

## DOCUMENT ADMINISTRATION

VERSION NUMBER	APPROVAL PROCESS	DATE
2.0	Prepared by: Aurélia Nguyen	
	Reviewed by: Programme and Policy Committee (PPC)	12 May 2016
	Approved by: Gavi Alliance Board	23 June 2016 Effective from: 23 June 2016
	Next review:	As per Board decision
	Terminology review update	15 February 2025

## **1. Goal and scope**

- 1.1. This policy outlines the requirements for countries self-procuring vaccines and injection safety devices using Gavi financial support in lieu of in-kind support
- 1.2. In line with the Paris Declaration<sup>1</sup> and the principles regarding aid effectiveness, Gavi countries have the option to self-procure vaccines and injection safety devices with Gavi support. This policy aims to ensure that only vaccines and injection safety devices of assured quality are purchased using Gavi funding.
- 1.3. Vaccines self-procured by countries as part of their co-financing obligation are out of scope of this policy. However, Gavi strongly encourages countries self-procuring co-financed vaccines to ensure that vaccines are of World Health Organization (WHO)-defined assured quality, such as those on the WHO list of pre-qualified products.
- 1.4. Vaccines and vaccine supplies subject to specific procurement terms, e.g. those procured under the Advance Market Commitment (AMC), which specify procurement requirements and/or the procurement modality, are out of scope of this policy.

## **2. Self-procurement of vaccines**

- 2.1. Countries wishing to self-procure vaccines and associated injection safety devices, in lieu of procurement through a Gavi Alliance procurement agency (e.g. United Nations Children's Fund (UNICEF) or Pan American Health Organization's (PAHO) Revolving Fund, may request financial support from Gavi equivalent to the amount Gavi would have provided to its procurement agency.
- 2.2. Countries that choose to self-procure vaccines using Gavi support must purchase vaccines of assured quality. This can be done through:
  - a) Selecting vaccines from the list of WHO pre-qualified products; or,
  - b) Ensuring that the vaccines purchased comply with WHO's definition of quality vaccines (as described in WHO's Technical Report Series<sup>2</sup>), for which there are no unresolved quality problems reported to WHO, and for which compliance is assured by fully functional National Regulatory Authorities (NRAs), as assessed by WHO in the countries where they are manufactured and where they are purchased.
- 2.3. The amount of financial support provided by Gavi is based on the presentation-specific weighted average price for the vaccine (or similar presentation) as forecasted by the Gavi Secretariat, in consultation with Gavi's procurement agencies.
- 2.4. If a country's negotiated procurement price is higher than the amount of financial support provided by Gavi, the government is required to pay the difference in order to purchase enough vaccines to reach the target population. If the price is lower than the amount of financial support provided by Gavi, the country shall invest the excess funds in the immunisation programme and report on the use of these funds in subsequent monitoring reports to Gavi.
- 2.5. Countries cannot use Gavi resources to procure vaccines not supported by WHO recommendations as outlined by the WHO's Strategic Group of Experts on

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<sup>1</sup> <http://www.oecd.org/dac/effectiveness/parisdeclarationandaccraagendaforaction.htm>

<sup>2</sup> Available at: <https://extranet.who.int/prequal/medicines/who-technical-report-series/>

Immunization (SAGE)<sup>3</sup>. To ensure the most efficient use of its resources, and in the interest of programmatic and financial sustainability, where self-procured products differ from Gavi-procured products, Gavi strongly encourages countries not to use its resources to procure less cost effective vaccines.

### **3. Self-procurement of injection safety devices**

- 3.1. Countries using Gavi's funds to self-procure auto-disable syringes are required to procure products pre-qualified under WHO's Performance, Quality and Safety system.<sup>4</sup>
- 3.2. For disposal boxes, countries self-procuring with Gavi funds must either:
  - a) Procure devices that appear on the relevant WHO list of prequalified products; or,
  - b) Submit to WHO a certificate of quality from a relevant national authority.
- 3.3. The amount of financial support provided by Gavi is based on the weighted average price for the product as forecasted by the Gavi Secretariat, in consultation with Gavi's procurement agencies.
- 3.4. If a country's negotiated procurement price is higher than the amount of financial support provided by Gavi, the government is required to pay the difference in order to purchase enough supplies to reach the target population.
- 3.5. If the price is lower than the amount of financial support provided by Gavi, the country shall invest the excess funds in the immunisation programme and report on the use of these funds in subsequent monitoring reports to Gavi.
- 3.6. To ensure the most efficient use of its resources, and in the interest of programmatic and financial sustainability, where self-procured products differ from Gavi-procured products, Gavi strongly encourages countries not to use its resources to procure less cost effective products.

### **4. Approval and monitoring for vaccines and injection safety devices**

- 4.1. Prior to self-procurement, Gavi or its designate will review the procurement mechanism proposed by the country to assess whether it adheres to the principles of good public procurement and the requirements of this Policy and make recommendations on minimum reporting requirements and possible improvements.
- 4.2. Following self-procurement, the country must submit a full report outlining the total quantities of vaccine and injection safety devices, as applicable, procured, and final costs to be compared against the budget allocated under the relevant Gavi Decision Letter. The country must submit satisfactory evidence that it purchased the vaccine doses (including the co-financing portion) and related supplies communicated by Gavi in the Decision Letter, by submitting purchase orders, invoices and receipts. Any balance of Gavi funds disbursed in support of country self-procurement should be reported to Gavi together with satisfactory evidence that the leftover funds have been used within the immunisation programme.

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<sup>3</sup> Strategic Advisory Group of Experts on Immunization. See:  
<https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization>

<sup>4</sup> WHO Performance, Quality and Safety catalogue:  
[http://apps.who.int/immunization\\_standards/vaccine\\_quality/pqs\\_catalogue/](http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/)

## **5. Timeline for implementation and review**

- 5.1. This policy comes into effect immediately upon Board approval.
- 5.2. The policy will be reviewed and updated as and when required by the Gavi Alliance Board.