



WHO-WTO Workshop Differential Pricing and Financing of Essential Drugs

Høsbjør, Norway 8-11 April 2001

Affordable Medicines for Developing Countries

Ellen 't Hoen, LL.M.

Médecins sans Frontières (MSF)

Access to Essential Medicines Campaign

8, rue Saint Sabin

75544 Paris Cedex 11, France

E-mail:ellen.t.hoen@paris.msf.org

Tel: + 33 1 40 21 28 36

www.accessmed-msf.org



Factors Affecting Access to Essential Medicines

R&D

Production

Approval

Quality

Distribution

Drug information, rationale use

Diagnosis/prescription/monitoring

Price

Compliance

Pharmacovigilance



Consensus Action Is Needed



Let us be frank about it: essential and life-saving drugs exist while millions and millions of people cannot afford them. That amounts to a moral problem, a political problem and a problem of credibility for the global market system. Gro Harlem Brundtland, Director General, World Health Organization



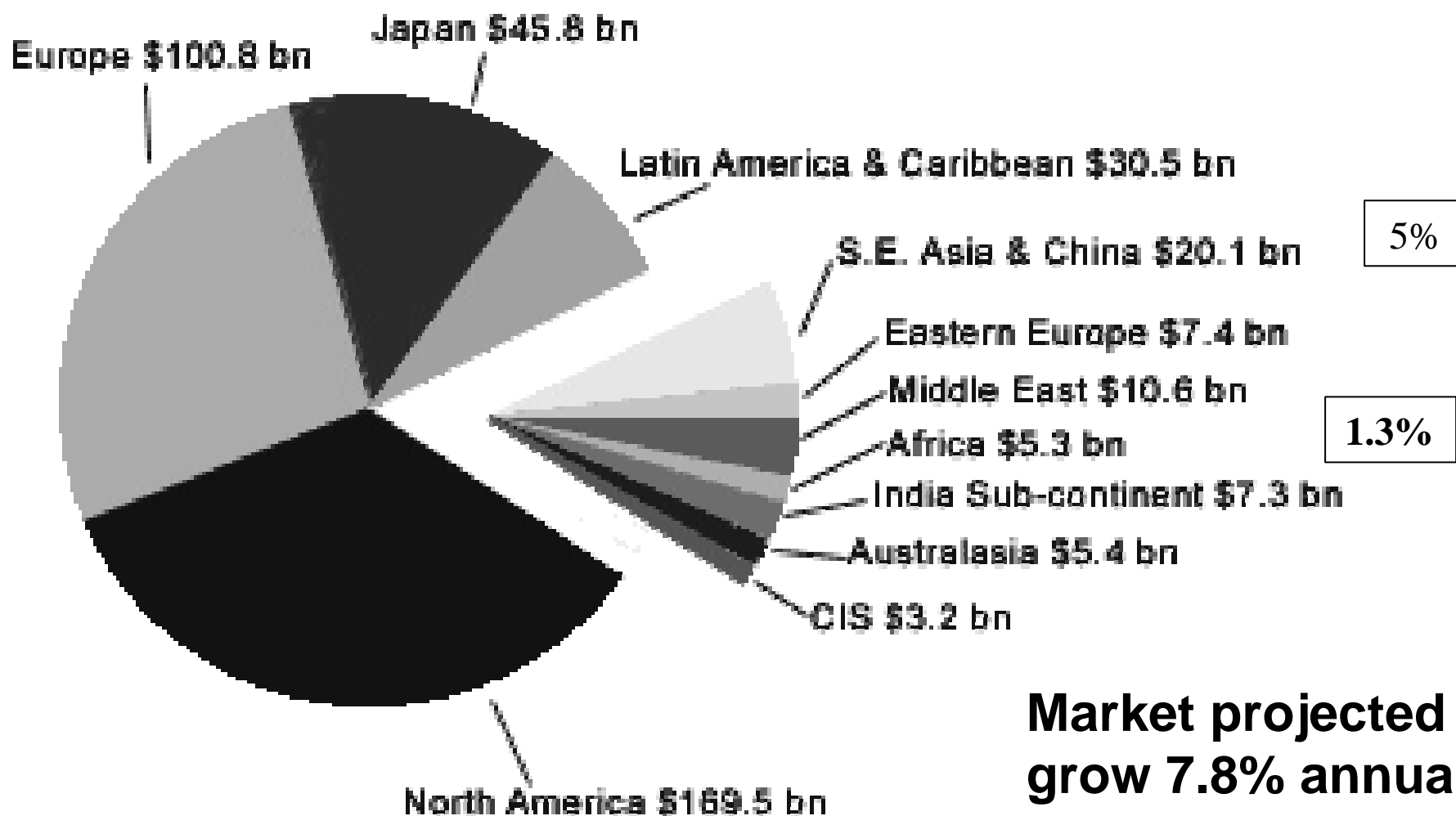
Every year malaria, tuberculosis and AIDS kill around 6 million people, almost all of them in the developing world. These premature deaths are a reproach to us all.

Part of the problem is poor countries' lack of access to drugs. The poor cannot afford expensive medicines. Keeping an AIDS patient alive for a year can cost up to \$15,000 - 24 times the average annual income in Zimbabwe, where one in four adults is HIV-positive.

Mike Moore, DG of the World Trade Organization



Global Pharmaceutical Market 2002 \$406 billion





Objective: Equitable Drug Prices

- ***The policy of assuring dramatically reduced drug prices so that they are truly affordable to the people who need them***
- ***A policy that is***
 - **sustainable (not based on charity or donations)**
 - **Strengthens developing countries' autonomy**
 - **Attracts donor funding**
 - **Not limited to HIV/AIDS medication only**



Strategies for Lowering Drug Prices

- ***Differential/tiered pricing (market segmentation) by Big Pharma***
- ***Local production under voluntary licensing agreements***
- ***Global procurement and distribution system***
- ***Increased competitiveness in the pharmaceutical market***



Differential/tiered Pricing

- ***Relies on spontaneous and voluntary lowering of prices***
- ***Drug firms prefer low volume –high price strategy***
- ***Requires separation of markets***
- ***Comes with strings attached or hidden agendas***
- ***Does not encourage sustainability or self reliance***
- ***Might hamper other, more sustainable approaches***



Local Production Under Voluntary Licensing

- *Based on voluntary licensing agreements (will??)*
- *Requires manufacturing capacity → agreements should allow for export to low income countries*
- *Encourages technology transfer and pharmaceutical industrial development in the South*
- *No risk of parallel-importation in high income markets*
- *Paradox: strong IP protection is a condition for technology transfer. In Practice: Voluntary licenses more likely when strong compulsory licensing system exists*



Global Procurement and Distribution System

- ***Experience and expertise with procurement exists (UNICEF)***
- ***Might work for specific diseases/ products***
- ***Requires a long term commitment***
- ***Does not solve structural problems***
- ***Might negatively affect local manufacturing capacity***
- ***Regulatory barriers (pre-qualification) and patent barriers in certain countries (exceptions)***



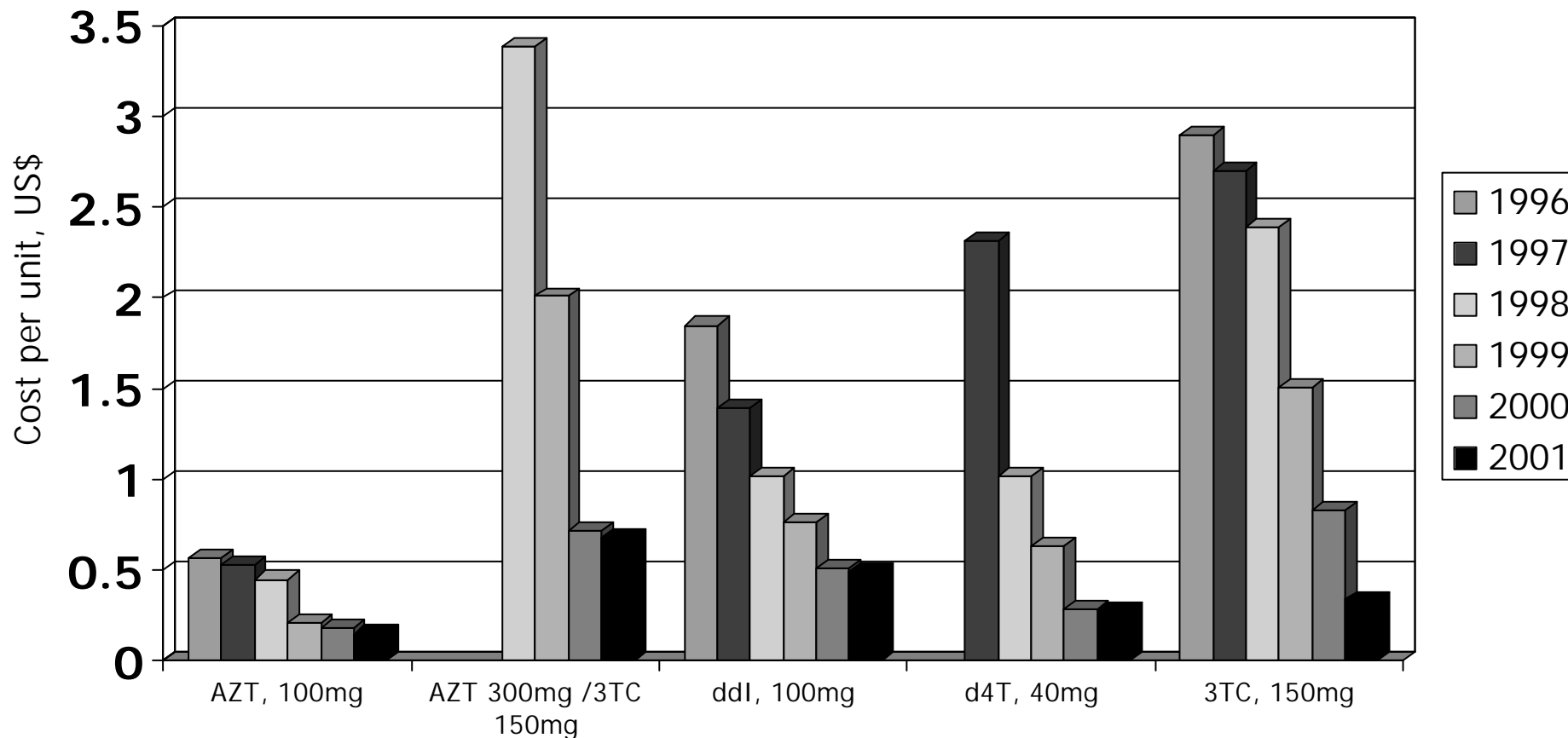
Increased competitiveness

- ***Proven effective***
- ***Encourages sustainable solutions and industrial development***
- ***Requires a pro public health and flexible interpretation of the TRIPS Agreement***
- ***Does TRIPS offer enough flexibility?***



Learning: Price reductions from generic competition

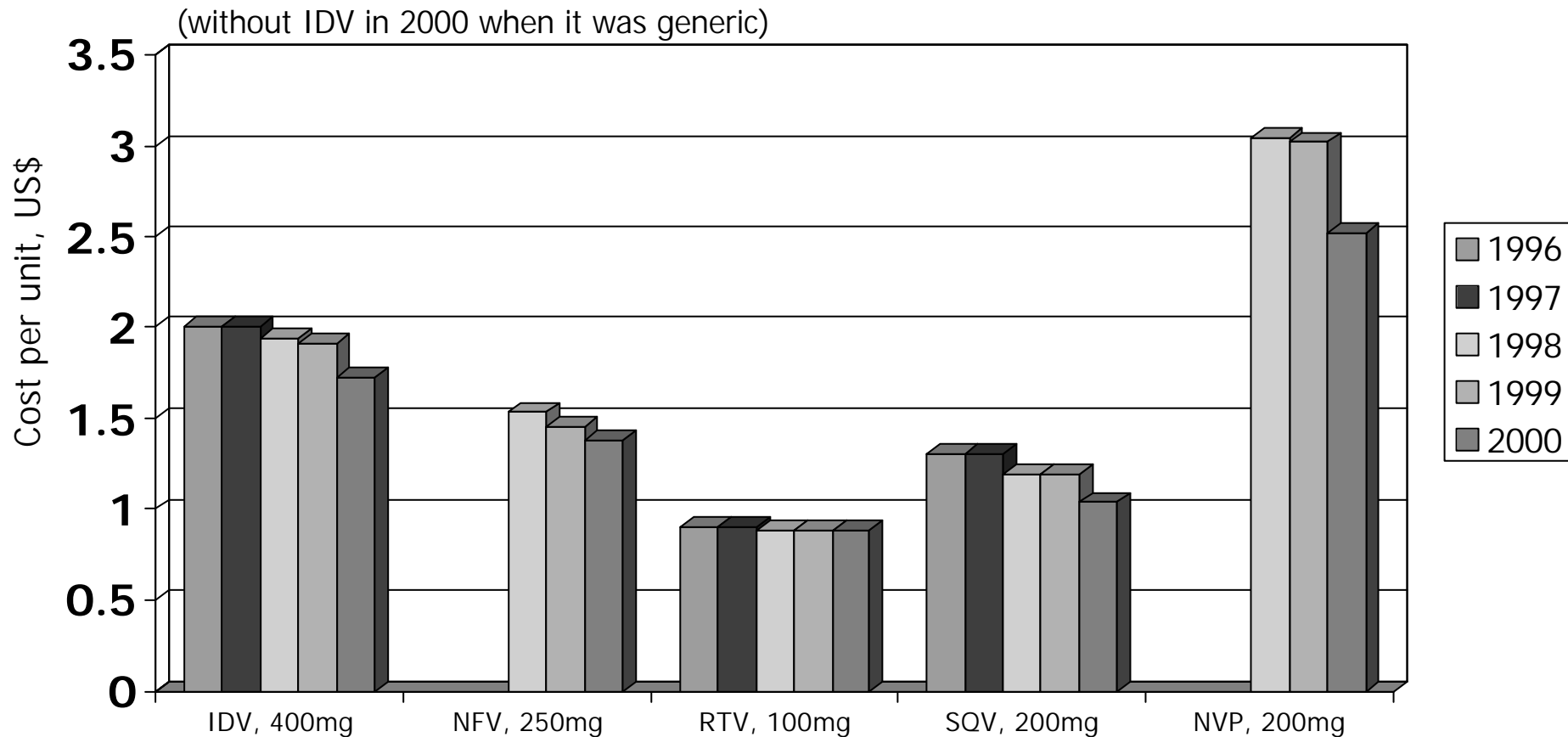
Average reduction: 82%





Learning: Price Stability w/o generic competition

Average reduction: 9%



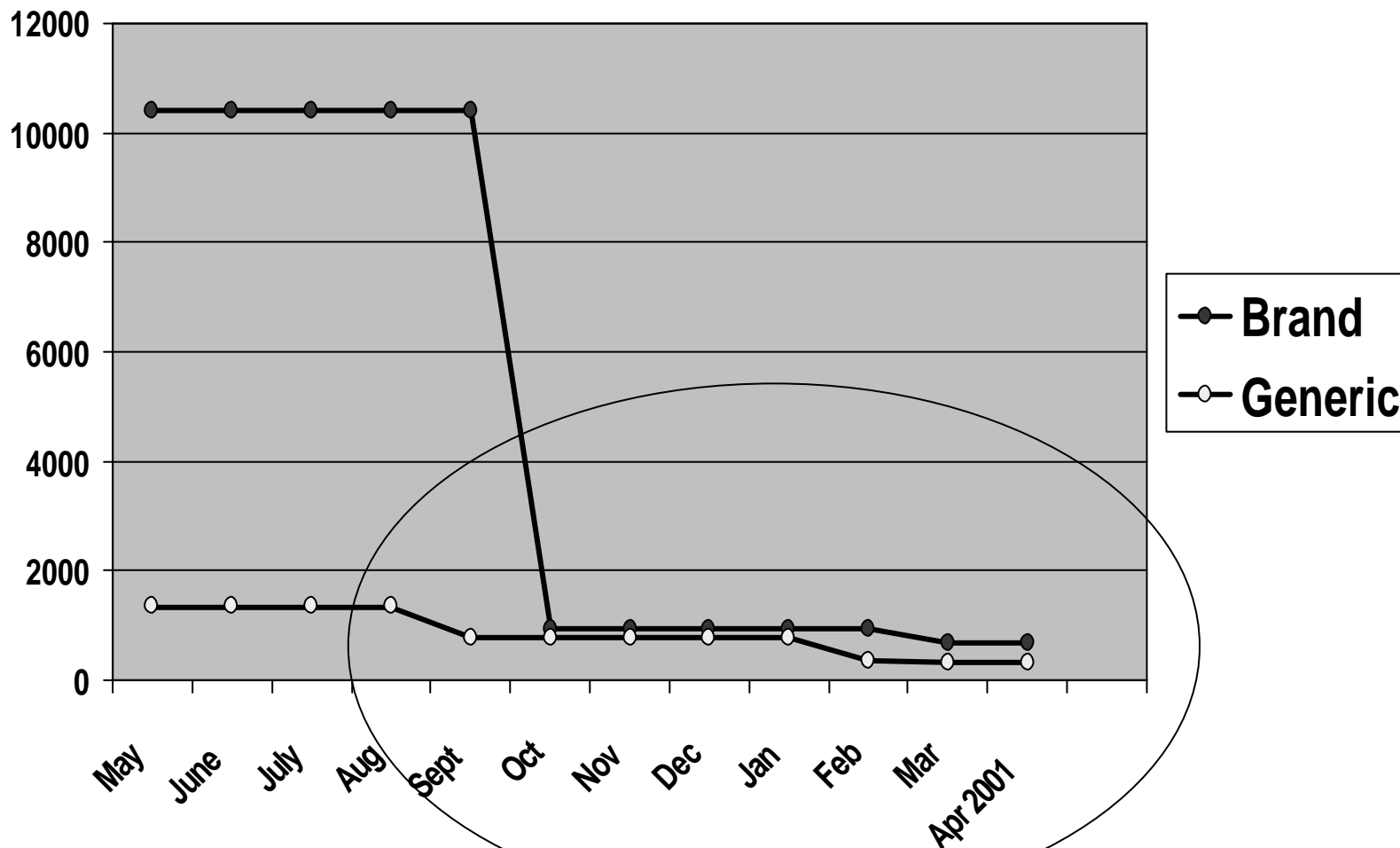
Ministry of Health, Brazil, unpub. data



Generic Competition

Sample AIDS triple-combination: lowest world prices

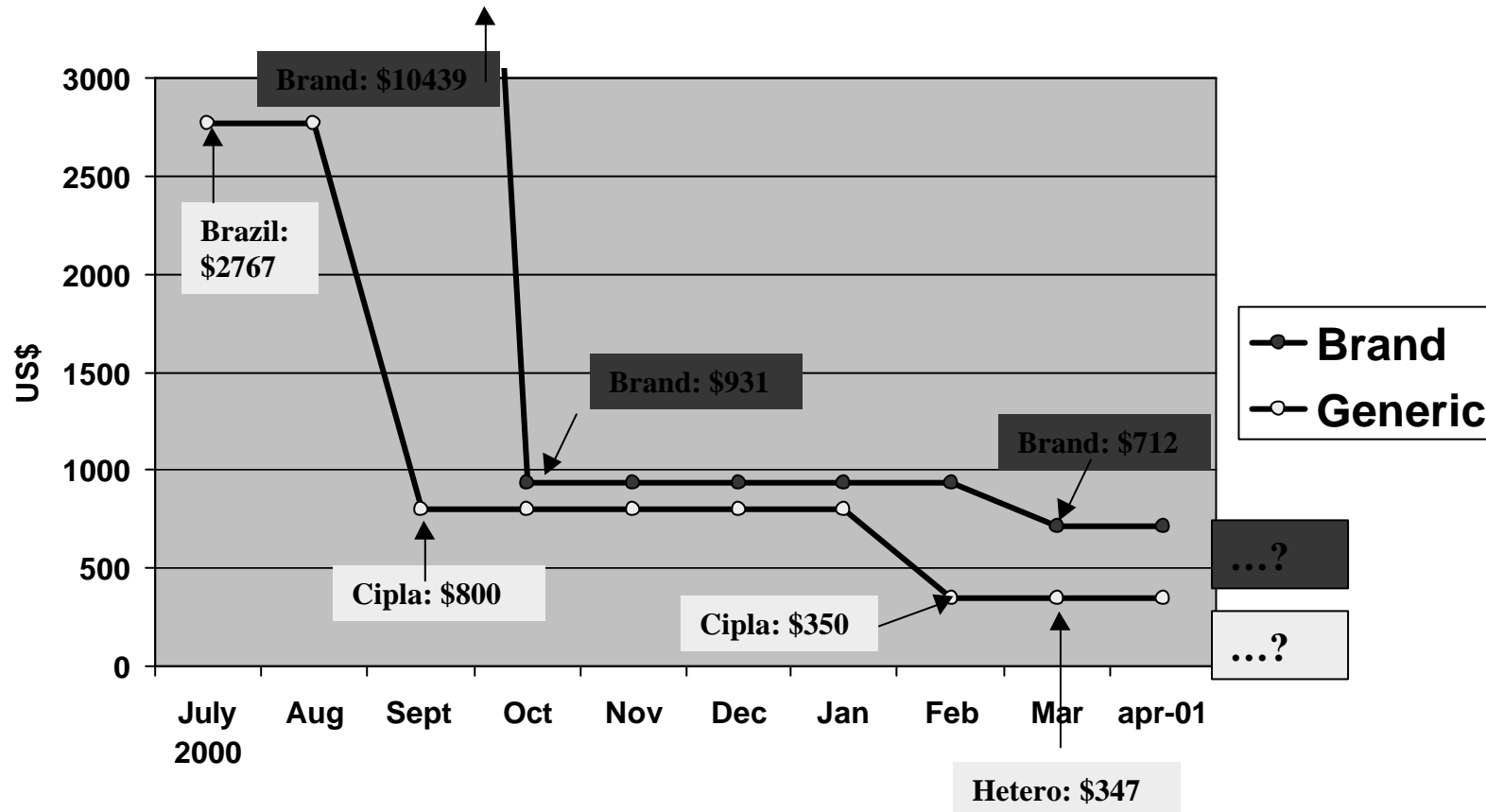
(stavudine (d4T) + lamivudine (3TC) + nevirapine)





Generic Competition

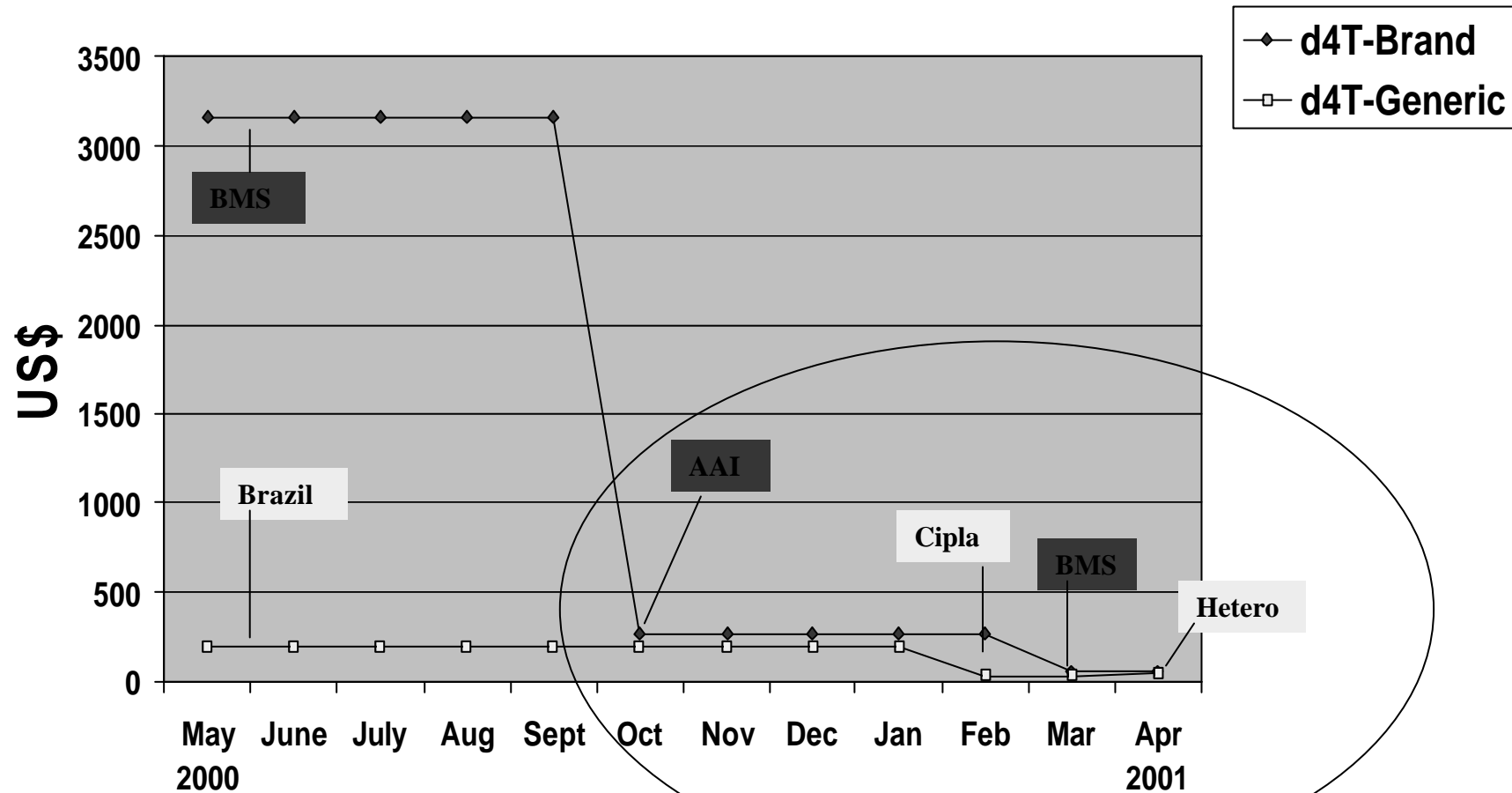
Sample AIDS triple-combination: lowest world prices
(stavudine (d4T) + lamivudine (3TC) + nevirapine)





Generic Competition

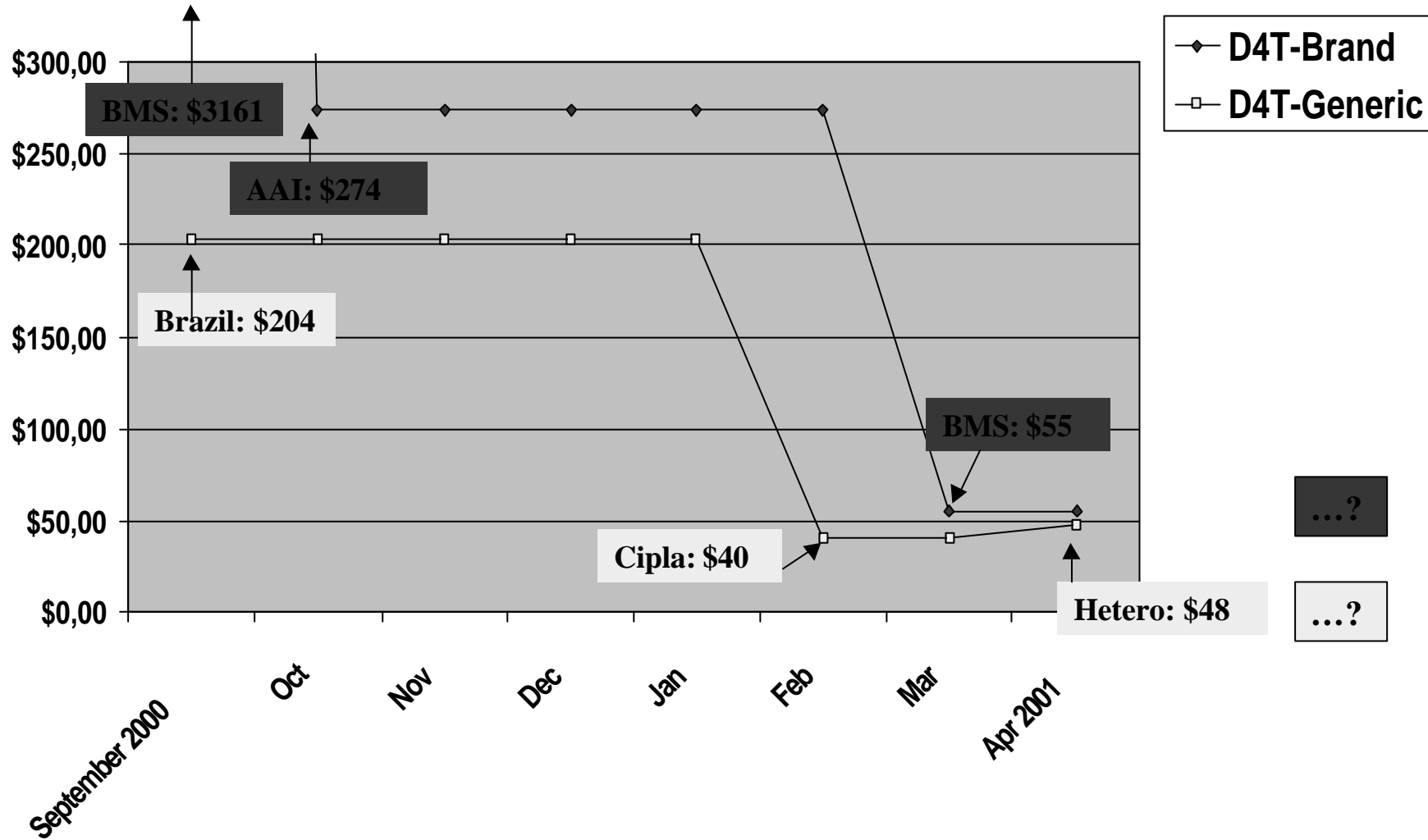
Prices of d4T (40 mg capsule) per patient/year
(lowest world prices)





Generic Competition: d4T

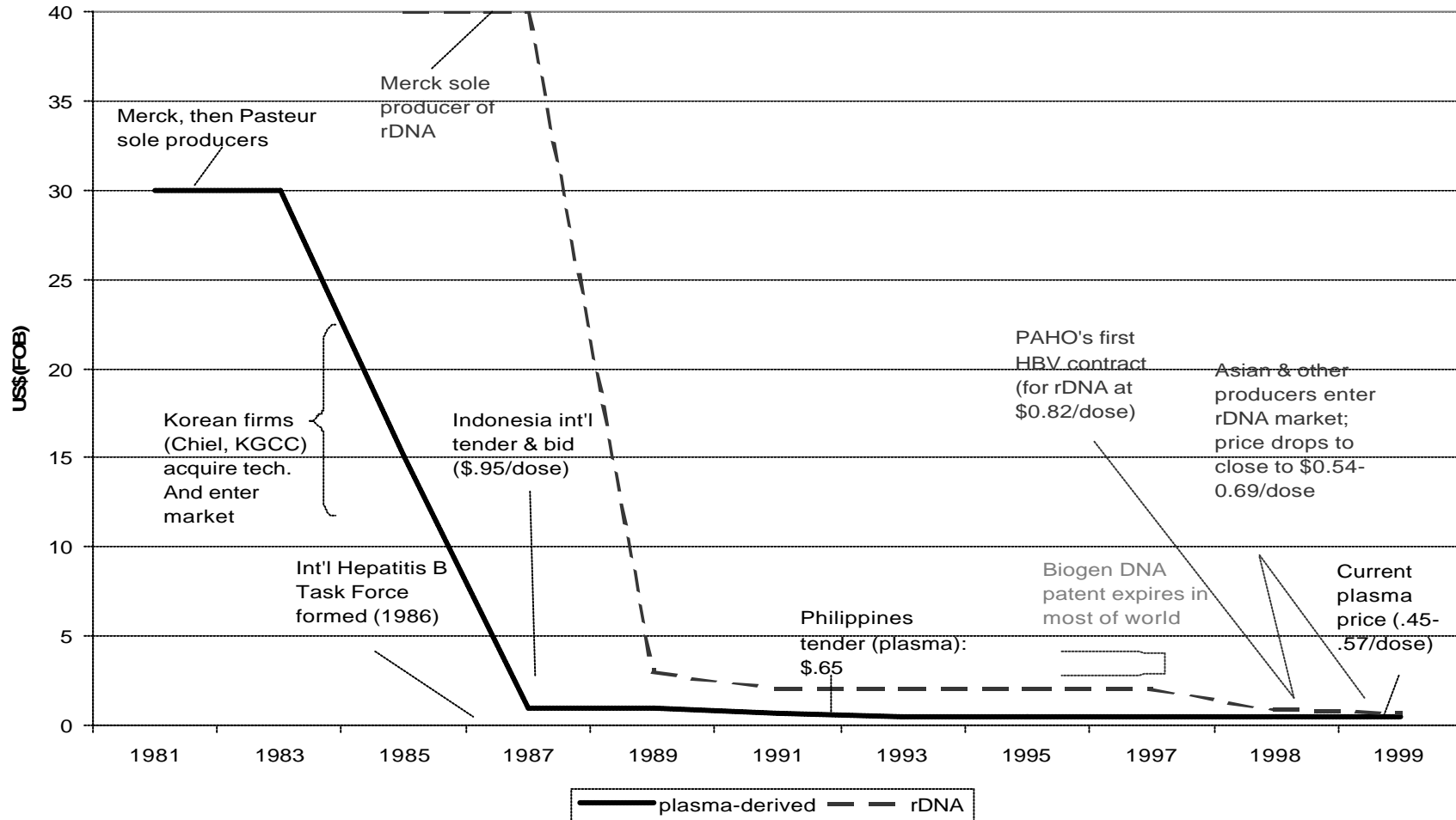
Prices of D4T (40 mg capsule) per patient/year
(lowest world prices)





Price Development of Hepatitis B Vaccine

Change in Prices Over Time of Hepatitis B Vaccine (Plasma-Derived and Recombinant DNA) offered to Developing Countries (lowest prices obtained) from Denise DeRoeck





Recommendations 1/3

- ***Not one single solution – mix of strategies that are mutually supportive***
- ***Enforceable regulation to encourage equity pricing and prevent parallel re-importation in the EU, north America and Japan***
 - Example: EU directive on equity pricing that ensures that equitable priced drugs cannot be put on the EU market



Recommendations 2/3

- ***Global procurement strategies for selected drugs***
 - **Designed to encourage and improve generic production**
 - **Overcome regulatory barriers: need for international pre-qualification activities**
 - **Overcome IP barriers: exceptions for globally procured goods**



Recommendations 3/3

- ***Actively encourage competition***
 - Recognise the role of generic manufacturing
 - Support to expand and upgrade generic production in developing countries
 - Take away barriers in the regulatory systems
 - Encourage technology transfer – targeted at countries that have production capacity
 - Encourage voluntary licensing agreements
 - Assist with implementation of fast track compulsory licensing
- ***Launch debate on how to reconcile TRIPS requirements with health needs – Health TRIPS Council in June 2001***