Emerging manufacturers—potential impact on vaccine market dynamics and price: A closer look at rotavirus vaccines

WHO SAGE Meeting
November 9-11, 2010

Deborah Atherly, PhD
Reducing childhood mortality through global access of rotavirus vaccines

- A robust pipeline and healthy market can contribute to global access through provision of vaccine supply that is:
  - Adequate
  - *Affordable*
  - Secure
  - Acceptable
Affordable vaccines are essential

- **To donors:**
  - Evidenced by this current economic downturn and GAVI shortfall—causing delays in vaccine introduction

- **To GAVI-eligible countries:**
  - Sustainable vaccination programs require affordable vaccines after GAVI eligibility and subsidies expire

- **To non-GAVI-eligible countries:**
  - Will need to self-fund (or find donor) and with health spending per capita that is often less than the current cost of a vaccine course, this will be challenging
Rotavirus vaccine introductions

- 24 countries have introduced vaccine nationally
- Birth cohort = 14 million

<table>
<thead>
<tr>
<th>Income Strata (World Bank, 2010)</th>
<th>Number of Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0</td>
</tr>
<tr>
<td>Lower-Middle</td>
<td>9</td>
</tr>
<tr>
<td>Upper-Middle</td>
<td>8</td>
</tr>
<tr>
<td>High</td>
<td>7</td>
</tr>
</tbody>
</table>
Current vaccines from GSK and Merck

- Meeting current demand *(est. 20-40m doses/yr)*
- High and middle income markets are primary focus
- Low-income public markets: *Discounted prices not expected to decline substantially*
- Potential for much higher capacity with additional investment
Supplier landscape: 2013-2017
Emerging suppliers

<table>
<thead>
<tr>
<th>Estimated combined capacity</th>
<th>200-400m doses/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butantan Institute (Brazil)</td>
<td></td>
</tr>
<tr>
<td>BioFarma (Indonesia)</td>
<td></td>
</tr>
<tr>
<td>Bharat Biotech International Ltd. (India)</td>
<td></td>
</tr>
<tr>
<td>Serum Institute (India)</td>
<td></td>
</tr>
<tr>
<td>Shantha Biotech (India)</td>
<td></td>
</tr>
<tr>
<td>Wuhan Institute of Biological Products (China)</td>
<td></td>
</tr>
</tbody>
</table>

Manufacturers considered most likely to enter the marketplace between 2013-2017
Demand projections: Current global utilization and GAVI forecast (represents 65 countries)

- Access to prices similar to GAVI, for graduating countries
- Countries that introduced prior to graduation assumed to continue purchasing vaccines with their own funds when commitment ends
Current rotavirus vaccine prices

- GSK and Merck vaccines in industrialized countries:
  - $120-$200 per course
- South African public sector (birth cohort = 1 million):
  - GSK: >$20 per 2-dose course
- PAHO Revolving Fund 2009 contracts (birth cohort = 18 million):
  - GSK---$15.00 for 2-dose course
  - Merck--$15.45 for 3-dose course
- GAVI Prices:
  - Latin America - PAHO prices
  - Remaining regions - TBD
Rotavirus vaccines: GAVI pricing trajectory—when, how and will we get there?

Competitive supplier market; predictable, sustainable demand
Working toward a competitive supplier market

- Supply-side interventions help lower market entry barriers and costs
  - Research and discovery largely publicly funded
    Including transfer/availability of IP
  - Clinical development costs often shared with public health partners or government
  - Shared costs of vaccine clinical trials and other studies in low-resource settings
  - Technical assistance (e.g. development, production, regulatory, legal)
  - Manufacturing costs more competitive compared to multinationals
- Historic pricing trends (e.g. Hep B and Hib-containing vaccines) suggest that declines require multiple suppliers in the market
Working toward sustainable demand

• Demand-side interventions
  • Subsidized vaccines (GAVI, other donors)
  • Global recommendation by SAGE
  • Country support for immunization system-strengthening
  • Country support with advocacy and decision-making

• Currently, short and long-term demand in developing countries is uncertain primarily due to insufficient funds

• Demand uncertainty translates into risk for manufacturers and therefore may:
  • Reduce the number of market entrants
  • Delay development efforts
  • Keep prices higher than desired
Rotavirus vaccines: GAVI pricing trajectory—when, how and will we get there?
Concluding thoughts

• Interventions must continue, in order to ensure timely global access to vaccines

• Pricing is a multi-dimensional strategy
  • Interventions must address supply and demand-side risks to reach lowest prices

• Dialogue with all stakeholders is critical
  • Manufacturers, Funding agencies, countries, global health organizations

• Strategic oversight and monitoring of the ‘market’ could be beneficial
  • Assist global public health community, donors and manufacturers to make decisions in a timely fashion
  • How and when to intervene