction Grant:</b> US\$494,000				
<b>11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):<sup>5</sup></b>				
Type of supplies to be purchased with Gavi funds in each year	2015	2016		
Number of IPV vaccines doses	431,600	772,400		
Number of AD syringes	416,900	734,400		
Number of safety boxes	4,600	8,100		
Annual Amounts (US\$)	US\$886,500	US\$1,586,000		
<b>12. Procurement agency:</b> UNICEF				
<b>13. Self-procurement:</b> Not applicable				

<sup>2</sup> Please refer to section 18 for additional information on IPV presentation.

<sup>3</sup> This is the entire duration of the programme.

<sup>4</sup> This is the total amount endorsed by Gavi for 2015 to 2017.

<sup>5</sup> This is the amount that Gavi has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

**14. Co-financing obligations:**

Gavi's usual co-financing requirements do not apply to IPV. However, Uzbekistan 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:** The Country shall provide the following clarifications to Gavi\*:  
Not applicable

*\*Failure to provide the financial clarifications requested may result in Gavi withholding further disbursements*

**18. Other conditions:**

If Uzbekistan 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 Uzbekistan.

Signed by,  
**On behalf of Gavi**



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



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

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**1. Type of support requested: IPV**

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> choice)
July 2015	2015-2018	5 dose; 1 dose; 10 dose

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

The IPV application was endorsed by the ICC on 15 September 2014, and signed by the Minister of Health and the Minister of Finance. Uzbekistan's ICC is mostly composed of government agencies (central, provincial and district levels) and WHO and UNICEF; with no CSO representatives. USAID and DFID have phased out of support of the health sector. The World Bank works in the health sector but their investments are not on immunisation. The only international agency supporting immunisation is Save the Children South Korea that works in urban areas where there are Korean populations. A NITAG was established in Uzbekistan in 2012. The NITAG unanimously endorsed IPV introduction into Uzbekistan's National Immunisation Programme (NIP) during a meeting on 20 June 2014.

**3. Situation analysis – Status of the National Immunisation Programme**

The NIP appears to be well established at all levels of the health care system. Immunisation services are delivered in the 5000 health facilities throughout Uzbekistan. The immunisation program is managed by the MoH State Surveillance Department and the NIP Manager is a Deputy Head of the Department. Planning, procurements and distribution of immunisation supplies, including vaccines, are managed by the Republican Centre for State Sanitary and Epidemiological Surveillance (RCSSES), which has a network in all provincial and district centres. Epidemiologists at RCSSES branches act as provincial and district EPI managers.

Uzbekistan appears to have maintained very high national immunisation coverage. However, coverage estimates are based on administrative data, and no assessments of administrative data systems have been conducted since 2012. The State Statistics Office is the agency responsible for data collection and the office reports directly to the President's Office, which would make it difficult for MoH to address all data related issues. There are issues with population data, particularly denominators. There has been no nationally representative household survey within the last five years. WHO and UNICEF recommend a high-quality survey to confirm reported administrative coverage. The new HSS investment focuses on data quality issues and improvement in the data systems. The HSS investment will help particularly with data collection from provincial to central levels, and computerise some of the processes to improve the data quality and reporting. The new HSS will also be used for conducting one or more coverage surveys.

The country responded well to polio outbreaks in neighboring countries in 2010 with SIAs in the border regions and managed to control any potential transmission. Since then the country is implementing SIAs. In 2014, they conducted SIAs including one

campaign particularly targeting border regions; with financial support from UNICEF and Russia. Due to the pressing global polio eradication calendar, Uzbekistan decided to shift HPV introduction to 2016 (initially planned for 2015). The country aims for dual introductions of IPV and PCV in July 2015. The PIE for penta introduction was conducted in November 2011 reported that the introduction went smoothly and the vaccine was well accepted by the population. Rotavirus vaccine introduction took place in June 2014, and the PIE was planned for October 2014.

#### **4. Overview of national health documents**

Uzbekistan's current cMYP (developed in May 2010 and revised in August 2013) covers the period 2011-2015. The country plans to revise the cMYP in May-June 2015, to include IPV introduction. The last EVM assessment was conducted in May 2012, and a progress report was submitted on the status of implementation of the EVM improvement plan.

#### **5. Gender and Equity**

G.I.I. NA; G.I.I. rank NA; MMR = 28/100,000. No sex-disaggregated data is available routinely. The 2002 DHS found no significant disparities by sex nor by wealth quintile in immunisation coverage.

Uzbekistan ranks 116 out of 187 countries based on the Human Development Index. There are disparities in well-being and life expectancy in this multi-ethnic country. Two-thirds of the population lives in rural areas. There are significant geographical difficulties that could limit access to immunization services but those areas are low density population areas, served by mobile immunisation teams and by appropriately adapted distribution of vaccines and supplies. Reaching the un-reached population is part of the Reaching Every District (RED) strategy. The RED strategy implies the use of additional strategies, such as outreach and mobile teams.

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

The government does not plan on co-financing IPV. Since 2007 the MoH has procured all traditional vaccines, and the government indicates commitment towards a gradual increase in vaccine co-financing levels with Gavi in 2014 and 2015. All Gavi support is reported in the National Health Sector budget. Financial resources for vaccines are clearly earmarked, with a separate budget line in the MoH budget.

The total operational costs for IPV introduction are estimated at US\$ 5,367,420; with VIG covering US\$ 494,000 (9.2%), government budget covering US\$ 443,553 (8.3%), partners providing US\$ 158,000 (2.9%) and Gavi-HSS covering US\$ 4,260,468 (79.3%). There is a logical flow of activities in the timeline provided and the unit costs in the budget provided appear reasonable. The country has asked that the funds be channelled through WHO or UNICEF, without budgeting the relevant agency's management costs. The confirmation of which agency is expected to be known in Q4 of 2014 when both agencies would have determined their budget ceilings for 2015 and their capacity to receive additional funds for IPV. The rationale



for channelling VIG through a UN agency is to ensure smooth implementation of the introduction activities while the government will administer the HSS grant. The country will require an external audit for the VIG if annual expenditure exceeds US\$ 250,000, but no funds have been earmarked for external audit fees in the budget.

## **7. Specific comments related to requested support**

### **New vaccine introduction plan**

The IPV introduction plan clearly outlines the justification for the introduction of one dose IPV into the NIP, in line with the Polio Eradication and Endgame Strategic Plan and the SAGE recommendation. In 2010-2011, the country carried out seven nationwide and sub-national vaccination campaigns against polio, which covered 98% children aged 0-5 years. A rapid AFP surveillance review conducted in 2011 and desk review in 2013 demonstrated a good surveillance. The Regional Certification Commission for polio eradication (RCC) downgraded risk of polio poliovirus importation to Uzbekistan from high in 2012 to low in 2014. The SIAs with tOPV were conducted in 2013, particularly targeting border areas with Afghanistan and Tajikistan, with high coverage achieved.

Uzbekistan plans a nationwide IPV introduction in July 2015. The presentation of choice is the 5-dose vial, with the 1-dose vial as second choice. The rationale of preference for 5- and 1-dose vials is to reduce expected high wastage due to sparse population in mountainous areas. The country is ready to accept multiple presentations of IPV, including 10-dose vials; however, in that case, the share of 10-dose vials should not exceed 50% of total shipment.

IPV will be administered at 4 months of age along with penta3 and OPV3, in line with SAGE recommendations. PCV will be administered at 2, 3 and 12 months of age, which the country has indicated will avoid the provision of 3 injections at a single EPI visit. IPV will be administered IM in the outer part of right thigh, followed by penta in the left thigh. The country has used an estimated coverage of 100% of surviving infants for dose calculations. The country official estimates and WUENIC data put the 2013 DTP3 coverage at 99%, so this is an appropriate estimation. The country provided wastage rates below the indicative wastage rates for two presentations (25% instead of 30% for 5-dose and 40% instead of 50% for 10-dose vials); however, this is not a concern as the correct indicative wastage rates will be used for the initial allocation of IPV doses by Gavi.

The IPV vaccine will be procured through UNICEF from WHO pre-qualified suppliers. At the moment, stand-alone inactivated polio vaccines are not licensed in Uzbekistan. Only Sanofi Pasteur vaccine DTaP-IPV (Tetraxim™) is registered. However, WHO pre-qualified vaccines supplied by UNICEF are authorized for use following an expedited authorisation process, which takes about 20 days after receipt of the vaccine in the country. Issue of proper licensing of the IPV product will be dealt with the manufacturer when the vaccine is identified for Uzbekistan by Gavi and in accordance with the overall approach and recommendations of WHO Regional Office for Europe.

Uzbekistan is planning to introduce IPV and PCV simultaneously in July 2015. The two VIGs will be used to address identified areas of concern and top up MoH funding. Prioritization of funding of essential activities will enable introduction of reporting tools, training, supervision, monitoring, cold chain and logistics upgrade, advocacy and communication. Gaps identified during the comprehensive cold chain inventory, planned for October 2014, will be addressed through the PCV and IPV VIGs and expected HSS funding. However, introduction of IPV alone, even in the 1-dose vial presentation, will not have a significant impact on cold chain.

#### **Vaccine management and cold chain capacity**

EVM: The key weaknesses, identified by the EVMA of 2012 at the central level are: (1) temperature monitoring, (2) buildings, cold chain equipment and transport systems, (3) maintenance, (4) distribution, and (5) MIS, supportive management functions. At lower levels the performance is more than satisfactory except for distribution at the Oblast level. The next EVMA is planned for May 2015.

**The cold chain, EVMAs and implementation of the Improvement plan (IP):** The last EVM was conducted in May 2012. The key weaknesses are at the central level: temperature monitoring; buildings, cold chain equipment and transport systems; maintenance; distribution; MIS, supportive management functions. At lower levels the performance is more than satisfactory except for distribution at the Oblast level. Good progress is achieved in the implementation of the EVM improvement plan. Of the EVM 18 recommendations, 33% (6) are fully implemented, 22% (4) are in progress and another 45% (8) remain to be initiated. The next EVMA is planned for May 2015.

Among the cold chain equipment still required 4 more cold rooms are needed at central level and one mid-sized ice-lined refrigerator is needed at provincial level. The current HSS support includes plans for major modernisation of the cold chain. In addition, gaps identified from the cold chain inventory can be addressed through the PCV and IPV vaccine introduction grants. Introduction of IPV alone, even in 1-dose presentation, will not have any significant impact on cold chain.

#### **Waste management**

The waste management system is in an early development stage in Uzbekistan. The waste is normally dumped in waste pits or landfills. In small health facilities, open-air burning of safety boxes is implemented. WHO is planning to join UNDP and GF in supporting development of a comprehensive HCWM plan, after which policies and practices may be reviewed accordingly.

#### **Training, Community Sensitisation & Mobilisation Plans**

Training on IPV will be integrated into all NIP training courses and educational materials. Trainings will be conducted at all levels: central, province and district. The content of the training workshops will include basic information on the rationale of IPV introduction and co-administration; efficacy and safety of inactivated polio vaccines; programmatic aspects, including vaccine administration, target age, vaccination schedule, IPV technical information, vaccine handling, and record-keeping; and contraindications and AEFI surveillance.



The MOH will develop a comprehensive communication plan on introduction of IPV based on WHO recommendations. The Gavi vaccine introduction grant would represent an important contribution to implementation of the planned communication and advocacy activities. Currently, an anti-vaccination movement is almost absent in Uzbekistan and vaccine refusals are rare. MOH does not envisage problems with uptake of IPV in the country.

### **Monitoring and evaluation plans**

All health workers will be trained on the updated data collection tools. Implementation of IPV introduction will be monitored through the NIP monitoring and evaluation system. The national policy for AEFI reporting is well defined, guidelines developed and the process for reporting is implemented. A National Investigation Committee for AEFI exists. AEFI surveillance is guided by the MOH decree. The AEFI guidelines will be updated to include information on IPV and refresher trainings conducted for the health staff.

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

There was relatively good consistency between proposal documents and all required documents were submitted with the application. Uzbekistan has maintained universal national immunisation coverage for two decades.

### **9. Overview of the proposal**

#### **Strengths:**

- Significant effort put into strengthening cold chain and continuing to do it
- Good communication, community sensitisation, and mobilisation plans
- Functioning AEFI system and good AFP surveillance
- Government funds traditional EPI vaccines and co-finances new vaccines
- A very comprehensive, clear budget was provided with the application

#### **Weaknesses:**

- It is unclear whether the cold chain capacity requirement at central level covered for rotavirus vaccine introduction.
- Waste management is inadequate
- Post-introduction evaluation was not detailed in the introduction plan
- External audit fees were not included in the budget.

#### **Risks:**

- Dual introductions of IPV and PCV not planned and implemented jointly
- The country is ready to accept mixed IPV presentations; maximum 50% in 10-dose vial presentation and the rest in lesser-dose vials. Such an implementation may be a big challenge for the logistics and health workers, adding avoidable burden to their duties, and is not advisable; except in the context of a pilot research project.

#### **Mitigating strategies:**

- Gavi HSS approved, and funding is pending the finalisation of FMA report (for an FMA conducted in May, 2014) and subsequent aide memoire.



## **10. Conclusions**

Uzbekistan has requested support to introduce one dose of IPV into the routine EPI system in-line with the Polio Endgame Strategic Plan and SAGE recommendations. The country has provided adequate justification and documentation to recommend approval of their proposal with recommendations as outlined in the below recommendations section.

## **11. Recommendations**

### **Approval with Recommendations**

#### **Recommendations to the Country:**

1. Inform Gavi of the implementing agency for the vaccine introduction grant and revise the budget to include the agency's management costs and the external audit fees.
2. Ensure cold chain readiness given the plans for concurrent vaccine introduction (IPV & PCV), and review and improve waste management.
3. Consider making Save the Children South Korea a member of the ICC, given the group's involvement in immunisation in some urban areas.