

# Human Papillomavirus Vaccine: Supply and Demand Update

UNICEF Supply Division

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## Human Papillomavirus Vaccine Supply and Demand Update - October 2020

This update provides information on human papillomavirus vaccine, including supply, demand, and pricing trends. It highlights continued supply constraints foreseen over 2020 and 2021, which also affects countries procuring through UNICEF. UNICEF requests self-financing middle-income countries to consolidate credible multi-year demand and to submit multi-year commitments through UNICEF.

### 1. Summary

- UNICEF's strategic plan for 2018-2021 seeks to ensure that at least 24 countries nationally introduce human papillomavirus (HPV) vaccine into their immunization programmes.<sup>1</sup> As of to date, 20 countries supplied through UNICEF, of which 15 supported by Gavi, the Vaccine Alliance (Gavi) and five countries having transitioned from Gavi support and self-finance their procurement, have introduced HPV vaccines since 2013. Fourteen middle-income countries (MICs) are also procuring HPV vaccines through UNICEF. From 2013 to 2019, UNICEF's total HPV vaccine procurement reached 30.9 million doses in support of girls. There is currently no gender-neutral programmes in countries supplied through UNICEF. Of the 30.9 million doses, UNICEF procured 28.3 million doses (91 per cent) for countries supported by Gavi, including those that transitioned from Gavi support and still access Gavi prices, and 2.6 million doses (9 per cent) on behalf of self-financing MICs.
- In December 2016, Gavi revised its programme strategy to support full-scale national HPV vaccine introductions with multi-age cohort (MAC) vaccinations. This substantially increased HPV vaccine demand through UNICEF from 2017. By July 2020, Gavi had approved applications from 27 countries for HPV vaccine national introduction and anticipates additional countries to submit applications in 2020/2021.
- Global HPV vaccine supply availability is currently insufficient to meet the aggregate demand. Consequently, HPV vaccine supply through UNICEF is also constrained and not sufficient to meet the increased requirements, which it projects could reach up to 45.5 million doses in 2021. As a result, countries introducing the vaccine with the support of Gavi will need to postpone their plans for MAC vaccinations. Self-financing MICs, for which UNICEF does not have a long-term arrangement (LTA) with suppliers, will not be able to access supply through UNICEF until supply availability improves with WHO's prequalification of pipeline vaccines.
- Currently, only two manufacturers have WHO prequalified HPV vaccines. On completion of the tenders issued by UNICEF in 2019 and 2020, UNICEF has established LTAs with Merck for Gavi supported countries and MICs from 2021 to 2025. An LTA was established with GSK for MICs from 2020 to 2023, and another one for Gavi supported countries and lower MICs (LMICS) from 2022 to 2025. Several manufacturers are developing HPV vaccines, including one licensed from Xiamen Inovax (China), which UNICEF anticipates could be WHO prequalified by 2021, in addition to two other candidates currently in phase three.
- HPV vaccination programmes use a mixture of schools, health facilities, and community outreach interventions in countries to ensure that they reach all adolescent girls. These programmes have been one of the most disrupted programmes due to the impact of COVID-19, which resulted in school closures and disruptions to routine immunization services. Many countries have had to postpone vaccinations until later in the year or move their programme approach to a health facility-based delivery strategy.
- HPV vaccine pricing remains high and varies significantly between different country income levels. Vaccine affordability is a concern for most self-financing MICs considering HPV introduction, as well as for many Gavi-supported countries seeking to sustain HPV vaccination once they transition from Gavi support and self-finance their HPV procurement.

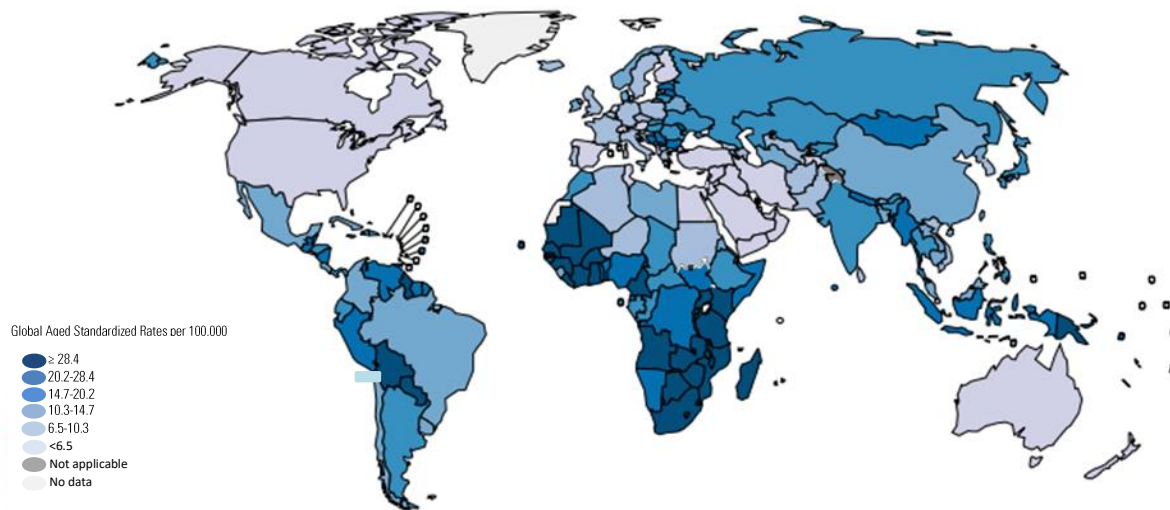
<sup>1</sup> United Nations, [Final Results Framework of the UNICEF Strategic Plan, 2018-2021](#), UN, New York, July 2017, p. 19.

## 2. General Brief and Background

Human papillomavirus is a group of more than 100 viruses, of which 14 can cause cancer. Nearly all cases of cervical cancer are attributed to HPV.<sup>2</sup> Cervical cancer is the second most common form of cancer in women living in less developed regions,<sup>3</sup> with an estimated 570,000 new cases a year resulting in an estimated 311,000 deaths. Eighty-five per cent of cervical cancer cases occur in low-income countries (LICs) and MICs, with sub-Saharan Africa and Asia accounting for the highest incidence rates.<sup>4</sup> Globally, two HPV strains (HPV-16 and HPV-18) cause about 71 per cent of all cases of invasive cervical cancer (Figure 1).<sup>5</sup>

The HPV vaccine is the first vaccine developed specifically targeting the prevention of cervical cancer. HPV vaccines do not prevent all forms of cervical cancer, and as such, they do not replace the need for cervical cancer screening. The World Health Organization (WHO) recommends countries to include HPV vaccination into national immunization programmes as part of a coordinated and comprehensive strategy that includes education, access to quality screening, and treatment. Immunization should primarily target girls aged 9 to 14 years of age, prior to becoming sexually active; and secondarily, to target girls aged 15 and above.<sup>6</sup> WHO recommends a two-dose schedule for girls aged 9 to 14 years, and a three-dose schedule for girls 15 years of age and above, in accordance with manufacturer guidance.<sup>7</sup>

Figure 1 WHO Age Standardized Rate Estimates for Cervical Cancer Incidence Worldwide - 2018



Source: World Health Organization

WHO has at present prequalified three vaccines from two manufacturers, which all protect against the main strains causing cervical cancer including HPV-16 and HPV-18 (Table 1).

Table 1 WHO Prequalified HPV Vaccines

Manufacturer	Type	WHO PQ	Formul	Vial	Shelf Life	VVM	Cold Chain Volume
GlaxoSmithKline (Belgium)	Bivalent	2009	Liquid	1 dose	60 months	Type 30	9.7 cm <sup>3</sup>
		2009	Liquid	2 dose	60 months	Type 30	4.8 cm <sup>3</sup>
Merck (USA)	Tetravalent	2009	Liquid	1 dose	36 months	Type 30	15.0 cm <sup>3</sup>
	Nonavalent	2018	Liquid	1 dose	36 months	Type 30	15.1 cm <sup>3</sup>

Source: World Health Organization

<sup>2</sup> World Health Organization, [Human Papillomavirus and Cervical Cancer](#), WHO, Geneva, January 2019.

<sup>3</sup> Ibid.

<sup>4</sup> International Agency for Research on Cancer, [Cervix Uteri](#), IARC, Lyon, 2018, p. 2.

<sup>5</sup> World Health Organization, [Human Papillomavirus Vaccines, WHO Position Paper](#), WHO, Geneva, May 2017, p. 244.

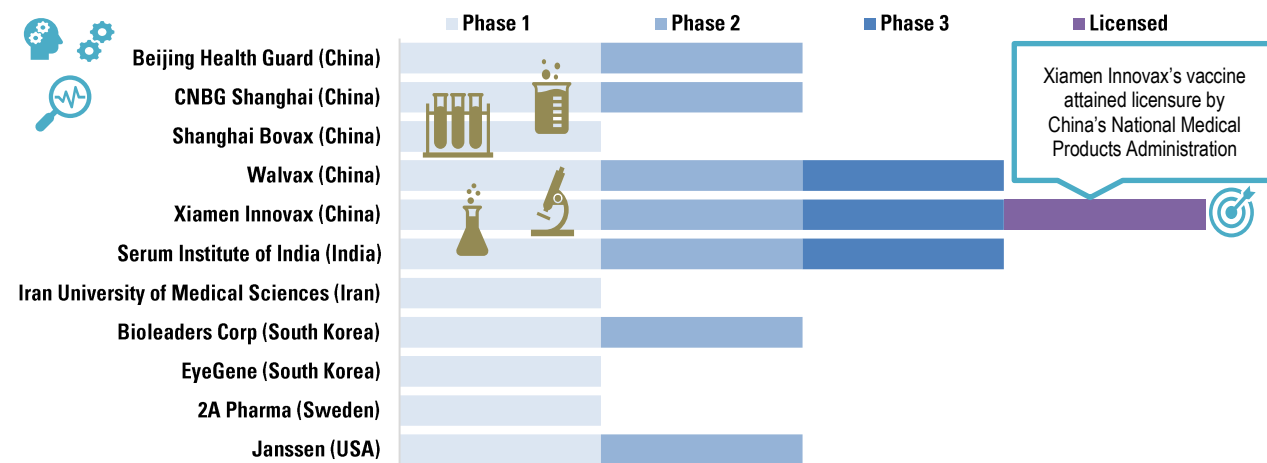
<sup>6</sup> Ibid., p. 266.

<sup>7</sup> Ibid., p. 249.

### 3. Innovation

There is currently only one other licensed HPV vaccine from Xiamen Innovax (China) that is not WHO prequalified and only for local markets, and which is currently undergoing WHO prequalification review.<sup>8</sup> UNICEF anticipates that the vaccine could be WHO prequalified by 2021. Several manufacturers are developing HPV vaccines, including tetravalent vaccines from CDIBP (China), Serum Institute of India, and Shantha Biotech (India),<sup>9</sup> as well as bivalent vaccines from Walvax (China), amongst others, all in different stages of development. Of the 27 new generation vaccine candidates under development that UNICEF is aware of, 60 per cent are in discovery or preclinical stage, with the other 40 per cent being in different phases of clinical development, including two candidates in phase 3 (Figure 2). The success of ongoing research and development efforts and the timelines for new products to reach the market will be critical to alleviate current supply constraints and improve market health. More information on some of the HPV vaccines targeting capsid antigens that are either licensed or in different stages of clinical trials can be accessed [here](#).<sup>10</sup>

Figure 2 Global HPV Product Pipeline - Non-exhaustive



Source: GVMM

PATH, an international, non-profit global health organization focusing on product, service, and system innovation, is coordinating a consortium of nine research institutions that are undertaking the evaluation of evidence for a possible single-dose HPV vaccination schedule. The Single-dose HPV Vaccine Evaluation Consortium, funded by the Bill and Melinda Gates Foundation (BMGF), whose main function is coordinating the research undertaken by members, is also reviewing the effectiveness of such a single-dose schedule to inform policy discussions, which will impact demand and supply requirements.<sup>11</sup>

### 4. Current Market Situation

As of September 2020, the value of the global HPV vaccine market was estimated to reach USD 1.869 billion (Figure 3, next page),<sup>12</sup> with some market reports estimating that it could reach USD 3.5 billion by 2025, based on an estimated compound aggregate growth rate (CAGR) of five per cent per year.<sup>13</sup> High-income countries (HICs) will make up most of this growth, as they represent approximately 78 per cent of the market value (Figure 3). Even though geographically the Americas represent currently 56 per cent of the value, most revenue increases are anticipated to come from the Asia Pacific region.

<sup>8</sup> Innovax, [NMPA Announce the Approval to Bivalent HPV Vaccine Type 16&18 \(Cecolin®\)](#), Innovax, Xiamen, December 2019.

<sup>9</sup> **Note:** Shantha Biotech became a subsidiary of Sanofi Pasteur in July 2009.

<sup>10</sup> Roden, Richard, Peter Stern, [Opportunities and Challenges for Human Papillomavirus Vaccination in Cancer](#), Nature Reviews Cancer, London, March 2018.

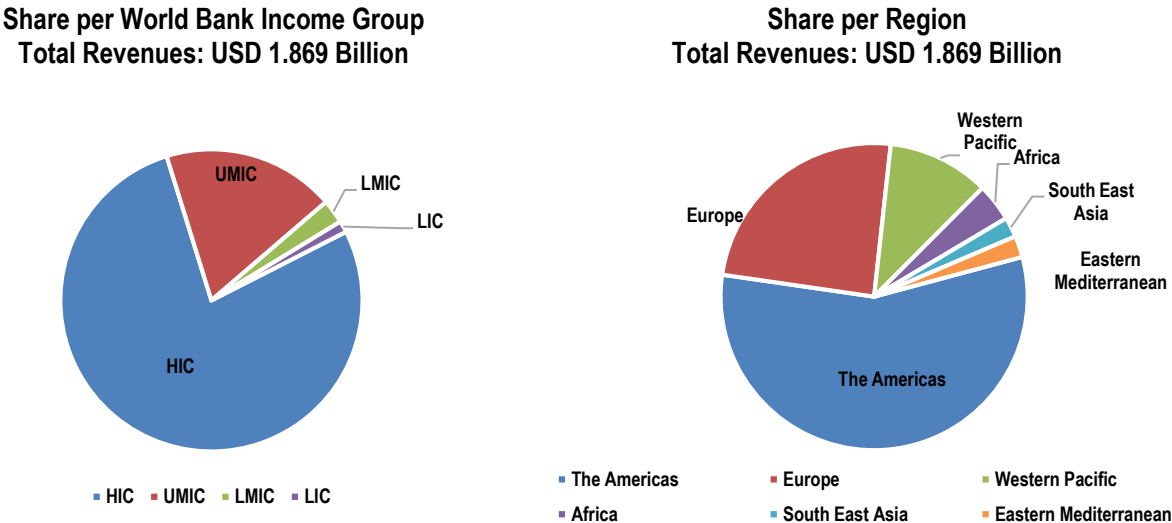
<sup>11</sup> PATH, [New Research Consortium to Evaluate Evidence for Single-dose HPV Vaccination](#), PATH, Seattle, January 2018.

<sup>12</sup> Linksbridge, [The Global Vaccine Market Model](#), Linksbridge, Seattle, 2020.

<sup>13</sup> Transparency Market Research, [Human Papillomavirus Vaccine Market-Global Industry Analysis, Size, Share, Growth, Trends, and Forecast 2017-2025](#), Transparency Market Research, Pune, March 2018.

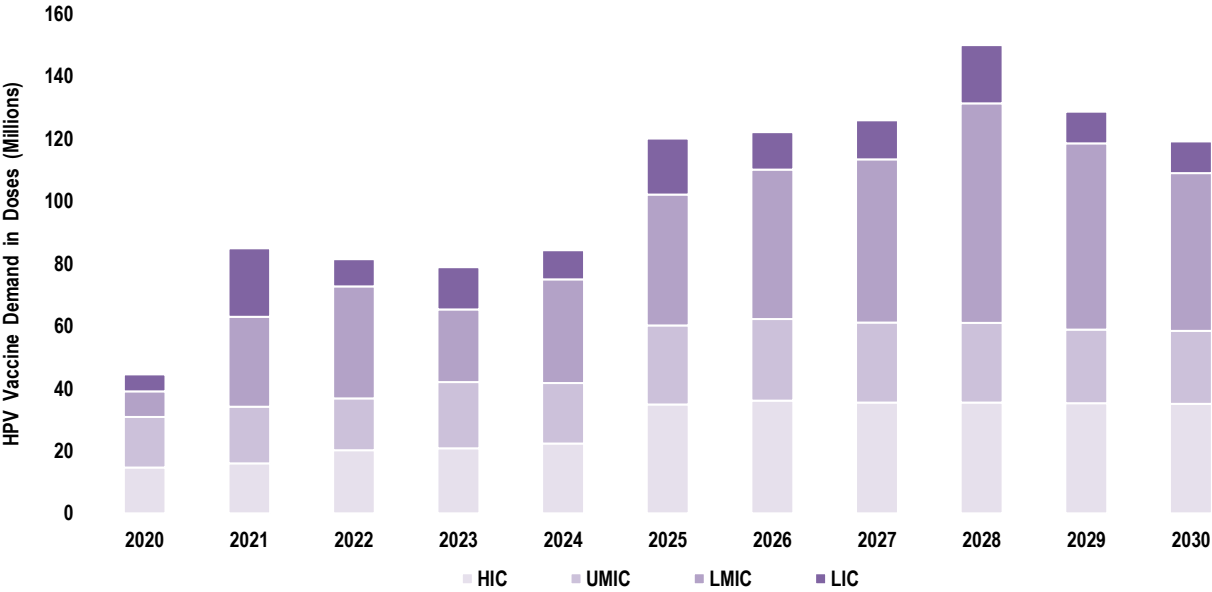
In 2020, the global market volume for HPV vaccines is anticipated to reach approximately 44.5 million doses (Figure 4),<sup>14</sup> having increased from an average of 30-35 million doses a year over 2010 to 2016,<sup>15</sup> representing an increase of 21 per cent over the past 4 years. HICs and upper middle-income countries (UMICs) will make up 69 per cent of the global market share, while LMICs and LICs account for 18 per cent and 12 per cent respectively. Currently, the estimated market share by volume is 23 per cent for bivalent, 52 per cent for tetravalent, and 25 per cent for nonavalent HPV vaccines.

Figure 3 HPV Total Market Value in USD as of September 2020



Source: GVMM

Figure 4 HPV Projected Global Demand by World Bank Country Income Group as of September 2020



Source: GVMM

Global country demand for HPV could increase substantially over the next ten years to possibly reach 120 million doses a year by 2030 (Figure 4). Some significant increases in demand will be due to the introduction of the vaccine in China and

<sup>14</sup> Linksbridge, *The Global Vaccine Market Model*.

<sup>15</sup> Gavi, the Vaccine Alliance, [Human Papillomavirus Vaccine Roadmap: Public Summary](#), Gavi, Geneva, December 2017, p. 1.

India, and the adoption of gender neutral immunization policies, as well as from the growing interest in preventing cervical cancer through immunization, spearheaded by WHO's global call to action to end cervical cancer, which remains one of the most frequent cancers in women.<sup>16</sup> However, as supply availability from manufacturers is constrained, and so UNICEF anticipates that it will not be sufficient to meet countries' demand through UNICEF in the near to medium term.

#### 4.1 Impact of COVID-19

Following the outbreak of COVID-19 and its effect on the airline industry, vaccine shipments and other critical deliveries have been heavily impacted due to the dramatic decline in available flights. The situation was further compounded by the lockdowns of receiving countries where airports were closed, which impeded UNICEF's ability to ship vaccines as per country and supplier shipment plans. Currently, the availability of commercial flights has been improving, although some destinations still remain difficult to access with limited flight and charter options available, in addition to country lockdown and airport closures. UNICEF is monitoring the situation daily. UNICEF considers land-transit options to ensure vaccines are delivered to countries, in addition to coordination with other aid agencies to consolidate shipment plans where feasible. Even though some costs have increased significantly, costs are starting to be more predictable. As flight options are increasing, UNICEF arranges special charters where vaccine shipments are being consolidated for multiple country delivery. Follow [@UNICEF](#) for updated tweets on deliveries.

Programmatically, HPV vaccination has been one of the most disrupted vaccines by the impact of COVID-19. HPV vaccines are delivered through a mixture of activities and strategies using schools, health facilities, and community outreach in countries to ensure that immunization programmes reach all adolescent girls. Routine immunization services have been disrupted in almost all countries (70 per cent of outreach and 60 per cent of facility-based services) due to country lockdowns. This includes the effects of health staff redeployments, the lack of personal protective equipment, and the reluctance of caregivers to access facilities. Countries have reported that there has been up to a 20 per cent drop in coverage rates.<sup>17</sup>

As of September 2020, although countries have started to intensify immunization services, and WHO issued guidelines on how to close immunization gaps and plan catch-up strategies,<sup>18</sup> UNICEF anticipates that it will take some time for many programmes to reinstate immunization services back to pre-pandemic levels. At the beginning of the pandemic, 192 countries closed their schools sending 1.6 billion students home. As of September 2020, 872 million students, or put another way, half of the world's student population in 51 countries, are still unable to go back to their classrooms.<sup>19</sup> Therefore, many countries that preferred using school platforms for the delivery of HPV vaccine have had to postpone vaccinations until later in the year, or move their programme approach to a health facility-based delivery strategy.

In addition, Mauritania, Sao Tome, and Sierra Leone have postponed their nationwide HPV vaccine introduction from 2020 to 2021. These disruptions and delays have resulted in postponing the delivery of approximately 5 million doses of HPV vaccine planned for 2020 to the first quarter of 2021.

#### 4.2 Overall HPV Demand through UNICEF

UNICEF's strategic plan for 2018-2021 includes a target to ensure that at least 24 countries introduce HPV into their national immunization programmes.<sup>20</sup> As of to date, 20 countries supplied through UNICEF, of which 15 supported by Gavi, and five countries that have transitioned from Gavi support and self-finance their procurement, have introduced HPV vaccines since the inception of Gavi's HPV programme in 2013. Fourteen MICs are also procuring HPV vaccines through UNICEF.

From 2013 to 2019, UNICEF procured 30.9 million doses of bivalent and tetravalent HPV vaccines for both Gavi-supported countries and self-financing MICs totalling USD 162.5 million.<sup>21</sup> In 2019, UNICEF procured twelve million doses at a value of USD 56.8 million, which represents a market share of approximately 27 per cent of the global volume and 2.7 per cent of the value. Countries have not yet procured any nonavalent vaccine through UNICEF to date (Figure 5, next page).

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<sup>16</sup> The International Papillomavirus Society, [WHO Is Calling for Global Action to End Cervical Cancer](#), IPVS, Geneva, May 2018.

<sup>17</sup> World Health Organization, [Pulse Survey on Continuity of Essential Health Services during the Covid-19 Pandemic](#), WHO, Geneva, August 2020, p. v.

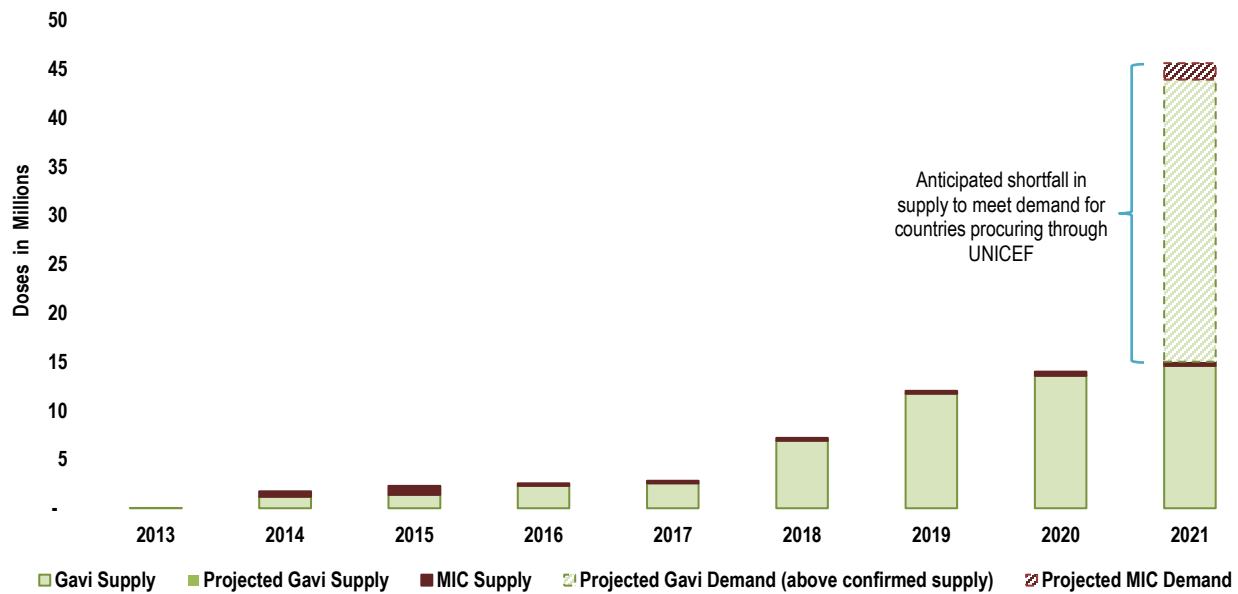
<sup>18</sup> World Health Organization, [Closing Immunization Gaps Caused by Covid-19](#), WHO, Geneva, August 2020.

<sup>19</sup> UNICEF, [ED Fore Remarks on New Back-to-School Safety Guidance](#), UNICEF, New York, September 2020.

<sup>20</sup> United Nations, [Final Results Framework of the UNICEF Strategic Plan, 2018-2021](#), p. 19.

<sup>21</sup> UNICEF, [Price Data Overview](#), UNICEF, Copenhagen, June 2020.

Figure 5 UNICEF HPV Supply and Projected Demand 2013-2021



Source: UNICEF Supply Division

UNICEF’s current total projected demand, which is based on Gavi’s 2019 strategic demand scenarios for 2020 and 2021 could reach up to 59.5 million doses, mostly (96 per cent) on behalf of Gavi-supported countries, with 13.9 million doses for 2020 and 45.5 million doses for 2021. However, based on suppliers’ indications on short-term supply availability, UNICEF was only able to secure 14 million doses for 2020 and 15 million doses for 2021, resulting in an anticipated shortfall of 30.5 million doses, which is more than half of the projected demand (Figure 5).

### 4.3 Gavi-supported Country Demand

Gavi country demand refers to the demand from the 73 countries that are either eligible for funding support through Gavi or have transitioned from Gavi support. Gavi has supported HPV vaccine introduction since 2012, and initially offered eligible countries two introduction pathways, either through small-scale demonstration projects, or by directly rolling-out national introduction.

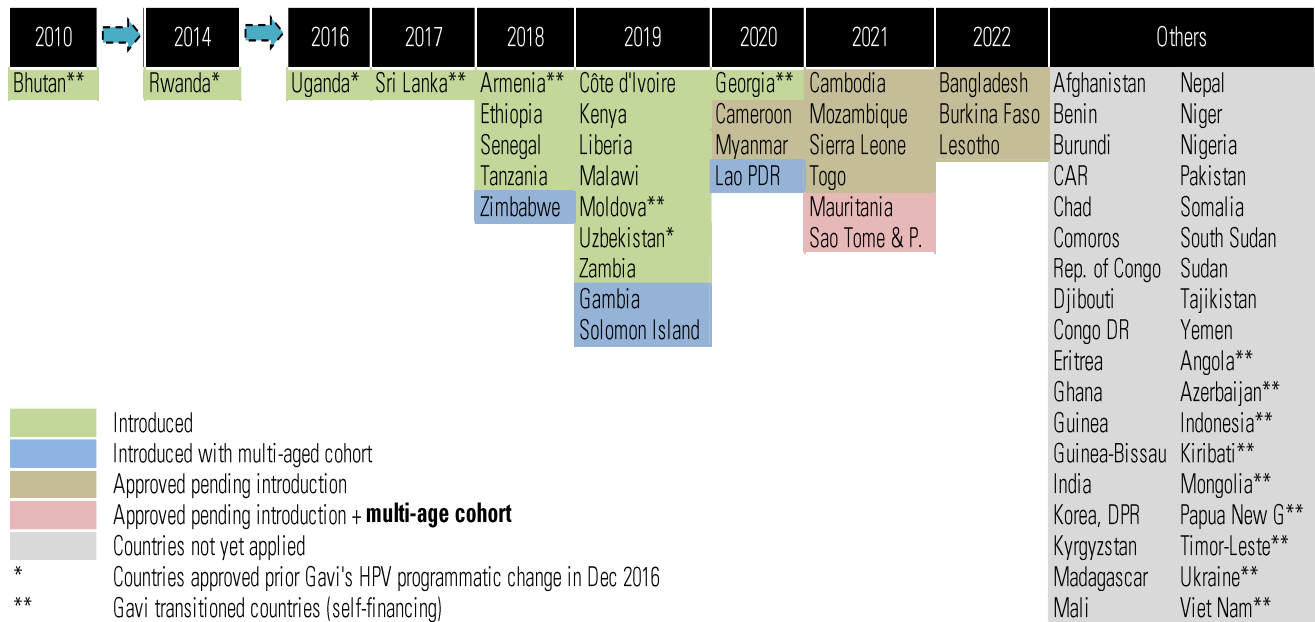
In December 2016, Gavi redesigned its HPV programme so that national introductions would no longer require prior evidence of experience in delivering HPV vaccines to adolescent girls. They also encouraged countries to immunize MACs from 9 to 14 years of age in the first year of their programme. Gavi estimates that up to 84 million girls could receive HPV vaccines between 2021 and 2025.<sup>22</sup>

As of September 2020, Gavi has approved 27 countries, of which 16 countries have introduced the vaccines, and 11 countries are pending introduction under the redesigned programme to support HPV vaccine introduction, including support for MACs in the first year of introduction (Figure 6, next page). The other countries: Armenia, Bhutan, Georgia, and Moldova introduced HPV after transitioning from Gavi support. Twenty-seven countries remain eligible to apply to Gavi for HPV support, but which have not yet done so, while nine countries having transitioned from Gavi support are yet to make a decision on HPV introduction.

UNICEF anticipates total unconstrained HPV vaccine country demand for Gavi-supported countries could reach up to 43.5 million doses in 2021, which includes MACs, but also previous MAC vaccination deferrals combined with additional country applications in 2019 to 2020 (Figure 5).

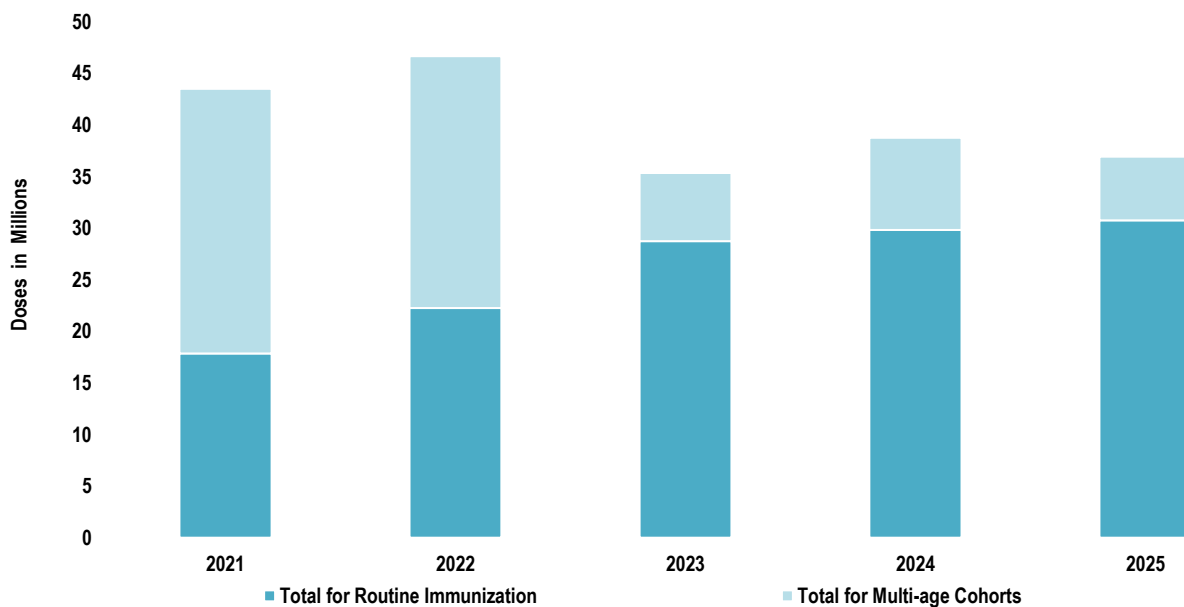
<sup>22</sup> Gavi, The Vaccine Alliance, [HPV Vaccine Manufacturers Commit to Provide Enough Supply to Immunize at Least 84 Million Girls in Gavi Countries](#), Gavi, Geneva, June 2020.

Figure 6 HPV Gavi Country Introduction Status through UNICEF 2020



Source: UNICEF Supply Division

Figure 7 Unconstrained UNICEF HPV Projected Demand 2021-2025 (Excluding India, Indonesia, and PAHO)



Source: Gavi

Manufacturers only allocated a limited supply of HPV vaccine to Gavi eligible countries of 13.58 million doses for 2020, which is only sufficient to support the existing programmes in 18 countries, and the introduction of HPV vaccines for routine immunization in an additional four countries in 2020. To date, four countries have introduced HPV with a MAC strategy and an additional two countries will introduce by 2021. In the context of limited HPV vaccine supply, WHO's Strategic Advisory Group of Experts (SAGE) on Immunization recommends that:



“all countries should temporarily pause implementation of boy, older age group (>15 years) and MAC HPV vaccination strategies until vaccine supply allows equitable access to HPV vaccine by all countries”.<sup>23</sup>

Therefore, until supply availability improves, future Gavi-supported MAC will be deferred. UNICEF anticipates that beyond 2020, Gavi supported demand through UNICEF could average at approximately 40 million doses a year over 2021-2025, depending on vaccine supply availability from manufacturers to support vaccine introduction and MAC campaigns (Figure 7, previous page).

#### 4.4 Gavi-supported Country Supply

UNICEF’s last HPV vaccine tender for Gavi supported countries secured supply to enable HPV demonstration projects and national introductions by establishing two five-year LTAs with two manufacturers covering 2013-2017. During this period, UNICEF procured 10.4 million doses of HPV vaccine for Gavi-eligible countries. As the demand from countries did not materialize in line with the level originally anticipated, manufacturers curtailed their production capacity through UNICEF to reflect its actual level. The increase in HPV vaccine demand, following Gavi’s HPV vaccine programme redesign, has now surpassed total supply availability from both manufacturers.

UNICEF extended its current LTAs with both manufacturers based on confirmed supply availability. UNICEF extended its LTA with Merck to 2020 and GSK to 2022, as well as having increased the total number of awarded doses for the period 2013-2022 to 42.7 million doses, from 14.3 million by 28.3 million doses (Table 2).

**Table 2 UNICEF HPV Vaccine LTA Awards for Gavi-Eligible Countries 2013-2022**

Manufacturer (Country)	Type	Price per Dose	LTA Duration	LTA Duration	Dose Increase	Total Awards
GSK (Belgium)	Bivalent	USD 4.60	10 years	2013-2022	2,320,000	4,830,660
Merck (USA)	Tetravalent	USD 4.50	8 years	2013-2020	26,000,000	37,822,820
<b>Total</b>					<b>28,320,000</b>	<b>42,653,480</b>

Source: UNICEF Supply Division

Whereas UNICEF had previously made incremental awards to manufacturers during 2013-2016 based on the forecast demand of approved country programmes, UNICEF’s limited awarded quantities in 2017-2022 were based on manufacturers’ supply availability. Those countries that have transitioned from Gavi support and now have to self-finance their vaccine procurement (i.e. Armenia, Bhutan, Georgia, Moldova, and Sri-Lanka) can access HPV vaccines at the prices for Gavi-eligible countries and supply through UNICEF’s LTA awards with manufacturers for Gavi-eligible countries subject to the agreement of the manufacturer.

In December 2019, UNICEF launched a tender for Gavi supported and transitioned countries as well as for MICs to secure supply for ongoing routine immunization programmes, routine introductions, and MACs. Two five-year LTAs were established with two manufacturers covering 2021-2025 for Gavi supported and transitioned countries (Table 3).

The awarded supply for 2021-2025 will not be sufficient to meet the demand forecast and MAC vaccinations in countries that will be introducing national programmes in 2018-2021 and may need to be postponed. With WHO’s prequalification pipeline of vaccines, supply availability should improve by 2022/2023, but it will be equally dependent on countries’ product preferences. UNICEF encourages countries that are considering applying to Gavi for HPV vaccine support, to do so nevertheless, bearing in mind that there could be a 24-month lead time for vaccine delivery. Besides encouraging countries to plan their introduction timing accordingly, it also signals ‘confirmed’ demand to manufacturers.

**Table 3 UNICEF HPV Vaccine LTA Awards for Gavi-Eligible and Transitioned Countries 2021-2025**

Manufacturer (Country)	Type	Price per Dose	LTA Duration	First Supply Availability	Total Awards
GSK (Belgium)	Bivalent	USD 5.18*	5 years	Q4 2022	17,300,000
Merck (USA)	Tetravalent	USD 4.50	5 years	Q1 2021	91,500,000
<b>Total</b>					<b>108,800,000</b>

Source: UNICEF Supply Division

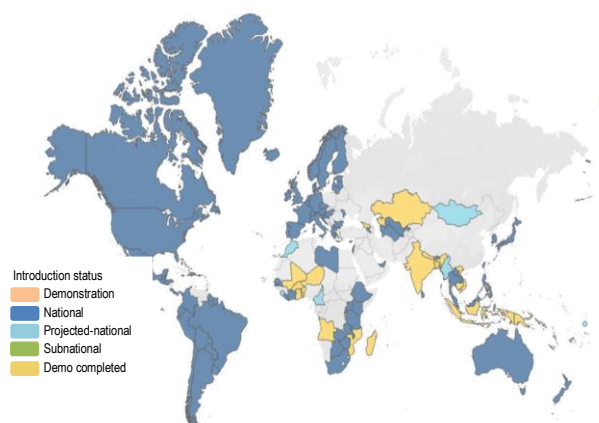
**Note** \*: This price takes effect from 2022.

<sup>23</sup> World Health Organization, [Meeting of the Strategic Advisory Group of Experts on Immunization, October 2019: Conclusions and Recommendations, No 47](#), WHO, November 2019, p. 550.

## 4.5 Middle-income Country Demand and Supply

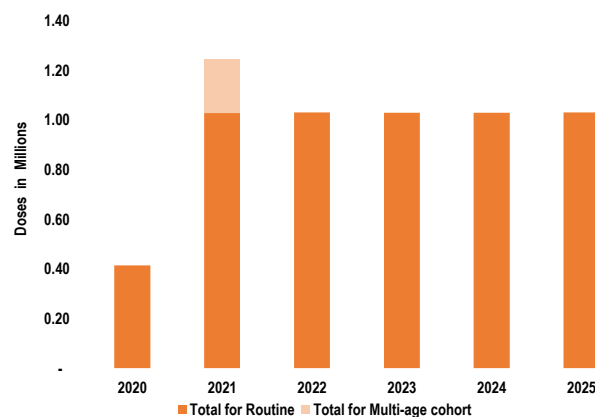
As of mid-year, 2020, 131 countries and territories currently have HPV vaccine in their national schedules. Most of these countries are HICs and UMICs, with many LICs and LMICs not yet having introduced the vaccine (Figure 8). Some MICs that are not eligible for Gavi support and self-finance their HPV vaccines procurement, channel their procurement through UNICEF. Since 2013 through to the end of 2019, UNICEF procured 2.6 million doses on behalf of eight countries and territories not supported by Gavi or eligible to access Gavi prices through ad-hoc tenders and an LTA established for several countries (Cook Islands, Fiji, the Maldives, Peru, the Philippines, Seychelles, Turkmenistan, and Vanuatu).

Figure 8 Status of HPV Vaccine Country Introductions Worldwide 2019



Source: PATH

Figure 9 HPV Projected Demand from MICs Indicating Interest to Procure through UNICEF 2020-2025



Source: UNICEF Supply Division

UNICEF launched tenders in December 2019 and June 2020 to secure supply for MICs, which concluded with UNICEF issuing two LTAs with two manufacturers to secure supply for 14 MICs (Table 4).

Table 4 UNICEF HPV Vaccine LTA Awards for Middle Income Countries 2020-2025

Manufacturer (Country)	Type	Vaccine Price Range per Dose	LTA Duration	Total Awards
GSK (Belgium)	Bivalent	USD 10.25 - 14.14	2020-2023	236,370
Merck (USA)	Tetravalent	USD 14.34 - 26.75	2021-2025	1,840,000
<b>Total</b>				<b>2,076,370</b>

Source: UNICEF Supply Division

Several MICs have approached UNICEF to secure supply for introduction of HPV vaccine, but due to the constrained supply availability globally and through UNICEF, UNICEF may not be able to meet requests through 2020 from countries that do not have LTAs in place (Figure 9). UNICEF anticipates based on WHO's prequalification pipeline of vaccines from 2021, that there should be additional supply to meet the demand requirements from MICs. UNICEF recommends all countries to forecast their HPV vaccine requirements for the next five years and make multi-year commitments to facilitate UNICEF's engagement with manufacturers to secure supply through 2021 and beyond.

## 4.6 Pricing

Most countries considering HPV introduction, as well as those seeking to sustain HPV coverage after they transition from Gavi support, and have to self-finance their HPV procurement, are concerned about the high level of HPV vaccine pricing. Both GSK and Merck have agreed with conditions and for a limited timeframe, to continue to provide countries that have transitioned from Gavi support with vaccines at the same prices they accessed when supported by Gavi (Table 2).<sup>24</sup> However, prices offered by manufacturers to MICs that self-finance their HPV vaccine purchases through UNICEF have been

<sup>24</sup> Gavi, the Vaccine Alliance, [Vaccine Price Commitments for Countries Transitioning Out of Gavi's Financial Support](#), Gavi, Geneva, November 2016.

significantly higher, and have ranged from USD 10.25 to USD 31.50 (Table 5). These prices represent between two and half to seven times the lowest price offered to Gavi-supported countries at USD 4.50.<sup>25</sup>

Table 5 UNICEF Middle-income Country HPV Vaccine Procurement 2013-2019

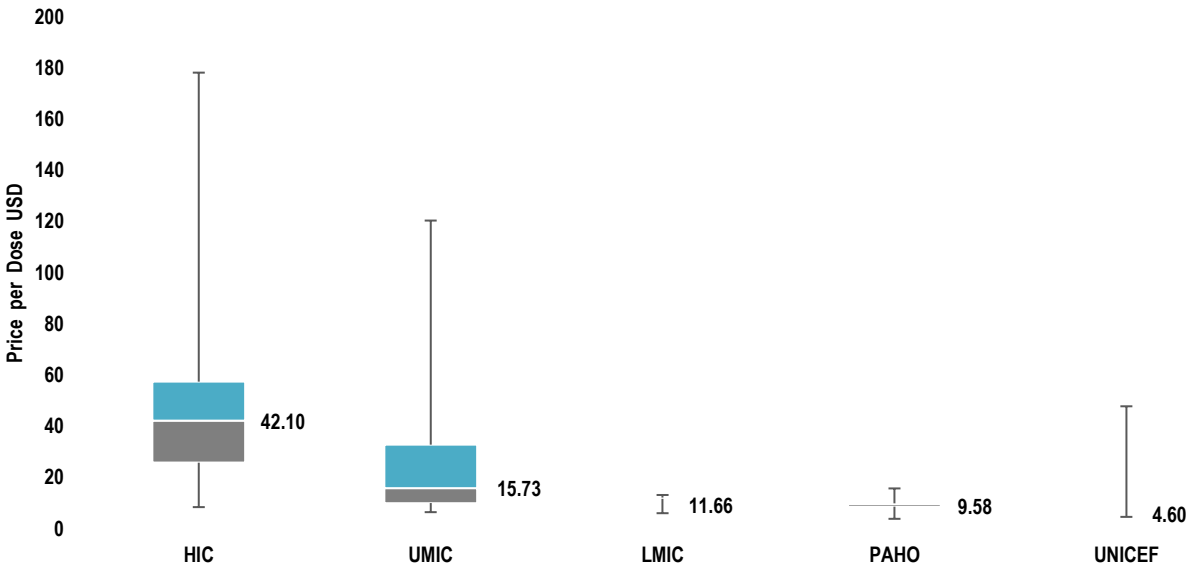
Vaccine	Manufacturer	Vaccine Price Range per Dose	Total Award in Doses
HPV	GSK (Belgium)	USD 10.25 - 31.50	8,800
HPV	Merck (USA)	USD 11.64 - 25.00	2,626,440
<b>Total</b>			<b>2,635,240</b>

Source: UNICEF Supply Division

Beyond procuring through UNICEF, Figure 10 highlights the notable variance in prices per dose offered to countries in different income classification tiers, as well as to countries in the same tier, and which is a growing concern for UNICEF and countries.<sup>26</sup> UNICEF advises self-financing MICs seeking to procure through UNICEF to forecast and plan their demand, and to consider longer-term commitments to achieve more affordable prices. Manufacturers may offer improved pricing and secure availability if the needs for vaccines are identified, planned, budgeted, and secured against longer timeline procurement commitments.

Through the establishment of multi-year commitments with countries to procure HPV vaccines through UNICEF for 3-5 years and UNICEF pooling the procurement on behalf of small countries, UNICEF negotiated LTAs with the suppliers to secure doses and a price reduction of 10.2 per cent and 55 per cent for three countries. In absence of a critical mass of demand from self-financing MICs based on country multi-year commitments, UNICEF was nevertheless able to negotiate tangible price-reductions with manufacturers resulting in savings that may be used to further strengthen routine immunization programmes and to immunize more children.

Figure 10 HPV Price per Dose Ranges per Income Group 2020 Showing Median Price <sup>27</sup>



Source: Source: MI4A: Market Information for Access to Vaccines, UNICEF Supply Division

<sup>25</sup> UNICEF has recently started to publish vaccine prices it procures on behalf of middle-income countries (MICs), including for HPV, see UNICEF, [Price Data Overview](#). UNICEF publishes detailed pricing as part of its Influencing Markets strategy, and broader commitments to wider information and price transparency, recognizing that the free flow of information and correcting information asymmetry is critical to underpin efficient markets.

<sup>26</sup> World Health Organization, [Vaccine Product, Price and Procurement \(V3P\) Web Platform](#), WHO, Geneva, March 2018.

<sup>27</sup> UNICEF uses a “box and whisker” chart to show data distributed per quartile. It highlights price data and ranges in sections each containing 25 per cent. The blue and black box spans the interquartile range showing 50 per cent of the price data, with the median price (called out) marked by a vertical line inside the box separating the two shaded halves, each containing 25 per cent of the data. The “whiskers” show the minimum and maximum price ranges of the data set. Looked at overall, the chart shows you the spread of a product’s price range per country income classification tiers.

## 5. Healthy Market Framework

The Bill and Melinda Gates Foundation, Gavi, and UNICEF, developed the Healthy Markets Framework (HMF).<sup>28</sup> The HMF is a tool to support market shaping and is used to assess and articulate a market's current and desired future state. UNICEF and partners use it to identify a set of attributes that measure the health of a particular market; to provide a process to value it specifically for vaccines; and to provide a framework to describe its desired healthy state. The Bill and Melinda Gates Foundation, Gavi, and UNICEF analysed the HPV vaccine market in 2017 (Figure 11).<sup>29</sup>

Figure 11 Application of the Health Market Framework to HPV Vaccine Market

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

The HMF rates the HPV market health as being low. Four of the eight attributes are rated as unmet: i. supply meets demand, ii. country preferences, iii. buffer capacity, and iv. total systems effectiveness. Three attributes are rated as partially met: i. individual supplier risk, ii. long-term competition, and iii. product innovation, and one attribute is rated as met: national regulatory authority risk. Overall, the assessment based on the HMF indicates a low state of market health. UNICEF anticipates it will evolve towards a moderate state of health by 2024 with the entry of new suppliers and additional capacity from existing suppliers.

Source: Alliance Supply and Procurement Roadmap 2017

## 6. Issues and Challenges

- Short to medium-term supply to support new HPV introductions in Gavi-supported countries and MICs interested in channelling their procurement through UNICEF for currently prequalified vaccines remains constrained. UNICEF anticipates that newly WHO prequalified vaccines possibly available from 2021, together with increasing availability from existing manufacturers in the medium term, could improve the availability of supply by 2022/2023. However, supply availability will be equally dependent on country product preferences. MACs may need to be delayed, which could lead to further loss of eligible cohorts. One supplier, currently supplying 95 per cent of UNICEF's supply, dominates the HPV vaccine market (Table 2), which represents a risk for supply security and competition. UNICEF anticipates new market entrants with WHO prequalified products from 2021 will help to diversify the supplier base.
- The limited visibility on medium- or long-term demand from self-financing MICs through UNICEF disincentivizes manufacturers from offering, planning, and securing, sufficient supply availability at more affordable prices in response to UNICEF tenders.
- Current HPV vaccine pricing levels and variances also remain a significant concern for countries to budget the necessary funding for long-term sustainable financing of HPV programmes.

## 7. Steps Forward

UNICEF will prioritise the following actions to achieve a healthy and sustainable market for all countries:

- UNICEF will work with Gavi, partners, and countries to adjust short- and medium-term plans for routine and MAC introductions in line with the timing of supply availability communicated by manufacturers.
- It will work with manufacturers of WHO prequalified products to review their production scale-up plans and supply lead times to deliver HPV vaccine for new country introductions, as well as to encourage potential new market entrants and pipeline suppliers to meet future demand at affordable prices.
- It will also collaborate with countries, partners and suppliers to improve access to affordable HPV vaccine supply for MICs, and to increase the transparency of prices secured for MICs. UNICEF will seek greater clarity on MIC requirements to provide industry with better visibility and predictability on the evolution of demand.

<sup>28</sup> Gavi, the Vaccine Alliance, [Markets Shaping](#), Gavi, Geneva, May 2017.

<sup>29</sup> Gavi, the Vaccine Alliance, [Human Papillomavirus Vaccine Roadmap: Public Summary](#), Gavi, Geneva, December 2017, p. 2.

- For self-financing MICs that wish to channel their procurement through UNICEF, UNICEF will engage with them to consolidate credible multi-year HPV vaccine demand and encourage countries to submit multi-year commitments through UNICEF.
- UNICEF will also engage with manufacturers to explore and develop innovative and flexible contractual modalities and financing mechanisms to secure access to multi-year HPV vaccine supply for MICs.

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Other UNICEF information notes can be found at: <https://www.unicef.org/supply/market-notes-and-updates>

UNICEF issues market and information notes on products and supplies that are essential for the needs of children, and by extension their families. While some products are easily available and affordable, the availability of others can be limited, or in some instances, non-existent in the quality and price required. UNICEF places a strategic focus on these supplies to shape healthy markets. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, competitive market landscapes, and product quality that is fit for purpose and in the right form for children.