Update on the Supply of HPV Vaccine & Proposed Actions

Towards Elimination of Cervical Cancer in the Americas
1-2 August 2019
Outline

- HPV Vaccine Global Supply Challenges
- HPV Vaccine Demand & Supply
- Trends in the Americas
- PAHO’s Proactive Response
VACUNACIÓN CONTRA EL VPH PARA LAS NIÑAS DE 9 A 14 AÑOS
Carla, Daniela y Stephanie recibieron la vacuna contra el VPH en Sacatepéquez, Guatemala. Desde la introducción de la vacuna VPH en la Región, más de 24 millones de dosis han sido gestionadas por el Fondo Rotatorio de la OPS para apoyar a los ministerios de salud y asegurar el acceso universal a vacunas seguras, eficaces y de calidad.

VACCINATION AGAINST HPV FOR 9-14 YEAR OLD GIRLS
Carla, Daniela and Stephanie received the HPV vaccine in Sacatepéquez, Guatemala. Since the introduction of the HPV vaccine in the Region, more than 24 million doses have been procured by the PAHO Revolving Fund to support the ministries of health in ensuring universal access to safe, effective and quality vaccines.

Resolution & Photo Exhibit PAHO Directing Council:
It is time to end cervical cancer, September 2018

Ministers of health commit to reducing cervical cancer cases and deaths by 30% in the Americas by 2030
HPV Vaccine: Overview of Global Demand and Supply

- Supply not sufficient to meet demand until 2024 (and then only with tight management and careful planning)
- Factors that could affect demand/supply balance
  - Increase in projected capacity does not materialize timely and in the expected size.
  - Increase in global demand.
  - Pipeline products do not reach market (or PQ) as forecasted.
  - Demand of 9 valent increases substantially.
  - Additional countries extend immunization to boys
  - Country introductions and coverage increases do not occur as planned

<table>
<thead>
<tr>
<th>Vaccine type</th>
<th>Manufacturer</th>
<th>Pharmaceutical form</th>
<th>Presentation</th>
<th>PQ date</th>
<th>Available to PAHO Revolving Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Papillomavirus (Bivalent)</td>
<td>GSK</td>
<td>Liquid: Ready to use</td>
<td>Vial 1 dose Vial 2 doses +</td>
<td>08-07-2009</td>
<td>Through 2019</td>
</tr>
<tr>
<td>Cervarix</td>
<td></td>
<td></td>
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<tr>
<td>Human Papillomavirus (Quadrivalent)</td>
<td>Merck</td>
<td>Liquid: Ready to use</td>
<td>Vial 1 dose</td>
<td>20-05-2009</td>
<td>Finalizing negotiations for continued supply</td>
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<td>Gardasil</td>
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<tr>
<td>Human Papillomavirus (Ninevalent)</td>
<td>Merck</td>
<td>Liquid: Ready to use</td>
<td>Vial 1 dose</td>
<td>09-02-2018</td>
<td>Not Available</td>
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<td>Gardasil 9</td>
<td></td>
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What has the WHO WG done thus far?

1. MI4A HPV Global Market Study

2. Presented HPV Market Study to SAGE Working Group, June 2019
Background: 40 countries in region administering HPV vaccine – mature regional program.

Since breakthrough on price negotiations with 2 suppliers in 2014, the uptake of the HPV vaccine in countries continued progressively to a level exceeding 2.5 million doses beginning in 2017.

In 2019, one of two global suppliers announced exit from regional (and global) market, leaving only one source of supply for HPV vaccine in the short term (at least until 2022).

Four (4) additional countries requesting HPV through the RF representing additional need of 1M ds (2019) and projected 2.5M ds (2020).

**ANTICIPATING LIMITED HPV VACCINE MARKET CONDITIONS in 2020**

- Ensure purchases of all available doses for 2019 (1.4M doses in orders placed or in process; 1.4M doses pending).
- Support country transition(s) from Bivalent to Quadrivalent vaccine as needed.
- Continue with negotiation of new terms for 2020-2021 with remaining supplier
  - Improve delivery times from 12 to 8, to 6 weeks following receipt of the order
  - This requires monthly updates of country demand requirements with supplier
  - Concern remains for volumes and price.

### Demand, Supply and Procurement of HPV Vaccine

**PAHO Revolving Fund, 2017-2020**

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
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<tbody>
<tr>
<td>Countries Demand</td>
<td>2.6</td>
<td>2.9</td>
<td>2.8</td>
<td>3.0[IV]</td>
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<tr>
<td>Supply (LTAs) (I)</td>
<td>5.3</td>
<td>4.5</td>
<td>2.8</td>
<td>(II)</td>
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<tr>
<td>Actual/Projected Procurement</td>
<td>2.8</td>
<td>2.5</td>
<td>1.4</td>
<td>(III)</td>
</tr>
</tbody>
</table>

(I) LTAs for 2017 and 2018 correspond to quantities estimated in the original agreements with suppliers without considering constraints (supply, funding).

(II) LTA for 2019 was adjusted to reflect the availability offered by the suppliers.

(III) Purchases 2019 (includes purchases in process as of 30 July 2019)

(IV) Demand for 2020 is to be covered with HPV Quadrivalent only, however, the supply for the full quantity is pending.
Collaborative Effort to Ensure Timely Supply

**Ministry of Health**
- Accurate Demand Plans (PAHO-173) & monitoring of national inventories
- National Bud. - Financing to support Demand Plan
- Timely confirmation of purchases

**PAHO/RF**
- Consolidation of Demand Plans (PAHO-173) & monitoring of inventories
- Acquisition Strategies (negotiations, monthly demand – supply monitoring)
- Timely Allocation of doses & placement of P/Os
TAG expresses deep concern over the current challenges facing the supply of HPV vaccine and stresses the importance of meeting countries’ needs in order to reduce the burden of cervical cancer. TAG calls on the global public health community to challenge HPV vaccine manufacturers to be operationally and ethically responsive to global vaccine supply needs and align with PAHO/WHO’s call for action for elimination of cervical cancer.

In view of the current supply challenge, all countries administering vaccines to girls and boys should prioritize vaccination of girls, achieving HPV coverage >80%. This will induce herd immunity and protect both girls and boys.

TAG encourages countries to implement school-based HPV vaccination and communication plans to accelerate vaccine uptake and maximize vaccination impact.
Next Steps

• Working with FPL/IM and NIPs, implement TAG recommendations.
• Review national HPV inventories and demand reconfirmations for Q3 and Q4 2019 to ensure all available doses (1.4 million) are procured.
• HPV vaccine supply and price concerns beginning in 2020 and for at least 2 years, given sole source.
  • Sustain close working relationships with NIPs to prevent risk of stock-outs.
• For 2020, finalize negotiations to ensure:
  • PAHO, as part of its technical cooperation, determines with Member States the supply allocations in environment of limited supply.
  • Successful implementation of workplan with supplier to improve delivery times to countries in alignment with RF benchmark of 6 weeks.
Gracias
Merci
Obrigado
Thank You!

www.paho.org/immunization