

Market & Supply Update

Human Papillomavirus (HPV) Vaccine

General Background

HPV vaccine is the first vaccine for the prevention of cervical cancer. The World Health Organization (WHO) recommends HPV immunization through regular vaccination of girls aged 9-13 years.

WHO prequalified HPV vaccine is currently only available from two manufacturers (see Table). The US Food and Drug Administration (FDA) recently also approved a 9-valent HPV vaccine. However, WHO has not yet assessed the acceptability, in principle, of this vaccine for purchase by United Nations agencies.

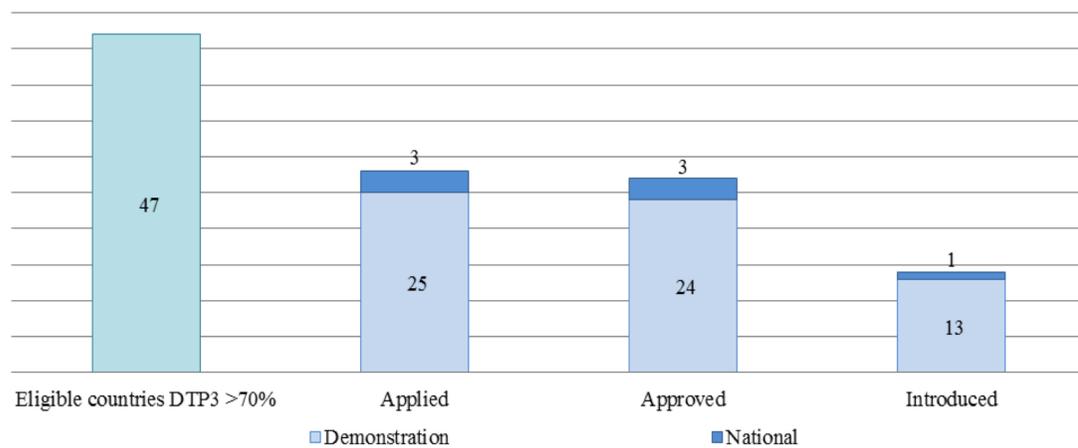
Since 2013, Gavi, the Vaccine Alliance, provides funding support for HPV vaccine introduction to eligible countries: Eligible countries with DTP3 coverage >70%, and demonstrated ability to deliver HPV vaccines to adolescent girls can apply for national introduction support. Countries lacking such experience can apply for support to conduct smaller-scale demonstration programs to gain the experience necessary to apply for national rollout.

For non-Gavi countries that self-finance their HPV vaccine purchases UNICEF has been exploring ways to secure affordable prices.

Current Market Situation

Gavi-Eligible and Graduating Country Demand

Gavi HPV Eligibility and Program Status (number of countries):



HPV vaccine delivery programs are still in their early stages with small-scale demonstration programs in most GAVI countries and only one country with nation-wide introduction. UNICEF estimates the total Gavi demand for 2013-2017 to reach 27.2 million doses. This estimate is lower than initially anticipated due to uncertainties inherent to HPV vaccine delivery in many countries, as well as delays in uptake and national introduction timings due to limited country programmatic readiness and competing priorities with other new vaccine introductions and public health programs. A recent WHO recommendation to reduce the HPV dosing schedule from 3 to 2 doses has contributed to further reduction. However, UNICEF anticipates the annual demand to increase significantly once Gavi demonstration programmes begin transitioning to nationwide introductions.

Gavi-Eligible and Graduating Country Supply

UNICEF has long-term arrangements with both manufacturers of WHO prequalified HPV vaccine for 3.5 million doses in aggregate at prices ranging from \$4.50/dose (Merck, 1-dose) to \$4.60/dose (GSK, 2-dose) to cover confirmed needs of Gavi-eligible countries for the period 2013-2017. The HPV vaccine quantity offered in response to a tender issued by UNICEF in 2012 is sufficient to cover the forecast needs. UNICEF has so far only awarded quantities to manufacturers based on confirmed demand and will make additional awards in 2015 and subsequent years as Gavi approves funding for new country applications to start national introductions or demonstration programmes. UNICEF anticipates that the supply for Gavi-eligible countries will continue to be unconstrained through 2017.

WHO prequalified HPV vaccines:

Vaccine Type:	Bivalent Human Papilloma Virus Vaccine (Types 16 and 18)	Bivalent Human Papilloma Virus Vaccine (Types 16 and 18)	Quadrivalent Human Papilloma Virus Vaccine (Types 6, 11, 16 and 18)
Manufacturer:	GSK (GlaxoSmithKline)	GSK (GlaxoSmithKline)	Merck Sharp & Dohme Corp
Vaccine Trade Name:	Cervarix	Cervarix	Gardasil
Country of Manufacture:	Belgium	Belgium	USA
Pharmaceutical form:	liquid	liquid	liquid
Presentation:	1 dose vial	2 dose vial. No preservative	1 dose vial
Route of administration:	intramuscular	intramuscular	intramuscular
Shelf life:	48 months at 2 - 8 °C	48 months at 2 - 8 °C	36 months at 2 - 8 °C
Cold Chain volume per dose (cm ³):	1 vial carton: 57.7 10 vials carton: 11.5 100 vials carton: 9.7	1 vial carton: 28.8 10 vials carton: 5.7 100 vials carton: 4.8	1 vial carton: 75 10 vials carton: 15

Non-Gavi Country Demand

Demand from self-funding middle income countries through UNICEF has so far been limited. UNICEF anticipates demand from these non-Gavi countries to reach 1 million doses for 2015 and expects future demand to increase as additional countries start HPV vaccine introductions.

Non-Gavi Country Supply

UNICEF supplies HPV vaccines to non-Gavi countries through a multi-year MIC New Vaccine tender, as well as other ad-hoc single-country tenders. To-date 3 countries have been supplied at least 1.49 million doses cumulative through UNICEF:

Manufacturer	Total Awards in Doses
Merck (USA)	1,488,960
GlaxoSmithKline (Belgium)	3,100
	1,492,060

Unlike most Gavi-supported countries, non-Gavi countries procuring through UNICEF self-finance the entirety of their HPV vaccine purchases. To date, non-Gavi countries have paid higher prices for HPV vaccine than Gavi-supported countries. The magnitude of this price differential is a growing concern for UNICEF and non-Gavi countries (as well as those countries graduating from Gavi support) since it might constitute a barrier to vaccine adoption in some countries or threaten the ability to maintain previously introduced HPV vaccines once countries graduate from Gavi support. UNICEF will continue to explore ways to secure more affordable prices for non-Gavi countries that self-finance their HPV vaccine purchases including thorough single-country tenders, pooled procurement, price referencing, and negotiation with manufacturers.

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