



4 *The market-shaping goal*

Shape vaccine markets to provide appropriate and affordable vaccines



Supply and Procurement Roadmap HPV (Human Papilloma Virus) Vaccine

PUBLIC SUMMARY

The GAVI Alliance Board has approved the opening of a window for funding HPV vaccination provided a sustainable price is committed by suppliers below US\$ 5.0 per dose. Following engagement with existing manufacturers, GAVI opened the funding window in March 2012; based on these discussions, the Secretariat is confident that GAVI will obtain an acceptable price when the tender process is concluded by UNICEF-SD later in 2012.

GAVI's goal is to initiate HPV vaccination as soon as possible. The 2012 HPV vaccine procurement will be the first for GAVI in HPV and set the scene for future HPV market dynamics. The Supply and Procurement strategy will be implemented in three sections which integrate a short, mid and long-term view:

1. Set the conditions for country approvals in 2012 and for initiating first vaccination programmes in 2013.

- The 2012 procurement round will concern supply for the period 2013-2017. During that period, two manufacturers are expected to have pre-qualified vaccines to offer while no new entrant is likely before 2018. Due to projected gradual vaccine uptake and higher programmatic complexities than usual (e.g. vaccination of a pre-adolescent / adolescent population, of girls only, need for local communities to be more involved), a five year period is necessary to provide sufficient perspective for all parties involved in the procurement.
- Acceptable prices below US\$ 5.0/dose are necessary for the programme to be initiated, especially in the context of programmatic costs that are significantly higher than any previous vaccination programme initiated by GAVI.
- Procurement timing: the first tender will be issued in October 2012, with awards to be made in December 2012. The tender will include the projected demand for countries that will be graduating before they introduce HPV vaccines (fully self financing) and invite manufacturers to quote tiered prices for these countries.
- The production capacity currently available can potentially match GAVI demand for the next five to ten years.

2. Establish during five years (2013-2017) the conditions for early success by introducing and scaling up HPV vaccination.

- Good deployment and high early vaccination uptake will have significant impact on demand.
- Strategic Demand Forecasts (SDFs) are particularly difficult to establish but critical to guide market shaping activities. They will be periodically reviewed and shared in transparency with interested parties.
- Programmatic success will be critical to help influence Market Shaping success:
 - Early implementation is supported by specific criteria for country approval for HPV vaccination funding, and by implementation of demonstration programmes.

- The value of HPV vaccination should be further increased by developing synergies with other adolescent and female-based interventions.
3. Seed the market conditions for long-term development of vaccination beyond 2017.
- Engage potential future new manufacturers. It is desirable that a further two or more HPV vaccine development programmes become fully prioritised in 2013/14 by new manufacturers for GAVI supply. Potential future new entrants will be encouraged to bid for the later years of supply in the current tender, should they believe they may have a candidate vaccine available for supply by then.
 - Support relevant partners and authorities to refine clinical end-point and regulatory requirements for future vaccines in support of appropriate and accelerated development where possible.
 - Support the development of new vaccination strategies and vaccine characteristics (target product profile) that will favourably impact vaccination efficiencies and market maturity.
 - HPV vaccine manufacturers have complex cross-royalty arrangements for the intellectual property attached to the vaccines. The effect of the HPV patent landscape has been reviewed for its impact on the development of new HPV vaccines.
 - Some market interventions were not retained. In particular, an Advanced Market Commitment was judged unattractive for HPV due to the level of already pledged prices and the timing expected for new entrants.

The market shaping goals 2012-2015 were analysed and weighted according to timeframe, to potential Market Shaping impact and to GAVI's potential influence capacity. The roadmap will be reviewed annually; the market shaping goals and priorities will be re-evaluated as needed in the light of market developments and evolving maturity.

1. **Priority 1: Cost of vaccine to GAVI and countries.** This objective is the critical market shaping goal for GAVI's HPV impact. Without it, there is no initiation of any support to countries and if achievements related to cost are modest, there is a risk that country programmes are not sustainable long term. It will be achieved through a mix of direct negotiation, open structure tendering, catalysing efforts towards potential new schedules, and supporting early programmatic success.
2. **Priority 2: Appropriate and innovative vaccines.** This reflects that HPV vaccine profile improvements beyond what exists, while welcome, are unlikely to bring major health outcome improvements. However, new entrant manufacturers are of interest to develop desired market maturity. To this end, WHO should advise on and set optimised acceptable clinical end-points and support ways of reducing regulatory timelines without compromising quality. Development of multi-dose

presentations are encouraged to reduce cost of goods and volume (cold chain and freight costs) while supporting programmatic efficiency with acceptable wastage rates.

- 3. Priority 3: Balance of supply and demand.** The balance of supply & demand is likely satisfied today with two reliable manufacturers each having an estimated volume capacity sufficient for GAVI's mid-term demand. GAVI may expect to have strong influence on demand and, therefore on capacity utilisation, if programmatic challenges are overcome. This objective will be supported by ensuring continued manufacturer interest in supplying GAVI markets through reliable forecasts, through an initial tender covering 5 years of supply, and through supporting early programmatic success.

HPV - Summary Visual Roadmap
GAVI Supply & Procurement Strategy

