Vaccine development and access for developing countries

Issues and options

Paul Wilson on behalf of Médecins Sans Frontières
and Oxfam International

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Successes over last decade

- ✓ Continuing increase in basic immunization coverage

  But great disparities remain.

- ✓ Introduction of additional vaccines to EPI package

  But most low-income countries still depend on increasingly insecure GAVI funding.

- ✓ Development of several important new vaccines

  But prices remain very high and vaccines are not necessarily adapted to developing country needs.

Challenges

A. Access to existing vaccines

- Health systems
- Supply
- **Affordability**

B. New vaccine development

- Vaccines for “neglected” diseases with little rich-world market
- More appropriate versions of vaccines developed primarily for high-income markets

Access challenges: important new vaccines

Vaccine	Global deaths	Licensure	US price (CDC)
Pneumococcal conjugate	800,000	2000	$71
Rotavirus	500,000	2004	$57-83
HPV	260,000	2006	$91

None of these vaccines is yet in widespread use in low- and middle-income countries.

Access challenges: affordability

The problem: very high prices for new vaccines

Two popular solutions:

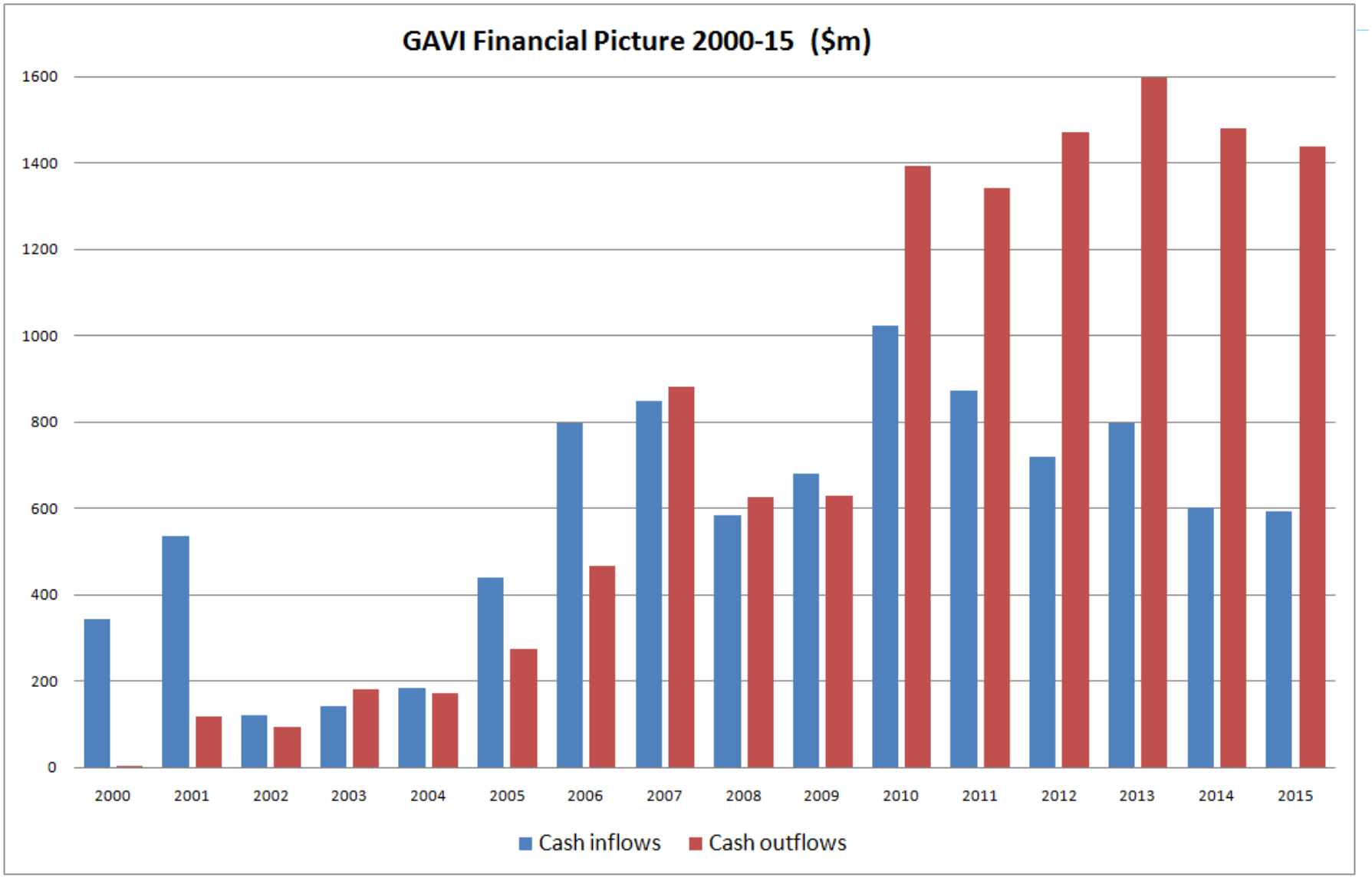
A. GAVI subsidy for the poorest countries

- Financial uncertainty
  - Rapidly growing commitments for penta, pneumo, and rota
  - Decline in revenues from IFFIm beginning after 2010
  - Effect of economic crisis on donors
- Decreasing reach: only 56 countries with GNI p.c. below $1500

B. Tiered pricing

- Can help to ensure lower, if not necessarily lowest, prices for the poorest countries
- Contentious for middle-income countries

GAVI's financial situation



From document for GAVI board, November 2009

Tiered pricing

Rationale

- Monopolist's profit maximization: price discriminate where possible
- Those who can afford to pay more should, to allow poorest to pay less
- Higher prices for OECD countries now relatively uncontroversial

Problem of affordability

- "Tiered prices" too high for lower-middle-income countries?
- Diversion of public health expenditure from other uses (large poor populations)

Problem of determining "right" prices for middle tier

- "Appropriate" mark-up varies with R&D costs, importance of high-income markets, **number of suppliers** (penta vs pneumo)
- Who sets?
- Ultimately about market power (**pooled procurement**)

Tiered pricing II

What is/should be the position of DC manufacturers?

- How will DCVM pricing strategies evolve as business models evolve?
- As R&D costs rise, how should benefits of price discrimination (for firms, and for some countries) be balanced against objective of affordability and access?

“De-linking” price from cost of R&D

A theoretical objection to tiered pricing: economic inefficiency

- In principle, best price is close to manufacturing cost
- Prices close to manufacturing cost would maximize access in all countries…But firms must cover cost and risk of R&D
- Tiered pricing one solution (costs recovered in higher-income markets)
- Another solution would be reward innovation separately (“prizes”), produce at close to cost through competition
  - R&D costs covered without hindering access
  - R&D incentives aligned with public health need
- But who funds and who decides?
- More challenging to facilitate competition for vaccines than drugs

The role of developing country manufacturers

Developing country manufacturers can bring down prices by:

- Producing at lower cost (in some cases)
  - Different business models
  - Higher volumes
  - Different cost structure
- Making markets more competitive

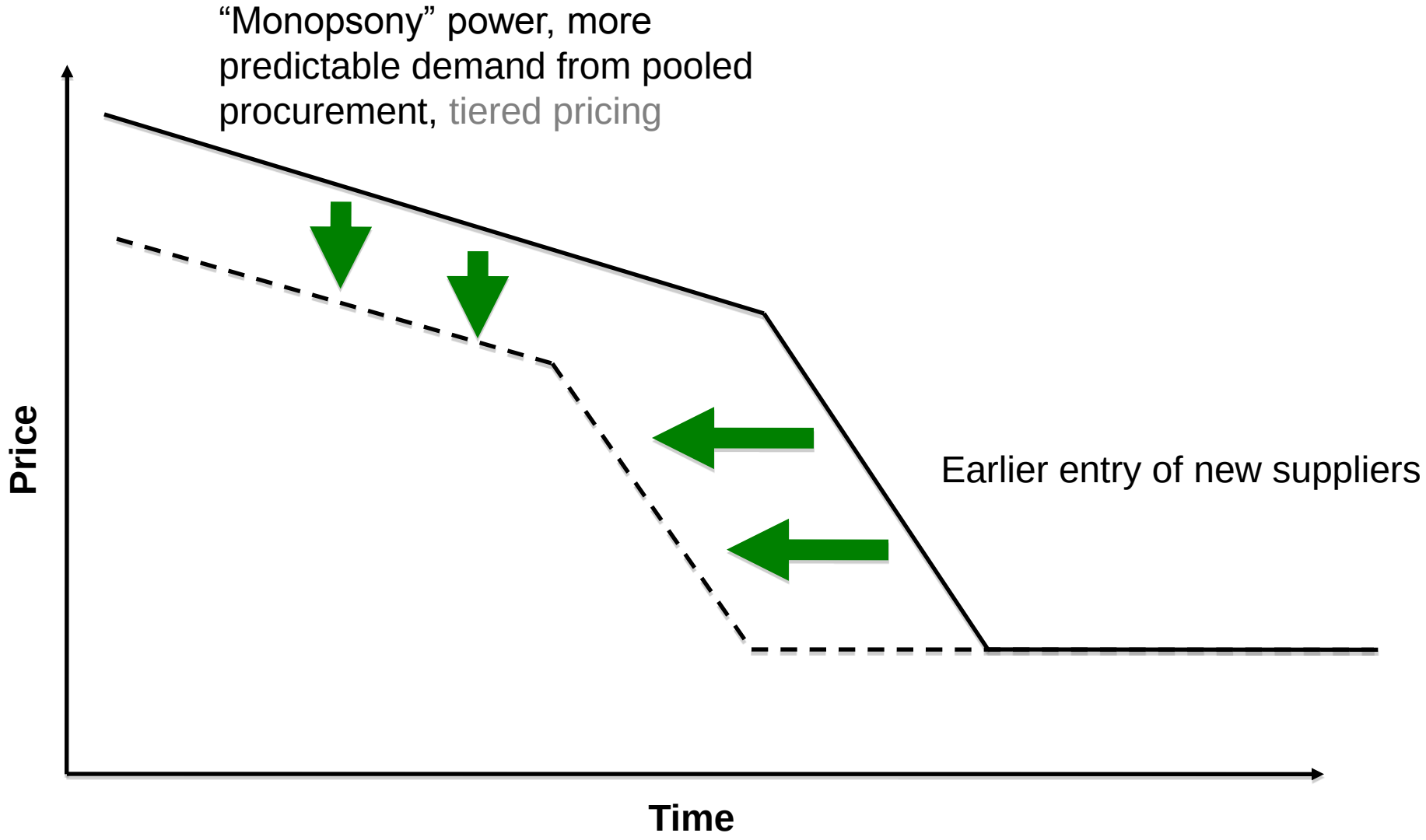
The entry of new suppliers can be facilitated by:

- Facilitating access to R&D financing
- Transferring technology and know-how (Rotavirus Vaccine Project, Meningitis Vaccine Project, IVI, WHO/NVI Technology Hub)
- Increasing IP transparency, preserving freedom to operate in developing countries (NIH/university licensing policies)
- Streamlining regulatory pathways for “follow-on” vaccines

Possible solutions to vaccine affordability

1. Strengthen pooled procurement mechanisms like UNICEF's and PAHO's to consolidate demand and enhance bargaining power, especially when only one or two suppliers
2. Find sustainable funding for GAVI
3. Use tiered pricing where necessary (new vaccines with few suppliers), but without neglecting interests (or weakening bargaining power) of MICs
4. **Reduce barriers to entry of new suppliers**
5. Explore mechanisms for separating prices from R&D costs

Pressures on vaccine prices



Research and development challenges

First or better vaccines against diseases largely specific to developing world (malaria, TB, HIV, but also dengue, other parasitic diseases)

- Private sector will not invest sufficiently in vaccines that don't promise large markets (the "90/10" problem)

Versions of existing vaccines better adapted to developing countries needs

- Relying on hand-me-downs often results in vaccines that are:
  - against the wrong serotypes
  - in the wrong presentations
  - too expensive

Possible solutions to R&D challenges

- PDPs and partnerships like the Meningitis Vaccine Project
  - Donor “push” funding
  - Partnerships with the product developers, **including developing country firms**
  - Built-in “access provisions”

- “Pull” funding mechanisms
  - Creation of viable, predictable demand (GAVI)
  - Advance market and purchase commitments
  - Prizes: de-linkage of price from R&D costs
  - Alignment of reward to innovation with public health benefit

- Access to technology
  - **Enhance and exploit R&D capacity of emerging suppliers**

- Governance & priority setting: who decides?

Advance market commitments

- Rationale (theory)
  - Drive development of needed vaccines by creating large subsidized markets
  - Trade higher donor-subsidized prices in short run for affordable prices in long-run
  - Encourage price competition, entry of new suppliers

- Pneumo AMC: may bring important vaccine to GAVI countries, but:
  - Little role in development of first two vaccines
  - Long-run price not affordable by poorest countries
  - Current structure has not (yet) encouraged price competition
  - **Role of DC manufacturers not clear. Will they be able to participate? Has it influenced their investment decisions?**

- Further AMCs
  - AMCs for early-stage vaccines would be prohibitively expensive.
  - Are there clear advantages over push funding of R&D (PDPs), conventional procurement?

Summary

- Greater access to existing vaccines *and* more needs-based R&D are both important
- Lower prices are crucial to ensuring access, but must not destroy incentives for R&D.
- Tiered pricing has an important role for some vaccines, but is not a panacea
- Developing country manufacturers have a central role in both access and R&D.
- How will this role change as firms grow and business models evolve? Can DC manufacturers achieve their ambitions yet preserve distinct mission?