Market Update

Human Papillomavirus Vaccine (HPV)

Vaccine Industry Consultation 2017
Outline

• Context
• Market analysis
• Demand Forecast
• Issues and Challenges
• Way forward
Cervical Cancer is the second most common form of cancer in women, with an estimated 528,000 new cases a year, resulting in 266,000 deaths.

Prevalence of HPV is 11.7% worldwide by 31st March 2017; 71 countries had introduced HPV vaccine in their national immunization programme globally.

There are two Human Papillomavirus (HPV) Vaccine strains (type 16 and 18) that cause about 70% of all cases of invasive cervical cancer, with type 16 having the greatest potential to cause tumour development.

The HPV vaccine is the first to be developed specifically targeting the prevention of cervical cancer. However, as HPV vaccines do not prevent all forms of cervical cancer, WHO recommends ensuring cervical cancer screening.

WHO recommends HPV immunization through the regular vaccination of girls aged 9-14 years in countries that identify cervical cancer prevention as a priority.
WHO Prequalified HPV Vaccines

- WHO prequalified HPV vaccines are available from two manufacturers, one in a bivalent form - preventing against two strains of HPV, and the other in a tetravalent form - preventing against four strains of HPV.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Type</th>
<th>WHO PQ</th>
<th>Formul.</th>
<th>Vial</th>
<th>Shelf Life</th>
<th>VVM</th>
<th>Cold Chain Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline (Belgium)</td>
<td>Bivalent</td>
<td>2009</td>
<td>Liquid</td>
<td>1 ds</td>
<td>48 months</td>
<td>Type 30</td>
<td>57.7 cm³</td>
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<tr>
<td>Merck (US)</td>
<td>Tetravalent</td>
<td>2009</td>
<td>Liquid</td>
<td>1 ds</td>
<td>36 months</td>
<td>Type 30</td>
<td>75.0 cm³</td>
</tr>
</tbody>
</table>

Source: WHO.

- HPV vaccine (9-valent) manufactured by Merck, has not been prequalified by WHO.
- WHO recommends a 2-dose schedule for girls under 15 years of age with an interval of at least six months between the first and second dose.
Gavi-Eligible and Middle Income Countries

- Gavi has been supporting HPV vaccination since 2012 but the pace of national introductions by September 2016 was slower than anticipated and demand 2013-2016 has not materialized as expected/planned.
- 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).
- Gavi’s revised HPV multi-age cohort programme aims to reach 40 million girls by 2020 and help avert 900,000 deaths, excluding potential herd effects.
- In 2013, UNICEF began procuring HPV vaccines for Gavi-supported programs and on behalf of self-financing middle-income countries (MICs).
- Following an international tender invitation in late 2012, UNICEF established LTAs with both manufacturers of WHO pre-qualified HPV vaccines for supply to Gavi-supported programs during the period 2013-2017.
- Initial awards were made against confirmed country demand. Additional incremental awards were made during the tender period as new country demand materialized and approval/timing for further introductions was confirmed.
- Demand from self-funding countries through UNICEF has so far been irregular → ad hoc tender invitations were issued in the absence of LTAs → (LTA for one MIC in place from 2017).
- Gavi, UNICEF-SD and partners agreed in 2017 to extend the current LTAs and delay the next tender to 2018 to allow insight from 2017 country applications and introductions to be integrated in the tender characteristics.
Historical procurement of HPV vaccines through UNICEF
HPV Programme update - 2013 to date

![Graph showing the status of HPV programmes from 2013 to date.](image-url)
HPV Healthy Market Analysis

- Supply does not meet demand for Gavi71 demand during two to three years 2017-2019.
- Due to supply constraint in the short-term, there is corresponding product-specific supply shortage.
- In the short-term, global buffer capacity is affected; expected to be above 33% from 2020.
- Both supplier are reliable and therefore, low-risk manufacturers from a technical perspective.
- NRA risk is considered low with current manufacturers.
- TSE is unmet with current vaccines at current price levels: HPV vaccines are safe, efficacious and cost-effective but HPV genotype coverage could be improved.
- In terms of long term competition, the current demand and supply for Gavi-supported countries is 95-100% dominated by HPV4.
- HPV9v is under review for prequalification and likely to be available to Gavi countries from 2019/2020.
Demand Forecast – Gavi Market

- Country applications for full national program implementation, in addition to catch-up campaigns for up to five age cohorts (to age 14).
- The first round of applications was in January 2017, the second round in May 2017 and a third round of applications in September 2017.
- Country preferences for HPV9 expressed in applications and reviews.
- Review the evolution of HPV demand in countries that previously initiated HPV programs.
Issues and Challenges

• Delay in country introductions.
• Demand uncertainty affecting market confidence.
• HPV vaccine price remains a concern for countries that are considering the long-term sustainability of financing programs for both self-financing and Gavi-graduating countries.
• Higher prices and uncertain financing further creates uncertainty in demand.
• Long delivery lead time.
• Lack of long-term demand visibility and industry response to the MICs new vaccine tender did not allow for the establishment of such.
Way forward

• Working with both current manufacturers to review their production plans and supply lead times for new HPV vaccine introductions.

• Encourage pipeline suppliers to meet future demand at affordable prices to support sustainable HPV programmes in countries.

• Extended the current LTAs through 2018 and secure the maximum offered supply.

• Issue new tender during Q1 2018 to cover the period beginning 2019 and beyond.