

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

**ADVAC 2013**

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France, 6 May '13

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## 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

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## 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.

Global Vaccine Landscape Report 2010-2020 - WVI 2013

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## Immunization Landscape

- Newer 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 *Nisseria 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 Action Vaccine Plan 2010-2020 - WHO 2013

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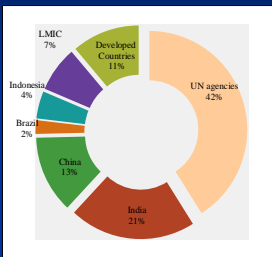
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## Global Vaccination: Supply scenario



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 supplies.

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## Global Vaccine supply



- 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.

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## 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.

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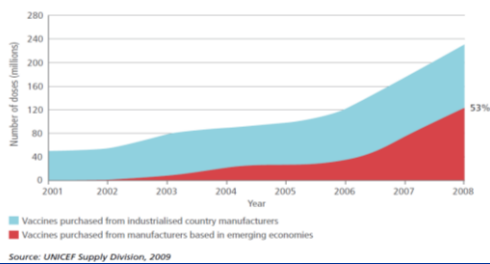
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## Rapid growth in Emerging Economy producers (DCVMs).

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




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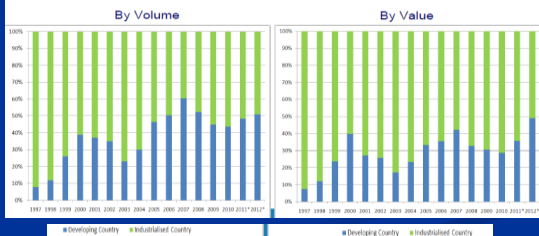
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## Vaccine Supplies to UNICEF

**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




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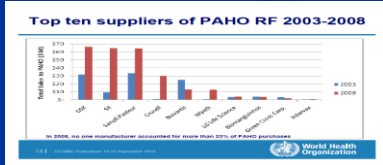
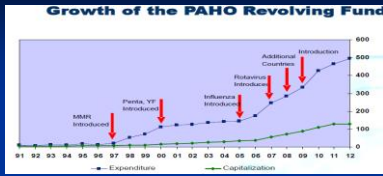
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## Major Trends (2000-2012)



(Vaccine 2010: 28, 2115-21)

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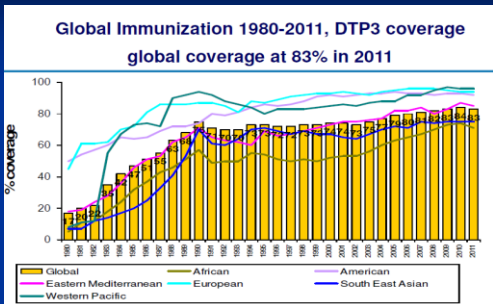
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## DC Vaccine Industry Contributions



WHO GIVS Goals-2011

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## DPT Vaccine Coverage: Still needs to be covered

**83% DTP3 coverage  
107 million children vaccinated**

Additional children to reach at different coverage level		Children unvaccinated
83%	0	22.4 million
90%	9.4 million	13.0 million
100%	22.4 million	0

WHO UNICEF Coverage estimates (Aug 2012, updated)

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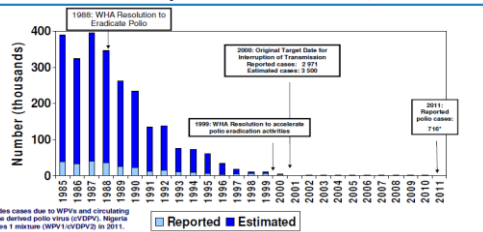
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## Polio Eradication

Progress in Polio Eradication, Estimated and Reported Polio Cases, 1985-2011

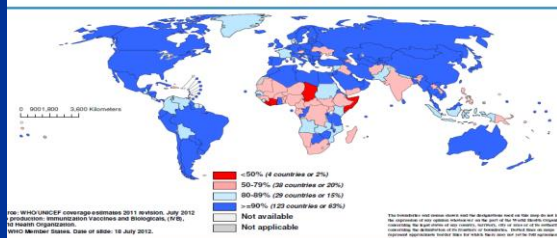


As of Year 2012, number of polio cases further dropped to 223.

Source: WHO/Polio database, August 2012

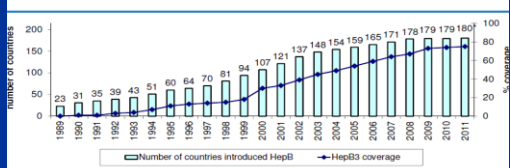
## Measles containing Vaccine coverage

Immunization coverage with measles containing vaccines in infants, 2011



## Hepatitis B Vaccine

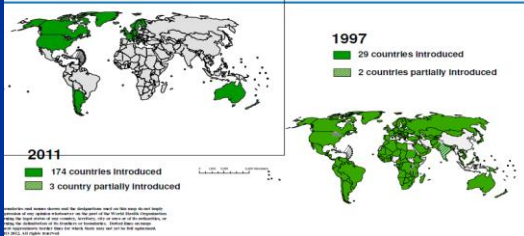
Number of countries having introduced HepB vaccine\* and global infant HepB3 coverage, 1989-2011



\*excluding 3 countries where HepB administered for adolescence

## Hib Vaccine

### Countries having introduced Hib vaccine In 1997 and 2011




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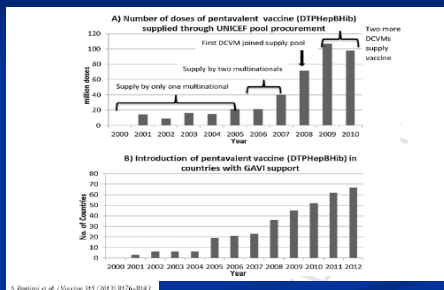
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## Pentavalent vaccine and UNICEF Supplies




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## 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

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## 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

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## Pricing and DCVMN

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

Presentation	Crucell	GSK	DCVMN (SI/BE)		
	Single dose	Two dose lyophilized	Single dose -liquid	Two dose lyo	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.

source: WHO Department of Immunisation, Vaccines and Biologicals' estimates and projections, November 2010

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

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## Supply of IPV and DCVM

- Existing price from developed country vaccine 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.

\* Pricing from IPV producer in Europe acquired by Indian Vaccine Manufacturer

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## Global Immunization : Coverage rates

Vaccine	Global Immunization coverage (1990) (%)	Global Immunization coverage (2011) (%)
DTP (Three doses)	75	83
Polio	75	84
Measles	73	83
Hepatitis B	1	75
Hemophilus influenzae type B	-	43
Rubella	83 countries in 1993	127 countries by end of 2008. Remarkable reduction of congenital 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 Papillomavirus Virus	-	Introduced in 43 countries

Data as on Oct 2012, WHO estimates. Percentages reported in 193 member countries of WHO.

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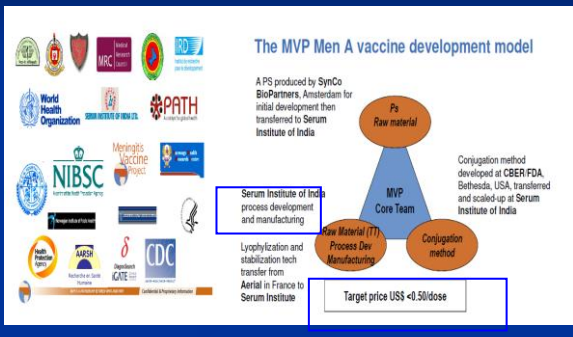
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## DCVM and Global Health Threats Meningitis Vaccine Project

Successful example of Global Partnerships



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## 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

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## DCVM and Global Health Threats

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

- Year 2006: GAP initiative 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 million doses/year.
- Year 2008: Additional 6 DC manufacturers were shortlisted for capacity building.
- April 2009: Pandemic Threat of H1N1 was announced and these manufacturers were asked to ready H1N1 vaccine for global use.
- July 2010: DCVMN members such as Serum Institute of India showed potential to ready vaccine (nasal live attenuated vaccine) and injectable (inactivated) H1N1 vaccine for global use in a year's time.

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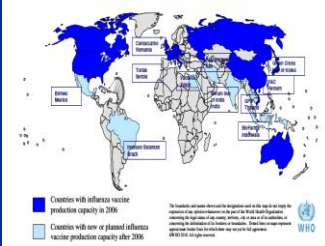
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### WHO Global Action Plan for Pandemic Influenza (GAP)

Countries with influenza vaccine production capacity in 2006 and following implementation of the WHO Technology transfer project



-This represents a leading example where pandemic threats led to capacity building.

-New manufacturers have been established in developing countries, which brings hopes to more adequate production capacity and equitable access in case of a future pandemic.

- By 2015, production capacity of more than 1 billion doses is expected by DC manufacturers.

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## DCVMN and Access to New Vaccines

Vaccine	Potential manufacturer	Country	Comments
<i>Pneumococcal Conjugate</i>	Bio-Manguinhos/GSK Chengda Institute/Pfizer SI, India/Pfizer	Brazil China India	3rd valent Three year project initiated in 09
<i>Rotavirus</i>	Bharat Biotech, Biological E, Serum Institute of India - Institute Biotech Chengda and Wuhan Institutes	India India Brazil China	Phase-3 clinical trials
<i>Meningococcal A Conjugate</i>	Serum Institute of India /MVP Project	India	WHO prequalified in 2010
<i>Rabies</i>	Zydus cadilla Serum Institute Vabiotech	India India Vietnam	Prequalified Licensed, Not prequalified Licensed, not prequalified
<i>JE</i>	Chengda Institute/Pfizer Biological Eon/Amersell Vabiotech	China India Vietnam	-LAV licensed in 7 countries (Not prequalified) -IC-51, Inactivated vaccine -Japanese technology, 3Ml/year
<i>Seasonal and Pandemic Influenza</i>	-Vabiotech -GPO -Institute Biotech -Serum Institute of India/Biotech -Biochem/Bharat Biotech/Zydus cadilla -Biofarma	Vietnam Thailand Brazil India India Indonesia	- -Phase III Vaccine Licensed and in market WHO prequalified

Vaccine 2010, 29, 2115-21.

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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, leishmaniasis, hook worm and Chagas disease—are in the pipeline to better protect low-income populations from these diseases in the endemic areas.

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## 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.

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

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## 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

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## 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, increases cold chain needs & waste disposal costs
Target Population	Birth Doses, Infants, Adolescents, & Adults	More vaccines delivered outside the EPI system
Vaccination Strategy	Routine ± catch-up, mass campaigns, school-based routine, school-based mass campaigns	Significant immunization logistics implications
Product Profile	Not all vaccines the same – differing dose schedule, serotypes, route of administration, preservative use	Country preferences become a major factor, immunization logistics need to be managed

Cited: WHO, Vaccines: a time and cost challenge 2019

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## Challenges

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

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## 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

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## 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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## Thank You



*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**

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