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The Market Shaping Goal

Shape vaccine markets to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries.

Supply and Procurement Roadmap

***Human Papilloma Virus
Vaccine***

[Public Summary](#)

Public Summary

Human papilloma virus (HPV) is the primary cause of cervical cancer, which is the fourth most common cancer in women, resulting in an estimated 266,000 deaths annually. Over 70% of the disease is vaccine-preventable, and 85% of the disease burden is in developing countries.

Gavi has been supporting HPV vaccination since 2012 but the pace of national introductions by September 2016 was slower than anticipated and Gavi was not on track to meet its target. As of January 2017, countries can apply directly for national introduction of HPV vaccine and for multi-age cohort vaccination (MAC) during the first year of introduction (9-14 years of age), in line with the SAGE recommendations of October 2016.

- Gavi's revised HPV multi-cohort programme aims to reach 40 million girls by 2020 and help avert 900,000 deaths, excluding potential herd effects.
- Country demand for the new programme is strong with 12 country approvals January-Nov. 2017, all integrating MAC. This dynamic shows a rapid uptake of the new strategy, helps emerging clarity on new demand, and increases the confidence in new demand forecasts.
- Larger volumes of HPV vaccines will be needed earlier than previously anticipated.

The projected Gavi expenditure between 2016 and 2020 is approximately USD 473 million. HPV vaccination in Gavi-supported countries is expected to avert 20 deaths per 1000 people immunised, which makes HPV the most impactful vaccine in Gavi's portfolio as measured in deaths averted per 1000 immunised.

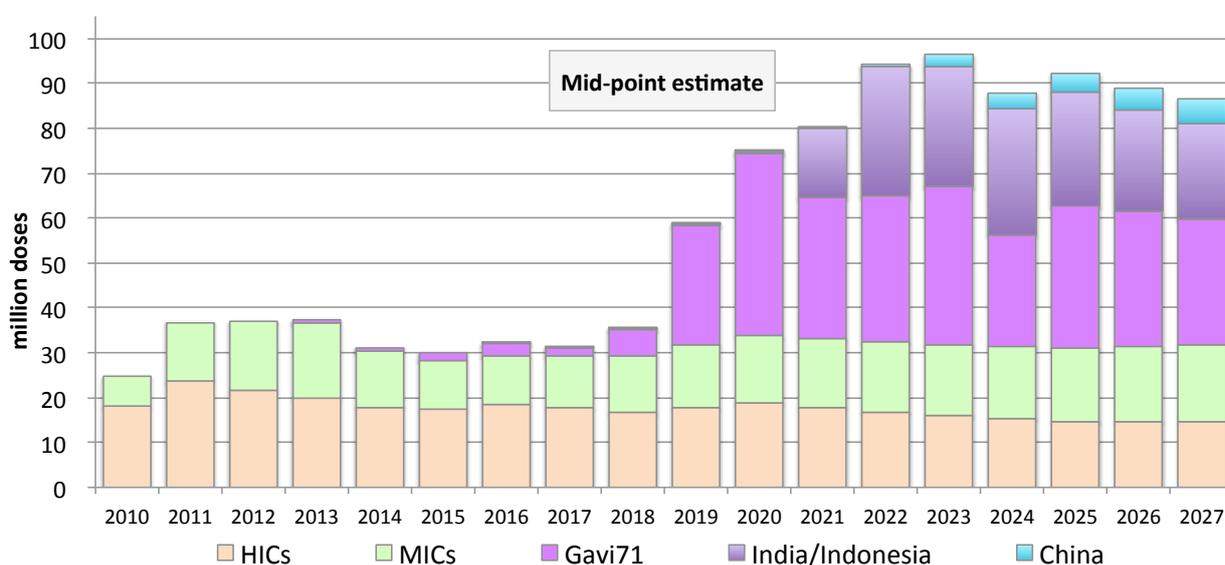
Market overview

Market volume: During the period 2010 to 2016, the total market volume was approximately 230 million doses, of which 5.5 million doses (md) were for Gavi-supported countries.

Global demand is expected to increase from 30-35 md in 2016 to 70-90 md/y in 2020. From 2021, annual peaks corresponding to multi-age cohorts may reach 90 to 100 md/y. The market is expected to stabilize at 80-90 md/y when multi-age cohort campaigns are completed in most territories, after 2026.

Gavi demand is expected to increase from 2.6 md in 2016 to 25-30md in 2019 and to 30-40md/y from 2020. Between 2020 and 2024, annual peaks will reach up to 45md (MAC).

Estimated historical & future market volume (million doses); 97% of the Gavi forecasted demand is approved for 2019, and 37% is approved for 2020 (November 2017 update).



Supply landscape: Currently, two manufacturers supply a WHO pre-qualified HPV vaccine: Merck (Gardasil or HPV4v) and GSK (Cervarix or HPV2v). Two to three new prequalified HPV vaccines may be available between 2018 and 2023, including Merck’s HPV9v that is already licensed and commercially available in high-income countries. Current evidence suggests that the 3 registered vaccines (2, 4 and 9-valent) offer relatively similar effectiveness for the prevention of cervical cancer (WHO SAGE, Oct 2016).

Balance of supply and demand:

Supply available to High Income Countries and Middle Income Countries is expected to meet demand for the foreseeable future (2018-2027).

Supply to Gavi-supported countries 2017-2019 cannot accommodate the approved and expected introductions under the new Gavi HPV program. Due to this supply shortfall, the Gavi demand estimates have led to a spreading of country introductions over time. Following this adjustment in demand, supply in 2018-2019 is expected to narrowly meet demand for both vaccines with very limited or no buffer capacity. In 2020 to 2022, there may be a supply shortfall for one vaccine, especially in 2022 when large MAC volumes may be needed.

From 2023, supply to Gavi is expected to exceed demand with adequate buffer capacity. Demand for India and China is not expected to impact availability of vaccines to Gavi and vice-versa.

In a high demand scenario, current manufacturers alone are unlikely to meet peak demand for the totality of Gavi, India, Indonesia and China.

Price: The price per dose to Gavi remains unchanged since 2013 at USD 4.50 for HPV4v and USD 4.60 for HPV2v.

Market Value: The global market value for HPV vaccines was USD 2.5 billion in 2016 and is expected to increase to about USD 3 billion in 2020.

Healthy Market Framework Evaluation

The HPV market is in a low state of health, a situation that will continue until 2019. It is expected to evolve towards moderate health from 2020. The lower rating in 2017-2019 is linked to the short-term supply shortfall for HPV4v due to manufacturing lead-times and insufficient industrial formulation/fill-finish capacity.

Currently, the HPV market does not meet five of the eight market attributes (supply meets demand, meet country preferences, buffer capacity, total systems effectiveness, long term competition), partly meets two (individual supplier risk, product innovation), and meets one (NRA risk).

Total System Effectiveness	Long Term Competition	Product Innovation
Buffer Capacity	Individual Supplier Risk	NRA Risk
Meet Country Preferences		
Supply Meets Demand		

Supply meets demand: **Unmet.** Gavi-country introduction plans are being spread over time due to insufficient supply.

Country presentation preference: **Unmet.** In the short-term, there will be a supply shortage of one vaccine; the manufacturer is actively seeking to increase production capacity in line with Gavi71 demand by 2020 when the product-specific shortage is expected to end. In the medium-term, there is a risk of another vaccine supply constraint, depending on Gavi country preferences. In the long-term, product-specific supply is expected to meet demand when new suppliers enter the market.

Buffer capacity: **Unmet.** There is no buffer capacity 2017-2020 compared to demand that is not constrained by lack of supply. From 2020, and excluding short-term manufacturing issues,

global buffer capacity is expected to be in line with Gavi's targets to mitigate potential risks of supply shortage.

Individual supplier risk: **Partially met.** Current HPV vaccine manufacturers are reliable and low-risk from a technical perspective.

NRA risk: **Met.** NRA risk is low with current manufacturers. New manufacturers are expected to provide further NRA diversity that carry moderate risk profiles so that the NRA risk is expected to remain low in the long-term.

Long-term competition: **Unmet.** One manufacturer supplies approximately 87% of the market volume. This market attribute may be partially met once new manufacturers enter the market.

Product innovation: **Partially met.** HPV9v is under review for prequalification.

Total systems effectiveness: **Unmet** with current vaccines at current price levels. HPV vaccines are safe, efficacious and cost-effective but many characteristics could be improved to positively impact TSE: lower cold chain requirements, improved HPV genotype coverage, and reduced vaccine costs; the price of a vaccination course (2 doses) is USD 9.0, the second highest among Gavi-supported vaccines. The potential efficacy of a 1-dose schedule is under clinical investigation.

Supply and Procurement Objectives

The supply and procurement objectives were analysed resulting in the following target outcomes:

- Manufacturers increase their supply to Gavi71 to ≥ 7 md in 2018 and ≥ 21 md in 2019.
- Manufacturers plan future supply output in line with Gavi operational forecasts.
- One new manufacturer supplies Gavi from 2021 and one other enters the market by 2023
- Gavi provides guidance on its desired target improvements for current vaccines and long-term strategy for new vaccines.
- The UNICEF-SD WAP/dose reaches its target value (confidential) for 2020 and for 2023.

Gavi's future market shaping exit conditions: Gavi will stop its market shaping efforts on HPV when demand trends are stabilized for Gavi71 countries, India and China, when three or more reliable suppliers are available and capable of meeting all country presentation preferences with a target buffer, and when prices are sustainable for Gavi-supported countries.

Supporting Stakeholder Action Plan

A concerted action plan ensures the coordination between Gavi Alliance stakeholders, designed to facilitate the achievement of the above supply and procurement target outcomes.

- UNICEF-SD's next procurement process for HPV vaccines will take place in 2018 for supply in 2019 and beyond.
- Independently of procurement activities, periodically engage with manufacturers to find solutions to mitigate supply constraints.
- Periodically review HPV market dynamics with manufacturers to ensure that manufacturers understand mid-term volume requirements and plan manufacturing accordingly.
- Mitigate risks associated to future potential market failures.
- Encourage pipeline manufacturers to develop candidate HPV vaccines that are appropriate for the Gavi market.
- Follow on-going 1-dose schedule evaluation by the global scientific community.
- Gavi partners define, agree, and prioritise the targets for improvements to HPV vaccines, including multi-dose vial preferences, controlled temperature chain (CTC) plans, cold chain volume preferences, and strategy for HPV vaccine improvements.