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

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. **ZITAG 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 (schedule 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	**29/09/2023**
2. Please indicate the stock level of the current presentation	
○ Central Level stock (number of doses)	**318,955 doses**
○ Second Level stock (number of doses)	**471,485 doses**
3. Date of the stock level information	**31/08/2023**

Polio eradication indicator	**2018**	**2019**	**2020**	**2021**	**2022**
4. WUENIC OPV1 coverage (%)	…	…	…	…	…
5. WUENIC OPV3 coverage (%)	**90%**	**89%**	**83%**	**87%**	**84%**
6. WUENIC IPV1 coverage (%)	**36%**	**73%**	**84%**	**80%**	**73%**
7. # AFP cases reported	**199**	**232**	**294**	**230**	**400**
8. non-polio AFP cases reported/100,000 population < 15 years	**3.4**	**3.9**	**4.7**	**4.1**	**4.6**
9. % AFP cases with 2 adequate stool specimens	**86%**	**85%**	**71%**	**71%**	**64%**
10. # cVDPV cases confirmed	**0**	**1**	**1**	**0**	**5**
11. # WPV cases confirmed	**0**	**0**	**0**	**0**	**0**

Narrative summary of country polio eradication status and challenges:

Zambia has been providing Oral Polio Vaccine (OPV) since the inception of the Expanded Programme on Immunisation (EPI) in 1975. Zambia detected its last two (2) indigenous wild poliovirus cases in 1995 from Kafue district in Lusaka Province and in 2001/2002, the surveillance system detected and investigated five (5) WPV cases imported from Angola into Kalabo and Shangombo districts of Western Province. The outbreak was effectively contained through two rounds of Polio Mop up campaigns in 2002 in 14 districts in Western and North-western provinces. From 1996 to 1998, Zambia conducted National Immunisation Days when the country introduced the Sub-National Immunisation Days. These immunisation days were later transformed into the Bi-annual Child Health Weeks. Zambia also embarked on Acute Flaccid Paralysis Surveillance with support from WHO in 1998. (MOH, 2021). In October 2005, Zambia was declared WPV free by the ARCC. The country had since maintained effective Acute Flaccid Paralysis (AFP) and Polio environmental surveillance systems to detect and respond to any poliovirus importation to maintain the polio free status.

Currently, 4 doses of OPV are given at; birth to 13 days (or, if missed at 9 months); 6 weeks; 10 weeks and 14 weeks of age, respectively. Inactivated Polio Vaccine (IPV) is also given at 14 weeks together with the third dose of OPV. In addition to the routine doses that each child receives for protection against polio, each child in the high-risk districts receives a dose of OPV during each round of the biannual Child Health Week until the age of 5 years.

Zambia sustained the polio-free status, until one case of circulating Vaccine Derived Poliovirus (cVDPV) was notified in Chienge in September, 2019 and another in Chavuma in November 2019. In response to the Chienge and Chavuma cases, the mOPV2 vaccination in selected districts in Luapula, Northern, Northwestern and Western was conducted. Prior to notification of these cases, Zambia participated in the switch from the trivalent OPV to the bivalent OPV in April 2016. The switch saw the removal of type 2 polio vaccine. The April 2016 global switch from the trivalent OPV to the bivalent OPV led to the introduction of one dose of the IPV into Routine Immunisation in 2018. This dose was given together with the OPV3 at 14 weeks of age. In June 2020, the country also conducted an IPV Catch up vaccination targeting children below the age of 5 years to catch up on the cohort that missed the type2 protection due the switch and those who missed the IPV after the switch as the coverage had been observed to be low. The delay in the introduction of IPV was due to the global shortage as Zambia was deemed to be a low-risk country.

In 2020, the Global Polio Eradication Initiative (GPEI) launched a new strategy for circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak responses as part of the Polio Eradication & Endgame Strategy. Included in this strategy was the implementation of a new tool for cVDPV2 outbreak response: novel oral polio vaccine type 2 (nOPV2) which is a modification of the existing oral polio vaccine (OPV) type 2 (OPV2), also known as Sabin OPV2). Zambia submitted its nOPV2 verification document in June 2022 and got approved on July 28, 2022 to use nOPV2 for cVDPV2 outbreak response.

In November 2022, another cVDPV2 outbreak was declared following detection of cVDPV2 from environmental samples in Kitwe, Mufulira and Ndola districts in the Copperbelt province. The country responded with two rounds of novel oral polio vaccine type 2 (nOPV2) SIA campaigns in four (Copperbelt, Luapula, North-Western, and Central) provinces and 44 districts, reaching 2.2 million under 5 years children. The SIA quality was good with improvement in LQAS results from 86% (38/44) in round 1 to 91% (40/44). Subsequently, in June 2023, the country recorded cVDPV2 from an AFP aged 7 years old in Mpulungu district, Northern province which is linked to the RDC-SKV-1 emergence in the Democratic Republic of Congo. During investigation of this case, we confirmed 4 cVDPV2 from healthy children which were also linked to the same case. Furthermore, another cVDPV2 from an environmental sample was confirmed in Lusaka district of Lusaka province in July 2023 which is also linked to the AFP case in Mpulungu. The country responded to these with a third round of nOPV2 SIAs in 7 provinces (Western, Eastern, Muchinga, Northern, Luapula, Southern, and Lusaka) and 84 districts in which we vaccinated 5.9 million children under 8 years. The SIA quality was good with 83% (70/84) districts passing the LQAS. The fourth round of nOPV2 to cover same target population and districts (84) is planned for in October 2023. All 10 provinces and 116 districts would have had at least two rounds of nOPV2 SIA at the end of the round 4.

In the past five-years (2018-2022), Zambia achieved the non-Polio AFP detection rate of ≥2/100,000 under 15 years population ranging from 3.4 to 4.7 with slight decline in stool adequacy rates from 86% to 64%. Considering that the country has low OPV and IPV coverages, and many international borders with neighbouring countries experiencing ongoing poliovirus type 2 circulation, children in the country are at high risk for polio infection particularly type 2. The introduction of the IPV dose 2 will therefore help reduce the population immunity gap and contribute to interruption of any possible poliovirus type 2 transmission or importation into the country.

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	1	2

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 ☐

e 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.

NA

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)	☒	Wastage of 5-dose vials have been within acceptable levels and are seen more 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.
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)	☒	IPV 2 will be administered alongside MCV1 at 9 months. The current formulation of IPV is administered intramuscular therefore there will be no changes in the route of administration
Strategic/epidemiological reasons	☒	The country is already using 5-dose vials and will want to maintain that
Other reason(s)	☒	(Please specify) The MCV being used in the country is 5-dose vial and the choice for the 5-dose vial will align with the MCV1.

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 immunisation 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

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

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 immunisation schedule.

ZITAG Recommendations:

In addition to recommending using nOPV2 for cVDPV2 as it had shown to provide comparable protection against poliovirus while being more genetically stable and less likely to be associated with the emergence of cVDPV2 in low immunity settings (meaning that nOPV2 had the potential to be a significant tool to help stop outbreaks more sustainably) the Zambia Immunisation Technical Advisory Group (ZITAG) recommended the following:

1. Zambia should introduce the second dose of IPV to increase protection against all polioviruses, including protection against paralysis caused by Vaccine Derived Poliovirus type 2;
2. Strengthen of vaccine safety surveillance for both Adverse Events Following Immunisation (AEFIs) and Adverse Events of Special Interest (AESIs);
3. Zambia should strive to achieving and sustaining high coverage for both OPV and IPV in all districts; and
4. There is also need to achieve and sustain all polio surveillance indicators at the respective levels

Programme Recommendations:

The country has adopted the SAGE recommendations by considering the first dose (IPV1) at 14 weeks and the second dose (IPV2) at 9 months respectively.

• 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)	01/07/2024	
• Planned Switch Date	02/09/2024	
• 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)	1,091,629	
• At what age/contact point will **IPV second dose** be administered?	09 months	
• Number of infants who will receive **IPV second dose** in the first year of the planned switch date (please adjust depending on month)	1,064,649	

Justification for schedule selection:

The risk of polio virus transmission is high considering the current epidemiology of the virus in the country, other neighbouring countries of Zambia, and the Central, Eastern and Southern African regions.

Two doses of IPV provide higher immunogenicity against type 2 poliovirus than one dose. The selected immunisation 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.

The country introduced the first dose of IPV which is given at 14 weeks and is considering introducing the second dose at 9 months, a schedule that coincides with the Measles Rubella first dose vaccination and other childhood interventions. This schedule is expected to give optimal protection against all three types of the poliovirus, and optimise operational costs of the National Immunization Program and the health system. Opportunity exists for any child who misses IPV2 at 9 months to be vaccinated any time using the second year of life platform and the bi-annual Child health week. This will likely contribute to increased uptake and coverage.

This option is considered most appropriate by the country because it is consistent with the existing national immunisation schedule and is likely to be acceptable to both health workers and caregivers. The country is considering the first dose (IPV1) at 14 weeks and the second dose (IPV2) at 9 months respectively.

Introducing the second dose of IPV (IPV2) will impact the whole immunisation programme and the primary health care platform in Zambia. All eight programme components will be impacted in a number of ways including the following:

EC1=Governance, Strategic Planning and Programme Management: IPV2 introduction will mean that any guidance involving MCV1, a vaccine together with which it will be given, will have to be critically considered for any such strategies. All EPI strategic documents including the EPI Manual, Child Health Booklet and Child Health Policy will have to be revised to reflect the two doses of IPV. All technical groups will have to take note of the addition and already produced documents such as the NIS 2022-2026 done before IPV2 introduction but relevant to its implementation would need to consider appropriate addenda.

EC2=Human Resource for Health: HRH needs for the programme at all levels will need to consider the expanded work load due to the addition of IPV2. Re-orientation of health workers will be key before and continued after introduction through mentorship.

EC3=Vaccine Security, Cold Chain and Logistics: Vaccine forecasting will have to double the dose requirements for IPV and all cold chain capacity assessments will have to be redone to include the IPV2. Vaccine distribution capacity has to also bear in mind the potential increase in the load to be delivered to provinces and districts or the frequency of doing that. Likewise, accompanying paraphernalia such as syringes and safety boxes will have to be accounted for.

EC4=Service Delivery: Health workers have to get used to giving 9 months old children two injections (MCV1 and IPV2) otherwise there will be data discrepancies.

EC5=Advocacy, Communication and Social Mobilisation: The MCV messages including posters, particularly those emphasising MCV1 will have to change to be integrated with IPV2.

EC6=Health Information Systems and Monitoring & Learning: All registers, Under-5 Clinic Cards (and all relevant Home-Based Records), HIA forms, DHIS2 and all EIRs and logistics management information systems will need

EC7=Vaccine Preventable Disease Surveillance & AEFI Surveillance

EC8=Immunisation Financing: While IPV is fully Gavi funded, delivery costs are still borne by the government and partners. Integrated sustainable IPV2-sensitive financing will have to be deliberately implemented.

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

The Country will not require additional Technical Assistance for the 2024 introduction of IPV second dose.

9. Switch Grant (PSG)

(a) Gavi contribution per child	
(b) Number of children in the birth cohort in the year when the switch is planned to start	1,064,649
Total Gavi contribution	**$ US 266,161.00**
Funds needed in country by (planned disbursement date)	**01/04/2024**

Attached is the completed Gavi Budgeting and Planning Template that shows how the Switch Grant will be used to facilitate the rapid and effective implementation of critical activities before and during the immunization.

10. Alignment with Gavi strategies

a. Alignment with Gavi strategies in terms of integration with other vaccines

Leveraging resources and infrastructure through an integrated approach enables Zambia to implement activities and confront multiple health priorities concurrently. Experiences and lessons from recent co-delivery/integration of two or multiple antigens will be replicated to strengthen routine immunization of IPV2. Examples of past integrations among others include the polio SIA/vitamin A, child health week and COVID 19 vaccination/Polio campaigns.

Zambia is currently in the finalization process of the national guidelines for integration of COVID 19 into RI and other PHC services as well as development of annual micro plans at the health facility and district levels. This will ensure that all available resources are coordinated including measles vaccine which has the same age target group with IPV2 and optimized for the strengthening of RI systems and improvement of performance coverages.

The IPV2 will be delivered together with MCV1 integrated with Vit A supplement to catch-up with those that missed their Vit A at 6 months.

The IPV2 introduction will benefit from the health system strengthening arising from the already existing integration strategies in country.

b. Alignment with Gavi strategies in terms of zero dose

Zambia's Zero-Dose Agenda aims to reach children who have completely missed out on vaccinations due to barriers like geographical remoteness, poverty, cultural/religious reasons, or weak health systems. The national EPI program through the costed National Immunisation Strategy (NIS) 2022-2026, focuses on identifying these under-vaccinated populations through data analysis, capacity building, community engagement and the provision of services to the zero-dose children.

During the planning and implementation of the IPV2 introduction, each district and facility will identify and plan for zero-dose children. The country intends to use aggressive communication to inform the communities about the zero-dose children and the need to come forward for vaccination as part of the NIS innovative strategies. Appropriate strategies in service provision such as outreach, static, (fixed), and mobile depending on the situation will be used to vaccinate zero-dose children. This includes capturing zero-dose children in other PHC programs.

The IPV2 introduction will be using much refined data on zero-dose children and GIS maps through the NIS implementation process for each facility catchment area. The IPV2 introduction will also use the GIS maps developed to identify missed communities to vaccinate zero-dose children. The training for IPV2 introduction will incorporate the NIS on zero-dose.

c. Alignment with Gavi strategies in terms of gender related issues

The country takes a gender-responsive approach through application of a gender lens to uncover unique barriers that differentially impact health and vaccination among genders. The country takes into account issues related to gender barriers during introduction of the IPV2 such as decision making, delivery of immunisation services and changing the narrative on male involvement in immunisation program.

Zambia integrates gender perspectives into immunization strategies to address sociocultural factors that influence vaccine uptake and health-seeking behaviours. Interventions are tailored to tackle gender-specific obstacles related to awareness, decision-making, mobility, availability and acceptability of immunisation services. This ensures immunization services meet the needs of all children regardless of gender. This will also apply during introduction of the IPV2 such as allowing female healthcare workers to provide immunisation services to female caretakers in places where cultural barriers are against males providing immunisation services.

Generally, in the country, women are multitasking including making decisions on family health matters like taking children for immunisation services and other income generating activities. Male involvement in taking care of child health is low. Taking this into account during the introduction of IPV2, immunisation services will be provided in places where women mostly operate from to ease movements.

To encourage male involvement, the IPV2 introduction will leverage on the already existing strategies such as giving priority to men who take children for immunisation services and Information packaging.

The Government of the Republic of Zambia 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: _____	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 ZITAG 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.*