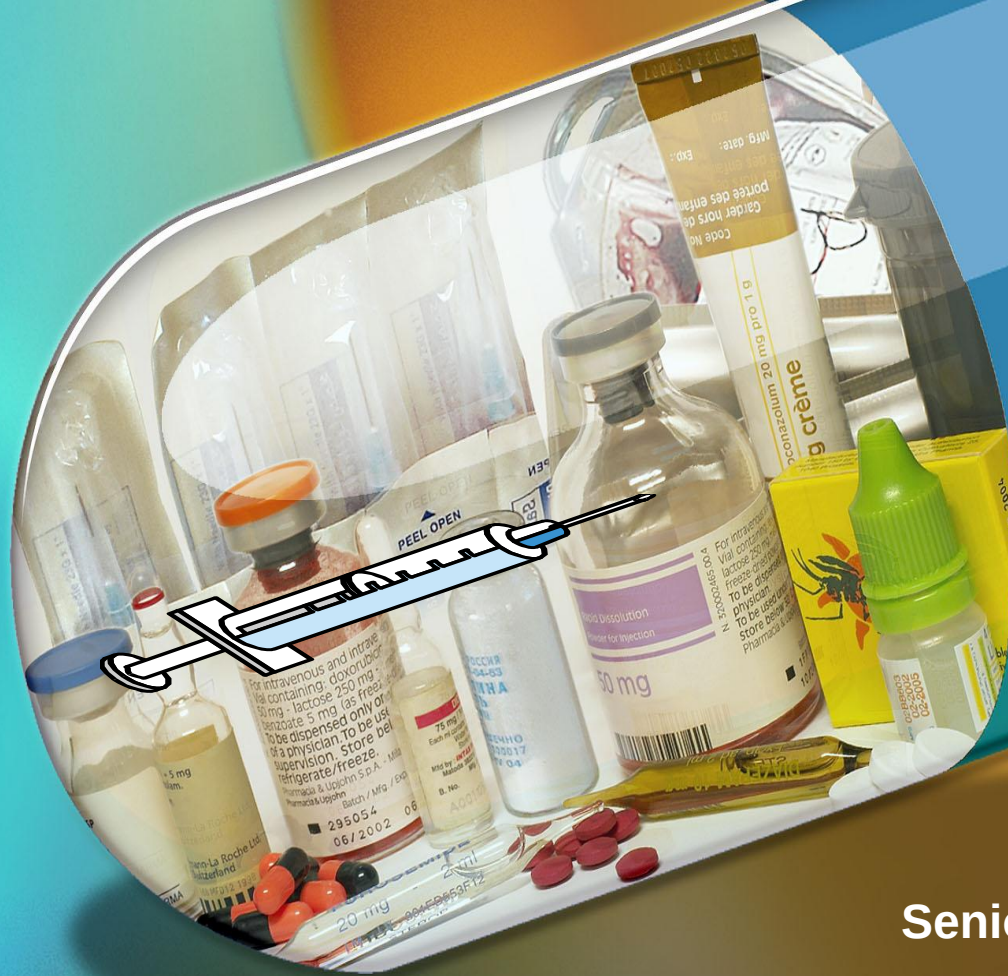


Discussion of this Document here:
<http://DrRimaTruthReports.com/?p=24226>



Global Vaccine Market Features and Trends

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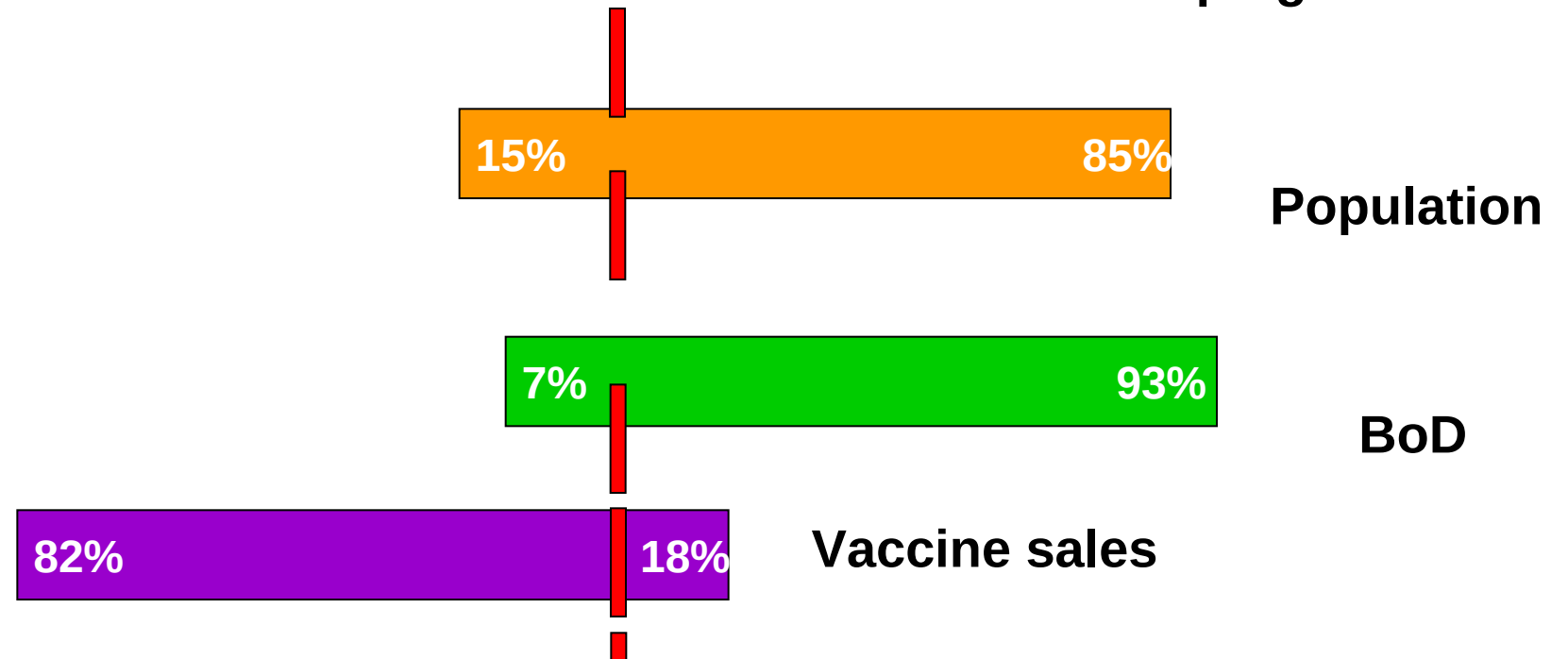
GLOBAL VACCINE MARKET

- MAIN FEATURES OF THE VACCINE MARKET ?
- NEW TRENDS SINCE 2000 ?
- IMPLICATIONS ?

Vaccine Market North – South GAP

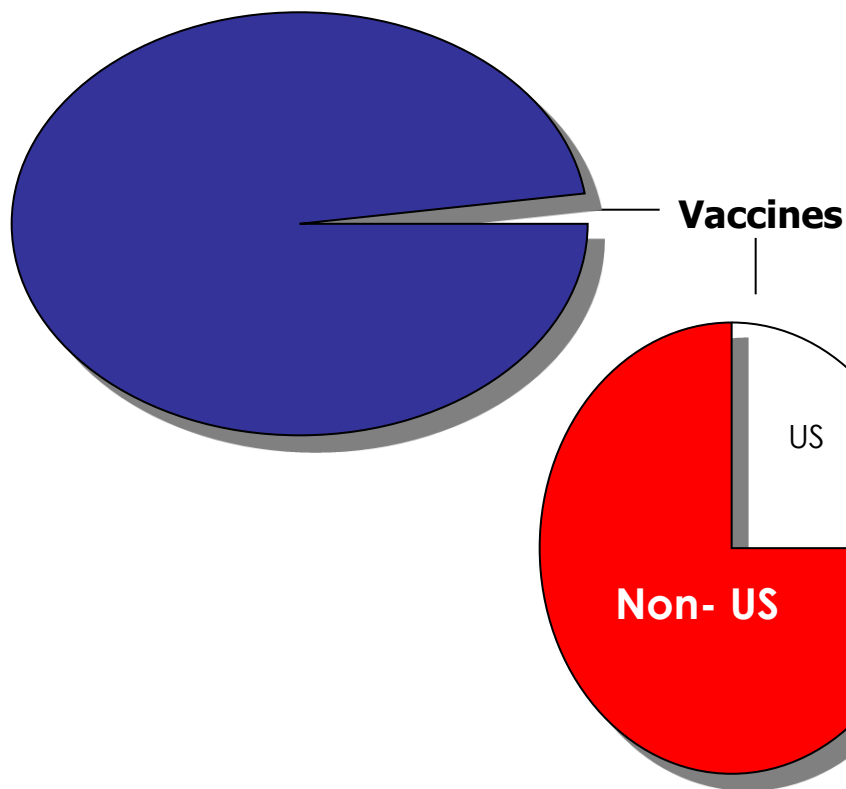
Industrialised countries

Developing countries



VACCINE MARKET STRUCTURE 2010

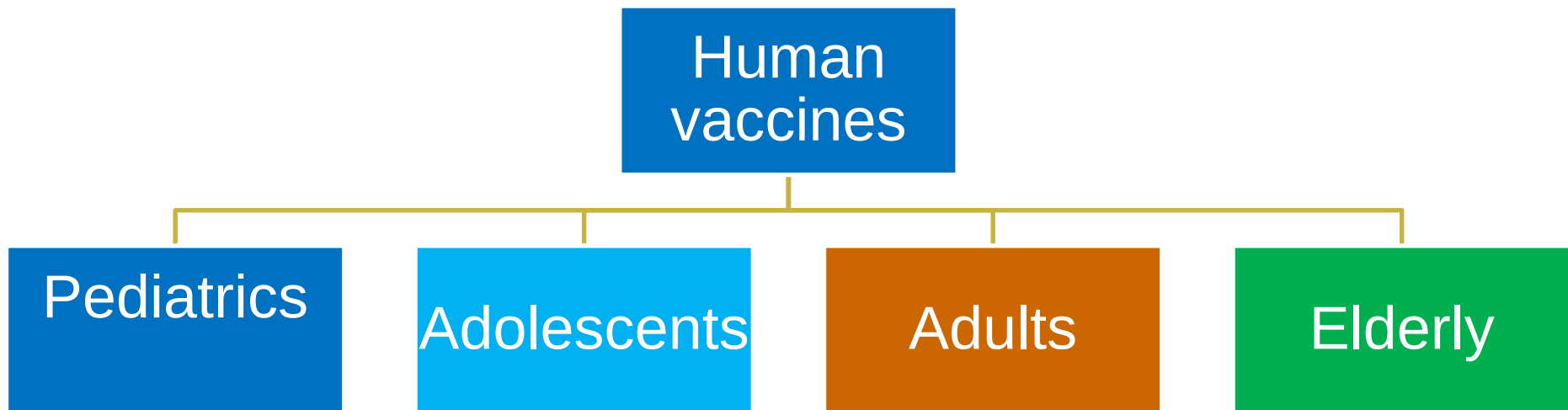
World sales for drugs



Small size market : 2/3% of the global pharmaceutical market but ...

Spectacular growth rate : 10 - 15% per year versus 5-7 % for Pharmaceuticals

Vaccine segments



GLOBAL VACCINE MARKET: RAPID GROWTH and CHANGING STATUS

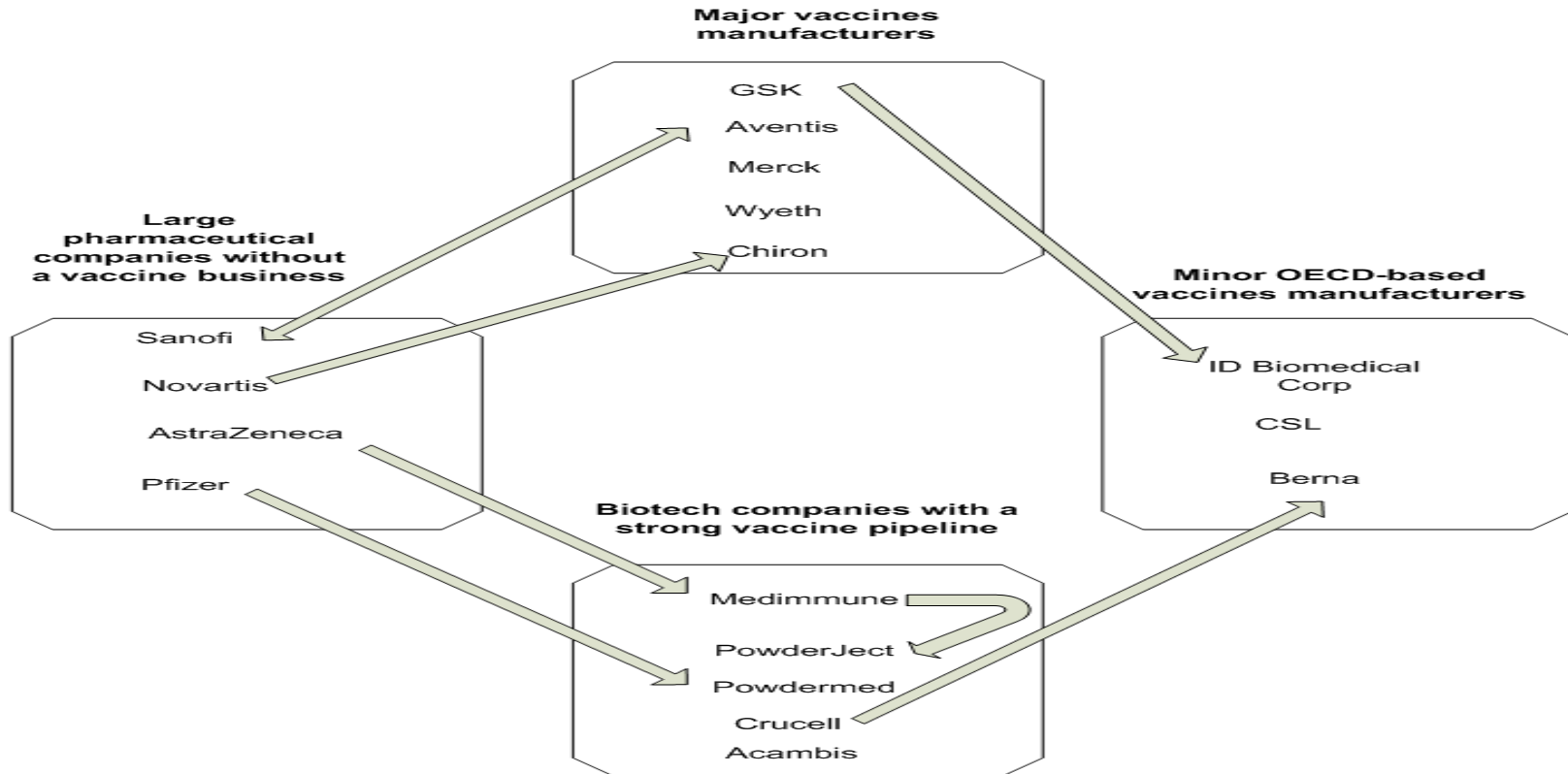
- Tripled in value from USD 5B in 2000 to almost USD 24 B in 2013
 - Influenza vaccine market: estimated at \$2.9 billion in 2011 to \$3.8 billion by 2018
 - US : \$1.6 billion in 2011 to \$2.2 billion in 2018
- Global market projected to rise to USD 100 B by 2025
- More than 120 new products in the development pipeline
- 60 are of importance for developing countries
- Vaccines: becoming an engine for the pharmaceutical industry
- Changing status of the vaccines within the pharmaceutical industry
- New business model for vaccines is emerging?

Main features of Vaccine market (2)

- **Newer and more expensive vaccines are coming into the market faster than ever before**
- **Growing concentration in OECD countries but also newcomers (Pfizer, J&J,...)**
- **Vaccine development: increasing investment**

MERGERS AND ACQUISITIONS 2002-2007: Illustration

Mergers and acquisitions in the vaccine industry, 2002-2007



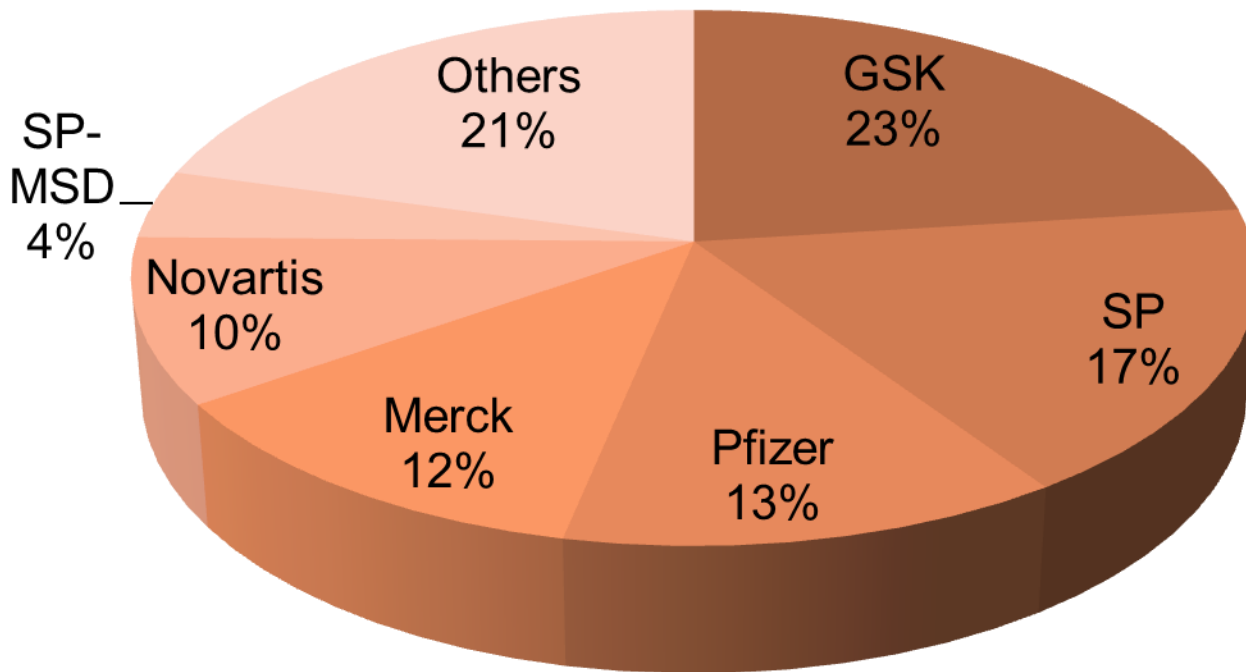
Note. Double arrows denote mergers, single arrows denote acquisitions where the origin of the arrow is the buyer. Headings (such as 'large pharmaceutical companies without a vaccine business') and company names refer to the situation in 2002.

Overview of major vaccine related acquisitions (2005-2012)

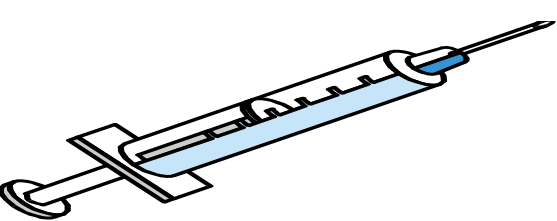
Target Company	Acquiring Company	Investment Made	Date Announced
1.Bilthoven Bio of Netherlands	Serum Institute of India Ltd	Euros 80M	July 2012
2.Zhejiang Tianyuan Bio	Novartis	\$ 125 M?	March 2011
3.Wyeth	Pfizer	\$68 bn	Jan 2009
4.MedImmune	AstraZeneca	\$15.6 bn	April 2007
5.Chiron	Novartis	\$5.1 bn	Oct 2005
6.Crucell	Johnson & Johnson	\$2.6 bn	Sep 2009
7. ID Biomedical	GSK	\$1.4 bn	Sep 2005
8.Shantha Bio	Sanofi Aventis	\$781 mn	July 2009
9.Acambis	Sanofi Aventis	\$549 mn	July 2008
10. Intercell	Novartis	\$363 mn	July 2007
11. Corixa	GSK	\$300 mn	May 2005
12. PowderMed	Pfizer	\$230 mn	Oct 2006
13. Coley	Pfizer	\$214 mn	Nov 2007

Source: VacZine Analytics + Fierce vaccine

Global vaccine leaders



- 5 large multi-national corporations make up 80% of the global market
- Major focus on new vaccine development for industrialised country markets



Top product sales in 2010



Brand name (producer)	Type/composition	2010 sales (US\$)
Pevnar-13 (Pfizer)	13-valent pneumococcal conjugate vaccine	\$2.4 billion
Proquad (Merck/Sanofi-Aventis)	Measles-mumps-rubella and varicella combination vaccine (MMR-V)	\$1.4 billion
Gardasil (Merck)	HPV	\$1.35 billion
Pevnar (Pfizer)	7-valent pneumococcal conjugate vaccine	\$1.2 billion
Fluzone (Sanofi Pasteur)	Influenza (seasonal and H1N1 strains)	\$1.2 billion
Infanrix and Pediarix) (GSK)	Infanrix = DTaP Pediarix = DTaP-HepB-IPV (combination DPT-based vaccines with acellular pertussis)	\$1.2 billion

Source: Krishan Maggon knoll (<http://knol.google.com/k/krishan-maggon/global-vaccine-market-2010/3fy5eowy8sug3/152....>)



Total sales First half 2012



	<i>Vaccine</i>	<i>Company</i>	<i>H1 Sales</i>	<i>Use</i>
1	Pevnar 13	Pfizer	\$1.847 billion	Pneumococcal infection
2	PENTAct-HIB	Sanofi	\$672 million	Diphtheria, Pertussis/whooping cough; Tetanus; Polio; Haemophilus influenza type b
3	Gardasil	Merck & Co	\$608 million	human papillomavirus (HPV)
4	Pediarix	GlaxoSmithKline	\$535 million	Diphtheria; Tetanus; Pertussis/whooping cough; Hepatitis B; Polio
5	Hepatitis Vaccine Franchise	GlaxoSmithKline	\$500 million	Hepatitis A; Hepatitis B
6	Celtura	Novartis	\$441 million	Swine flu
7	Varivax	Merck & Co.	\$392 million	Varicella virus
8	Cervarix	GlaxoSmithKline	\$285 million	HPV
9	RotaTeq	Merck & Co.	\$284 million	Rotaviral gastroenteritis
10	Synflorix	GlaxoSmithKline	\$274 million	Pneumococcal infection; Otitis media
11	Rotarix	GlaxoSmithKline	\$266 million	Rotaviral gastroenteritis

Total sales First half 2012 (2)



	Vaccine	Company	H1 Sales	Use
12	Zostavax	Merck & Co.	\$224 million	Shingles; Herpes
13	Prevnar 7	Pfizer	\$222 million	Pneumococcal infection; Otitis media
14	Fluzone/Vaxigrip	Sanofi	\$219 million	Influenza
15	Menactra	Sanofi	\$217 million	Meningitis
16	Pneumovax	Merck & Co.	\$213 million	Pneumococcal infection
17	Adacel	Sanofi	\$207 million	Diphtheria; Pertussis/whooping cough; Tetanus
18	MMR-II	Merck & Co.	\$180 million	Measles, Mumps, Rubella
19	Boostrix	GlaxoSmithKline	\$165 million	Diphtheria; Tetanus; Pertussis/whooping cough
20	Biothrax	Emergent BioSolutions	\$88 million	Anthrax

Sources: EvaluatePharma; Fiercevaccines, Sep 2012



VACCINE MARKET : GROWTH FACTORS ?

Combination of :

- Importance of communicable diseases and new threats
- Cost effectiveness of immunizations
- New funding opportunities (Gov, PPP, donors, Foundations,..)
- New research techniques and manufacturing technologies
- Increasing demand, new target population, larger emerging markets
- Higher prices, improved profitability for the industry (blockbuster vaccines..)

Developing countries: vaccine market share and trends

Developing country market

80 % of population / less than 20% of global market

Regular and rapid growth in volume and dollar value

Emerging
economies and
markets

UN market

Private sector in
Low and Middle
income countries

MNC : Key strategies for developing countries

3 main targets:

- Emerging economies
- UN markets (UNICEF/GAVI and PAHO)
- Private sector, middle income group markets

3 main strategies

- Partnerships with emerging economies and manufacturers
- Accelerated uptake and Differential pricing
- Field presence and active marketing, different presentations

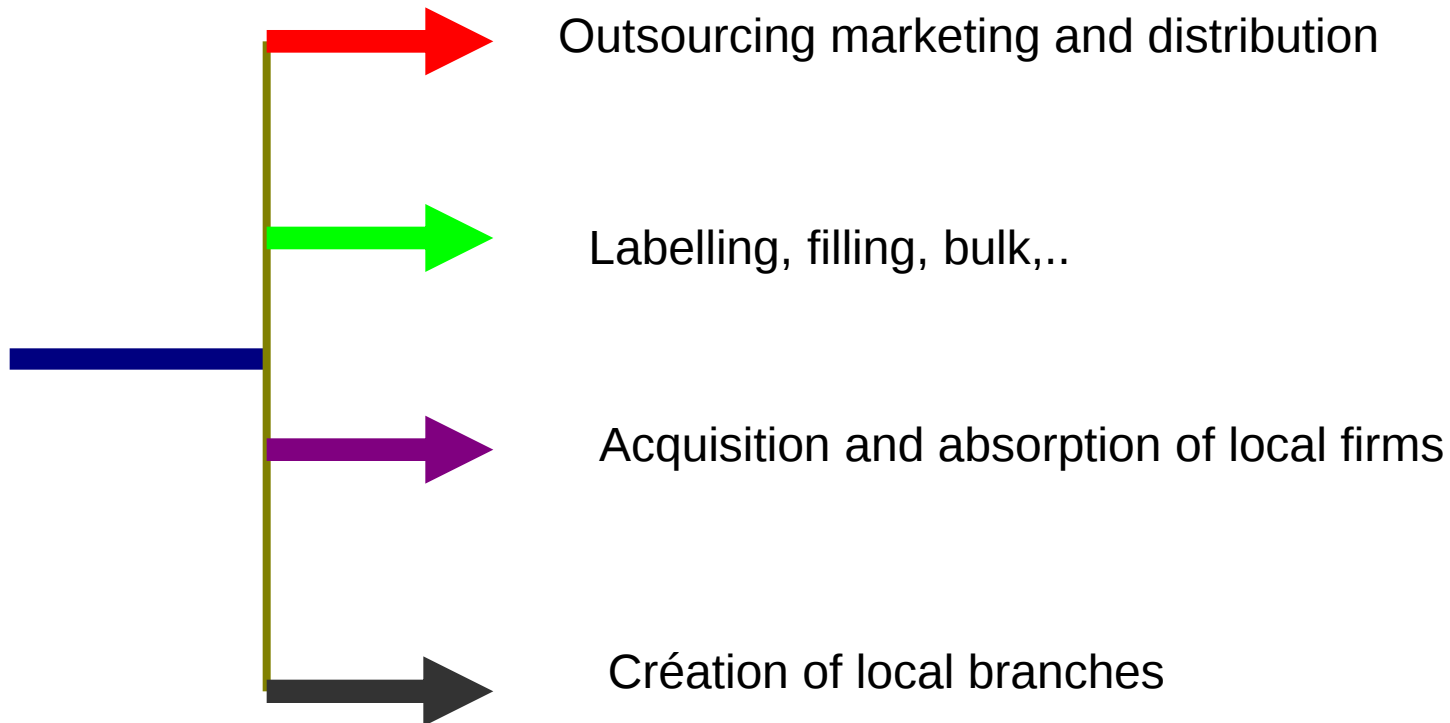
Arrangements with emerging economies and manufacturers

- Various types of arrangements, contracts and partnerships
- Taking into account country potentials and particularities:
 - size of population and potential market,
 - legislation favouring or not domestic production and TT,
 - production costs, scientific and technical capacity, price regulation,
 - NIP, immunization in the private sector,
 - regional influence,..
- Directly with countries and local manufacturers or through PPP or PDP

Various types of arrangements

Objectives:

lower costs, increase production capacity, competitive position
access to large public and private market, ...



A new trend: more active vaccine marketing in DC

- ❑ Emerging markets such as Mexico, Brazil, Turkey, Indonesia, Russia, China and India are among key priorities for MNC
- ❑ Singapour, Malaysia, Vietnam, Philippines, Egypt, GCC and others: second line
- ❑ Wide licensing and registration of new and innovative vaccines
- ❑ Increased presence of sale forces and MNC representatives : "pharma like model"

New business MNC model is emerging?

- More mapping, market segmentation and price differentiation
- Outsourcing selected part of R&D, production and commercialization/Access to promising markets and local capacities, low costs
- Risk sharing with countries and funders
- Collaborative networks and active presence at GHIs

UN Market: UNICEF and PAHO



Spectacular increase in the last 10 years



Both UNICEF SD and PAHO



Polio, measles, new vaccines



National, regional and global priority



MDGs, GIVS, GAVI, AMC, IFFim, GPEI,
Measles partnership, BMGF, DOV/GVAP

UN MARKET (in value)

	2002	2011	%
UNICEF SD	\$ 220 million	\$ 1,03 Billion	+ 468%
PAHO RF	\$ 120 million	\$ 400 million	+ 333%
Total	\$ 340 million	\$1,430 billion	+ 420%



Around 7, 5 % of total vaccine sales

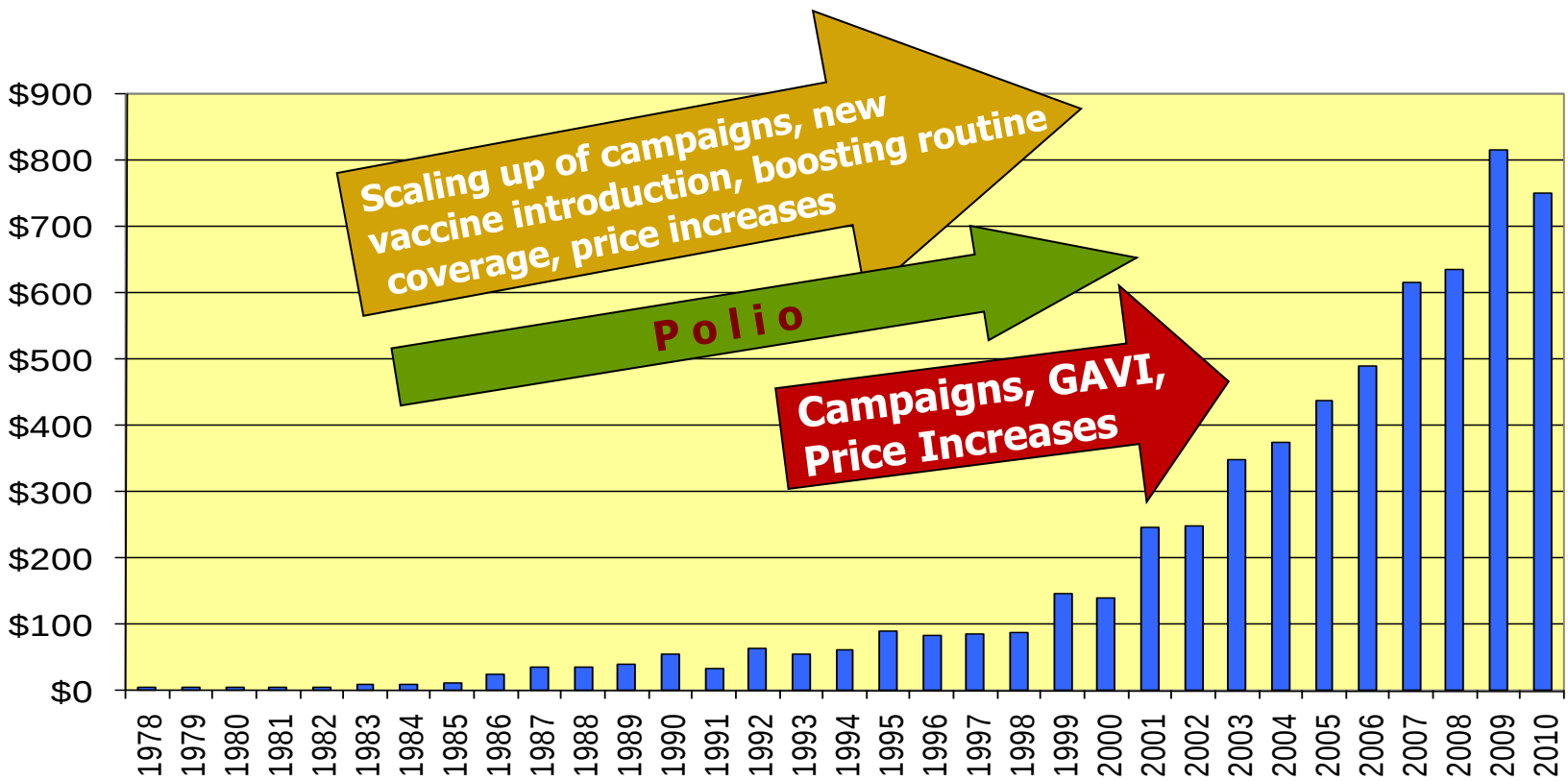
Sources: our WHO estimates based on UNICEF SD and PAHO RF data



**World Health
Organization**

UNICEF annual **vaccine procurement** has increased five fold since 2000 - supporting UNICEF Programmes and on behalf of Partners, Global Programmes Governments and NGO's

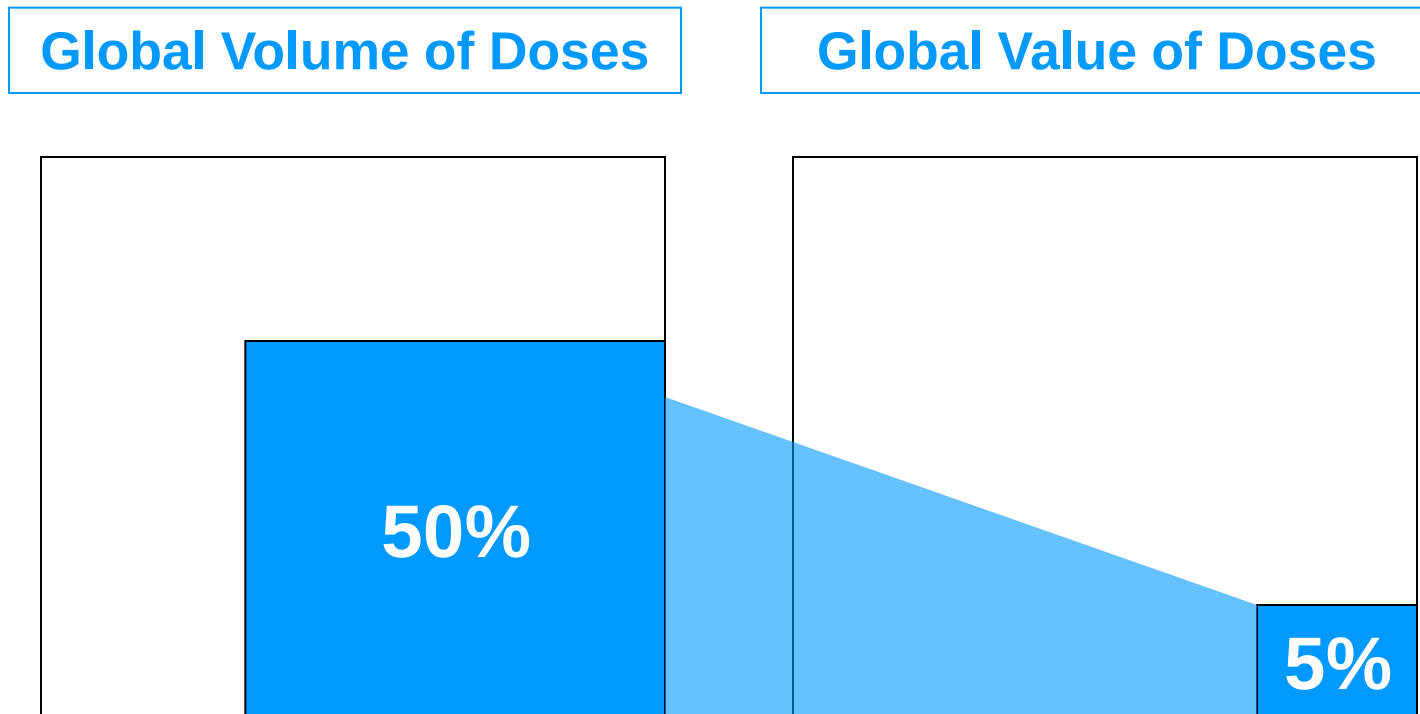
UNICEF SD Annual procurement value of vaccines, in million USD



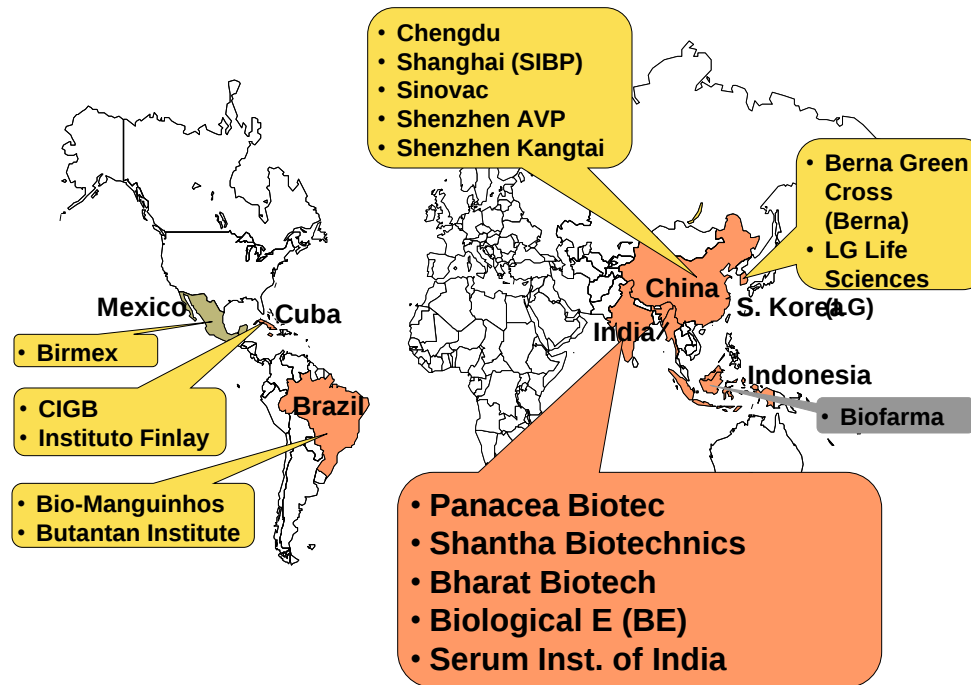
The arrows indicate the main programme drivers for the increased procurement value.

Source UNICEF Supply Division

The UNICEF 2012: buying 50% of the global volume of vaccine doses, mainly EPI vaccines, but representing only 5% of total market value

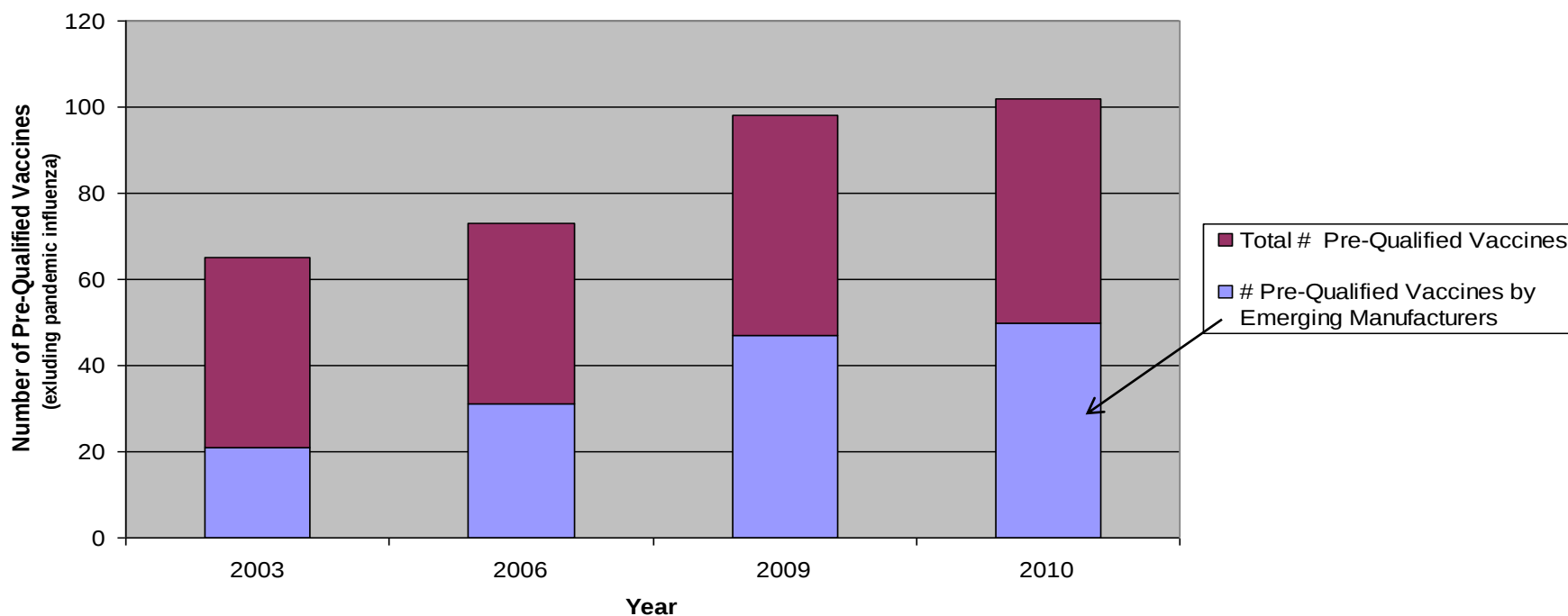


EMERGING MANUFACTURERS ARE PLAYING AN ACTIVE ROLE



Year	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
2003	66	21	32.3%	6
2006	73	31	42.5%	6
2009	98	47	48.0%	6
2010	102	50	49.0%	7

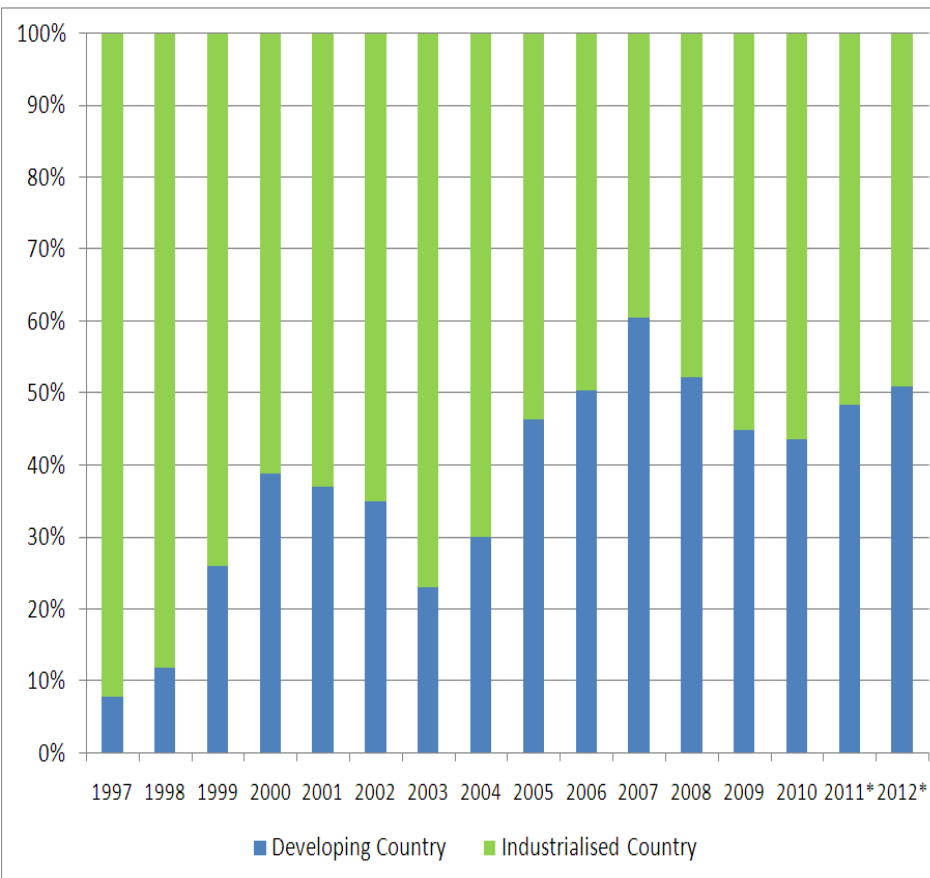
Number of Pre-Qualified Vaccines by Year with Shares from Emerging Manufacturers



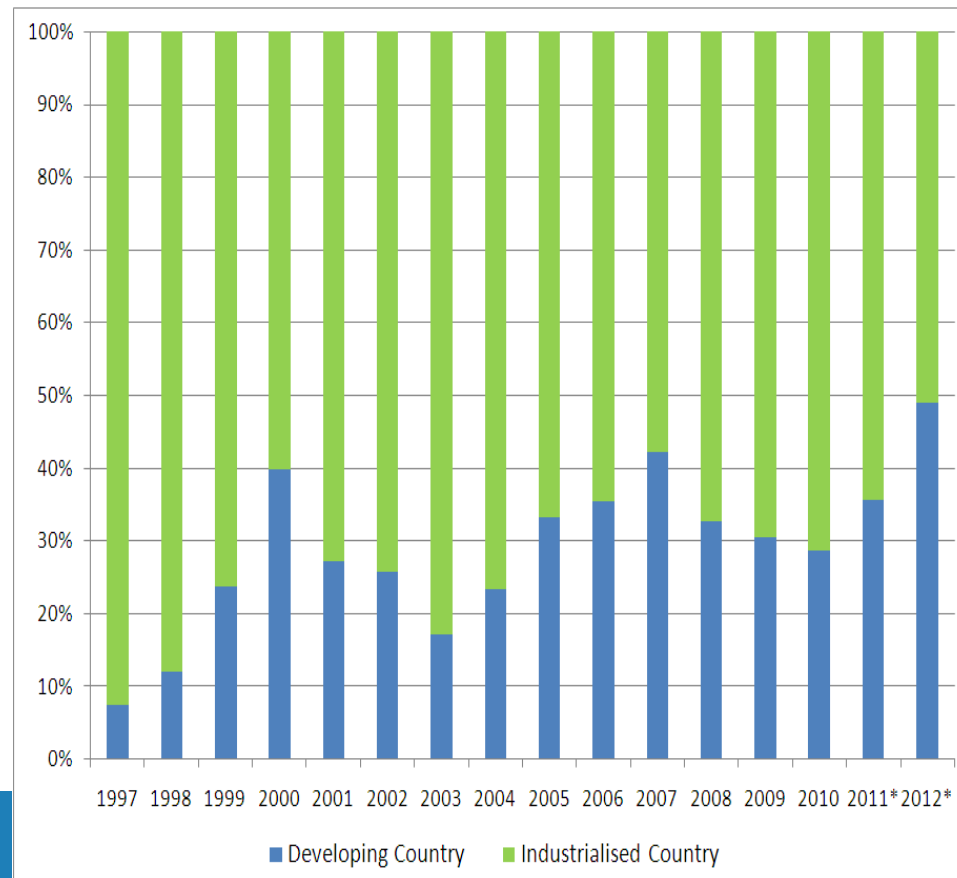
Emerging vs. Industrialized manufacturers

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

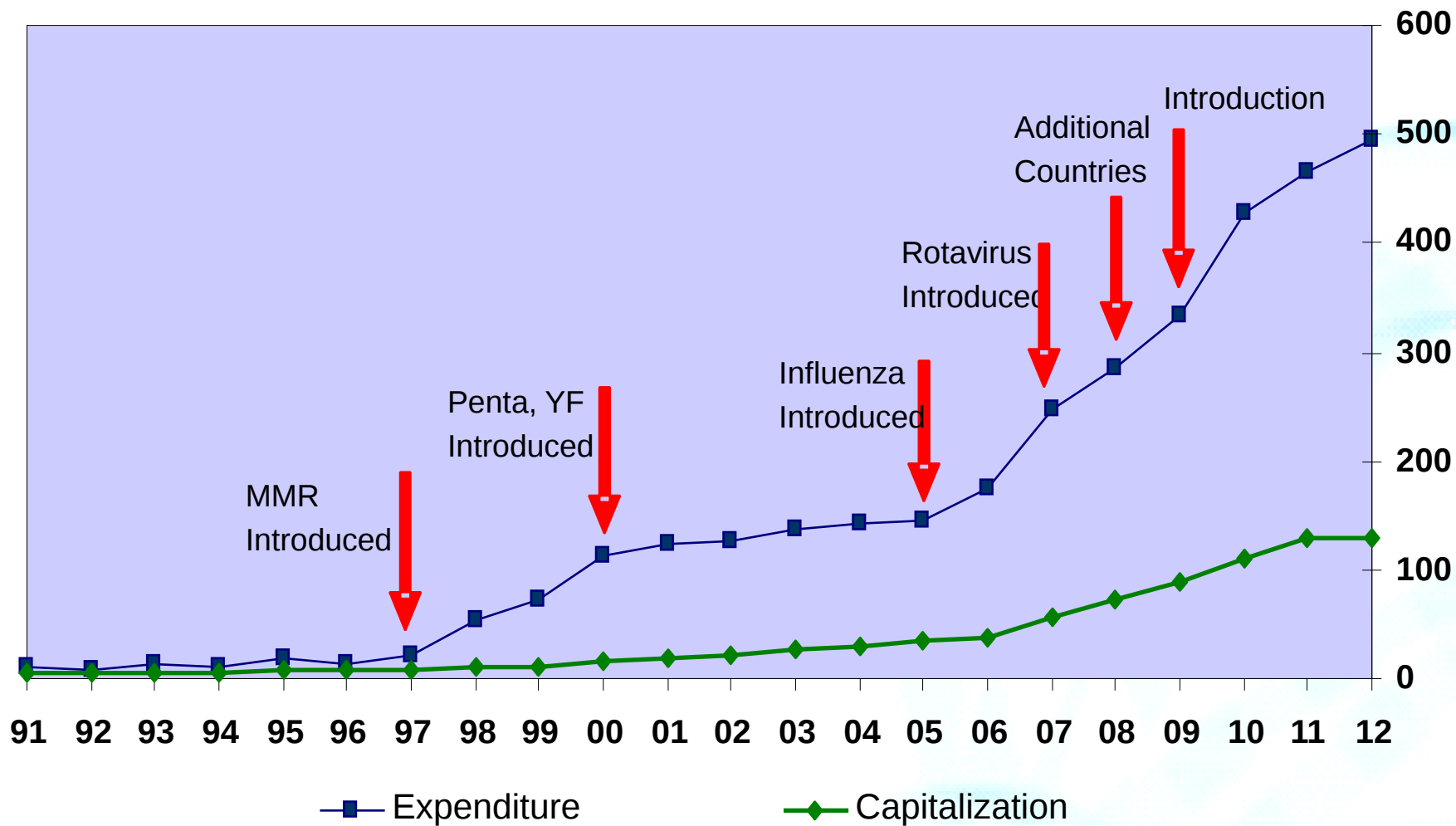
By Volume



By Value



Growth of the PAHO Revolving Fund



The PAHO Revolving Fund

Update: 2012



60 products
28 antigens

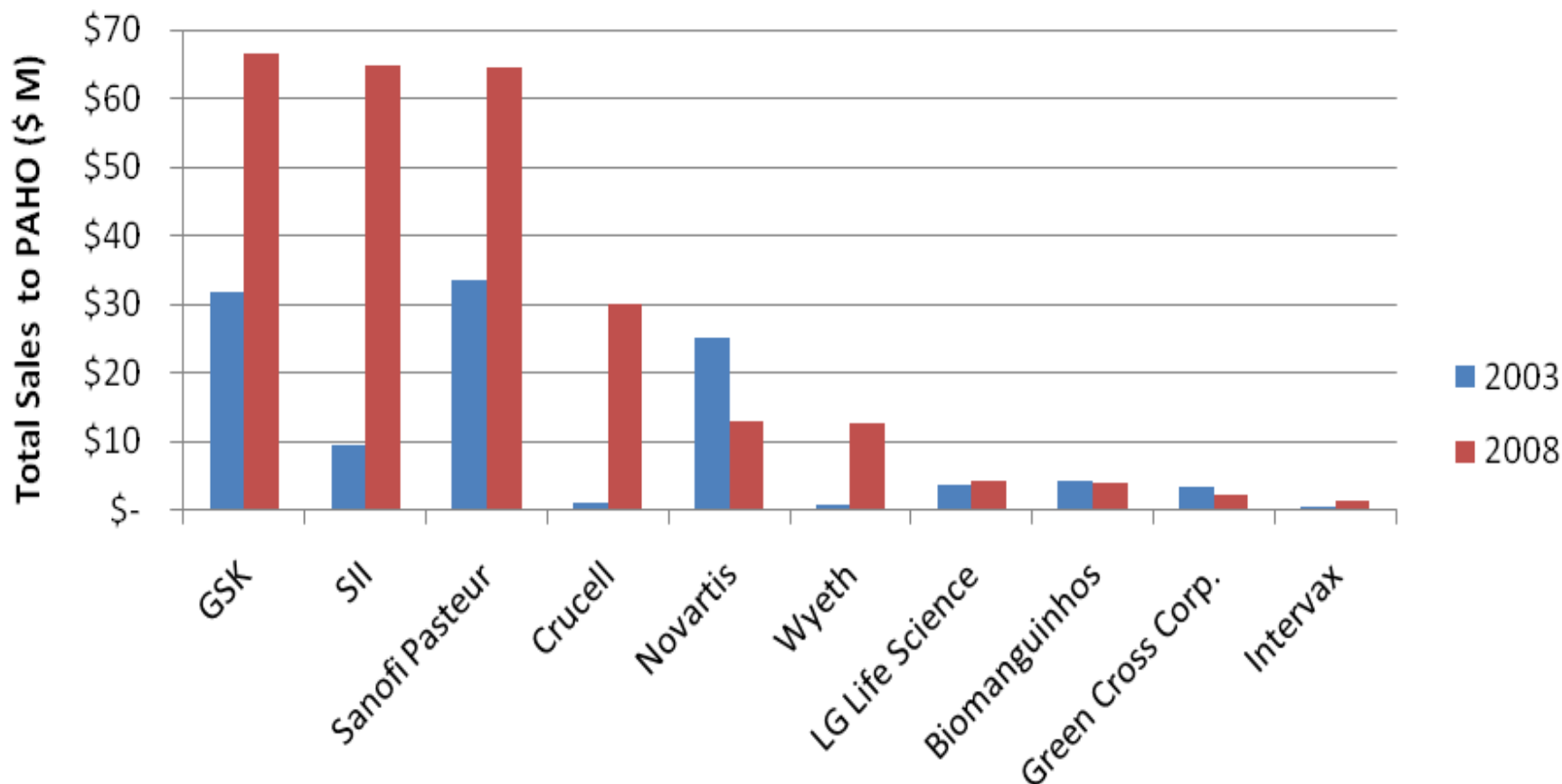


39 countries & territories



Expected Purchases: US\$ 405 million
Capital Fund: US\$ 100 million

Top ten suppliers of PAHO RF 2003-2008



In 2008, no one manufacturer accounted for more than 23% of PAHO purchases

NEW TRENDS ?

New trends ?

Demand side

- Vaccines and vaccinations : on the top of GoV and UN agenda, unmet needs
- Accelerate uptake and increasing demand in LIC
- Middle Income countries including emerging Countries

Supply

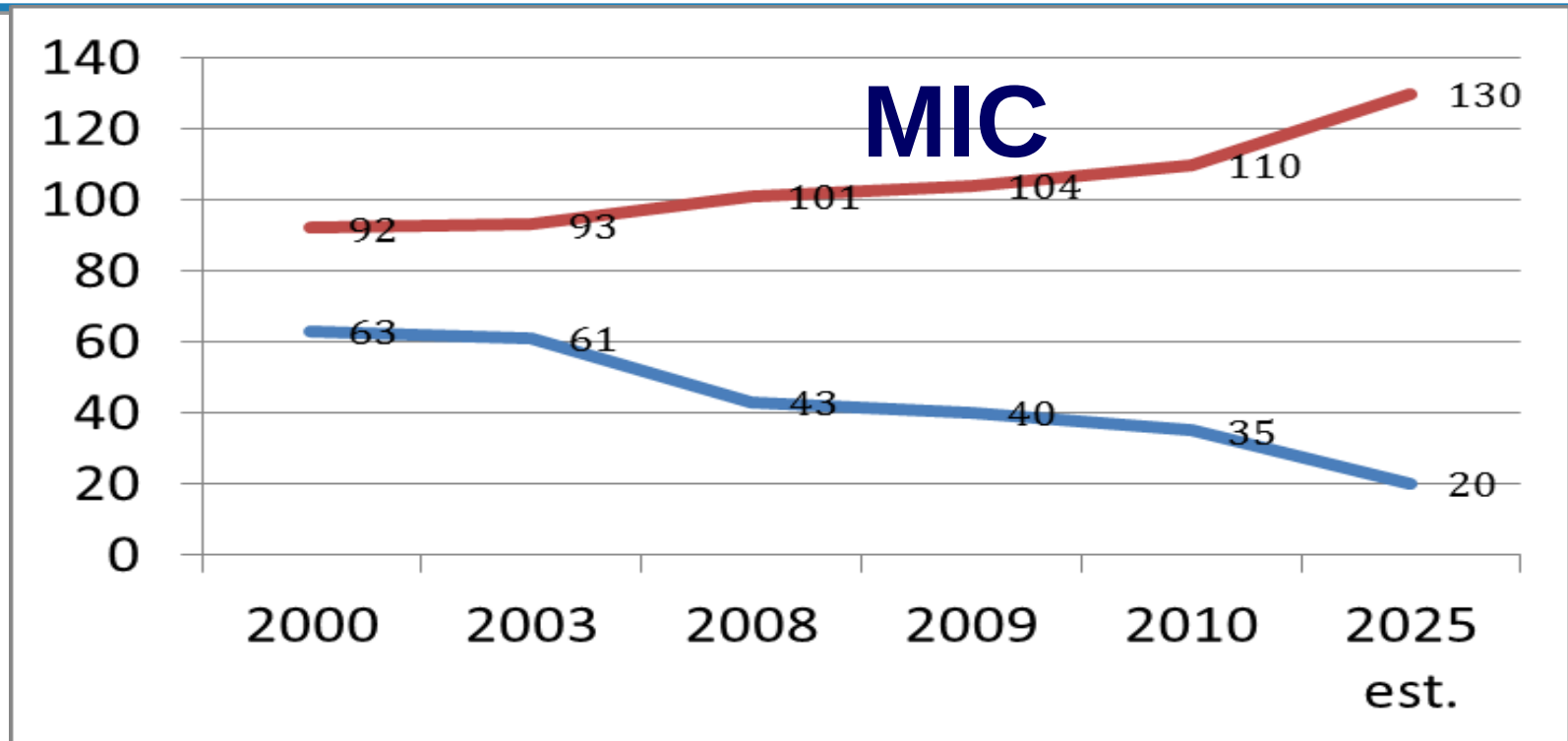
- Increasing capacity
- Remaining tensions on products
- New production and supply strategies

Funding

- GoV resources
- Donors
- Private foundations

More players on demand, supply and financing

By 2025, there will only be 20 LICs

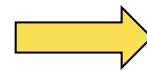


Number of countries by income classification and year

RED = MIC;

BLUE = LIC

Source: Leo and Moss, 2011
CGD A. Glassman



Development of "MIC vaccine market products"

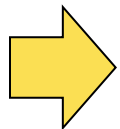
New trends in the last 5 years and their implications

1) Supply side

- Newcomers: Pfizer, Novartis, Johnson and Johnson,...
- New contractual arrangements between MNF/EM/EE
- Outsourcing of production in developing countries
- New commercial and marketing strategies (high volume/lower price, donation, active marketing,...)
- Product/market segmentation and differential pricing
- **MNC: new products and presentations with high return,**
- EM: basic and underutilized products high volume/low price
- Persistent supply tensions (basic and new vaccines)

Variety of tools to accelerate new vaccine access and to manage risks

- Innovative procurement approaches as pull mechanisms (AMC)
- Push mechanisms to accelerate vaccine supply (such as Men A)
- Long term commitments may be needed to fund vaccines to stimulate capacity expansion (such as YF)



New supply and procurement strategies

- Reduce risks for both producers and purchasers
- Increase predictability and co-responsibilities

Innovative Finance Achieving Results

Tools Used	Transaction Examples	Goal
Volume Guarantee & Prepayment	Rotavirus Vaccine: - Volume guarantee provided for a portion of the quantities with some volumes paid for in advance - Contract duration of 5-years covering 132M doses - New vaccine launched and sustained at lower price - Financing provided by GAVI, with strategic and technical support from the Gates Foundation ("BMGF")	\$15 per course → €3.76 per course >\$400M in savings over 5 years - Prepayment understood to facilitate expected expansion of manufacturing capacity - Accelerated introduction of Rotavirus vaccine made possible through certainty provided by commitment in new markets
Volume Guarantee	Oral Polio Vaccine (OPV): - Firm contract signed for 2011-2012 with large bulk and fill-finish manufacturer who at the time was considering exit of market - Duration of 2-years originally covering 270M doses per year (540M doses total) - Financing provided by BMGF	- Decrease in price offered to <\$0.118 per dose generated significant savings versus current WAP of >\$0.13 - Delayed exit of manufacturer by >2 years - Increased visibility for manufacturer and certainty of UNICEF procurement during fragile OPV market
Volume Guarantee & Prepayment	Pentavalent Vaccine (lyophilised): - Contract signed with new entrant to Pentavalent market with volume paid for in advance - Duration for <1 year covering 10M doses - Financing provided by GAVI	- New entrant to market secured volume and able to offer extremely attractive price of \$1.80 per dose, - Expanded vaccine security with expanded manufacturing capacity in a fragile market
Volume Guarantee	PCV - Volume guarantees for 20/10/5% of quantities or years 1/2/3 of 10 year contract - Financing provided by GAVI and WB	Part of overall AMC structure to achieve tail price of max. \$3.50 and sufficient production quantities to meet demand

Source: UNICEF SD, DCVMN meeting, Nov 2012

Vaccine Market:

Positive trends and Main Issues

- Positive trends

- Immunizations: on the top of the agenda: DOV and GVAP
- Promising vaccine pipeline, R&D
- Growing support: GAVI partners + Gov funding
- Multiple initiatives, PDPs and PPPs
- New players on supply and funding
- More WHO PQ vaccines leading to competition, price decrease
- Strategic role of UNICEF SD and PAHO and increasing role of funders

- Concerns :

- Oligopoly, limited supply for DC and Shortage risks
- Upstream factors : Technology transfer and IPRs, R&D for most needed vaccines, DCVM R&D capacity , ..
- New vaccine costs and prices
- Financial sustainability ? Govt responsibilities role
- Future of International initiatives
- Future of Emerging Manufacturers
- Impact of the financial crisis?