



# **WHO-WTO Workshop Differential Pricing and Financing of Essential Drugs**

**Høsbjør, Norway 8-11 April 2001**

## **Affordable Medicines for Developing Countries**

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# 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 cost too much while millions of people cannot afford them. That amounts to a public health crisis, a political problem, and a failure of our current market system.**

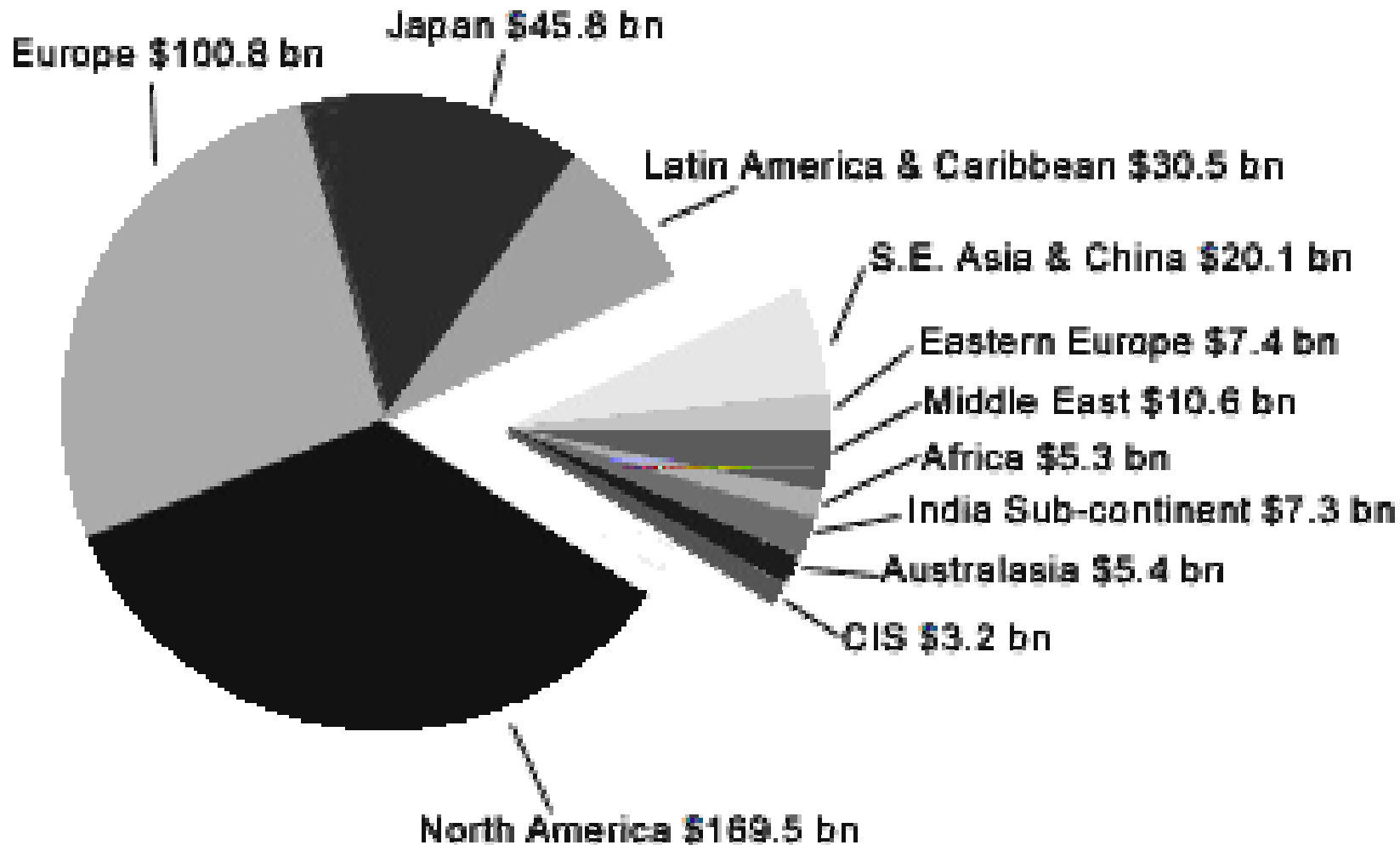


***Every year malaria, tuberculosis and AIDS kill around 6 million people, almost all of them in the developing world. These premature deaths are a reproach to us all. ....***

***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***



# 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***







# Local Production Under Voluntary Licensing

- *Based on voluntary licensing agreements (will??)*
- *Requires manufacturing capacity è 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)***

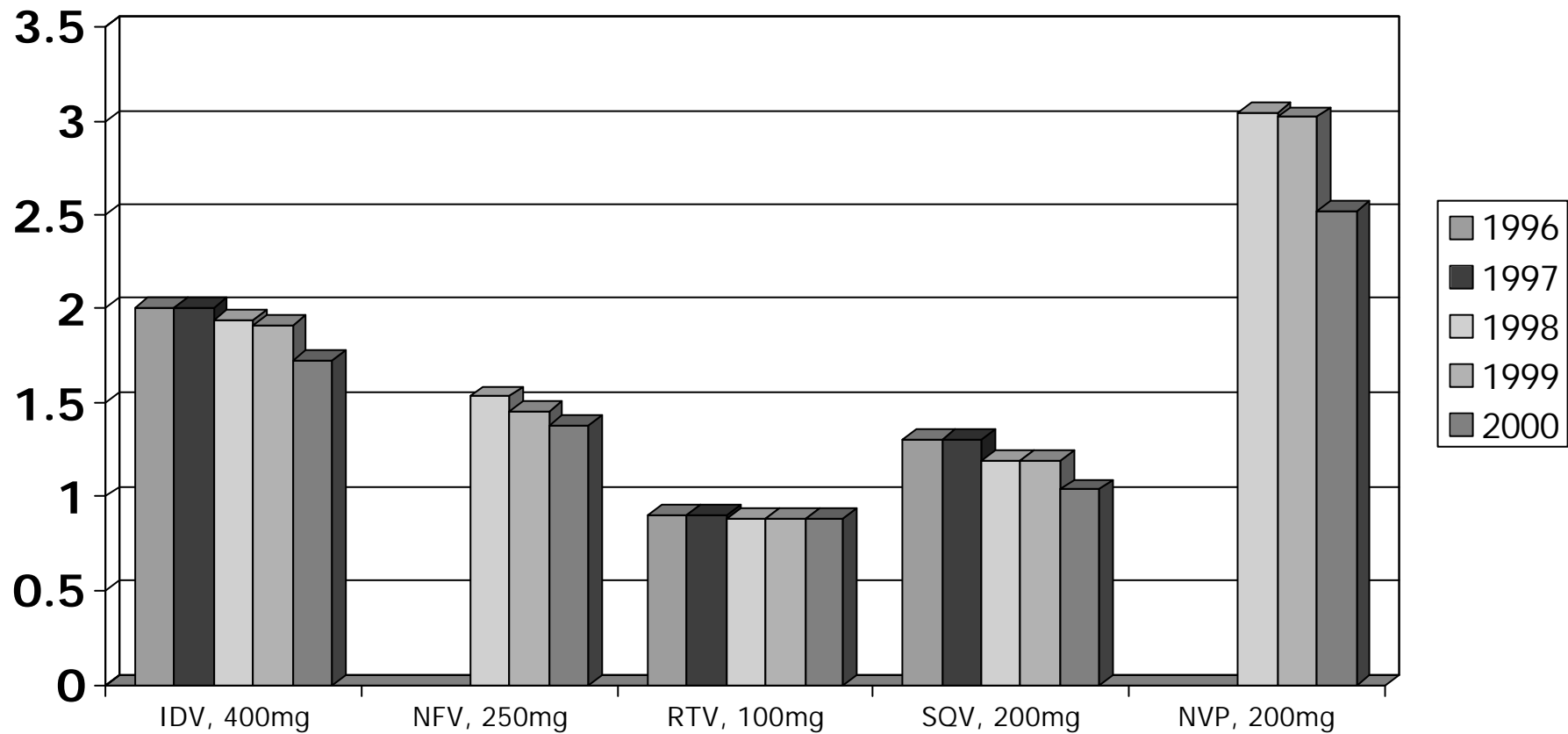


# Increased competitiveness

- ***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

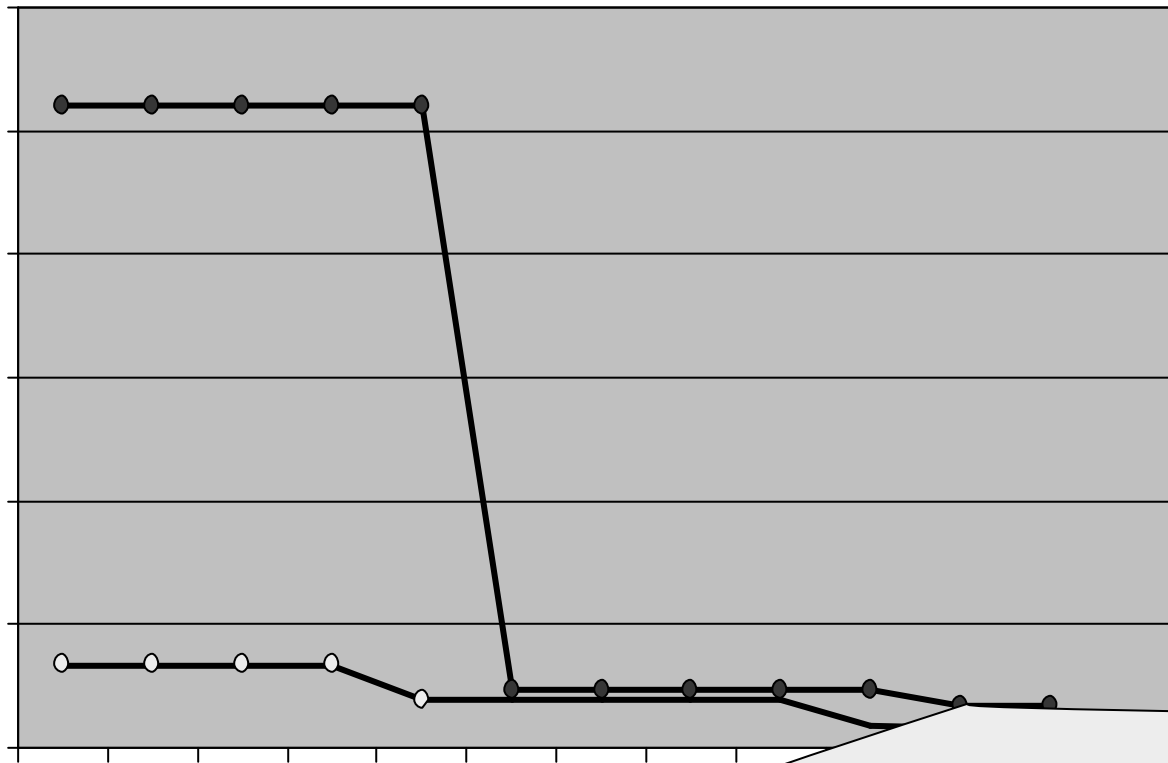


Ministry of Health, Brazil, unpub



# Generic Competition

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

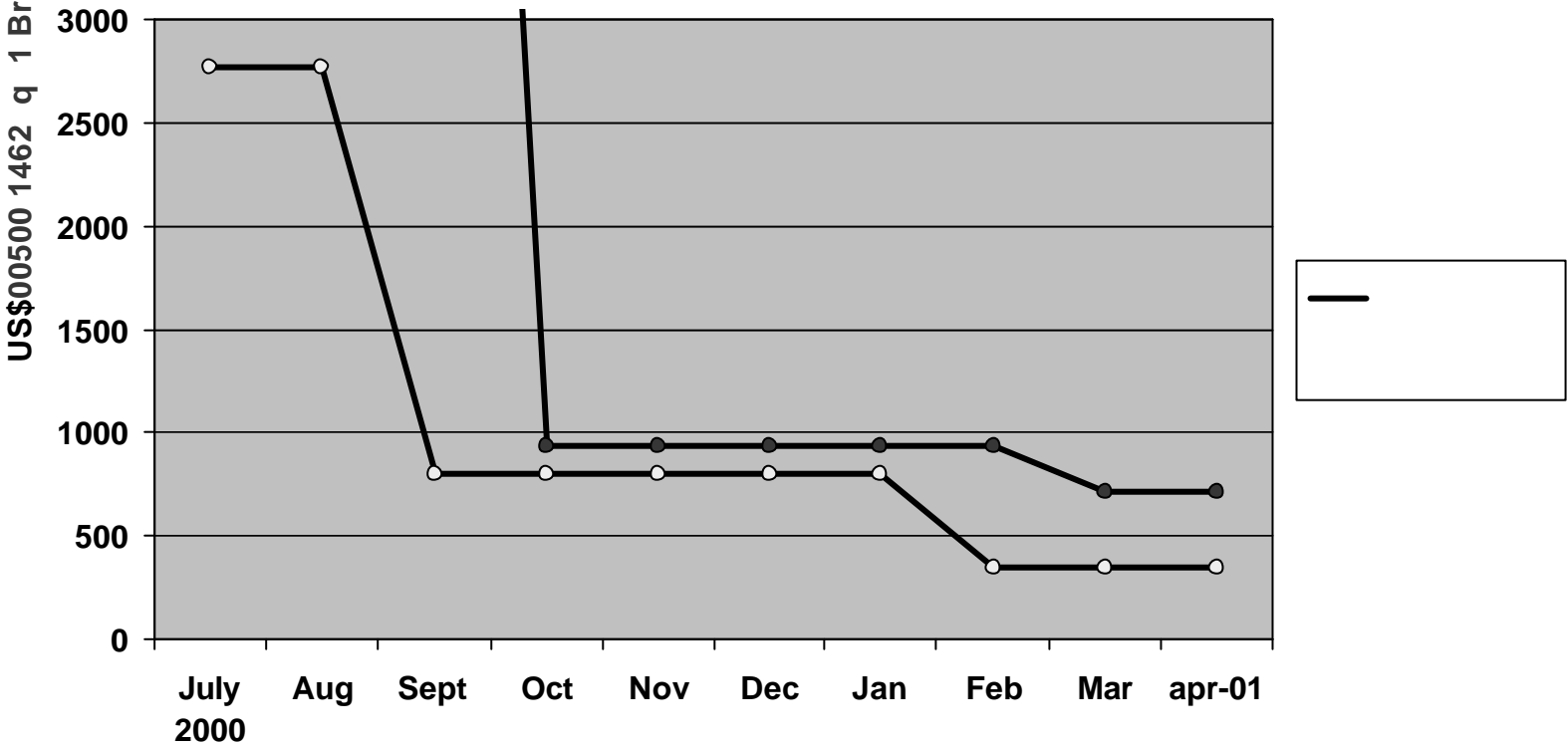


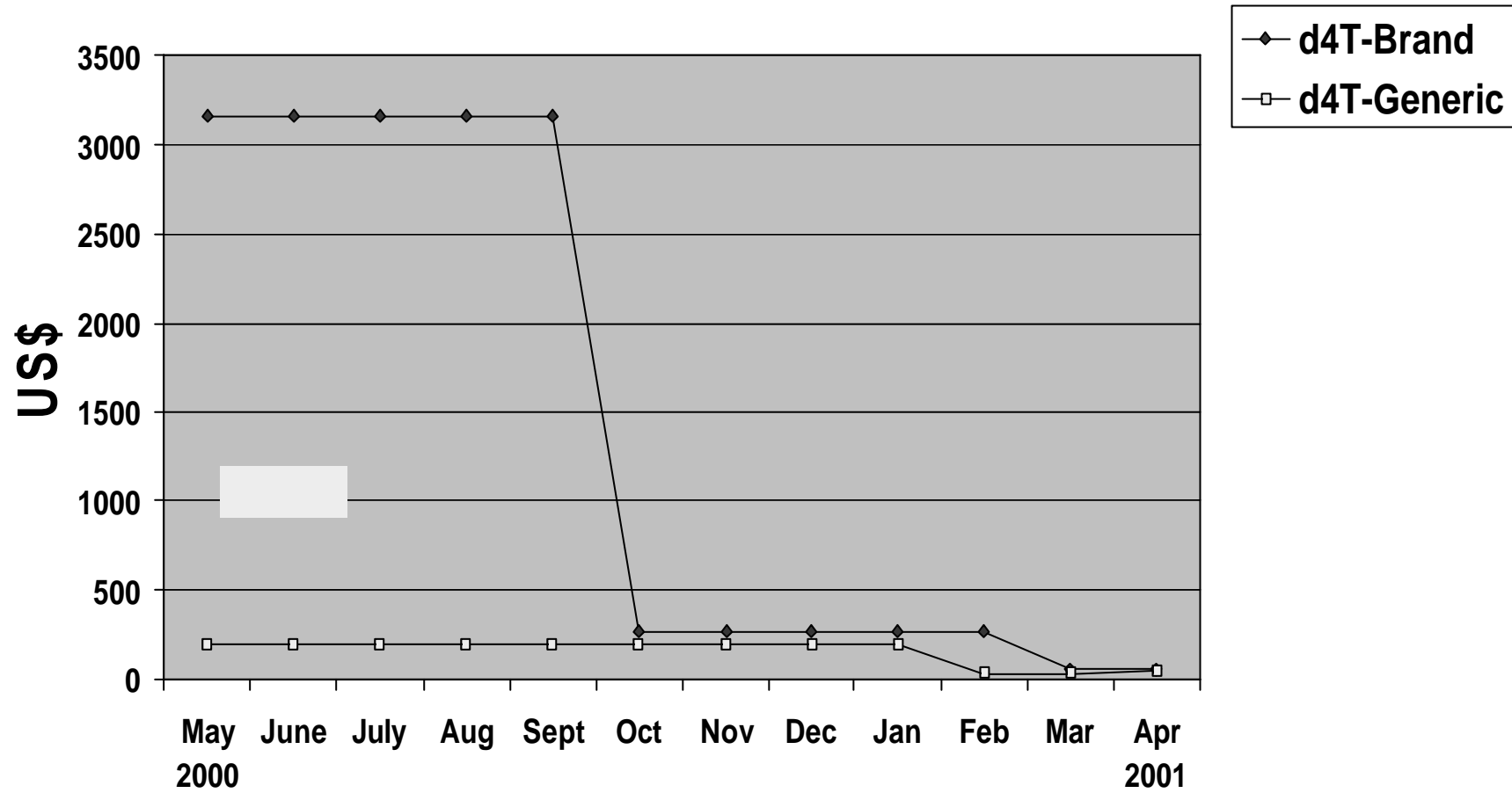


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# Generic Competition

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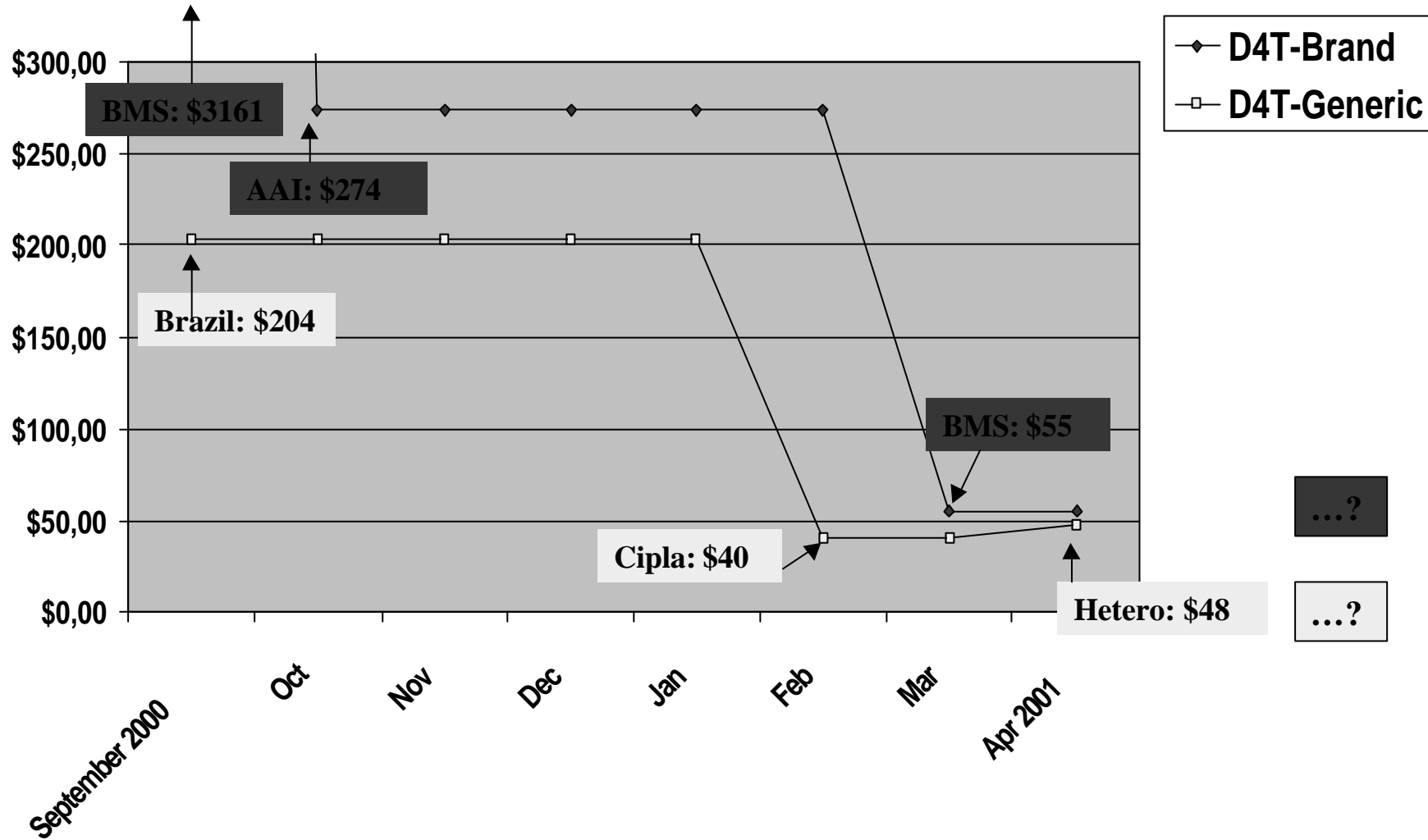






# Generic Competition: d4T

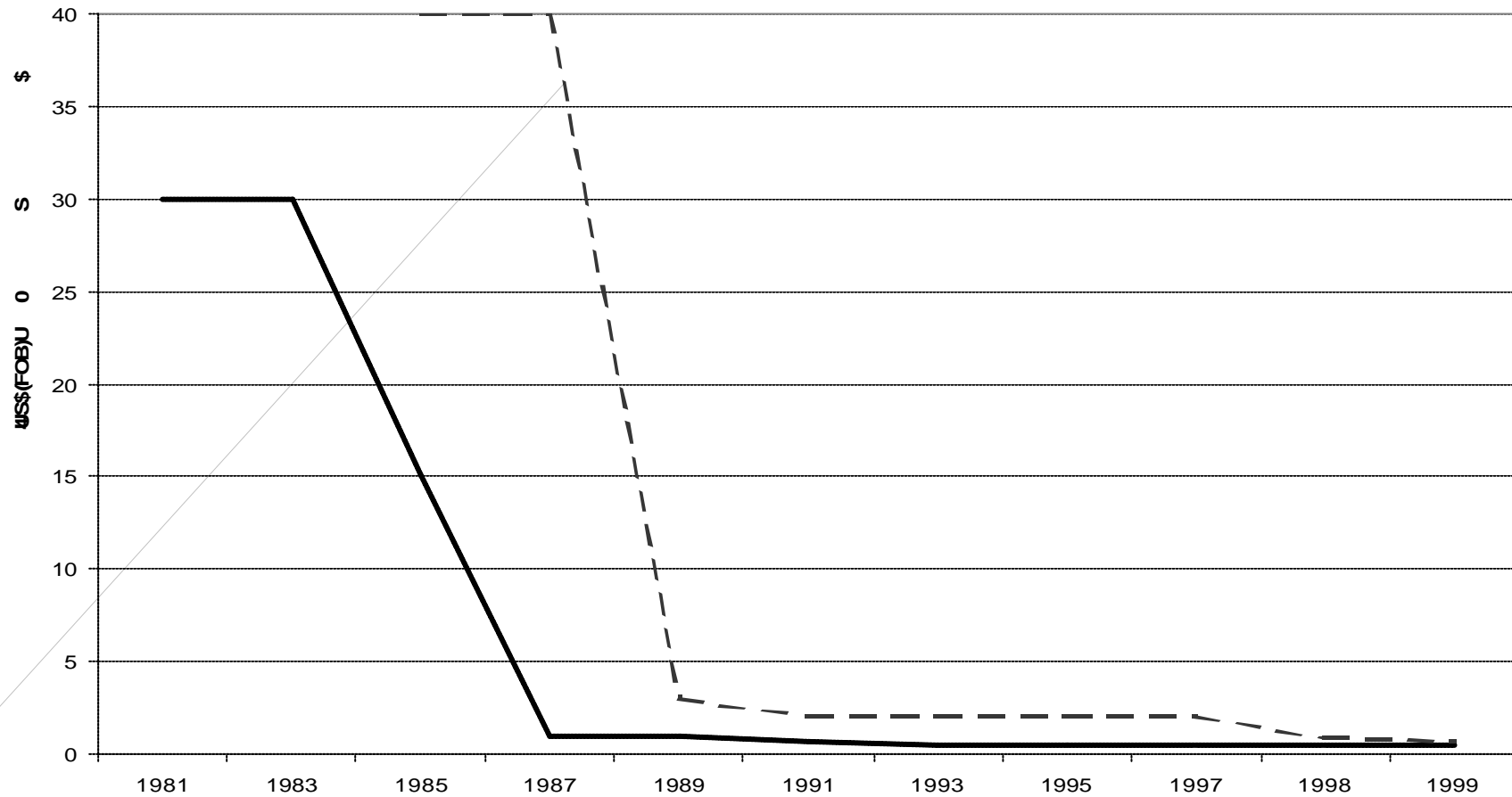
Prices of D4T (40 mg capsule) per patient/year  
(lowest world prices)





# 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***