

Opportunities for Emerging Vaccine Markets

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Outline

- Immunization landscape
- Vaccines: Global supplies
- Opportunities for Emerging Vaccine Markets
 - MNCs and DCVMN Increased focus on emerging markets
 - Vaccine Affordability
- The way forward

Immunization Landscape

- Last decade, great advances have been made in developing and introducing new vaccines and expanding the reach of immunization programmes
- More people than ever before are being vaccinated. Access and use of vaccines by age groups other than infants is expanding.
- Number of deaths caused by traditional vaccine preventable vaccines (diphtheria, pertussis, measles, neonatal tetanus and poliomyelitis) have fallen from an estimated 0.9 million in 2000 to 0.4 million in Year 2010.
- Annual number of deaths among children under five years of age fell from an estimated 9.6 million in 2000 to 7.6 million in 2010, despite an increase in number of children born each year.
- Through global innovative international collaboration, an affordable conjugate vaccine against *Nisseria meningitidis* serogroup A was developed and is now in use in African Meningitis belt.
- Newer vaccines, including pneumococcal conjugate vaccines and vaccines against rotavirus and HPV, are currently being rolled out globally.

Global Vaccine supply



International
Federation of
Pharmaceutical
Manufacturers &
Associations

- Comprise 25 leading international companies.
- Majority of revenue stake owned by Big 5 Pharma.
- Represents research-based pharmaceutical and biotech companies.
- Generates 80-85 % of total revenue in global vaccine market.
- Contributes 12-15 % in volumes to global vaccine requirement.



- ❖ Formed in Year 2000. As of September 2012, it has 37 members in 14 countries representing Latin America, Middle East, Africa, and the Asia-Pacific region.
- ❖ WHO prequalified production facilities. High volume low cost business models
- ❖ In 2012, Emerging vaccine manufacturers catered to 50 % of procurement volumes and 50 % by value of UNICEF shares.
- ❖ Largely kept prices of traditional vaccines affordable in spite of declining interest of Big Pharma in EPI vaccines.

Global Vaccine Markets

- The global pediatric vaccine market will likely hit a value of more than \$23 billion by 2015.
- From 2005 to 2011, pediatric vaccines doubled their market share.
- Vaccine Market no more a triad, US, EU and Japan
- Potential of emerging markets now being recognized. (BRIC, Innovative developing countries).

Emerging markets: Growth story

1. Initially focussed on Local generics businesses, no real IP laws
2. Implementation of IP laws based on TRIPS harmonisation, local science base started emerging. clinical trials/manufacturing (India, China, Brazil).
3. Local businesses start innovating – “IDCs” – innovative developing countries
4. Local innovative businesses want to internationalise.

Opportunities in emerging markets

Country	Birth Cohort (in millions)
Russia	1.6
India	25.1
China	18.7
Mexico	2.2
Brazil	3.7

- Largest birth cohorts in emerging markets
- Many markets currently addressed through GAVI/UNICEF mechanisms (including AMCs)
- Multi-nationals have stronghold in MICs in addition to the developed market.
- Few manufacturers from DCs are making inroads in these markets.

Changing Market Dynamics

- MNCs, Big Pharma showing signs of reduced interest in supplies of EPI vaccines.
- Manufacturers based in developing or emerging countries are positioning themselves to fill this gap. Driving benefits from local economies and cost effective manufacturing bases.
- The attractiveness of markets can be judged from the recent acquisitions:
 - Acquisition of DC manufacturer (Shantha Biotech) by Sanofi Aventis) and use of its R &D and manufacturing facilities to target local and UN supplies.
- Few manufacturers from emerging economies have taken significant steps to enhance their capabilities to undertake development of newer vaccines and target international markets.
 - Recent acquisition of Bilthoven Biologicals by Serum Institute of India Ltd highlight this aspect

DCVMN and Access to New Vaccines

Vaccines	DCVMN manufacturer	Country	Comments
Pneumococcal Conjugate	BioManguinhos/GSK Chengdu Institute/PATH SII, India/PATH Finlay Institute	Brazil China India Cuba	Under development
Rotavirus	Serum Institute of India -Instituto Butantan -China National Biotech Group -Biological Evans	India Brazil China India	Phase-3 Phase-2 Under development Under development
Meningococcal vaccines Includes polysaccharide and conjugate vaccines	Biological Evans China National Biotech Group Finlay Serum Institute of India Ltd Panacea Biotech BioManguinhos	India China Cuba India India Brazil	Under development Under development Under development Under development Under development Under development
Japanese encephalitis vaccine	Vabiotech Bharat Biotech Indian Immunologicals Panacea Biotech	Vietnam India India India	Under development Phase 3 Under development Under development
Seasonal and Pandemic Influenza Vaccines (also includes vaccines with oil in water adjuvants)	-Vabiotech -GPO - IVAC - Butantan - Chinese National Biotech Grp - Birmax - BioManguinhos	Vietnam Thailand Vietnam Brazil China Mexico Brazil	Under development Phase III Under development Phase I/II (new adjuvant) Under development Under development Under development

DCVMN and Access to New Vaccines

Vaccines	DCVMN manufacturer	Country	Comments
Malaria vaccine	Bharat Biotech	India	Under development
Typhoid Vaccine	Finlay Institute	Cuba	Under development
Dengue Vaccine	Biological Evans Bio-anguinhos/Bionet	India Brazil	Under development
Yellow fever	ANLIS	Argentina	Phase III
Hepatitis A	Bio-manguinhos	Brazil	Under development
Leishmaniasis	Bio-manguinhos	Brazil	Under development
Leptospirosis	Bio-manguinhos	Brazil	Under development
HPV Vaccine	Serum Institute CCGEB Innovax Indian Immunologicals	India Cuba China India	Under development Under development Under development Under development
Chikungunya	Indian immunologicals	India	Under development
Anthrax vaccine	Panacea Biotech	India	Phase III

DCVMN and Newer vaccines

- Another example of outstanding innovation within the DCVMN is the development and recent approval of the world's first hepatitis E vaccine, which was developed by Xiamen Innovax Biotech.
- Vaccine against yellow fever is also licensed and prequalified. Recently JE from BE is also licensed and another JE vaccine from China is currently undergoing PQ process.
- Further, vaccines against neglected diseases—such as dengue fever, Hand-foot and mouth disease, leishmaniosis, hook worm and Chagas disease—are in the pipeline to better protect low-income populations from these diseases in the endemic areas.

Vaccine Pricing and Affordability

- Year 1974: EPI program was launched.
- Year 1999: Total cost of full course of EPI vaccine averaged USD 1.37
- Year 2000: Adding two priority vaccines-Hepatitis B and Hib to EPI vaccines increased the cost to USD10.
- Year 2011: The expansion of EPI Program have raised the price of purchasing the full course of vaccine in GAVI country to 38.80 USD. (Price does not include programmatic or cost associated with vaccine wastage).
- Price of vaccine became a significant issue for immunization stakeholders in Year 2011, when GAVI faced a US \$ 3.7 billion financial shortfall for its 2011-2015 programme implementation.
- In Past 5 Years: WHO is recommending high unit cost products such as pneumococcal conjugate vaccine and rotavirus vaccine for global use in infants and HPV vaccines for adolescents.

DCVM and Global Health Threats Meningitis Vaccine Project

Successful example of Global Partnerships



MVP IS A PARTNERSHIP BETWEEN WHO AND PATH

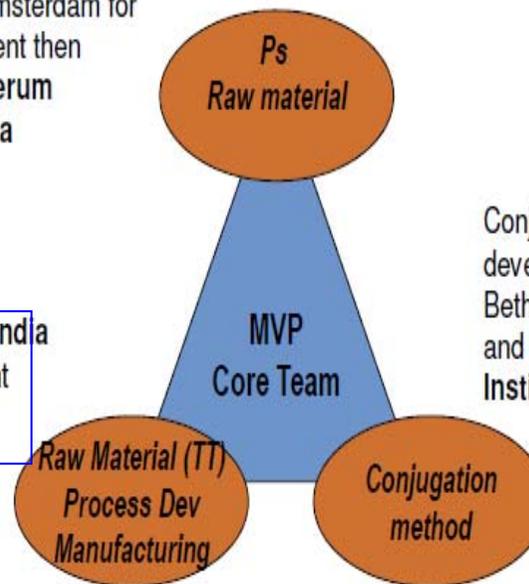
Confidential & Proprietary Information

The MVP Men A vaccine development model

A PS produced by SynCo BioPartners, Amsterdam for initial development then transferred to Serum Institute of India

Serum Institute of India process development and manufacturing

Lyophilization and stabilization tech transfer from Aerial in France to Serum Institute



Conjugation method developed at CBER/FDA, Bethesda, USA, transferred and scaled-up at Serum Institute of India

Target price US\$ <0.50/dose

DCVMN and Rotavirus Vaccines

- Year 2006: USD 15.00 for full course; PAHO supplies
- Year 2011: Big Pharma manufacturers reduced the price in range of 5.00 to 10.00 USD per course following sales of 30 million doses.
- Two DCVMN members are expected to have vaccine by Year 2015. One of member have announced its plan to launch this vaccine at USD 1.00 per dose.

DCVMN and Pneumococcal Vaccines

- Year 2000: PCV 7: CDC Purchase price was USD 44.25/dose.
- Year 2009; PCV 13 CDC Purchase price was at 71.04 USD per dose.
- Following deliberation in Year 2007, access to PCV 7 and 13 was supported by AMC with initial target price of USD 2.00 per dose. Finally the price was locked in with tail price of 3.50 USD/dose.
- No competition from low cost producers as on date. However, some DCVMN members are expected to enter this segment of vaccines by Year 2016.

Summary

- Emerging Markets are in transition. Strengthening of local industry, large birth cohorts and market size attractiveness to MNCs. Affordable vaccines will hold the key.
- MNCs declining interest in EPI vaccine supplies. Will observe more of acquisitions, partnerships with local industry
- Local industry eyeing global and local markets for EPI vaccines and taking significant steps to undertake development of newer vaccines.
- Partnerships and funding from international agencies such as WHO, NIBSC, PATH, etc played an important role in capacity building of emerging manufacturers.
- Emerging Vaccine Manufacturers have moved from dependency to self sufficiency to finally emerge as global suppliers for affordable vaccines.

Discussion

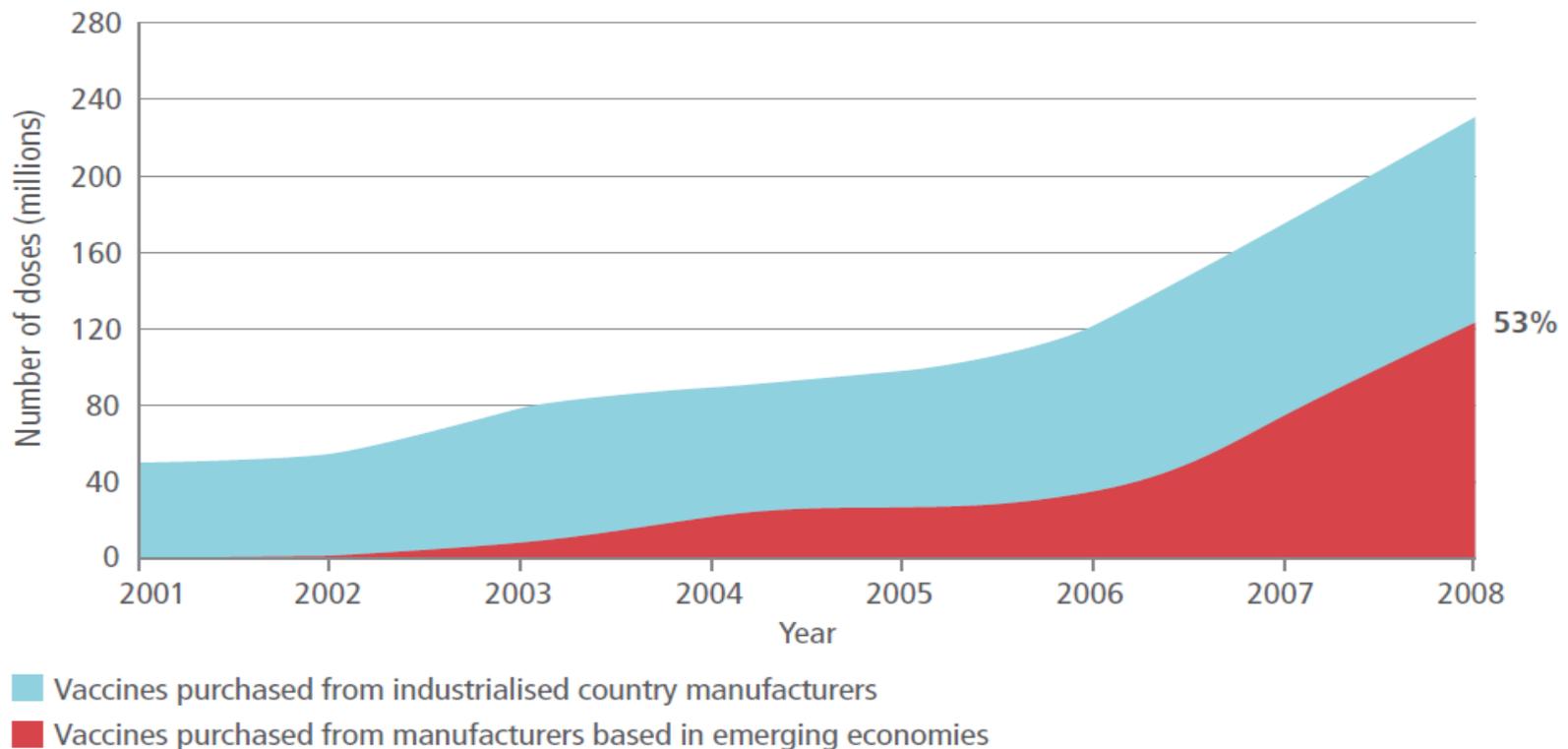
- Do we have sufficient funding provisions for sustaining decade of vaccine targets and objectives
- For how long can we keep vaccine affordable in lieu of increasing product complexities, regulatory expectations, product development costs, inflation, challenges in advocacy and lack of political will.
- Can partnerships, collaborations, product development partnerships help us.
 - MenafriVac as a case study.

Thank You

Background slides

Rapid growth in Emerging Economy producers (DCVMs).

Figure 16: Origin and volume of GAVI-funded vaccines – growing proportion of manufacturers based in emerging economies



Source: UNICEF Supply Division, 2009

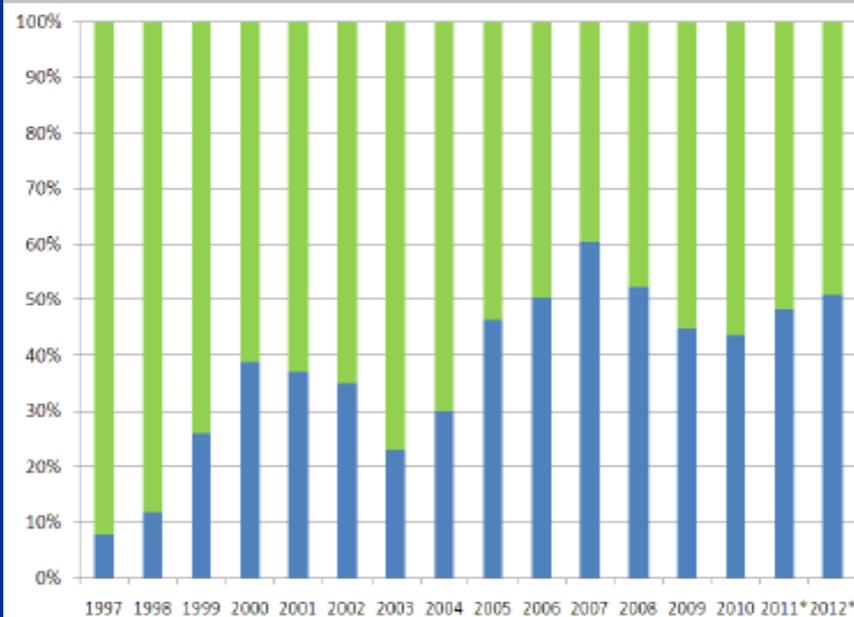
Vaccine Supplies to UNICEF

UNICEF SD

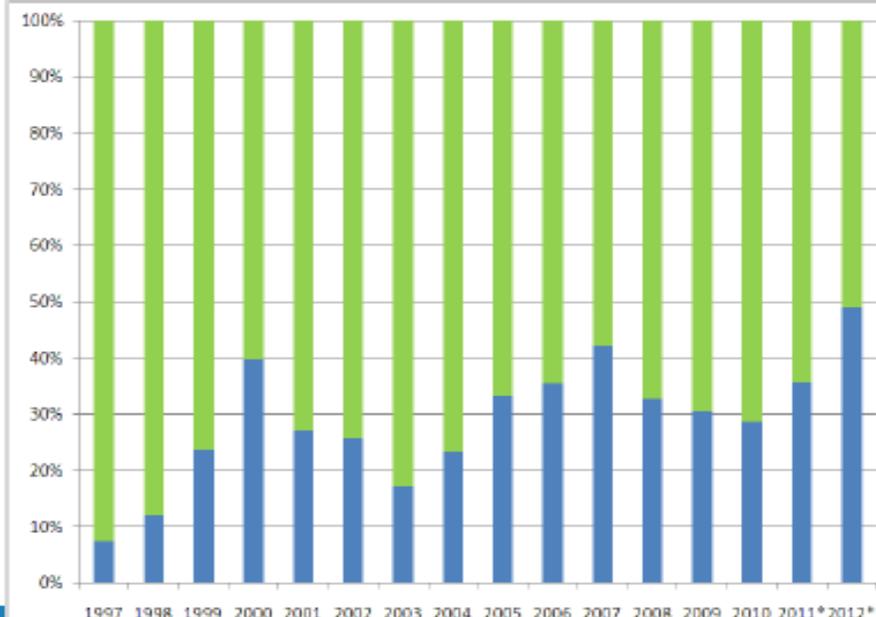
Emerging vs. Industrialized manufacturers

Emerging Market Country Manufacturers make up approximately 50% of procurement volumes in 2010 and 30% by value, predominantly due to lower but increasing participation in new vaccine markets and differing cost bases

By Volume



By Value

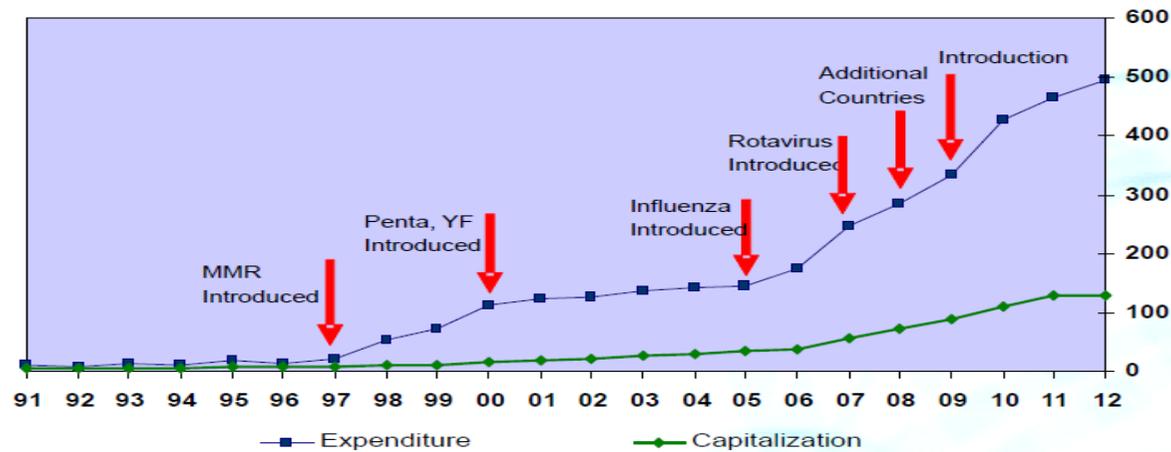


■ Developing Country ■ Industrialised Country

■ Developing Country ■ Industrialised Country

Major Trends (2000-2012)

Growth of the PAHO Revolving Fund



Top ten suppliers of PAHO RF 2003-2008

