EMERGING MANUFACTURERS AND EMERGING MARKETS: WHAT ARE THE LINKS?

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Questions

1. How important are the emerging vaccine markets? What are their trends, components and features?

2. How are emerging vaccine manufacturers dealing with the emerging markets?

3. What are the current issues and potential options for the emerging manufacturers?
What are we talking about ....

- Emerging manufacturers?

  - Relatively **new** manufacturers?
  - Manufacturers **located in** developing countries?
  - Manufacturers located in developing countries active in the global market?
  - Manufacturers located in **and owned** by developing countries and **active** on the global market?

Huge diversity and variety of dynamics
## EM: a diverse group

<table>
<thead>
<tr>
<th>1. Manufacturers with very few products only for domestic market</th>
<th>2. Manufacturers with a large number of products only for domestic market</th>
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<tbody>
<tr>
<td>3. Manufacturers with few products targeting both domestic and UN markets</td>
<td>4. Manufacturers with a large number of products targeting domestic, UN and private markets</td>
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<td>5. Manufacturers with a large number of products targeting domestic, UN, private and OECD markets</td>
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+ **Legal status:** public/private with various options
Presence of emerging manufacturers/vaccine market segments

<table>
<thead>
<tr>
<th>Manufacturer A</th>
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<tr>
<td>Emerging Manufacturers</td>
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<th>Domestic Market</th>
<th>Global Market</th>
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<th>Public MIC</th>
<th>Private OECD</th>
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<tr>
<td>Public UN</td>
<td>Private MIC</td>
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<th>Basic Vaccines</th>
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<td>Manufacturer B</td>
<td>Presence of emerging manufacturers/vaccine market segments</td>
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<tr>
<td><strong>Global Market</strong></td>
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<tr>
<td>OECD Public &amp; Private</td>
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<tr>
<td>MIC Public &amp; Private</td>
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<td>UN</td>
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<td><strong>Domestic Market</strong></td>
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Presence of emerging manufacturers/vaccine market segments

- Manufacturer C

Global Market
- OECD
- MIC
- UN

Domestic Market
- Public
- Private

Basic Vaccines

New Vaccines
Emerging economies provide a promising commercial opportunity for vaccine manufacturers due to their:

- Higher disease burden resulting large unmet medical and health needs
- Fast growing economies with strong GNI per capita growth
- Governments that are increasing efforts to assure vaccine supply and to improve immunization infrastructure and coverage rates
- Expanding middle classes that create a significant private sector opportunity in many countries
- Attractiveness to the industry as vaccine markets as well as hubs for relatively low-cost manufacturing and clinical trials
EMERGING MARKETS?

Dow-Jones list

As of May 2010, Dow Jones classified the following 35 countries as emerging markets:

- Argentina
- Bahrain
- Brazil
- Bulgaria
- Chile
- China
- Colombia
- Czech Republic
- Egypt
- Estonia
- Hungary
- India
- Indonesia
- Jordan
- Kuwait
- Latvia
- Lithuania
- Mauritius
- Mexico
- Morocco
- Oman
- Pakistan
- Peru
- Philippines
- Poland
- Qatar
- Romania
- Russia
- Slovakia
- South Africa
- Sri Lanka
- Thailand
- Turkey
- United Arab Emirates

Dow Jones: American publishing and financial information firm

Bottom line:

- Viable markets: countries with rapid growth, predictable demand and credible capacity to pay

- Importance of both public and private sector

- Markets with potential and actual significant influence on both supply and demand
Growth of the emerging markets: Vaccines Sales for leading country markets 2007-2023

- Rapid growth (more than 10% per year) and increasing share of the global market

- Fragmented Market:
  - Dominant countries: China, India, Brazil, Turkey, Indonesia and Mexico.
  - Second line: Singapore, Malaysia, Vietnam, Philippines, Egypt, GCC...
  - Leading vaccine countries in North America and Europe may lose market share.
  - UN market for LIC, treated as one market, will grow with a CAGR of 11%, to reach $3 bn by 2015.

- Importance of the private sector, new target groups, novel vaccines and presentations

- Higher transaction costs, high prices

Source: visiongain, 2008
Notes: Data based on ex-manufacturer prices, 2007 figures are actual sales, other are forecasts.
How are EM dealing with Emerging Markets?
Signs of positive trends ...

- Increasing number of EM with PQ products
- More functional NRAs in vaccine producing countries
- UN agencies (UNICEF and PAHO) are increasingly supplied by EM (both basic and underutilized vaccines)
- Rapid spread of EM presence in the emerging markets

Increasing role of EM on the global vaccine market
<table>
<thead>
<tr>
<th>Year</th>
<th>Total # Pre-Qualified Vaccines (excluding pandemic influenza)</th>
<th># Pre-Qualified Vaccines by Emerging Manufacturers (excluding pandemic influenza)</th>
<th>% of Pre-Qualified Vaccines by Emerging Manufacturers</th>
<th># Emerging Manufacturer Countries with Functional NRA’s</th>
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<tr>
<td>2003</td>
<td>66</td>
<td>21</td>
<td>32.3%</td>
<td>6</td>
</tr>
<tr>
<td>2006</td>
<td>73</td>
<td>31</td>
<td>42.5%</td>
<td>6</td>
</tr>
<tr>
<td>2009</td>
<td>98</td>
<td>47</td>
<td>48.0%</td>
<td>6</td>
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<tr>
<td>2010</td>
<td>102</td>
<td>50</td>
<td>49.0%</td>
<td>7</td>
</tr>
</tbody>
</table>

**Number of Pre-Qualified Vaccines by Year with Shares from Emerging Manufacturers**

- **Total # Pre-Qualified Vaccines (excluding pandemic influenza)**
- **# Pre-Qualified Vaccines by Emerging Manufacturers (excluding pandemic influenza)**
- **% of Pre-Qualified Vaccines by Emerging Manufacturers**
- **# Emerging Manufacturer Countries with Functional NRA’s**

Source: WHO-IVB-QSS. As of September 6, 2010
VACCINE PROCUREMENT THROUGH UNICEF 2000-2010: actual and percentage of emerging manufacturers

Vaccine procurement through UNICEF, 2000 - 2010
(number of doses)

- Billions of doses
- Suppliers from industrialized markets
- Suppliers from emerging markets

Vaccine procurement through UNICEF, 2000 - 2010
(USD value)

- USD Millions
- Suppliers from industrialized markets
- Suppliers from emerging markets

Source: UNICEF SD

*2010 data estimates
Top ten suppliers of PAHO RF 2003-2008

In 2008, no one manufacturer accounted for more than 23% of PAHO purchases
Various strategies of the EM regarding emerging vaccine markets
Various EM's Strategies Regarding Emerging Vaccine Markets

- Main distinction is between public and private EM
  - Public sector companies target EPI programmes and prefer inter-governmental relationships and contracts (both industrial and commercial)
  - Private sector firms have a more opportunistic and pragmatic strategy targeting both public and private markets at the domestic and global level

- The split between public and private sector should be nuanced according to country context and corporate strategies
Various EM's Strategies Regarding Emerging Vaccine Markets (2)

- Public sector emerging manufacturers tend either
  - To fully protect their captive domestic market (Indonesia, India, China, Vietnam, Brazil,..)
  - To enter in technology transfer and commercial agreements with multinationals to keep a certain presence on their domestic market

Various strategies and attitudes are explored and implemented…
Various EM's Strategies Regarding Emerging Vaccine Markets (3)

- Private sector EM tend to target:
  - Publicly funded EPI programmes
  - Global health initiatives
  - Domestic private markets

- A wide range of products and presentations

- Various types of arrangements with MNF and within the targeted countries (Gov, wholesalers, local agents,..)
Strengths and Challenges

- EM are expanding their product portfolios offering WHO PQ quality vaccines (basic and increasingly more NUVI)
- Competitive prices and contractual terms
- Recognized by UN, GHI and product development initiatives
- Gaining experience and expertise in production, research/development, regulation and PMS
Challenges

- Image and reputation: "high volume, low cost, poor quality"
- Speed to market new products, price, return on investment and intra DCVMN competition
- Limited access to capital markets and novel technologies
- *Modest on-the-ground marketing and distribution facilities.* Limited capacity to inform, market, advocate,..
- Costs of recognition of their products and presence in countries (legal requirement and restrictions, local agent,..)
- EM often focus on a limited number of products /MNF have wide presence, large portfolio and in depth knowledge of countries and players
- Modest capacity to act as a group (DCVMN,..) to influence global policies and initiatives
Preliminary Concluding Points

- Emerging countries market is the future.
- MNF have well developed strategies and business plans and are making massive and diversified investments.
- A new division of labor is ongoing. Will EM supply only basic and under used vaccines for the public sector and UN agencies, be instruments for MNF strategies, or move in other directions?
- OECD market: What is the additional cost of Euro or US FDA Quality assurance?
- Do EM have an explicit and consistent strategy regarding global, UN, emerging and OECD markets?
- Without this strong strategy, does EM network risk disappearing as an alternative manufacturer group and as a global public health and global vaccine market player?

Individual firm, group and global efforts and investment are highly needed.
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