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

Ellen 't Hoen, MSF
Høsbjør, 8-11 April 2001, WHO-WTO Workshop Differential Pricing
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%

Cost per unit, US$

AZT, 100mg
AZT 300mg /3TC 150mg
ddi, 100mg
d4T, 40mg
3TC, 150mg

Brazilian National AIDS Program, unpub. data

Ellen 't Hoen, MSF

Høsbjør, 8-11 April 2001, WHO-WTO Workshop Differential Pricing
Learning: Price Stability w/o generic competition

Average reduction: 9%

(without IDV in 2000 when it was generic)

Cost per unit, US$

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)

- **Brazil:** $2767
- **Cipla:** $350
- **Hetero:** $347
- **Brand:**
  - July 2000: $10439
  - Aug: $931
  - Sept: $712
  - Oct: $931
  - Nov: $931
  - Dec: $931
  - Jan: $931
  - Feb: $931
  - Mar: $931
  - Apr-01...

Ellen ‘t Hoen, MSF  Høsbjør, 8-11April 2001, WHO-WTO Workshop Differential Pricing
Generic Competition

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

Ellen 't Hoen, MSF

Brazil

AAI

Cipla

BMS

Hetero

BMS
Generic Competition: d4T
Prices of D4T (40 mg capsule) per patient/year
(lowest world prices)

- BMS: $3161
- AAI: $274
- Brazil: $204
- Cipla: $40
- BMS: $55
- Hetero: $48
- ...?

Ellen ’t Hoen, MSF
Høsbjør, 8-11 April 2001, WHO-WTO Workshop Differential Pricing
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

- Merck, then Pasteur sole producers
- Korean firms (Chiel, KGCC) acquire tech. And enter market
- Indonesia int'l tender & bids ($0.95/dose)
- Int'l Hepatitis B Task Force formed (1986)
- Philippines tender (plasma): $0.65
- Biogen DNA patent expires in most of world
- PAHO's first HBV contract (for rDNA at $0.82/dose)
- Asian & other producers enter rDNA market; price drops to close to $0.54-0.69/dose
- Current plasma price (.45-.57/dose)

Denise DeRoeck

Ellen 't Hoen, MSF
Høsbjør, 8-11 April 2001, WHO-WTO Workshop Differential Pricing
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**