INACTIVATED POLIO VACCINE (IPV) SWITCH REQUEST
by **Republic of Moldova**

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	31/01/2022
2. Please indicate the stock level of the current presentation	
○ Central Level stock (number of doses)	30.840 doses
○ Second Level stock (number of doses)	12.000 doses
3. Date of the stock level information	31/01/2022

Polio eradication indicator	**2016**	**2017**	**2018**	**2019**	**2020**
4. WUENIC OPV1 coverage (%)	97,6	95,0	94,9	94,9	91,9
5. WUENIC OPV3 coverage (%)	90,9	90,3	93,7	93,7	87,3
6. WUENIC IPV1 coverage (%)	N/A	N/A	N/A	97,5	90,7
7. # AFP cases reported	7	2	3	4	3
8. non-polio AFP cases reported/100,000 population < 15 years	1,2	0,3	0,4	0,6	0,4
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:

The Republic of Moldova continuously ensures the implementation of measures to keep the country polio free status, get in 2000. In 2020 the activities were carried out according to a national action plan approved by the Ministry of Health for the years 2019-2021. This plan built on the 2019-2023 endgame Strategy and this is in line with the Strategic Action Plan for the final phase of end polio for 2013-2018, approved by the World Health Assembly (AMS), document WHA66/2013/REC/3. The main focus of the country to achieve the scope of strategy regarding to polio free status is to keep high vaccination coverage of children. In 2020, the national vaccine coverage against poliomyelitis for children aged 1 year was 87.3%, 2 years old - 93.7%, with the first revaccination at the age of 3 years were 96.2% of children, at 7 years - 92%. However, in 2020, vaccination with the third dose of polio vaccine to children aged 1 year was below 90% in 10 sub-national territories, being a concern moment for country. In 2020, due to the imposed restrictions and the suspension of vaccinations, immunization coverage rates were even lower. By realizing the WHA resolution (WHA68.3) of May 26, 2015 the country on April 30, 2016, has switched from the trivalent oral polio vaccine (tOPV) to the bivalent oral polio. During the period 2000-2020 cases of paralytic polio, compatible with polio and cases of vaccine-associated polio were not recorded. Polio virological investigations are conducted in the laboratory of the National Agency for Public Health accredited by the WHO in 1998 and re-accredited annually. In 2020, in order to monitor the circulation of polio viruses in the population and the environmental objects, have been investigated 152 samples of stool (6 from 3 patients with AFP, 30 from healthy children, 116 from patients with enterovirus infection). From the investigated samples, were isolated 4 vaccine strains of poliovirus and 3 enterovirus strains. In 2020, 16 wastewater samples were examined, all with negative results. The last vaccine polio vaccine strain was isolated on 04.04.2019. All containment measures on the polio are carried out in the country. The containment measures in accordance with Phase I and Phase II of GPA are implemented. In the WHO-accredited laboratory only are conducting researches on polioviruses, materials potentially containing the polio vaccine virus and isolated viruses are destroyed by autoclaving immediately after the end of the study. All isolated poliovirus strains are sent to the Regional Reference Laboratory for confirmation and within the typical differentiation.

Starting with 2022, Moldova has introduced the second dose of IPV vaccine at age of 22-24 months, through a MoH Order, nr. 1230 from December 29, 2021.

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)	1	N/A	N/A	N/A

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

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.

No license or approval by Local Authority, because the vaccine has WHO Pre-qualification.

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, 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.

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

• 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	01/01/2022	
• At what age/contact point will **IPV first dose** be administered?	6 month	
• Number of infants who will receive the **IPV first dose** in the year of the planned switch date (please adjust depending on month)	34,000	
• At what age/contact point will **IPV second dose** be administered?	22-24 month	
• Number of infants who will receive **IPV second dose** in the first year of the planned switch date (please adjust depending on month)	32,000	

Justification for schedule selection:

Please provide contextual information such as local epidemiology, programmatic implications, and feasibility of delivery to justify the selected schedule.

In this context, when creating the vaccination schedule, it was taken into account that the child should not be given more than 2 injectable vaccines during an immunization session. In this context, dose 2 of IPV could be given at the age of 9 or 10 months, but this would mean an additional visit for vaccination. The possibility of the second dose of IPV being applied at the age of 22-24 months, concomitantly with DTP4 (and bOPV4). The country practiced the administration of IPV at 22-24 months, to include with a dose of IPV of children whose dose was not administered in the years 2016-2018 due to lack of insurance with IPV vaccine. It is important that the dose interval is as long as possible to create a more lasting immunity,

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	……..#
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 REPUBLIC OF MOLDOVA 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.

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: Svetlana NICOLAESCU	Name: _____
Date: February 03, 2022	Date: _____
Signature: Digitally signed by Nicolaescu Svetlana Date: 2022.02.03 13:05:19 EET Reason: MoldSign Signature Location: Moldova	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

[6] *Required in all cases.*

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