Financial Sustainability of the current model to introduce new vaccines: What is needed to create a more enabling environment

Presented by

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Presentation Outline

- The GAVI financial sustainability model
  - From theory to practice
  - Experience to date
  - Current challenges
- Tired pricing theory and practice
  - Implications for newly available vaccines
- Developing country manufacturer
  - Potential contributions to ensuring timely access of affordable vaccines

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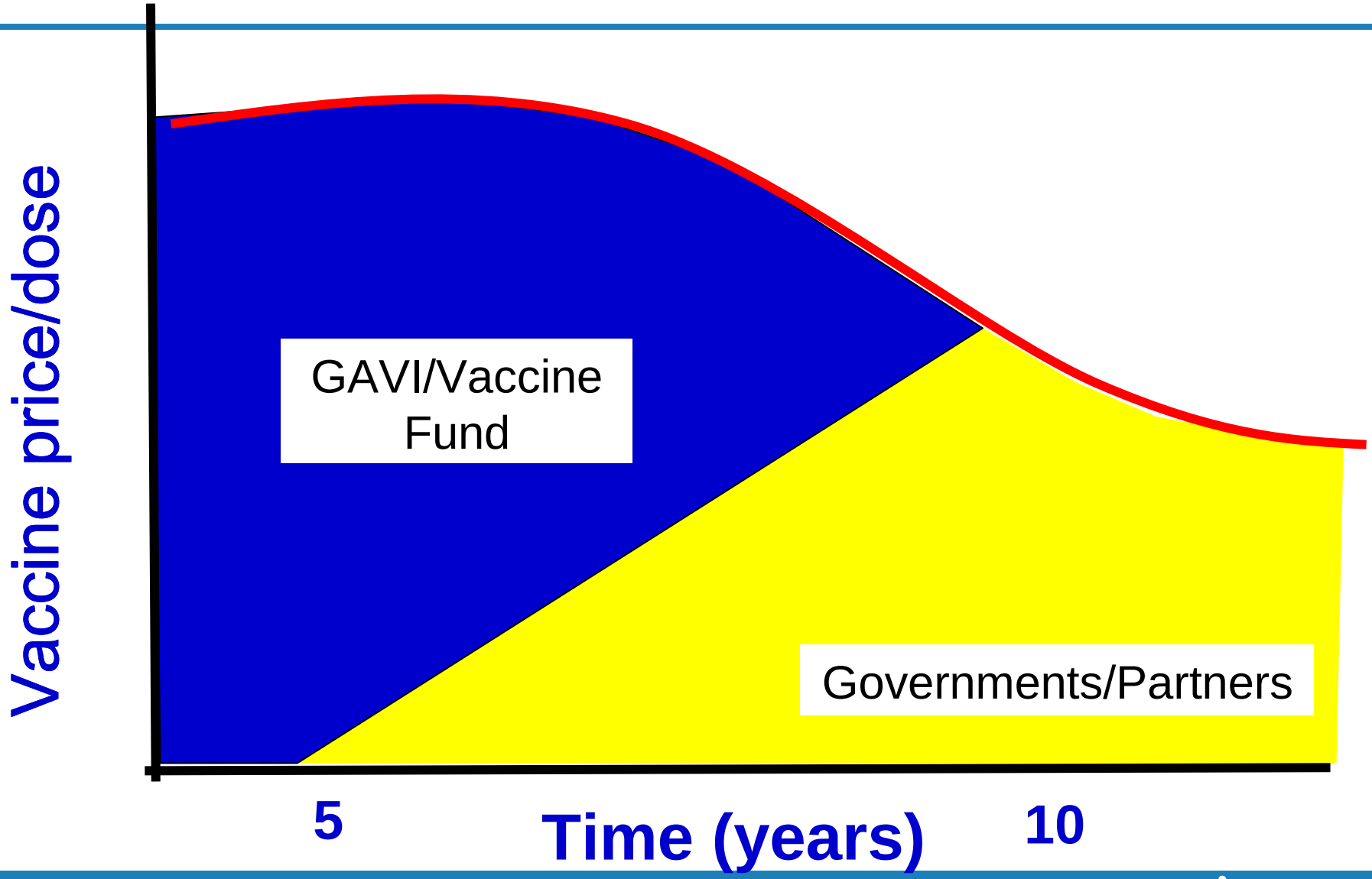
GAVI's Mission

- Increase access to immunization in the world's poorest countries
- Catalyse new activity (vaccine uptake) and reduce inequities in access between rich and poor countries
- Help address inadequate, unpredictable resources for immunization
  - MOH budgets limited and unprotected from economic shocks
  - Unpredictable external resources
    - Vulnerable to changing partner trends
    - Support tied to partner priorities
    - Encourages dependence on partners
- Augment existing funding for vaccines (not replace)
  - Reduce time to access by poor countries
  - Increase demand
  - Stimulate manufacturer investments
  - Reduce vaccine prices to affordable levels
- Ensure financial sustainability of catalytic support in medium term and shift global resources to support newer vaccines

GAVI strategy for financing new vaccine introduction



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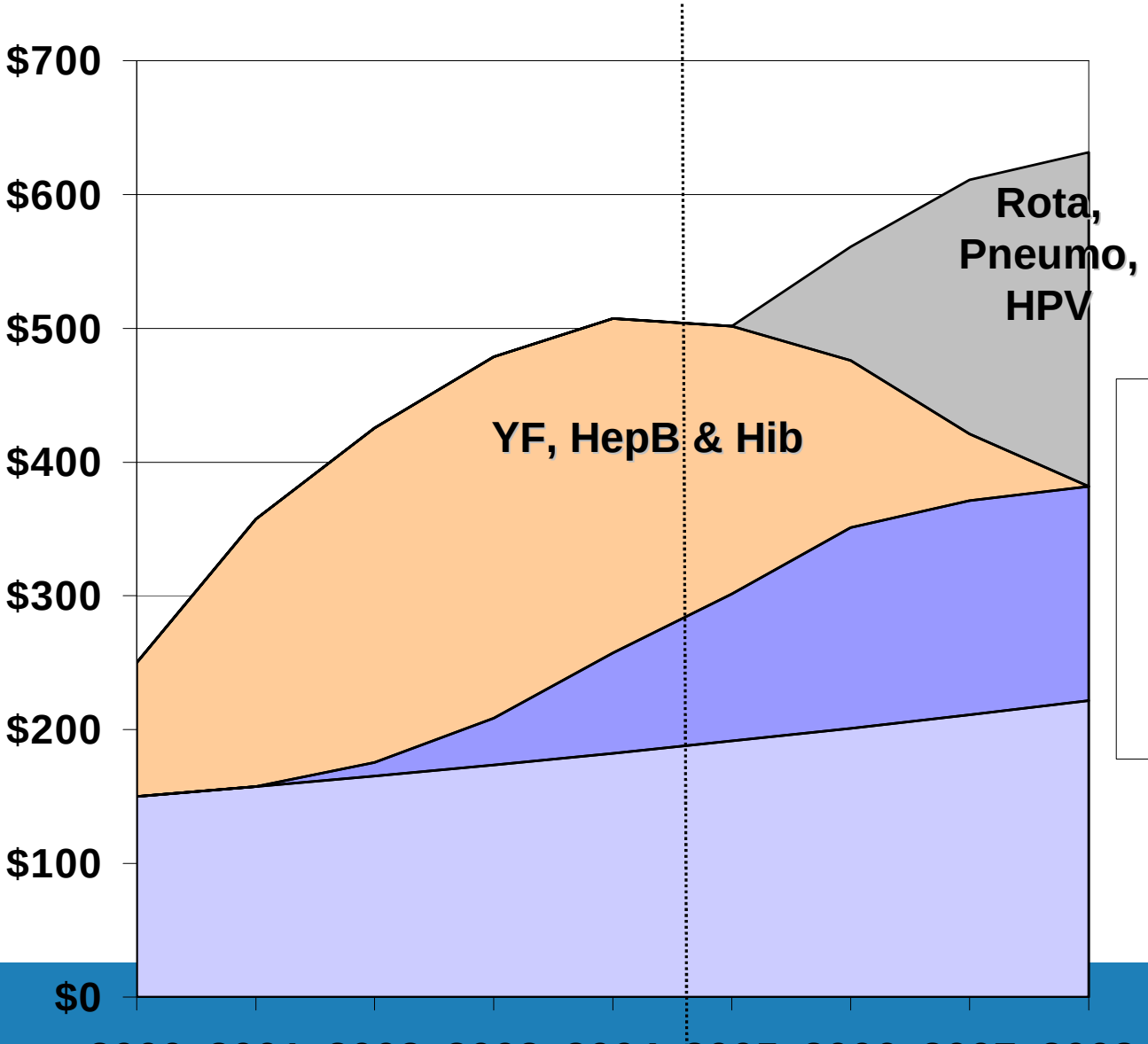
The GAVI Financing Model: Catalysing Funding for New Vaccines in the world's poorest countries



Principles:

- YF, HepB and Hib introduction
- System strengthening (90% DTP3)
- Performance based funding
- Multiyear commitments (5 years)

GAVI Phase II

GAVI Phase I

Catalysic Funding

Current Investments (Gov & Partners)

Financing assumptions:

- Vaccine price reduction
- Additionality of GAVI resources
- Catalytic funding
- Financial sustainability

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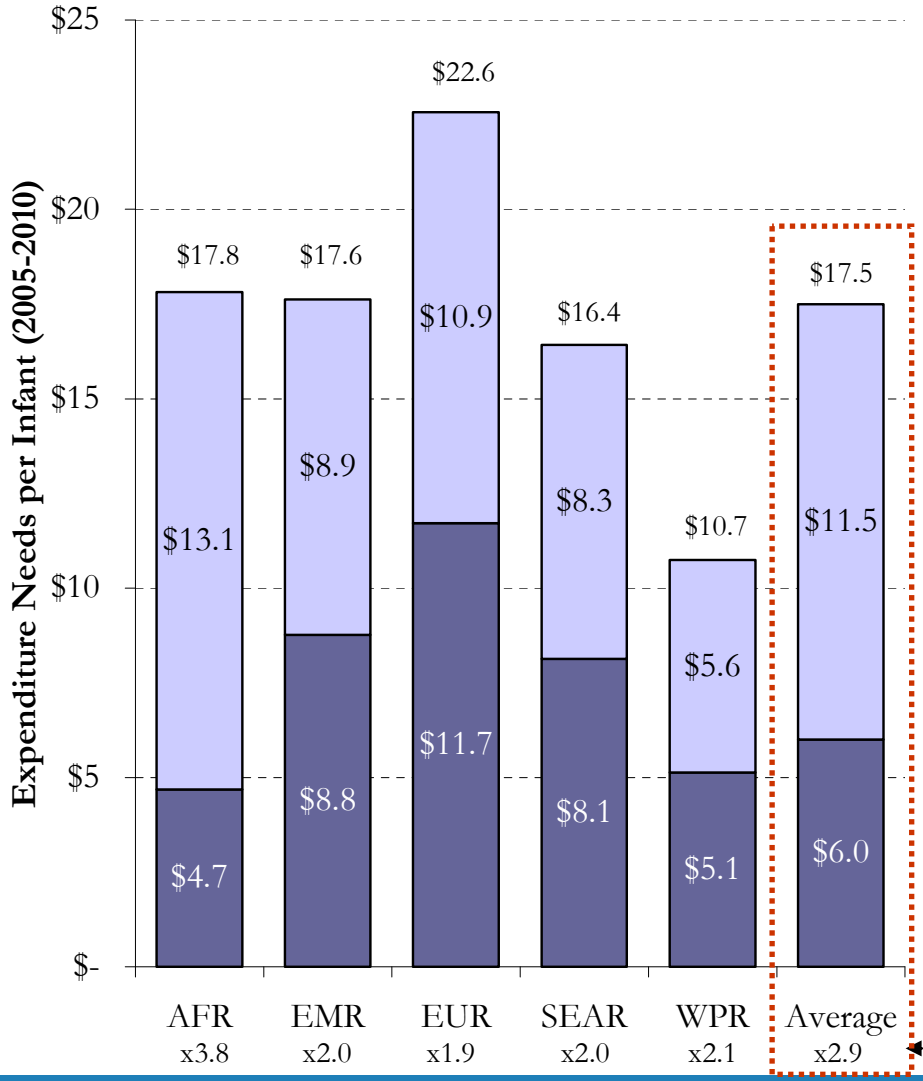
Immunization Expenditure Trends



- Total expenditures are on the rise (routine)
- To sustain gains and scale up coverage with HepB and Hib vaccines
- $6 in the baseline to an average of $17.5 per infant during 2005-2010
- Average scale up by a factor of 3
- Important regional differences

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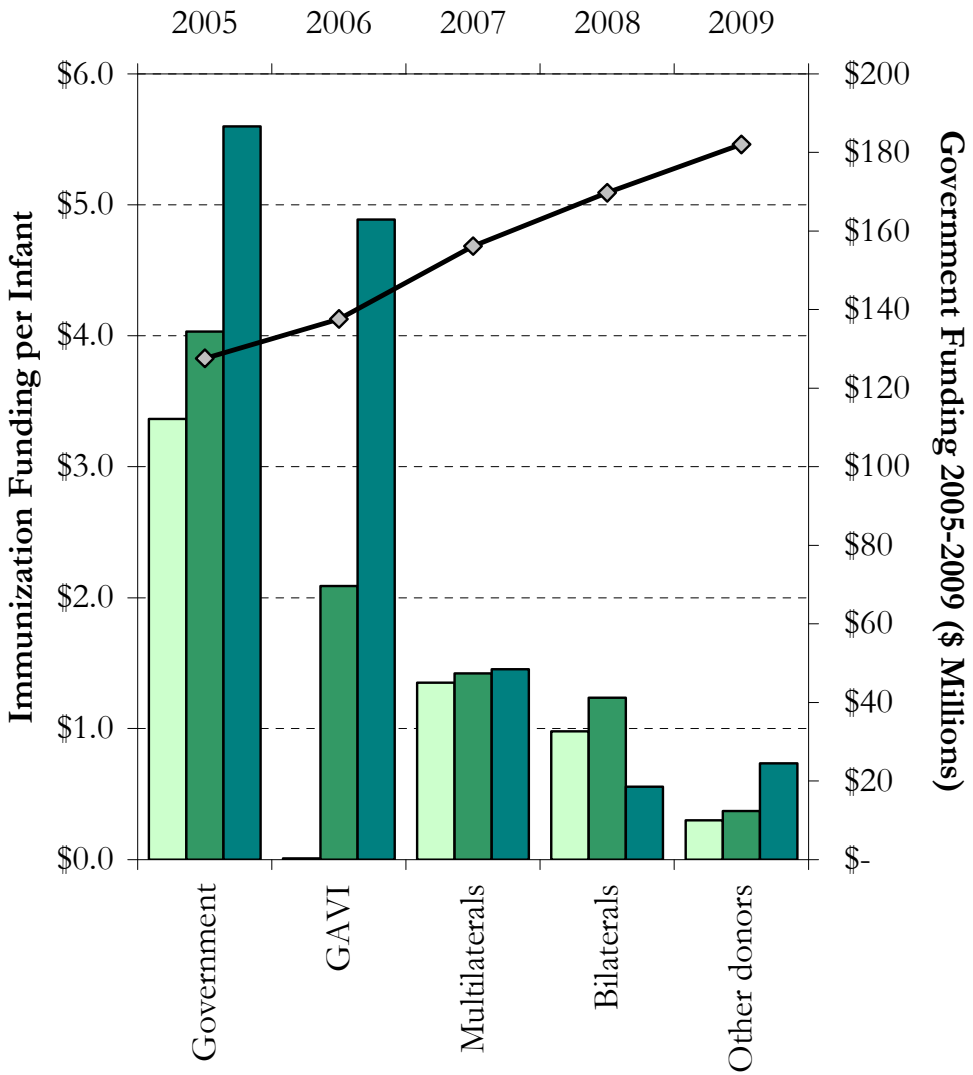
Immunization Financing Trends



- Total financing for routine is also on the rise and projected to increase in the future (optimistic scenario)
- Rises noticed for most sources of funding and in all regions
- Majority of the increase from national governments (22%)
- Second largest investments are from GAVI (not including phase II)
- While some substitution of funding is known of, there is no indication that overall GAVI has displaced resources

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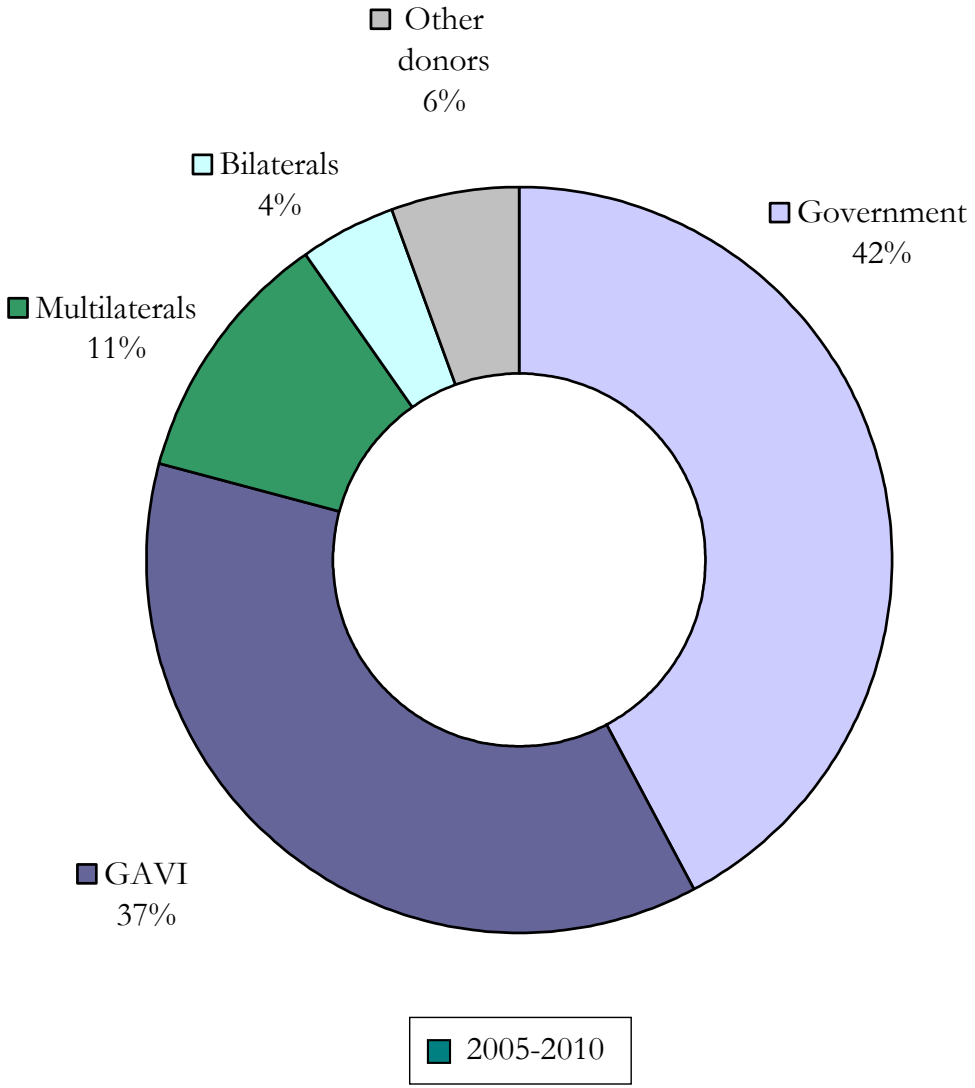
Immunization Financing Trends



- Changing financing profile – GAVI has become a major source (37% and rising)
- Multilateral support is third largest source for routine
- If campaign funding is included, multilaterals would represent the second largest funding source (30% and bilateral would account for 14%)
- Noting measurement challenges of bilateral support

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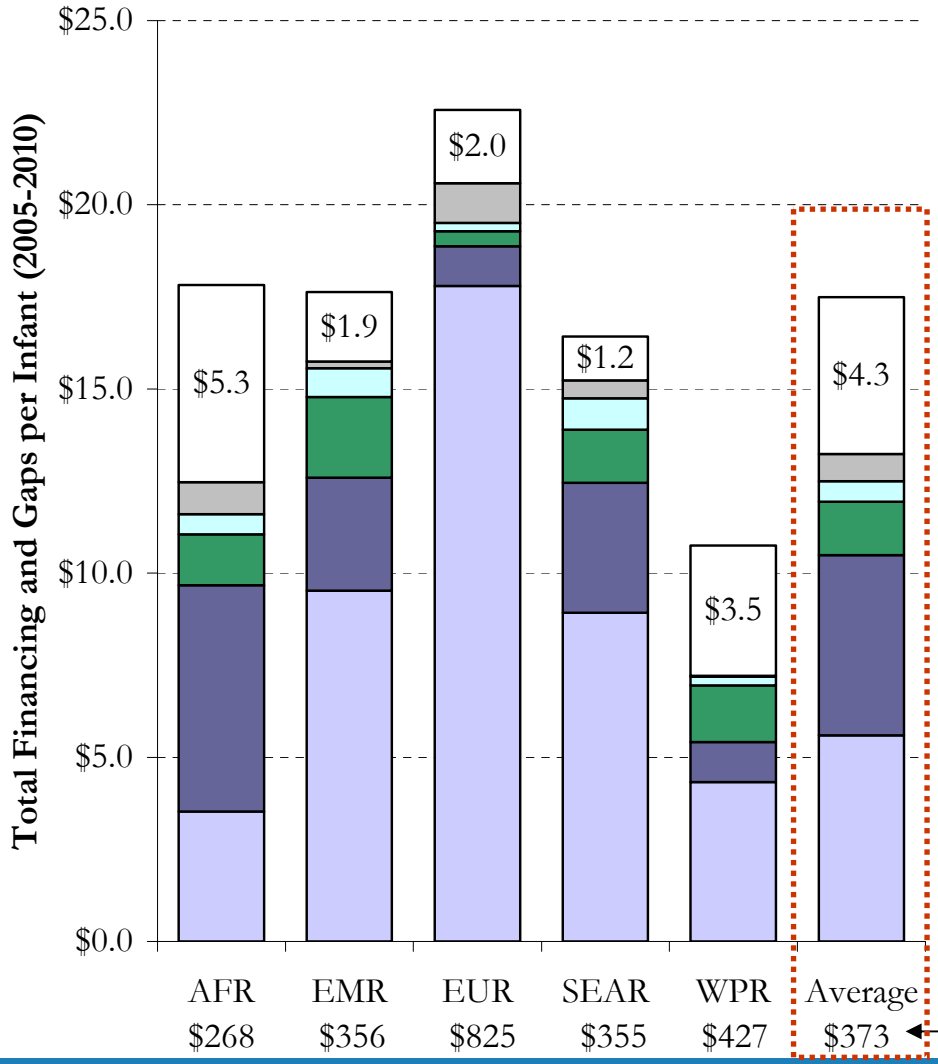
Trends in Funding Gaps



- On average, $4 funding gap per infant to reach goals of scaling up and completing the HepB and Hib agenda
- Variability in funding gaps and Government's ability to finance immunization across regions
- AFR has the least ability to pay and account for majority of countries
- AFR most dependant on GAVI

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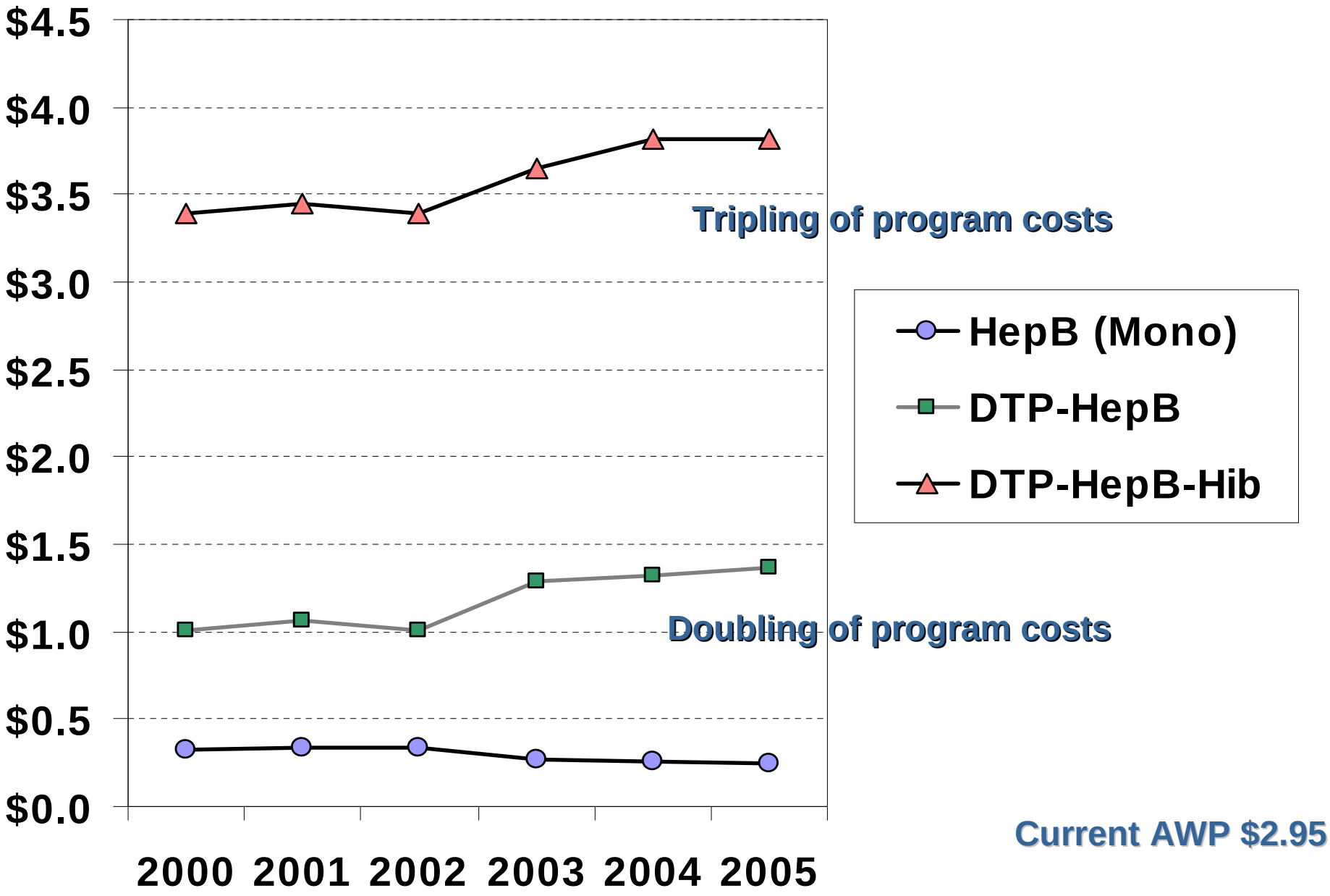
Financial Sustainability

	Gov. Health Expenditures	Externally Funded HE	Proj. Immunization Expenditures (2005-2010)	Gov. co-financing vaccines
	GHE per capita	% GHE	% GHE	$ per infant
Overall	$7.8	22%	4%	$0.8
AFR	$7.1	42%	9%	$0.7
EUR	$25.7	5%	1%	$3.4
HepB (mono)	$11.3	8%	1%	$1.6
DTP-HepB	$8.4	53%	6%	$1.1
DPT-HepB+Hib	$5.4	51%	9%	$0.5

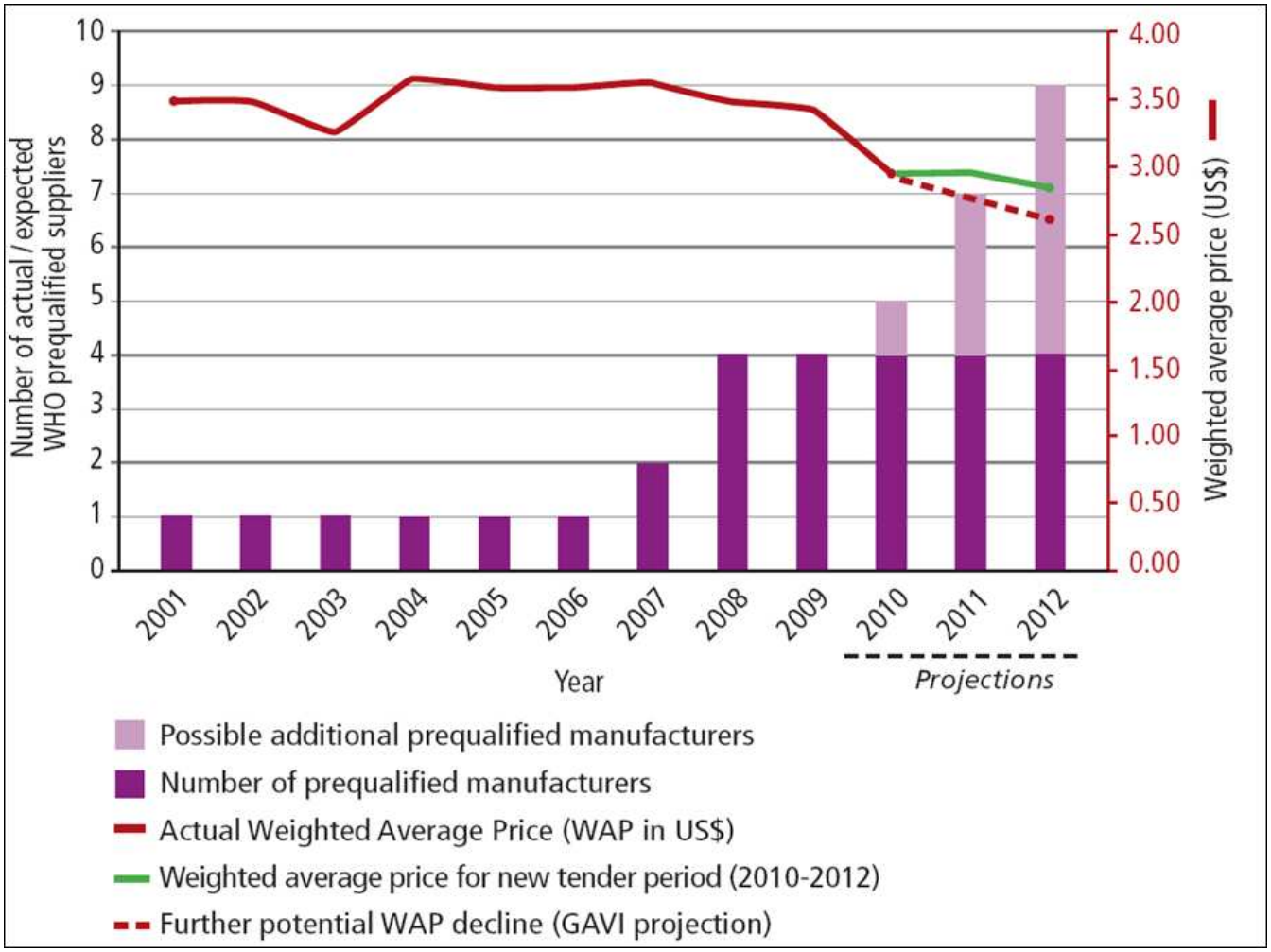
- Countries with the lowest co-financing levels and least ability to pay have introduced the most expensive vaccines
- These same countries have the lowest levels of health financing and highest % of it being externally funded
- This situation corresponds to the majority of countries in AFR

Trends in HepB – Hib Prices



Current AWP $2.95

GAVI Impact on Pentavalent vaccine market dynamics: price and supply



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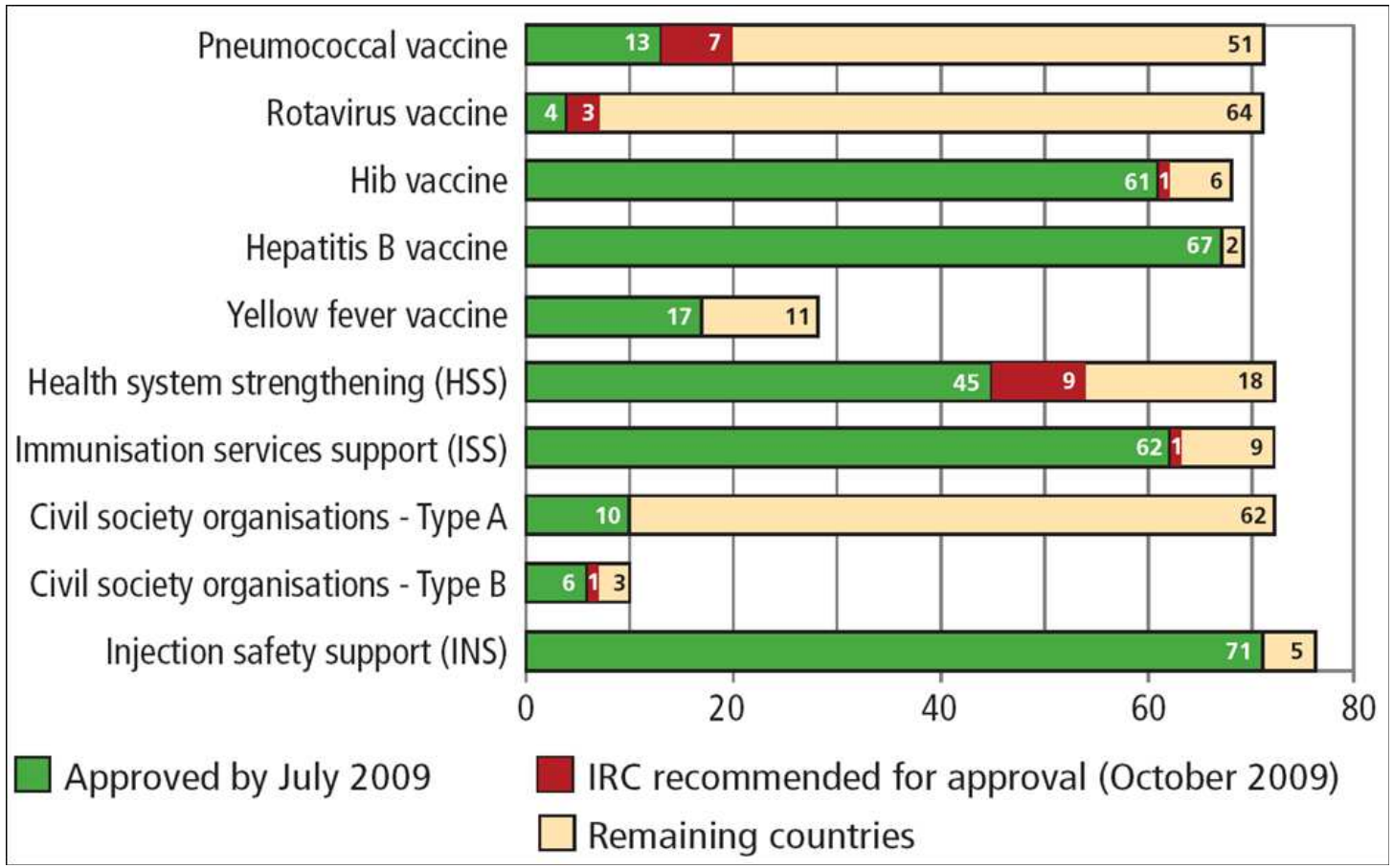
GAVI Impact on vaccine uptake in LICs



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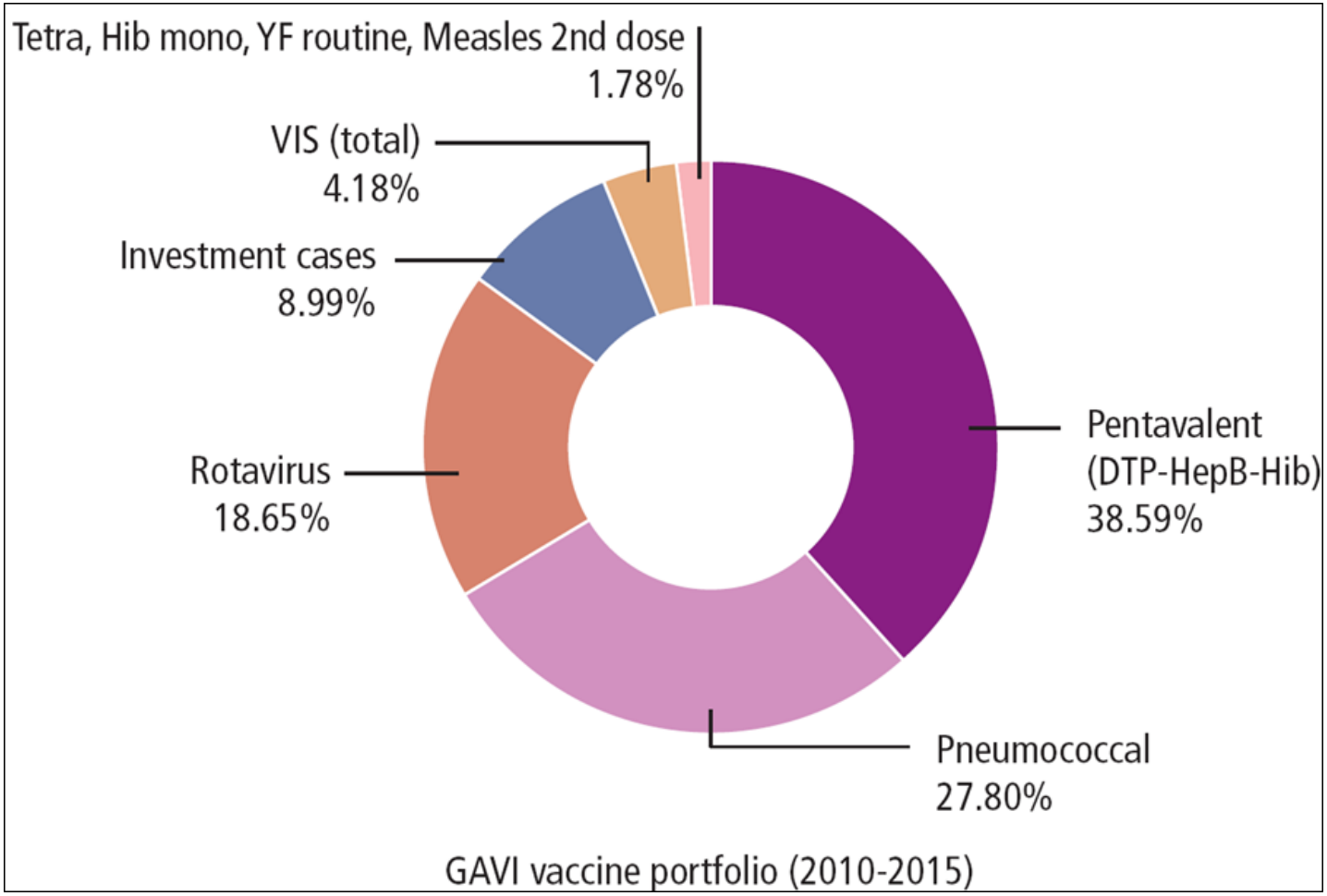
GAVI's Projected share of vaccine expenditures 2010-2015



Pneumococcal excludes AMC donors' contributions.
Total projected expenditure (2010-15) US$ 2.89 billion.

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GAVI's Results

- Huge impact in vaccine introduction in the poorest countries
- Longer time needed to stimulate vaccine market (5 years not enough)
  - Stimulate demand
  - Entice new entrants
  - Forster competition (DCMs)
  - Achieve intended price reduction
- Affordability of current vaccines to national governments far from assured (Hib)
- Current country co-financing equates to a small fraction of total vaccine costs given price of new vaccines
  - Affordability concerns still very prominent
  - Financial sustainability far from assured
- Challenges with accelerated uptake and sustained introduction of new vaccines (pneumo, rota, HPV, ...)
- Further innovations and investments needed to impact vaccine supply and price
- Significant amounts of funding required (external and national) if agenda to be completed and expected health impact achieved

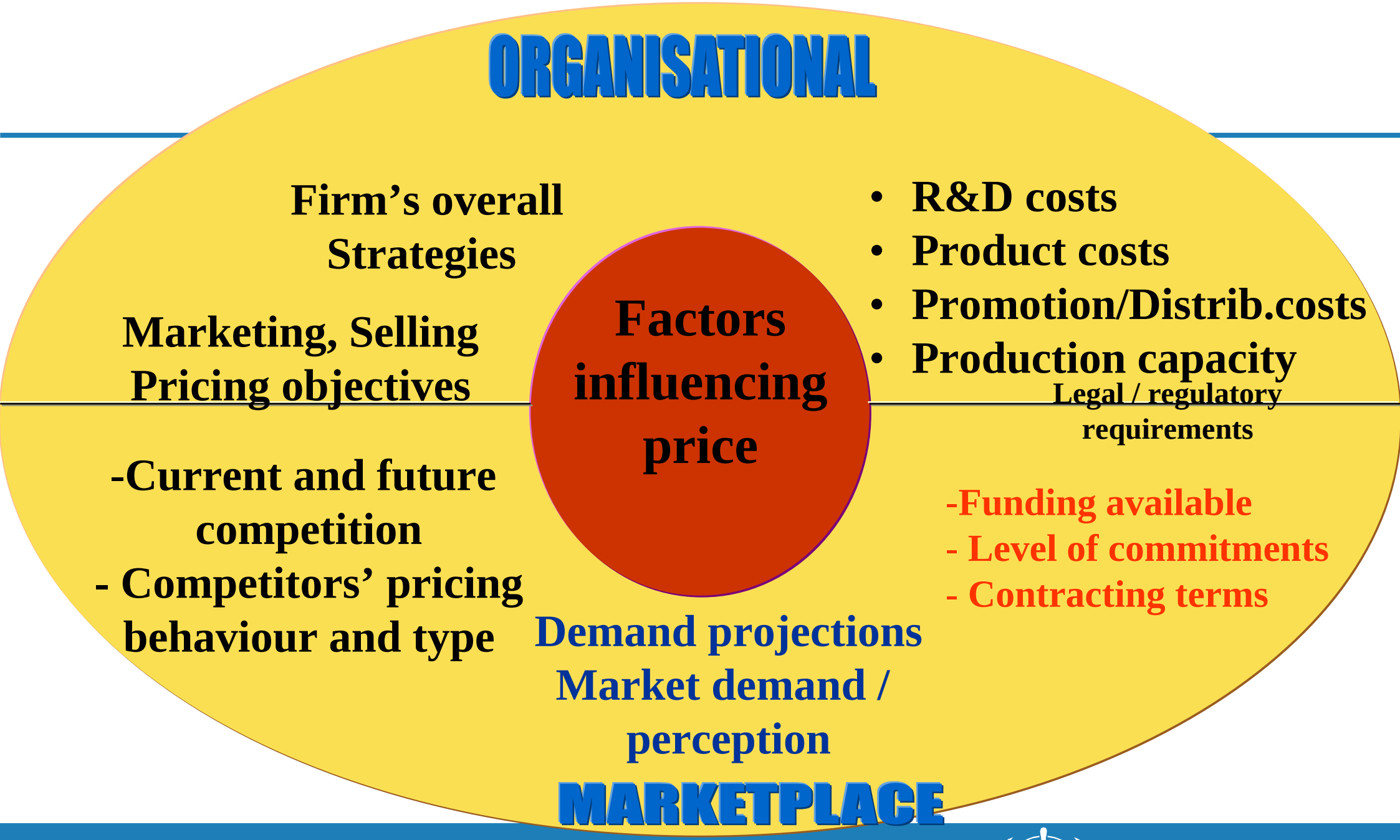
Tiered Pricing

SIMPLE THEORY and COMPLEX PRACTICES

Different classes of buyers charged different prices for same product

- **LICs charged reduced prices (e.g. HepB) compared to open market through bulk procurement systems (UNICEF, PAHO)**
- **Reduce financial barriers and improve access to vaccines in LICs while providing manufactures with a profitable market in richer markets**

- **Prices: are the result of multiple factors and not determined solely by the country income level**



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Experience to Date and Challenges

- Possible only under certain facilitating conditions
- Generation of Demand,
  - Aggregated and predictable demand
  - Large production capacity,
  - Similar product across markets,
  - "Equitable" differentiation,
  - Available and predictable external funding,
  - Reliable procuring entity ...reducing transaction costs for manufacturers
- Issues with who defines
  - Priorities?
  - Country eligibility to a lower price?
  - For how long?
- Entry of emerging manufacturers was effective in bringing down price of traditional vaccines (HepB) but still to be tested with newer vaccines (Pneumo, Rota, HPV, ...)
- Affordability and profitability of new vaccines targeting LICs only (e.g. Malaria)
  - Provide less profit incentives to manufactures due to high R&D costs
  - Possible attraction may be price subsidy of targeted products by donors (e.g. GAVI Pneumococcal AMC, ...)

Global Vaccine Market: Rapid growth and changing status

- Tripled in value from USD 5B in 2000 to almost USD 17 B in 2008-2009.
- 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 big pharma
  - Changing status of the vaccines within the pharmaceutical industry

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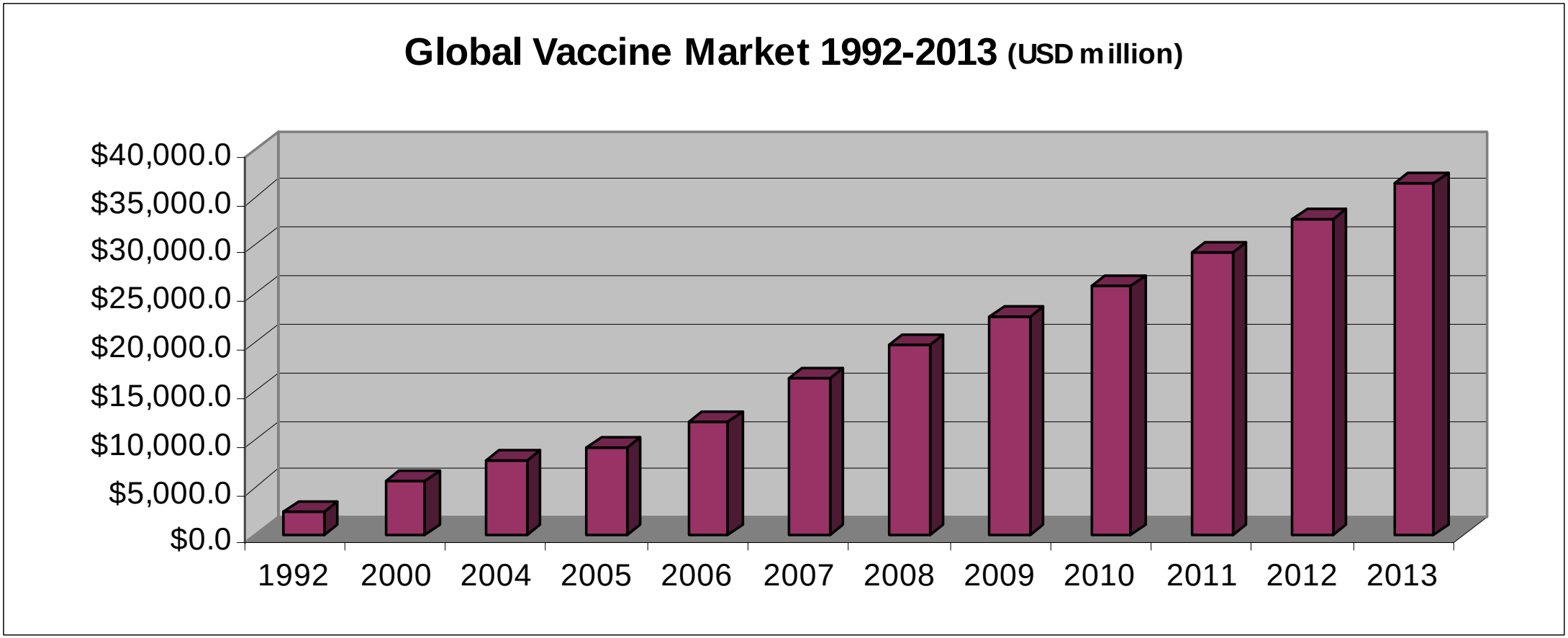
The Evolution



Sources: different estimates and projections (WHO, Industry, Frost and Sullivan, Biomarket group, Bionest, Kalorama,.)

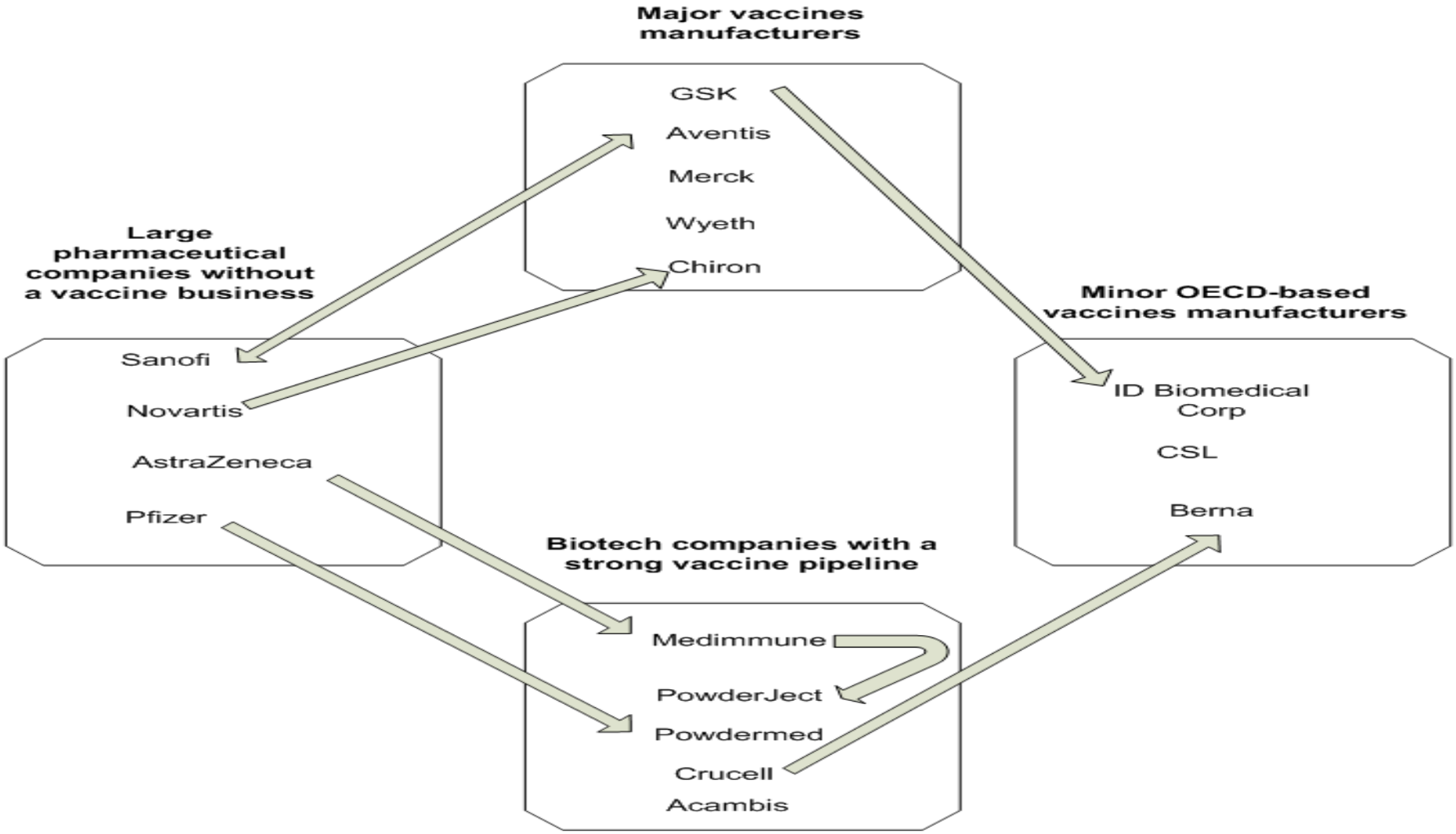
2009-2012: projections

Vaccine Industry Characteristics

- 80 % of population make up less than 20% of global vaccine market
- "Blockbuster" sales for some innovative vaccines
  - Regular and rapid growth in volume and dollar value
- Very segmented
- Shifting disease threats
- Expanding target groups and applications
  - Of benefit to big pharma or to emerging manufacturers or to both
- Expanding market (middle income countries)
- Accelerated uptake of NUVI in low income countries (GAVI, IFFim, AMC,..)

- Developing country manufactures
  - Emerging markets such as Mexico, Brazil, Turkey, Indonesia, Russia, China and India are among key priorities for MNC
  - Singapour, Malaysia, Vietnam, Philippines, Egypt, GCC,: second line
  - Wide licensing of their new and innovative vaccines (Prevnar®, Gardasil® and Rotateq®,…)
  - Increased presence of sale forces and MNC representatives : "pharma like model"

Mergers and acquistions 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 'large pharmaceutical companies without a vaccine business') and company names refer to the situation in 2002.

Challenges and opportunities for emerging manufacturers

- Are the EM making the best use of current opportunities and global initiatives?
- Financial sustainability of current model based on GHIs
- Effects of more business-oriented approach to supplying priority vaccines
- Are the EM acting as a more and more powerful, harmonized and innovative players or not?
- How can the international community contribute to building an enabling environment to promote competition, better response to priority needs and a health vaccine market ?