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

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].

Where applicable, the switch request should be submitted as an integral part of the Full Portfolio Planning process, in which case the information requested in this form may be included in relevant documents of the Application Kit (https://www.gavi.org/our-support/guidelines) in line with the Gavi Support Detail Instructions.

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	23/06/2023
2. Please indicate the stock level of the current presentation	
○ Central Level stock (number of doses)	5450 doses
○ Second Level stock (number of doses)	10,727 doses
3. Date of the stock level information	23/06/2023

Polio eradication indicator	**2016**	**2017**	**2018**	**2019**	**2020**
4. WUENIC OPV1 coverage (%)	…	…	…	…	…
5. WUENIC OPV3 coverage (%)	87	87	87	87	87
6. WUENIC IPV1 coverage (%)	44	N/A	39	87	87
7. # AFP cases reported	17	08	14	15	23
8. non-polio AFP cases reported/100,000 population < 15 years	2.6	1.3	2.3	2.4	3.6
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 Acute Flaccid Paralysis (AFP) surveillance and structures for Polio Eradication Initiative (PEI) were established in 1997. The last polio case was clinically confirmed in 1984 and the country's documentation for polio free status was accepted by the Africa Regional Certification Commission (ARCC) in 2005. The immunization schedule has four doses of bivalent oral polio vaccine given at birth, 6, 10 and 14 weeks with one dose of IPV added at 14 weeks. The country has not reported any cases of WPV or VDPV/cVDPV since the polio free status was granted in 2005, however Lesotho remains at risk of polio importation due to emerging cases of polio in the east and southern African region.

Lesotho achieved a non-polio AFP rate of more than 2 per 100,000 under 15 years population in the last five years (2018-2022) except in 2021 when the non-polio AFP rate was 0.9. Stool adequacy rate in the last five years (2018-2022) was 100%. Some challenges to AFP surveillance include inadequate knowledge of health workers on polio/AFP surveillance due to high attrition rate leading to low detection/reporting of AFP cases, silent reporting in some districts and lack of community and Environmental surveillance systems. There were stock outs at service delivery level which continue to put children at risk of contracting poliovirus. The country is in the initial stages of implementation of Event Based Surveillance (EBS) to increase sensitivity of AFP detection rate.

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.

The application of regulatory approval will start after the IPV Switch has been granted. On average, it takes two months for the regulatory approval to be issued by the pharmaceutical department. The National regulatory allow for expedited registration of a WHO prequalified vaccine. The licensing process can be finalized before shipment arrival in 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)	☒	Multi-dose vials which observe MDV Policy have reduced wastage rate in addition to being cost effective than single dose vials
Vaccine's clinical profile (e.g. country specific data, safety profile)	☒	The available data indicate that known adverse events following IPV administered alone are limited to non-serious reactions. Local reactions, as may occur with any inactivated vaccine, are most common. There is currently no country specific data on the safety of IPV
Logistic considerations (e.g. VVM type, size of cartoons)	☒	The current IPV has VVM type 2 which is highly heat sensitive, therefore another formulation with a higher VVM Type e.g.: 7 or 11 will be selected. In addition, the country prefers cartons of 10 vials/50 doses or more which are easy to handle during packing and distribution.
Vaccine programmatic suitability (e.g. dose schedule, ease of administration)	☒	The current formulation of IPV is administered intramuscular therefore there will be no changes in the route of administration
Strategic/epidemiological reasons	☒	As the country is aligned to the Global Polio Eradication Initiatives (GPEI), introduction of the second dose of IPV demonstrates commitment towards implementation of the 2020 SAGE recommendations
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)	01/11/2023
• Planned Switch Date	01/01/2024
• Number of children in the **birth cohort** in the year when the switch is planned (where known, align with Gavi's multi-year approval for vaccines)	30,244
• At what age/contact point will **IPV first dose** be administered?	14 weeks
• Number of infants who will receive the **IPV first dose** in the year of the planned switch date (please adjust depending on month)	30,244
• 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)	30,244

Justification for schedule selection:

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

- The risk of polio importation has increased due to emerging cases of polio in the east and southern African region.
- IPV second dose will be administered with MCV 1 at nine months, therefore strengthening the uptake of MCV 1 and other routine vaccines
- In addition to introducing a second dose of IPV, there will be a switch from the current single dose to a multidose vial which is cost efficient
- Single dose vials occupy more volume than multi-dose vials, therefore switching to a multi-dose vial will ensure effective use of available cold chain capacity
- Introducing an additional dose of IPV is aligned with the Polio Eradication Initiative which aims to remove oral polio vaccines from routine immunization program, when readiness criteria are met.
- Two doses of IPV provide higher immunogenicity against type 2 poliovirus than one dose.
- The selected immunization schedule is ideal as it aligns with the recommendation that the older the age at the first dose and the longer the interval between doses, the higher the immunogenicity

Describe alignment with Gavi strategy in terms of integration, zero-dose agenda and gender focus:

Please provide elements of the plan of action that are relevant to the review of the application and highlight consistency with these strategic objectives

The Social and Behaviour Change (SBC) communication with focus on male involvement in immunization will be intensified through HSS, TCA and CDS with implementation of country specific and targeted strategies. The immunization services are integrated with other PHC services such as Nutrition, Integrated Management of Childhood Illnesses (IMCI), Family planning, deworming and health education and promotion. Strategies for tracking the zero dose children which include use of community registers and active defaulter tracking will be strengthened to ensure that children receive all routine vaccines including IPV 2. In Lesotho, women are empowered in health decision making however, men will be encouraged to take an active role in seeking and participating health services particularly on Immunization e.g Men taking children for vaccination or accompanying their partners to health facilities.

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 the switch is included in the approved technical assistance plan. If gaps in technical assistance are detected, 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	30,244
Total Gavi contribution	(a x b) $ US **7,561**
Funds needed in country by (planned disbursement date)	30/11/2023

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 Lesotho 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 LG Chem Ltd Eupolio 5 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: _____	Name: _____
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

[6] *Required in all cases.*

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