# Role of Developing Country Vaccine Industry For Meeting Global Vaccine Needs

# ADVAC 2013

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France, 6 May'13

# Outline

- Immunization landscape
- Vaccine supplies: Global needs
- Vaccine Industry: DCVMN Overview
- Role of DCVM
  - UN Supplies
  - Vaccine Affordability
  - Global Vaccination Coverage
  - Global Health Threats
  - Newer Vaccines and making them accessible to all
- Challenges and 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.
- Vaccines against Hepatitis B and Haemophilus influenzae type b have become part of immunization schedules in 179 and 173 countries respectively
- 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.

### Immunization Landscape

- New er vaccines, including pneumococcal conjugate vaccines and vaccines against rotavirus and HPV, are currently being rolled out globally.
- Through global innovative international collaboration, an affordable conjugate vaccine against Nesseria meningitidis serogroup A was developed and is now in use in African Meningitis belt.
- There are now several licensed vaccines being used to prevent, or contribute to the prevention and control of 25 vaccine preventable infections.

# **Global Vaccination: Supply scenario**



Vaccine requirements: Distribution of 128 million children (WHO estimates)

- India, Brazil, China, Indonesia have production capacities to meet their country demands.
   Big Pharma: Assured Market in developed world at high prices.
- Market in developing world through UN agencies (UNICEF,
- GAVI, PAHO).
   Countries such as Egypt, Mexico, Turkey, Algeria procure vaccine directly from private
- markets.
   UN agencies: rest of world supplies which constitutes 40 % of volume of global vaccine

### Global Vaccine supply

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supplies.



- 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.

### DEVELOP MANUFAC

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Formed in Year 2000. As of September 2012, it has 37 members in 14 countries epresenting Latin America, Mddle 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.



# **DC Vaccine Industry**

Markets\*

Emerging markets growing at 16-17 %.
China expected to become # 2 market after North America by 2020.

 Growth drivers
 Large population, Unmet vaccination needs and low vaccination rates
 Increasing governments focus on prevention/Childhood rates
 - Fast growing private markets for vaccines
 Innovative international initiatives to meet demand



 Future growth Expectations
 Combination vaccines, -Influenza, -Traveller vaccines, Neglected Tropical diseases.



# Expanding sustainable access in emerging markets

Global Birth Cohort Distribution Estimate of Annual Births, m



ccine Volume 31, Supplement 2 2013B81 - B96

- Vast majority of births in Asia, Africa, Latin America
- Many markets currently addressed through GAVI/UNICEF mechanisms (including AMCs)
- Multi-nationals have stronghold in MCs in addition to the developed market.
   Dramatic drop in immunization
- Dramatic drop in immunization coverage in MCs/LMC, despite the fact that they can afford to introduce new vaccines.
- Few manufacturers from DCs are making inroads in these markets.

### Supply & Access to Vaccines: Global trends

- Sizeable Increase in Funding:
   Greater emphasis on adding new products into national immunization programs. -Funding sources: Bill and Melinda Gates Foundation, GAVI, International Finance Facility for Immunization(IFFIm) and other innovative finance schemes such as AMCs., therefore more funds available to countries.
   Demand for DPT-HepB/Hib has increased from 61m (2008) to 180 m (2012) because of GAVI funding.
- Changing vaccine supply landscape -Developing Countries Vaccine Manufacturer Network (DCVMN) played a major role in supplying EPI Vaccines at affordable prices and meeting millennium development goals. -Several DCVMN members have developed capacity to undertake new vaccine development.

# Rapid growth in Emerging Economy producers (DCVMs).













**DC Vaccine Industry Contributions** Global Immunization 1980-2011, DTP3 coverage global coverage at 83% in 2011 100 80 % coverage 60 40 20 8 8 8 8888 102 102 African European American South East Asian WHO GIVS Goals-2011



# DPT Vaccine Coverage: Still needs to be covered

Additional ch at different c	ildren to reach overage level	Children unvaccinated
83%	0	22.4 million
90%	9.4 million	13.0 million
100%	22.4 million	0







# Measles containing Vaccine coverage
















# **Contributions to Global Health-2**

- Rubella supplies to PAHO programme.
- Partners: CDC, Canadian Public Health Association, GAVI, UNICEF, USAID, Rotary International & Sabin Vaccine Institute.
- SII was major contributor of MR, MMR and Rubella vaccine supplies to this programme.

- Significant contribution to vaccine requirements in programme which resulted in elimination of congenital rubella syndrome (CRS) in regions of Americas.

The last confirmed indigenous rubella case was reported in Jan 2009.
 It is reported that timely and consistent vaccine supplies have
prevented 112500 CRS cases over a 15 year period in Latin America
and Caribbean.

- Significant contribution to MDGs by one quarter reduction in mortality in children aged <5 years between 1990 and 2002 in Americas

# 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.

The Right Shot: Extending the reach of Affordable and Adaptable Vaccines. www. Msfaccess.org; April 2012

# Pricing and DCVMN

### 2011 Price Per dose of DTP-Hep-B-Hib (Pentavalent)

	Crucell	GSK	DC	VMN (SII/BI	E)
Presentation	Single dose	Two dose Iyophilized	Single dose -liquid	Two dose Iyo	Ten dose liquid
Country of manufacture	Republic of Korea	Belgium	India	India	India
2011 price per dose	\$2.80- 3.20	\$2.95	\$2.25-2.50	\$2.25	\$1.19- 2.11

DCVMN supplied Pentavalent vaccines, mainstay of GAVI Purchase at prices almost 40 % less than Crucell, a European company. GAVI's support for pentavalent vaccine has averted 474,000 future deaths.

The Right Shot: Extending the reach of Affordable and Adaptable Vaccines. www. Msfaccess.org; April 2012

# Supply of IPV and DCVM

- Existing price from developed country vacine manufacturer (Big Pharma): 4.50 Euros/dose.
- EVM\* Price: 2.50 Euros/dose
- DCVM price: 1.25 Euro/dose in single dose container. 0.90 Euro/dose in multidose container for immediate use. Future pricing may reduce to 0.60 Euros/dose in multidose vial.

Global	Immunization :	Coverage	rates
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Vaccine	Global Immunization coverage (1990) (%)	Global Immunization coverage (2011) (%)
DTP (Three doses)	75	83
Polio	75	84
Measles	73	83
Hepatitis B		75
Hemophilus Influenzae type B		43
Rubella	83 countries in 1993	127 countries by end of 2008. Remarkable reduction of congential rubella syndrome in Americas with reduction of 99.99 % confirmed cases between 1990-2011.
Pneumococcal Vaccine		Introduced in 72 countries
Rotavirus Vaccine		Introduced in 31 countries
Human Papillmavirus Virus		Introduced in 43 countries

**DCVM and Global Health Threats Meningitis** Vaccine Project Successful example of Global Partnerships The MVP Men A vaccine development model RD 🤳 A PS produced by SynCo BioPartners, Amsterdam for initial development then transferred to Serum Institute of India \*PATH Raw ma ----NIBSC Conjugation method developed at CBER/FDA, Bethesda, USA, transferre and scaled-up at Serum Institute of India ner

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process development and manufacturing

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

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AARSH Content IGATE MVP

Target price US\$ <0.50/dose



# MenAfric Vac: Impact

### **Potential Impact of MenA Conjugate** Vaccine Programs



- Prevent 123,000 deaths
- Prevent permanent disability in 287,000 children and adults •
- Save approximately \$99.7 million in direct medical costs
- Eliminate epidemic meningitis as a public health concern in Africa

MVP and NIBSC presentation

### **DCVM and Global Health Threats**

### WHO Global Action Plan for Pandemic Influenza (GAP)

- Sear 2006: GAP intiative was planned and 5 DC manufacturers were approached for seasonal and H5N1 influenza vaccine production capacity building.
- Each member was expected to generate production capacity of 50
- capacity builling.
- manufacturers were asked to ready H1N1 vaccine for global use.
- July 2010: DCVMN members such as Serum Institute of India



-New manufacturers have been countries, which brings hopes to

of more than 1 billion doses is expected by DC manufacturers.

### **DCVMN** and Access to New Vaccines

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# **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 lowincome populations from these diseases in the endemic areas.

# **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 vacane by Year 2015. One of member have announced its plan to launch this vacane at USD 1.00 per dose.

The Right Shot: Extending the reach of Affordable and Adaptable Vaccines. www. Msfaccess.org; April 2012

### **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.

The Right Shot: Extending the reach of Affordable and Adaptable Vaccines. www. Msfaccess.org; April 2012

# Challenges: Are we prepared

Characteristic	Change	Implication
Price	Many have higher costs (> \$10/ treatment)	Impacts affordability & vaccination sustainability
Presentation	Multidose to smaller vial sizes (1-2 dose vials)	Minimizes vaccine wastage, in creases cold chain needs & waste disposal costs
Target Population	Birth Doses, Infants, Adolescents, & Adults	More vaccines delivered outside the EPI system
Vaccination Strategy	Routine <u>+</u> catch-up, mass campaigns, school-based routine, school-based mass campaigns	Significant immunization logistics implications
Product Profile	Not all vaccines the same – differ by dose schedule, serotypes, route of administration, preservative use	Country preferences become a major factor, immunization logistics need to be managed

# Challenges

- Absence of proper forecasting of demand from countries as well as procurement agencies
- Major challenge is to keep the plant running anticipating no dear forecasting of demand
- Special challenges for pandemic vaccines or vaccine requirement in an outbreak
- Lack of political will to address these challenges

# The way forward

- These challenges needs collaboration among stakeholders
- Political will
- Advocacy
- Capacity building of DCs with respect to state of art supply chains, logistics and immunization systems
- Funding
- Sustainable and affordable pricing

The long-term goal of the Network is to supply high-quality vaccines to all people where needed in a sustainable manner, rendering vaccines a universal good

### Summary

- DCVM have moved from dependency to self sufficiency and has finally emerged as global suppliers for affordable vaccines.
- DCVM look forward to supplies and markets in developed world:

- Will have to overcome challenges and would need partnerships/collaborations with scientific community and Big Pharma to address issues of access, IP. -Support from international agencies/foundations in terms of funding and advocacy.

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We have to choose between a global market driven only by calculations of short-term profit, Or one which has a human face – Kofi Annan

We at DCVMN believe in second option