

**A summary of requirements for assuring the quality of products  
purchased with Gavi funds**

**Frequently asked questions**

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Gavi-supported countries can obtain vaccines and injection safety devices in two ways:

1. UNICEF or PAHO's Revolving Fund procures products using Gavi funds on behalf of Gavi-supported countries, or
2. Gavi-supported countries can request the equivalent financial support from Gavi to be used for self-procurement.

**1. Is this a new policy?**

In December 2012, the Gavi Programme and Policy Committee (PPC) clarified the procedure to be followed should countries elect to use the option of self-procurement. In June 2016, the Gavi Board approved these guidelines and formalised them in the self-procurement policy.

**2. Can Governments self-procure all Gavi-supported vaccines?**

The option of self-procurement does not apply to pneumococcal vaccines that must be procured through UNICEF Supply Division (including the co-financed portion) due to the terms of the Advance Market Commitment.

**3. How can countries self-procure with Gavi funds?**

Rather than procuring through UNICEF or PAHO's Revolving Fund, Gavi-supported countries can request financial support equivalent to the amount Gavi would have provided to the relevant procurement agency.

These funds should only be used to purchase vaccines and related injection safety devices (auto-disable syringes and disposal boxes) that comply with international expectations of assured quality.

Gavi also strongly encourages countries not to use its resources to procure less cost-effective vaccines.

**4. How much financial support can a Government receive for self-procurement?**

The amount of support is determined by the weighted average price of the vaccine or immunisation safety device, as forecasted by Gavi and its procurement agencies. If the Government's negotiated price is higher, the country is required to pay the difference to

purchase enough vaccines or supplies to cover the target population. If the negotiated price is lower, the Government should invest the remainder of the funds in the immunisation programme and report on the use of these funds to Gavi.

### **5. What are the quality requirements when self-procuring vaccines with Gavi support?**

The Government shall only procure vaccines using Gavi support that: (i) are from the WHO pre-qualified list of vaccines; or (ii) comply with WHO's definition of quality vaccines (as described in WHO's Technical Report Series), where there are no unresolved quality problems reported to WHO, and where compliance is assured by fully functional National Regulatory Authorities (NRAs) as assessed by WHO in countries where the vaccines are both manufactured and purchased.

The WHO pre-qualified list of vaccines is available on the WHO web site:

[http://www.who.int/immunization\\_standards/vaccine\\_quality/PQ\\_vaccine\\_list\\_en/en/](http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/)

The WHO list of Technical Report Specifications is available on the WHO web site:

<http://www.who.int/biologicals/vaccines/en/>

### **6. What are the quality requirements when self-procuring injection safety devices with Gavi support?**

Unsafe injections represent a well-established risk and there is no widely-applied national quality assurance mechanism such as exists through NRAs for vaccines. The Government shall procure only auto-disable syringes that are pre-qualified under WHO's Performance, Quality and Safety system:

[http://www.who.int/immunization\\_standards/vaccine\\_quality/pgs\\_prequalified\\_devices/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/pgs_prequalified_devices/en/index.html)

For syringe and needle disposal boxes, the Government shall either: i) procure boxes that appear on the relevant WHO list of prequalified products; or ii) submit to WHO a certificate of quality from a relevant national authority.

### **7. What does a fully functional NRA mean and where can more information be found?**

National Regulatory Agencies are responsible for ensuring that products released for public distribution (e.g. pharmaceuticals and biological products, such as vaccines) meet national standards of quality and safety. Countries self-procuring vaccines with Gavi funds must be able to ensure that international expectations of quality and safety for the product have been met. The NRAs in both the country of manufacture and the country of purchase must have been evaluated by WHO to be functional for this purpose.

More information on NRAs and their critical control functions is available here:

[http://www.who.int/immunization\\_standards/national\\_regulatory\\_authorities/role/en/index.html](http://www.who.int/immunization_standards/national_regulatory_authorities/role/en/index.html)

[http://www.who.int/immunization\\_standards/vaccine\\_quality/expedited\\_review\\_procedure.pdf](http://www.who.int/immunization_standards/vaccine_quality/expedited_review_procedure.pdf)

## **8. What steps are required following a decision by the Government to self-procure?**

During the application or renewal process for New Vaccine Support, self-procuring countries should:

- Indicate with their application where they wish to receive the funds
- Describe which vaccine and injection safety supplies will be procured and the procurement mechanism
- Describe how the quality requirements of vaccines and related injection safety supplies will be assured, as described above
- Plan their vaccine procurement and co-financing contributions in accordance with country planning and budget cycles, clearly indicating the timing of procurement in the application

Gavi will request that WHO confirm whether the products comply with international expectations of assured quality.

Prior to self-procurement, Gavi will conduct a review of the proposed procurement mechanism to assess whether it satisfies generally acceptable procurement methods and to make any recommendations on minimum reporting requirements and improvements. The country will receive the total funding for the procurement in a lump-sum from Gavi only after it agrees to implement the recommendations.

The Government must submit satisfactory evidence that it purchased the vaccine doses and related supplies communicated by Gavi (including the co-financing portion), including by submitting purchase orders, invoices and receipts.

Additional information can be found in the New and Underused Vaccines Support Guidelines available at <http://www.gavialliance.org/support/apply>.

## **8. Who is responsible for investigating safety or quality defects reported from the field with products that have been self-procured with Gavi funds?**

The Government that self-procures will be responsible for conducting such investigations. The Government must submit satisfactory evidence to Gavi, for verification by WHO, that such investigations have been conducted thoroughly and in a timely manner.

## **9. Who will be liable if injury or harm is caused by products that have been self-procured?**

Consistent with the Partnership Framework Agreement, Gavi shall not be liable for any injury or harm arising in relation to the vaccines that the country self-procured. Gavi encourages countries to make appropriate arrangements with manufacturers to allocate responsibility in case of harm or injury arising.

## **10. Can Governments self-procure with their own co-financing funds?**

While the Self-procurement policy relates only to countries wishing to procure with Gavi funds, governments may also self-procure their co-financed portion of vaccines and devices. Gavi

strongly encourages countries self-procuring co-financed vaccines and injection safety devices to ensure they are of WHO-defined assured quality, such as those on the WHO list of pre-qualified products or as otherwise described above and that the [programmatic suitability](#) of the product has been considered. Please see the [Co-financing policy](#) for more details.