

Product Portfolio Management¹

Vaccines

VIS decisions to include a new antigen in the Gavi portfolio are informed by analyses of impact, cost and cold chain requirements, amongst other attributes, as they relate to the available or expected vaccine presentations and products for the antigen. However, beyond the antigen 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. The following principles guide the Gavi Secretariat for adding a new vaccine presentation or product to the Gavi "product menu":

1. The new vaccine presentation or product must be consistent with SAGE recommendation(s) and the relevant 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 (for example, to provide countries with a new vaccine presentation in a manner timely for uptake of this new presentation with as few delays as possible following first availability to enable a shift to a preferred presentation for programmatic and/or cost reasons, and where WHO prequalification is anticipated).
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 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 respond to 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).

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. The presentation or product would then be added to the '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.

¹ As approved by the Gavi Board in the [Supply and Procurement Strategy 2016-20](#), in June 2016

Cold Chain Equipment

With regard to CCE, Gavi only supports equipment included in the WHO Performance Quality Safety (PQS)² Catalogue that meets the following requirements:

- **User-independent (“Grade A”) freeze protection** to prevent freezing of vaccines,
- **Extended operating temperature range** to ensure the equipment operates correctly even during large changes in ambient temperature,
- **Temperature monitoring and logging** to assure better temperature control of vaccines, and
- **Voltage regulation (for on-grid devices only)** to protect equipment from electrical damage.

² PQS qualification means that a device has passed a series of performance, quality and safety tests set by WHO.