

INACTIVATED POLIO VACCINE (IPV) SWITCH REQUEST by Ghana

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 presentation¹.

1. Checklist

	To process this request,	Gavi requires v	vour country	to submit the	following ite	ms/documents
--	--------------------------	-----------------	--------------	---------------	---------------	--------------

1.	Signature of Ministry of Health	IVA
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	

<u>Requests will not be reviewed until complete</u>. 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 <u>Gavi's guidelines for reporting & renewal</u>

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 <u>Gavi budgeting and planning template</u>

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

Date of the form
 Please indicate the stock level of the current presentation
 Central Level stock (number of doses)

Date of the stock level information

Second Level stock (number of doses)

83,920 doses 08/06/2023

Polio eradication indicator		2017	2018	2019	2020	2021
4.	WUENIC OPV1 coverage (%)					
5.	WUENIC OPV3 coverage (%)	94%	98%	97%	92%	98
6.	WUENIC IPV1 coverage (%)	NA	55%	97%	93%	98
7.	# AFP cases reported	554	505	633	702	819
8.	non-polio AFP cases reported/100,000 population < 15 years	4.3	3.6	4.7	5.3	6.0%
9.	% AFP cases with 2 adequate stool specimens	89	87	89	86	92.4%
10	. # cVDPV cases confirmed	0	0	19	12	0
11	. # WPV cases confirmed	0	0	0	0	0

Narrative summary of country polio eradication status and challenges:

Ghana has consistently achieved high immunization coverage rates in routine immunization and mass campaigns. The country's documentation for wild poliovirus (WPV) free was accepted by the African Regional Certification Commission for Polio Eradication (ARCC) on 10 October 2007. There has not been transmission of wild poliovirus in the country since the last poliovirus case was detected on 08 November 2008. Ghana remains free of wild poliovirus.

In July 2019, Ghana recorded an outbreak of circulating vaccine-derived poliovirus type 2 (cVDPV2). A total of 31 cases (19 in 2019 and 12 in 2021) have been confirmed and response SIAs have been conducted to help break transmission. Since June 2020, no case of cVDPV2 has been confirmed.

The continuous circulating of the cVDPV2 in the African Region remains a challenge considering the high level of migration among countries especially in the West African sub-region. There are pockets of non-dose children and under-served communities in the country and these presents a huge challenge. The limited funding for polio eradication activities from government is also a huge challenge.

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



SWITCH REQUEST FORM FOR INACTIVATED POLIO VACCINE, version Mar 2021

Is the new presentation licensed in the country?

Yes		No 🗆	
res	Δ	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.

NA 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		Nο	∇
162		INO	\sim

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)

	wain Kea	ison(s) Comment
Cost Driving Considerations (e.g. wastage rate, price, price commitments)		Wastage of 10-dose vials have been within acceptable levels
Vaccine's clinical profile (e.g. country specific data, safety profile)		
Logistic considerations (e.g. VVM type, size of cartoons)		The cold chain requirement is comparatively lower
Vaccine programmatic suitability (e.g. dose schedule, ease of administration)		Fits into the system as most vaccine are 10-dose vials
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,

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



SWITCH REQUEST FORM FOR INACTIVATED POLIO VACCINE, version Mar 2021

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.



SWITCH REQUEST FORM FOR INACTIVATED POLIO VACCINE. version Mar 2021

•	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)	01/01/2024	
•	Planned Switch Date	01/03/2024	
•	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)	1,226,896	
•	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)	1,226,896	

Justification for schedule selection:

NITAG recommends that the first dose of IPV is given at 14 weeks and the second dose at 9 months, a schedule that coincides with the Measles Rubella first dose, Yellow Fever vaccinations and other childhood interventions. This schedule is expected to give optimal protection against all three types of the poliovirus, and optimize operational cost of the National Immunization Programme and the health system. Opportunity exists for any child who misses IPV2 at 9 months to be vaccinated any time after, up to five years as contained in the EPI catch-up policy. This will ensure maximum uptake and coverage.

This option is considered most appropriate by NITAG because it is consistent with the existing national immunization schedule and is likely to be acceptable to both health workers and care givers. NITAG thus recommends the first dose (IPV1) at 14 weeks and the second dose (IPV2) at 9 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	1,258,355
Total Gavi contribution	(a x b) \$ US 314,588.75
Funds needed in country by (planned disbursement date)	01/10/2023

Please attach the <u>Gavi Budgeting and Planning Template</u> 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. Alignment with Gavi strategies

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

Optimizing resources and infrastructure through an integrated approach allows Ghana to tackle multiple health priorities concurrently. The country is currently in the final stages of integrating COVID-19 vaccination into the routine immunization schedule nationwide. To guide this process, national guidelines for COVID-19 vaccination integration are nearing the end of development and will soon be disseminated across all regions.

b. Alignment with Gavi strategies in terms of zero dose

Ghana's Zero-Dose Agenda aims to reach children who have completely missed out on vaccinations due to barriers like poverty, geographical remoteness, conflict or weak health systems. The national EPI program focuses on identifying these under-vaccinated populations through data analysis and community engagement. Innovative strategies are then co-created with partners and stakeholders to bridge access gaps and deliver essential immunizations to even the hardest-to-reach children.

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

Applying a gender lens helps uncover unique barriers that differentially impact health and vaccination among genders. Ghana 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. This ensures immunization services meet the needs of all children regardless of gender.



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

The Government of GHANA 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 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 Health⁶ (or delegated authority)

Minister of Finance⁷ (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.