

Annex B: Gavi's Product Portfolio Management (PPM) Principles¹

- Following the Vaccine Investment Strategy (VIS) and the funding approval of a new disease by the Gavi Board, the decision on which new vaccine(s) to include in the Gavi portfolio is informed by analyses of their impact, cost and cold chain requirements, amongst other attributes. However, beyond the disease approved by the Gavi Board, the decision does not specify which specific product presentation(s) are to be offered to countries and then procured through Gavi's procurement agencies.
- Where a Board decision exists (i.e., VIS decisions or other vaccine investment decisions by the Board), the PPM principles guide the Gavi Secretariat for adding a new vaccine presentation or product to the Gavi "product menu". The Market Shaping team is responsible for assessing these principles, with support from relevant Secretariat teams and other partners as needed.

The PPM principles are:

1. The new vaccine presentation or product must be consistent with WHO Strategic Group of Experts on Immunization (SAGE) recommendation(s) and WHO position paper (where one exists) for the related antigen.
2. The new vaccine presentation or product must be WHO prequalified, unless a compelling reason to make an exception exists (e.g. a new product/presentation may be added to the menu when WHO prequalification is anticipated to enable advanced country switch planning (i.e. for programmatic and/or cost reasons) and timely access to this product/presentation as soon as possible after WHO prequalification).
3. The new vaccine presentation or product must have a reliable supply base. Adding the new presentation or product to Gavi's product menu should contribute to an environment of consistent, uninterrupted supply. The product should be manufactured by a reliable supplier and be available in sufficient quantities to contribute to the supply base without creating risks to supply security.
4. The estimated costs of the new vaccine presentation or immunisation related product should be within the range of the current fully-loaded, wastage adjusted vaccine costs to immunise an individual and should account for any increased procurement costs that are commensurate with evidence-based benefits of the new vaccine presentation or product and/or with decreased costs in vaccine delivery.
5. The new vaccine presentation or product must be likely to be able to meet country demand and preferences. Where required to avoid supply security risks or to further other market shaping objectives, a new presentation may be added to replace an existing one (e.g. a 2-dose vial presentation may be replaced by a 5-dose vial presentation, rather than expanding the market to include both presentations).

¹ As approved by the Gavi Board in the Supply and Procurement Strategy 2016-20 in June 2016.

- When the above conditions are met, the procurement of the new vaccine presentation or product is considered to fit, in principle, in the context of the original Board decision and required approval from the Gavi Chief Vaccine Programmes and Markets Officer (CVPMO). The presentation or product would then be added to the Gavi “product menu” and offered to countries. On occasion, the Alliance might need to limit the choices offered in the portfolio, for the purpose of consolidating demand, leveraging purchasing power, or ensuring uninterrupted supply. Decisions on active portfolio management will be taken in consultation with countries and communicated to manufacturers in a timely manner to prevent interruption of programmes and supply.