Pre-Tender Consultation: Human Papilloma Virus (HPV) vaccine

Vaccine Industry Consultation
September 2019
20 countries and 4 territories have gender-neutral vaccinations schedules.

Initiatives that will impact global demand:
• WHO Cervical Cancer elimination goal
• Adoption of gender-neutral vaccination by High Income Countries (HICs)

UNICEF Strategic Plan
• Young People’s Agenda
• 24 Gavi countries have introduced HPV vaccines into their national immunization programme by 2021

By end of 2019, 24 countries (Gavi and MICs) will have introduced HPV vaccination into their national immunization programme with procurement through UNICEF.

Background

HPV Global Introduction Status 2019

- Introduced into National Program: 121 countries & territories (48%)
- Planning Introduction by end of 2021: 37 countries & territories (15%)
- No decision: 94 countries & territories (37%)

Source: PATH August 2019
Gavi opened funding window for HPV vaccine

Tender launched

LTAs for Gavi countries established

WHO recommended 2-dose schedule

Redesign of HPV programme approved by Gavi Board

Demo: 23 countries National: 3 countries

LTA established covering demand of 1 MIC

19 Gavi countries approved for routine and multi-age cohorts vaccination (introduction dates between 2018 – 2021)

Supply insufficient to meet demand

Shortfall in supply

19 Gavi countries approved for routine and multi-age cohorts vaccination (introduction dates between 2018 – 2021)
## HPV Gavi Country Introduction Status Procuring through UNICEF

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<tbody>
<tr>
<td>2010</td>
<td>Bhutan**</td>
<td>Rwanda*</td>
<td>Uganda*</td>
<td>Sri Lanka**</td>
<td>Armenia**</td>
<td>Malawi</td>
<td>Sierra Leone</td>
<td>Mozambique</td>
<td>Afghanistan</td>
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<td>2014</td>
<td>Ethiopia</td>
<td>Zambia</td>
<td>Myanmar</td>
<td>Togo</td>
<td>Angola</td>
<td>Lesotho</td>
<td>Azerbaijan</td>
<td>Madagascar</td>
<td>Bangladesh</td>
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<td>2016</td>
<td>Senegal</td>
<td>Solomon Island</td>
<td>Cameroon</td>
<td>Benin</td>
<td>Mongolia</td>
<td>Burkina Faso</td>
<td>Nepal</td>
<td>Burundi</td>
<td>Niger</td>
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<td>2017</td>
<td>Zimbabwe</td>
<td>Cote D’Ivoire</td>
<td>Ghana</td>
<td>Kenya</td>
<td>Lao PDR</td>
<td>Liberia</td>
<td>Mauritania</td>
<td>Moldova</td>
<td>Uzbekistan*</td>
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<td>2018</td>
<td><strong>Self-financing countries (carried out demo with Gavi funding except Bhutan)</strong></td>
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**Notes:****
- Countries that were approved prior to the change in Gavi's HPV programme in Dec. 2016
- Self-financing countries (carried out demo with Gavi funding except Bhutan)
2-dose Base Demand Forecast for Gavi Countries (excludes India and Indonesia)

- **Predictable**: Approved countries that have introduced and will be introducing between 2019 and 2021
- **Likely**: Countries that have indicated an interest to apply in 2019 - 2021
- **Possible**: Limited intelligence on their application dates

![Graph showing doses in millions from 2021 to 2030 for different categories: Predictable - Routine, Predictable - MAC, Likely - Routine, Likely - MAC, Possible - Routine, Possible - MAC, and 1-dose base.](image-url)
Assumptions for 2-dose Base Demand Forecast

- Introduction dates based on information from HPV partners except for Nigeria
- Unconstrained supply from 2021
- MACs phased over 2 years for countries with cohorts >5M, MACs completed in 1 year for cohorts <5M
- MACs at 9 year olds assumed to lose a cohort for each year of delay
- Coverage proxy based on DTP1 and DTP2 coverage for 1\textsuperscript{st} and 2\textsuperscript{nd} dose. A 0.5% increase is assumed each year until a maximum of 95% for 1\textsuperscript{st} dose and 93% for 2\textsuperscript{nd} dose or a historic high if above these values.
- Routine in school – 85% of proxy; routine out of school – 50% of proxy; MAC: 75% of routine coverage.
- Wastage: 5%
- Coverage source: WUENIC
- Program progression: Y1: 110%, Y2: 110%, Y3: 85%, Y4: 85%, Y5: 95%
- Population: Country estimates projected forward assuming UN growth rates
Indicated Demand Forecast for MICs Through Annual Forecast

- Based on UNICEF annual forecast and indications from countries
- Countries
  - Turkmenistan: LTA in place for 2017 – 2020
  - Pacific Island Countries: Cook Islands, Fiji, Nauru, Niue, Samoa, Tokelau, Tonga, Tuvalu, Vanuatu (routine and MAC)
  - Maldives (Routine and MAC)
  - Botswana (Routine)
  - Seychelles (Routine)
  - Morocco (Routine)
  - Namibia (Routine)
  - Eswatini (Routine and MAC)
Challenges

Supply is constrained in the medium term for Gavi countries and MICs. UNICEF seeks to secure sufficient supply of HPV vaccine in the medium term.

Changes in demand with the possibility of a one-dose schedule from 2023.

Near monopolistic market thus UNICEF plans to improve the supplier base.

HPV vaccine pricing levels and variances remain a significant concern for countries thus UNICEF is seeking price improvements.

Accelerate introduction of HPV in MICs in line with UNICEF strategic plan. UNICEF will provide long-term demand forecast visibility for MICs, including pooling of demand by 2020. Engage with suppliers to develop innovative and flexible contractual modalities and financing mechanisms to secure supply for MICs.
Tender Objectives and Duration for Gavi Market

UNICEF will launch a tender in Q4 2019 to secure sufficient supply of HPV vaccines for Gavi supported countries for 2021 and beyond.

Tender Objectives:

1. Secure sufficient HPV vaccine supply to meet scale-up in demand.
2. Achieve a reduction in the weighted average price (WAP).
4. Improve demand predictability and understanding of product preferences by countries.

Tender duration: 5 – 7 years
Thank You