MARKET UPDATE

Pneumococcal Conjugate Vaccines (PCV)

Vaccine Industry Consultation
15-16 November 2016
Outline

- The product
- Gavi Market - Status of Country Introductions
- Gavi Market - Call for supply Offer
- Middle-Income Countries (MICs) Market
- Issues and Challenges
- Information available on the UNICEF website
The Product

- An infection caused by a type of bacteria called streptococcus pneumoniae /pneumococcus which can cause pneumonia, meningitis, blood infections, and ear infections.

- The vaccine protects children from pneumonia in children under five years of age (13%).

- Products:
  - PCV13-1  4 (2017)

- Pipeline manufacturers:
  - Serum Institute of India (India)
  - Panacea Biotec Ltd. (India)
  - Others?

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>PCV10</th>
<th>PCV13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation</td>
<td>2-dose vial  ➔  4-dose vial</td>
<td>1-dose vial  ➔  4-dose vial</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>Liquid</td>
<td>Liquid</td>
</tr>
<tr>
<td>Preservative</td>
<td>None  ➔  Yes</td>
<td>None  ➔  Yes</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>GSK</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Administration</td>
<td>Intramuscular</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Serotypes covered</td>
<td>1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F</td>
<td>1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F</td>
</tr>
<tr>
<td>WHO Prequalified</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Schedule</td>
<td>3 doses</td>
<td>3 doses</td>
</tr>
<tr>
<td>Primary packaging</td>
<td>3 mL vial</td>
<td>2 mL vial</td>
</tr>
<tr>
<td>Shelf life at 2-8°C</td>
<td>36 months</td>
<td>36 months</td>
</tr>
<tr>
<td>Cold chain volume per ds</td>
<td>4.8 cm3  ➔  Reduced req.</td>
<td>12 cm3  ➔  Reduced req.</td>
</tr>
<tr>
<td>Vaccine Vial Monitor</td>
<td>VVM 30</td>
<td>VVM 30</td>
</tr>
<tr>
<td>Handling of open vials</td>
<td>6 hours  ➔  28 Days</td>
<td>N/A  ➔  28 Days</td>
</tr>
<tr>
<td>Wastage rate†</td>
<td>10%  ➔  Unchanged</td>
<td>5%  ➔  Increase to 10%</td>
</tr>
</tbody>
</table>
Gavi Market – Demand and Forecast Procurement, 2010 - 2017

- Advance Market Commitment (AMC) – innovative financing mechanism
- 6 valid Supply Agreements with 2 suppliers: GSK and Pfizer
- Supply is steady and in accordance with the Supply Agreements
Gavi Market - Status of Country Introductions
Gavi Market – Call for Supply Offer

- The last Call for Supply Offers was issued in August 2012 with the conclusion of Supply Agreements in July 2013.

- Consultations among partners took place in 2016 to examine:
  - GAVI Strategic Demand Forecast (SDF) version 11 and 12 and
  - the level of contracted supply through existing supply agreements,
  As a result, the partners have agreed that there is no need for issuing a Call for Supply Offer in 2016 and that the currently contracted quantities suffice to meet the expected demand in the short term.

- Re-assessment of the situation in 4Q 2016 for a possible Call for Supply Offer in 2017 based on
  - information from the next SDF and
  - outcomes of the next rounds of GAVI applications

Based on the forecasted demand there will a call for supply offer in 2Q 2017
Middle-Income Countries (MICs) Market

- UNICEF: enabling role
- Make challenges transparent
- Quantify demand and address associated deficiencies
- Secure commitment from countries
- Procurement strategy
- Tender: 1Q 2017
Issues and Challenges

• Delays in country introductions - competing priorities between new vaccines, programmatic readiness, storage capacity and Vaccine registration.

• PCV prices for non-AMC eligible MICs are preventing introductions.

• Country product preference and demand for the MDV presentations is uncertain and could have an impact on demand forecasts – price to be one of the main drivers.

• Increased demand from new introductions, including India, against current awards per year, could risk the balance between supply and demand.
Information available on the UNICEF website

http://www.unicef.org/supply/index_60990.html

http://www.unicef.org/supply/index_67883.html