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

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		DD/MM/YYYY
2.	Please indicate the stock level of the current presentation		
	○ Central Level stock (number of doses)	50 951	doses
	○ Second Level stock (number of doses)	53 259	doses
3.	Date of the stock level information		01/07/2021

Polio eradication indicator	2016	2017	2018	2019	2020
4. WUENIC OPV1 coverage (%)	98,5	98,7	97,9	97,9	92,5
5. WUENIC OPV3 coverage (%)	97,6	96,9	96,3	96,2	84,5
6. WUENIC IPV1 coverage (%)	87,9	95,9	94,9	94,9	80,2
7. # AFP cases reported	26	24	24	18	2
8. non-polio AFP cases reported/100,000 population < 15 years	1,18	1,08	1,07	1,07	0,08
9. % AFP cases with 2 adequate stool specimens	92	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:

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)				

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.Вакцина

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)	☐	.....
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)	01/06/2022
• Planned Switch Date	01/07/2022
• At what age/contact point will **IPV first dose** be administered?	3 months
• Number of infants who will receive the **IPV first dose** in the year of the planned switch date (please adjust depending on month)	127 400
• At what age/contact point will **IPV second dose** be administered?	6 months
• Number of infants who will receive **IPV second dose** in the first year of the planned switch date (please adjust depending on month)	63 700

Justification for schedule selection:

The last case of detecting type 1 wild poliovirus in Azerbaijan was registered in 1995. Currently, the country is certified by WHO as a polio-free area.

In 1997, the Ministry of Health of the Republic of Azerbaijan joined the WHO ERB's Acute Flaccid Paralysis Epidemiological Surveillance Program.

There is no Poliomyelitis laboratory in the Republic. The samples taken from children with suspected AFP, together with the environmental ones, are analyzed by the reference laboratory of the Institute of M. Chumakov Poliomyelitis and Viral Encephalitis of the Academy of Medical Sciences, Russian Federation.

Azerbaijan belongs to the group of countries with a low risk of AFP.

Implementing poliomyelitis and AFP surveillance program is entrusted to the Republican Center for Hygiene and Epidemiology (RCH&E), which is part of the Ministry of Health. At the regional level, the territorial Centers of Hygiene and Epidemiology, which are part of the RCH&E, are responsible for implementing the program. They continuously monitor preventive measures (immunization of children), gather and report data on morbidity, take samples from patients and the environment, and send them to the Central Virological Laboratory.

The single-dose IPV vaccine was introduced in the Republic on February 15, 2016. The country prioritized the single-dose IPV vaccine for the below reasons:

- the country does not apply the WHO's multi-dose open vial policy,
- the country has many medical institutions with a low number of the target population and, as a consequence, the predicted high wastage in rural areas when using multi-dose vials,
- reducing missed opportunities.

The poliomyelitis vaccination coverage over the past 5 years is given in Section 3, Country Background and Polio Eradication Status. According to the table, coverage of the 1 and 3 OPV doses in the Republic is quite high. The exception was 2020 (92.5 % and 84.5 % coverage, respectively), the year of the transition to medical insurance and the start of the COVID-19 pandemic. The transition of the primary care setting under the jurisdiction of the Compulsory Insurance Agency from 1/1/2020 and restrictive measures due to the pandemic (leaving home in quarantine, including visiting medical institutions, with a special permit only) affected vaccination coverage. The same was true for the IPV vaccine with the coverage fallen to 80.2 % in 2020.

Vaccines for routine childhood immunization are procured through the UNICEF Supply Chain. The Central Warehouse may store an annual supply of vaccines; however, vaccines are supplied in several batches during a

year. The refrigerating (3 chambers) and freezing (2 chambers) chamber volume is **183.12** and **144.2 m³**, respectively.

10 refrigerated vehicles with a total volume of **228 m³** deliver quarterly a 3-month supply of vaccine for routine immunization to 62 warehouses of municipal and regional Hygiene and Epidemiology Centers. From here, the vaccine is distributed to medical institutions involved in the immunization program, which may store a monthly supply of vaccines.

The Republican Center for Hygiene and Epidemiology oversees the adherence to the safe cold chain functioning and uninterrupted operation of refrigeration equipment at all levels.

Currently, the Republic's immunization schedule provides for the vaccination of children with 5 doses of bOPV (at birth and the age of 2, 3, 4, and 18 months) and 1 dose of IPV (6 months). With the introduction of the second IPV dose, the bOPV0 dose will not be administered, and the remaining 4 bOPV doses will remain in the immunization schedule until polio eradication is certified.

Having considered the WHO recommendations for the introduction of the second IPV dose into the vaccination schedule, the Ministry of Health considers it appropriate to vaccinate children with IPV1 at 3 months, and IPV2 at 6 months. Thus, the vaccination schedule will be as follows:

Age	Vaccinations
within 12 hours	HepB
4-7 day	BCG,
2 months	DTPHepBHib, PCV, bOPV
3 months	DTPHepBHib, **IPV**, bOPV
4 months	DTPHepBHib, PCV, bOPV
6 months	PCV, IPV
12 months	MMR, VitA
18 months	DTP, bOPV, VitA
6 years	MMR, DT, VitA

This decision, approved at the CCM, was made since the vaccination schedule provides for one injection of the DTPHepBHib vaccine in combination with bOPV at 3 months, and adding the IPV vaccine to them maintains a stable injection load on the child – two injections at 2, 3, 4, and 6 months.

Herewith, simultaneously injecting several vaccines to a child is a mobilizing factor for parents, increasing their responsibility for the timely immunization of children from several infections, therefore, transferring the IPV2 vaccine from 6 months to a later period may increase the missed opportunities and thereby affect the coverage rates.

If the GAVI Secretariat approves the application from the Republic of Azerbaijan, the Ministry of Health considers it expedient to start vaccination with the second IPV dose from 7/1/2022.

This will give us time to prepare for implementing it, i.e., inform the population, train the medical staff, making changes to reporting forms, and prepare and distribute new schedules.

8.

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	……..#
Total Gavi contribution	(a x b) $ US……
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 Azerbaijan 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 product/presentation.

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.

Deputy Minister of Health	**Head of the Financial and Economic Department of the Ministry of Health**
Name: **Viktor Gasimov**	Name: **Azad Veliyev**
Date:	Date:
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