Please use this form to send Gavi the necessary information to review your country’s request to switch to a different vaccine product, presentation, schedule or use. Fill in the light blue fields. For definitions and requirements, please consult the Gavi guidelines for vaccine optimisation. For multiple switch requests submitted in parallel, please use separate forms, one for each switch request. Please use the exact same vaccine product and presentations description as provided in [Gavi’s Detailed Product Profiles list](https://www.gavi.org/news/document-library/detailed-product-profiles).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Country name** | **Switch from** | **Switch to** | **Planned switch date**  | **Switch grant requested**  |
| **Imaginary** | **Rotarix (RV1, 1 dose/plastic tube, liquid)** | **Rotavac,**  (**RV1, 10 doses/vial, frozen)** | 1.10.2023 | Yes [x]  No [ ]  |

1. **Documents checklist**

To process this request, Gavi requires your country to submit the following items/documents:

|  |  |  |
| --- | --- | --- |
| 1. **Signature of Ministry of Health[[1]](#footnote-2)** (necessary for all requests, see later on this form)
 | [x]  |  |
| 1. Switch impact assessment (necessary for all requests, see next page on this form)
 | [x]  |  |
| 1. If required[[2]](#footnote-3) : supportive NITAG recommendation or ICC endorsement (minutes of a meeting endorsing the switch decision)
 | [x]  |  |
| 1. If this switch increases the country’s co-financing financial costs:[[3]](#footnote-4) signature of Ministry of Finance
 | [ ]  |  |
| 1. If a switch grant (SG) is requested: Budget[[4]](#footnote-5) in the Gavi template
 | [x]  |  |

Requests will not be reviewed unless complete.

1. **Country context**

|  |  |
| --- | --- |
| 1. Switch reason:

Country’s elective choice | Yes [ ]  No [x]  |
| Gavi Alliance request[[5]](#footnote-6) | Yes [x]  No [ ]  |
| 1. Routine vaccination already started?[[6]](#footnote-7)
 | Yes [x]  No [ ]  |
| 1. Did the country experience stock-out of this antigen over the past 12 months??
 | Yes [ ]  No [x]  |
| 1. Current stock level of the current presentation
 | Central level ……………….…………(n of doses)Second level ……………….…………(n of doses) |
| 1. If the implementation includes off-label use, has a national policy change been agreed?
2. Is the new presentation licensed in the country?
 | Not applicable [x]  Yes [ ]  No [ ] Yes [x]  No [ ]  |
| If the answer is no, 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, and confirm if the licensing process will be completed before shipment: |
| …… |
| 1. Does the country procure immunization supplies through UNICEF or the PAHO Revolving Fund?
 | Yes [x]  No [ ]  |
| If the answer is no, please attach a description of the alternative mechanism of supply and delivery of immunization and the vaccines or goods that the country intends to procure through this mechanism: |
| ……. |

1. **Switch impact assessment summary**

A switch will impact one or more of the six dimensions listed below. Gavi will request each application to have assessed each dimension to surface potential trade-offs between the benefits and downsides of the switch. Please fill in the table based on EPI and or NITAG assessment. Examples are provided in the guidelines in annex.

**Simplified switch impact assessment**

|  |  |
| --- | --- |
| ***Administration*** *(e.g. single dose, liquid form, oral, dose schedule)* | No change [ ]  Impacted [x] This switch from a single-dose tube to a multi-dose vial will require additional steps in preparing the dose for administration. |
| ***Cold chain requirements****(e.g. larger or smaller space needed)* | No change [ ]  Impacted [x] This switch will free up refrigerated space and occupy a smaller volume of frozen space. Sufficient frozen space capacity is available to accommodate Rotavac.HealthcareWorkers training will include briefing on how to thaw doses for administration and how to re-freeze left over doses for later use. |
| ***Effectiveness or safety****(e.g. different vaccine composition)* | No change [x]  Impacted [ ] As per WHO position paper, no significant difference expected. |
| ***Coverage*** *(acceptability, reach)* | No change [ ]  Impacted [x] The dose schedule will change from 2 to 3 because Rotavac requires a third dose given at 14weeks, in addition to the 2 doses given at 6 and 10 weeks. Children already receive the Penta vaccine at week 14 so this switch will leverage an existing touchpoint. However, minor decrease in full-vaccination coverage (3 doses) might happen. To mitigate this risk, adequate supervision and training will be implemented and the vaccination cards will be re-printed to include the 3rd dose of Rotavac. |
| ***Financial Sustainability*** *(e.g. cheaper or more expensive)* | No change [ ]  Impacted [x] Significant positive difference with vaccine cost savings of >50% |
| ***Supply*** *(availability / security / locally-made)* | No change [ ]  Impacted [x] This vaccine product switch will enable access to available supply |

|  |  |  |
| --- | --- | --- |
| Will this switch increase the country’s financial costs (for example the co-financing amount)? If yes, please add the Ministry of Finance signature to this form. | Yes [ ]  | No [x]  |
| Is there enough cold chain capacity at all levels to accommodate the vaccine in the 3-5 years after the switch? | Yes [x]  | No [ ]  |

4. Switch Grant (SG)

Countries may apply for an additional switch grant to facilitate switch planning and implementation. This grant intends to cover a portion of the one-time investments associated with the product, presentation, or use switch such as planning, training, supervision, document production and printing, and social mobilisation. The ceiling for the grant is US$ 0.25 per surviving infant in the year of implementation (for infant vaccines) and US$ 0.80 per girl in the yearly target age cohort for HPV. Please attach the [Gavi Budgeting and Planning Template](https://www.gavi.org/library/gavi-documents/guidelines-and-forms/budgeting-and-planning-template---user-guide/) to show how the Switch Grant will be used to facilitate the rapid and effective implementation of critical activities before and during the switch.

5. 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 Product Switch Grant. In this case, the relevant costs must be indicated in the budgeting and planning model.

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

**Imaginary**‘s Government of 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 from **Rotarix (RV1, 1 dose/plastic tube, liquid)** to **Rotavac,**  (**RV1, 10 doses/vial, frozen)**

The co-financing commitments in this request include the amount of support in supplies requested from Gavi, and the financial commitment of the Government for the procurement of the above-mentioned vaccine(s).

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 needed 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**[[7]](#footnote-8)** (or delegated authority) | (if needed)Minister of Finance[[8]](#footnote-9) (or delegated authority) |
| Name  | Name |
| Date  | Date |
| Signature  | Signature |

*Please email this form and every attachment requested to* *proposals@gavi.org* *with the Ministry of Finance and the Gavi Senior Country Manager for your country in copy.*

1. A signature from a delegate of the Minister is acceptable [↑](#footnote-ref-2)
2. As reflected on Gavi’s guidelines for vaccine optimization support: NITAG supportive recommendation is required if the switch changes the dose schedule, or the target population or the vaccine composition) [↑](#footnote-ref-3)
3. The signature is not required if the switch is forced by supply disruption [↑](#footnote-ref-4)
4. Using the [Gavi budgeting and planning template](https://www.gavi.org/library/gavi-documents/guidelines-and-forms/budgeting-and-planning-template---user-guide/) [↑](#footnote-ref-5)
5. For example due to policy changes or supply disruptions [↑](#footnote-ref-6)
6. In some cases countries approved to introduce with one vaccine product had to switch to a different option before launch due to unavailability [↑](#footnote-ref-7)
7. Required in all cases. [↑](#footnote-ref-8)
8. Required if the switch will result in higher financial costs. See point 6. [↑](#footnote-ref-9)