INACTIVATED POLIO VACCINE (IPV) SWITCH REQUEST
by **Uzbekistan**

Please use this form to send Gavi the necessary information to review your country's request to switch to the IPV 2-dose schedule (introducing IPV second dose) and/or change presentation[1].

1. Checklist

To process this request, Gavi requires your country to submit the following items/documents:

	YES	N/A
1. **Signature of Ministry of Health**	☒	
2. **ICC endorsement** (minutes of a meeting endorsing the switch decision)	☒	
3. **NITAG recommendation** (meeting minutes)	☒	☐
4. If this switch increases the country's financial costs:[2] **Signature of Ministry of Finance**	☐	☒
5. If a switch grant (SG) is requested: **Detailed Budget**[3]	☒	☐

Requests will not be reviewed until complete. Please use the checklist above to verify items/documents before submitting country request.

2. Reason for Switching

Introduction of IPV second dose (use switch) ☒
(complete sections 3 and 7-10)

Supply of the current vaccine is disrupted (product/presentation switch) ☐
(complete sections 3-10)

Country's own voluntary choice (product/presentation switch)

- Availability of preferred vaccine (the country has been unable to use its preferred vaccine or presentation before due to a supply constraint) ☐
- A new Gavi-supported vaccine or presentation or use is available ☐
- Country needs have changed (e.g. new epidemiology data, increased price sensitivity) ☐
- Current vaccines profiles have changed (e.g. a price reduction, a VVM type change) ☐
- Switch to intradermal injection with fractional dose IPV (one fifth of a full dose)[4] ☐

(complete sections 3-10)

[1] *Please consult Gavi's guidelines for reporting & renewal*

[2] *The signature is not required if the switch is forced by supply disruption or the country does not co-finance IPV*

[3] *Using the Gavi budgeting and planning template*

[4] *Gavi supports a schedule of two full or two fractional doses in line with current SAGE recommendations*

3. Country Background and polio eradication status

1. Date of the form	01/05/2021
2. Please indicate the stock level of the current presentation	
○ Central Level stock (number of doses)	300960 doses
○ Second Level stock (number of doses)	250930 doses
3. Date of the stock level information	01/04/2021

Polio eradication indicator	2016	2017	2018	2019	2020
4. WUENIC OPV1 coverage (%)	99,9	99,8	99,9	99,6	99,7
5. WUENIC OPV3 coverage (%)	99,9	98,3	98,3	97,9	97,3
6. WUENIC IPV1 coverage (%)	0…	0	99,5	99,6	88,7
7. # AFP cases reported	141	146	132	134	55
8. non-polio AFP cases reported/100,000 population < 15 years	1,5	1,6	1,4	1,4	0,5
9. % AFP cases with 2 adequate stool specimens	100	100	100	100	100
10. # cVDPV cases confirmed	0	0	0	0	0
11. # WPV cases confirmed	0	0	0	0	0

Narrative summary of country polio eradication status and challenges:

Uzbekistan, along with the rest of the WHO European Region, was certified polio-free in 2002. The country has successfully responded to the multi-country wild poliovirus type 1 (WPV1) outbreak in Central Asia in 2010 and significantly invested in the national polio programme since then, through high-quality supplementary immunization activities in 2010-2014, enhancing acute flaccid paralysis (AFP) and environmental polio surveillance, training of health personnel at national and local levels, and strengthening preparedness to the outbreak and events. In June 2020, in its 34th meeting, the European Regional Commission for Certification of Poliomyelitis Eradication (RCC) concluded that the risk level of poliomyelitis transmission after the potential import of the virus into Uzbekistan was considered low, same as in previous years.

Following the discontinuation of tOPV in 2016 and due to short supply of IPV globally, Uzbekistan, along with other countries of the European Region, did not receive IPV vaccine until 2018 – IPV was introduced in the country only on 4 May 2018 (one dose at the age of 4 months). Therefore, children in Uzbekistan born between January 2016 and February 2018, who never received tOPV after its discontinuation and did not receive IPV due to its unavailability, did not have any immunity to type 2 poliovirus. This gap is not closed until now as the IPV vaccine for catching up the missed population is not expected to arrive before end May 2021, in best case.

The high risk and possible explosive consequences of having a poliovirus type2 – naïve population were repeatedly highlighted by the RCC during their annual risk assessment review of the Region. In the last meeting in June 2020, the RCC expressed a concern with worsening of polio epidemiological situation in Afghanistan (wild polio type 1 and circulating vaccine derived poliovirus type2 cases reported right on the border with the countries of European Central Asia – Tajikistan, Turkmenistan and Uzbekistan), and recommended Uzbekistan and its neighbours to close the immunity gap as soon as possible, enhance surveillance and ensure that coverage and surveillance data is available sub-nationally.

The similar gap in Tajikistan has already led to local transmission after cVDPV2 importation from Pakistan in November 2020 and ongoing outbreak with 7 confirmed cases as of 30 April 2021. Since February 2021, after being notified on the outbreak in Tajikistan, Uzbekistan has taken all necessary measures to ensure early detection and preparedness to cross-border transmission, including enhanced AFP surveillance, expended environmental surveillance with establishment of addition ES site in Termez, catch-up IPV immunization in Surkhandarya province with vaccine available in RI stock, and prioritization of testing samples. On 31 March, NITAG has recommended MOH to initiate verification of readiness to novel OPV2 use in case of possible importation, the verification process is ongoing.

4. Presentation/product choice

Presentation	**IPV, 1 dose/vial**	**IPV, 2 doses/vial**	**IPV, 5 doses/vial**	**IPV, 10 dose/vial**
Form	Liquid	Liquid	Liquid	Liquid
Doses in each unit	1	2	5	10
Please rank in order of preference (1= First Choice)	4	3	2	1

For further information on presentation and product choices please refer to **Gavi's Detailed Product Profiles**

Is the new presentation licensed in the country? Yes ☒ No ☐

If the preferred presentation does not yet have a license or approval, please provide the time to obtain a license or approval and specify whether national regulations allow for waiver or expedited registration procedure of a WHO Prequalified Vaccine. Please confirm if the licensing process will be completed before shipment.

Uzbekistan is using standalone IPV since 2018 and the requested presentation is licensed in the country.

5. Vaccine procurement

Gavi expects most countries to procure immunization supplies through UNICEF or the PAHO Revolving Fund.

Does the country need an alternative means of supply and delivery of immunization supplies (funded by the country or by Gavi)?

Yes ☐ No ☒

If you answered Yes, please attach a description of the mechanism and the vaccines or goods that the country intends to procure through this mechanism.

6. Reason(s) for Choice of Product or Presentation (as many as apply)

	Main Reason(s)	Comment
Cost Driving Considerations (e.g. wastage rate, price, price commitments)	☐	……
Vaccine's clinical profile (e.g. country specific data, safety profile)	☐	……
Logistic considerations (e.g. VVM type, size of cartoons)	☒	Limited storage capacity, hence multidose vials are preferred
Vaccine programmatic suitability (e.g. dose schedule, ease of administration)	☐	……
Strategic/epidemiological reasons	☐	……
Other reason(s)	☐	(Please specify) ……

7. Programmatic Considerations

In October 2020, WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommended that a second IPV dose be introduced by all countries that currently administer one IPV dose and bOPV in their routine immunization schedules. (Weekly Epidemiological Record. 2020; 95:585-608.[5])

Regarding the use of IPV in routine immunization, SAGE made the following observations:

- Two doses of IPV provide higher immunogenicity against type 2 poliovirus than one dose;
- The older the age at the first dose and the longer the interval between doses, the higher the immunogenicity; and
- Two fractional doses of IPV (fIPV) administered intra-dermally provide similar immunogenicity as two full doses of IPV, but only when the first dose is given at ≥ 14 weeks of age and the time interval between the two doses is ≥ 16 weeks.

SAGE recommendations:

The preferred schedule is to administer the first IPV dose at 14 weeks of age (with DTP3/Penta3), and to administer the second IPV dose at least 4 months later (possibly coinciding with other vaccines administered at 9 months of age). This schedule provides the highest immunogenicity and may be carried out using full dose IPV or fractional intradermal IPV (fIPV) without loss of immunogenicity.

SAGE added that countries may consider alternative schedules based on local epidemiology, programmatic implications and feasibility of delivery. As an alternative to the preferred schedule, countries may choose an early IPV schedule starting with the first dose at 6 weeks of age (with DTP1/Penta1) and the second dose at 14 weeks (with DTP3/Penta3). This alternative schedule offers the advantage of providing early-in-life protection; however,

[5] https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf?sequence=1&isAllowed=y

there is a lower total immunogenicity achieved. If this schedule is chosen, full dose IPV should be used rather than fIPV due to lower immunogenicity of fIPV at early ages. Regardless of the 2 dose IPV schedule used, introduction of the second IPV dose would not reduce the number of bOPV doses used in the routine immunization schedule.

• Is there enough cold chain capacity at all levels to accommodate the vaccine in the current and future years?	Yes ☒ No ☐
• Delivery date requested for the new vaccine product or presentation (actual shipment will depend on vaccine availability)	01/09/2021
• Planned Switch Date	02/10/2021
• At what age/contact point will **IPV first dose** be administered?	4 months
• Number of infants who will receive the **IPV first dose** in the year of the planned switch date (please adjust depending on month)	803700#
• At what age/contact point will **IPV second dose** be administered?	9 months
• Number of infants who will receive **IPV second dose** in the first year of the planned switch date (please adjust depending on month)	803700#

Justification for schedule selection:

Uzbekistan follows SAGE and NITAG recommendation on administering IPV1 at the age of 4 months, together with penta3, and IPV2 in 5 months, at the age of 9 months. The justifications for the opted schedule arethe following:

- The country wants to ensure highest possible protection for the population, given the increasing number of cVDPV2 cases in the close neighborhood – Afghanistan, Pakistan, and most importantly the ongoing cVDPV2 outbreak in Tajikistan. Evidence suggests that this proposed schedule provides the highest immunogenicity using full dose IPV.
- While multiple injections are, in general, acceptable in Uzbekistan, adding the 3rd injectable vaccine to any visit to the health facility will inevitably discourage parents and may reduce uptake of not only IPV but other routine vaccines
- There is no currently visit scheduled at 9 month of age. The program and NITAG still recommend adding this visit as the benefits of adding another visit outweigh the risk of drop-outs due to multiple injectable vaccine administration. The 9-month visit fits in the calendar for catching up with missed doses without waiting till the next visit at 12 months.

8. Use of Financial Support to Fund Additional Technical Assistance Needs

Through the participation of Gavi / TCA partners, Gavi funds tailored and differentiated technical assistance in response to specific country needs. Please review the currently approved Technical Assistance Plan (also known as the "Single Technical Assistance Plan") to assess whether the support required to implement a new vaccine is included in the approved technical assistance plan. If gaps in technical assistance are detected for support to new vaccines, the additional technical assistance required may be funded by the Switch Grant. In this case, the relevant costs must be indicated in the budgeting and planning model.

9. Switch Grant (PSG)

Countries may apply for a switch grant to facilitate this transition. This grant intends to cover a portion of the one-time investments associated with the product, presentation, or use switch (e.g. training, document production and printing, procurement of cold boxes). The ceiling for the grant is US$ 0.25 per child in the birth cohort of the year of the switch. If you don't request a switch grant, please leave the table below as is.

(a) Gavi contribution per child	0.25 $ US
(b) Number of children in the birth cohort in the year when the switch is planned to start	803700
Total Gavi contribution	(a x b) $ US**200925**
Funds needed in country by (planned disbursement date)	DD/MM/YYYY

Please attach the Gavi Budgeting and Planning Template to show how the Switch Grant will be used to facilitate the rapid and effective implementation of critical activities before and during the immunization.

10. Signature(s) from Government and coordination and advisory committees

The Government of Uzbekistan would like to continue the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support to switch to the IPV 2-dose schedule and/or switch IPV vaccine **IPV, 10 dose/vial**.

Please note that Gavi will not review this request without the signature of the Minister of Health or their delegated authority.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for implementing all activities, including domestic funds and any voluntary vaccine co-financing will be included in the annual budget of the Ministry of Health.

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this request.

Minister of Health[6] (or delegated authority)	**Minister of Finance[7] (or delegated authority)**
Name: Dr. Yusupaliev B.K.	Name: Khaitov K.I.
Date: _____	Date: _____

[6] *Required in all cases.*

[7] *Required if the switch will result in higher financial costs. See section 1.*

Signature: _____ Signature: _____

Please email this form and every attachment requested to proposals@gavi.org with the Gavi Senior Country Manager for your country in copy.

Required attachment:

1. **Minutes of the ICC meeting** where this request was discussed and approved, with signatures.

Optional attachment:

2. **Minutes of the NITAG meeting** where this switch and the IPV schedule was recommended