



Intellectual Property

Implications for access to new
treatments –legal and economic
aspects

Ellen 't Hoen
MSF Access to Essential Medicines Campaign
Ellen.t.Hoen@paris.msf.org



Objectives of TRIPS

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

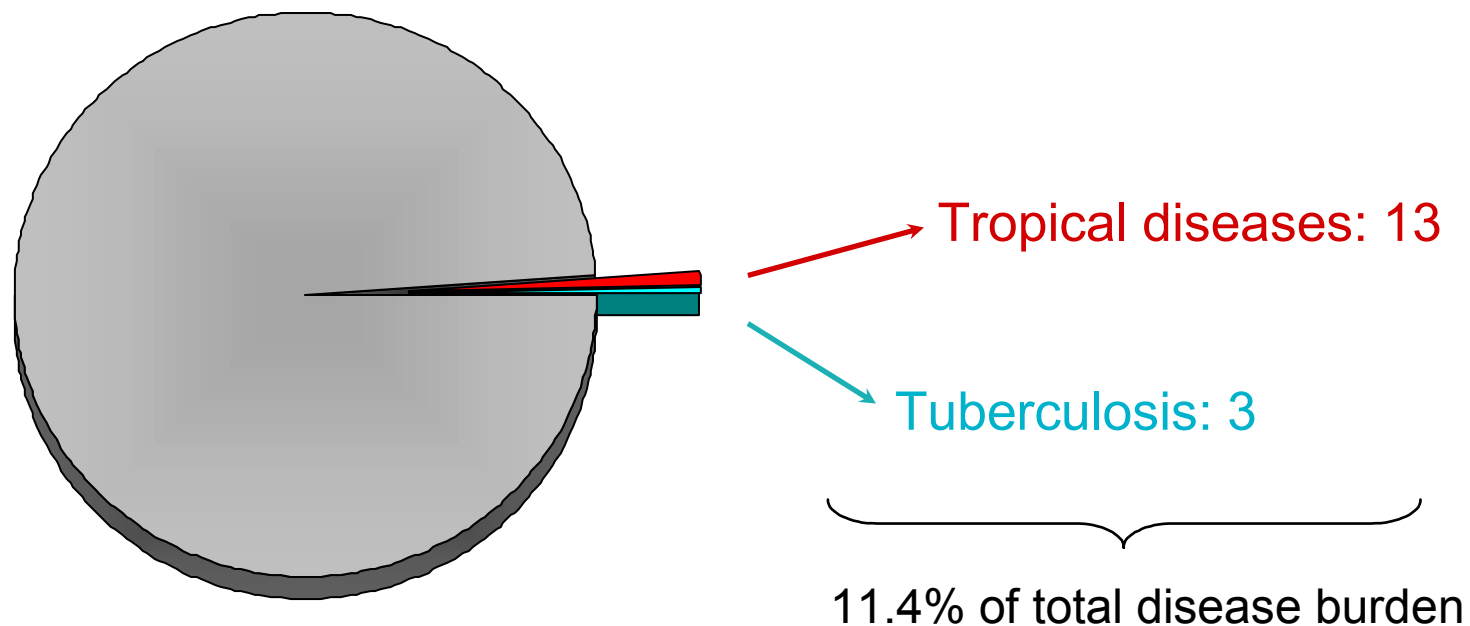


Patents

Patent system is a social policy tool.
Primary justification for granting patents is the benefit to society as a whole by promoting innovation in exchange for a limited monopoly.

Drug Development Outcome

1975-1999: **1393** new chemical entities
marketed



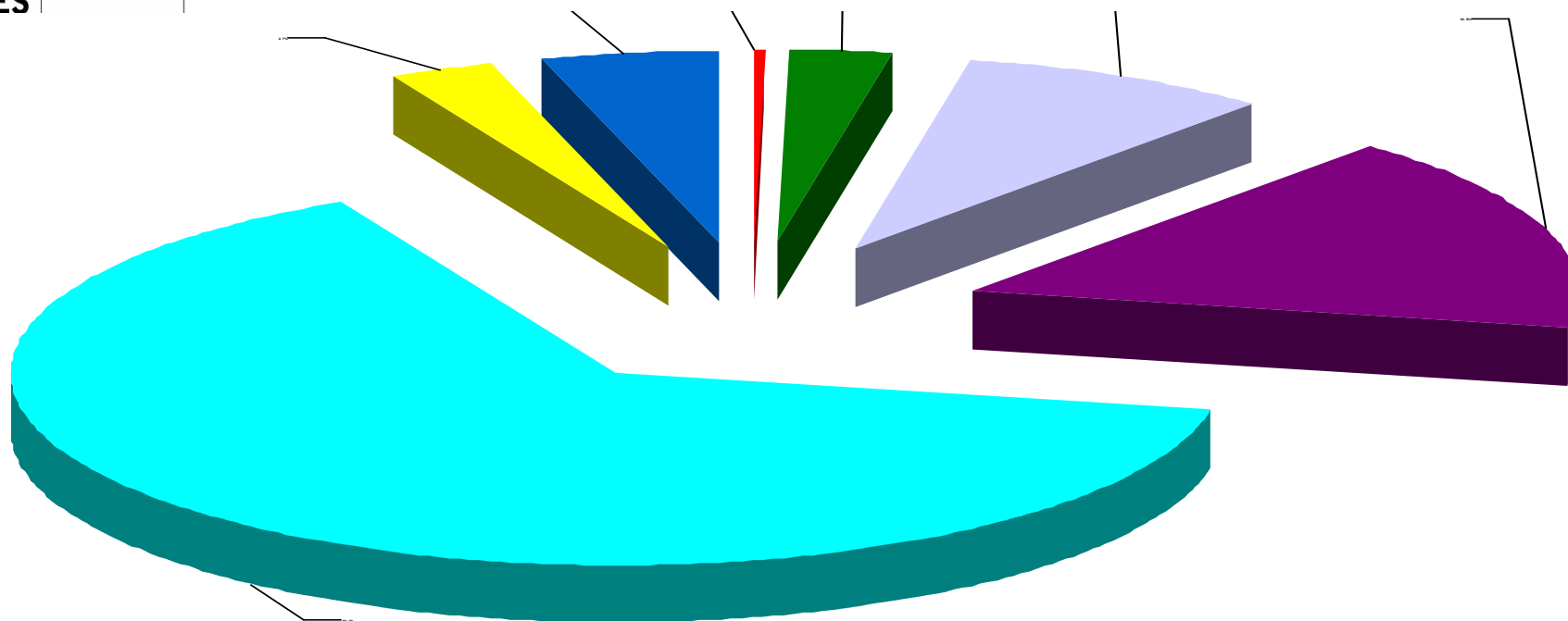


10/90 Gap

- “The pattern of new medicines R&D reflects market opportunities rather than global public health priorities. Only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden — the so-called 10/90 Gap.”

WHO World Drug Situation 2004

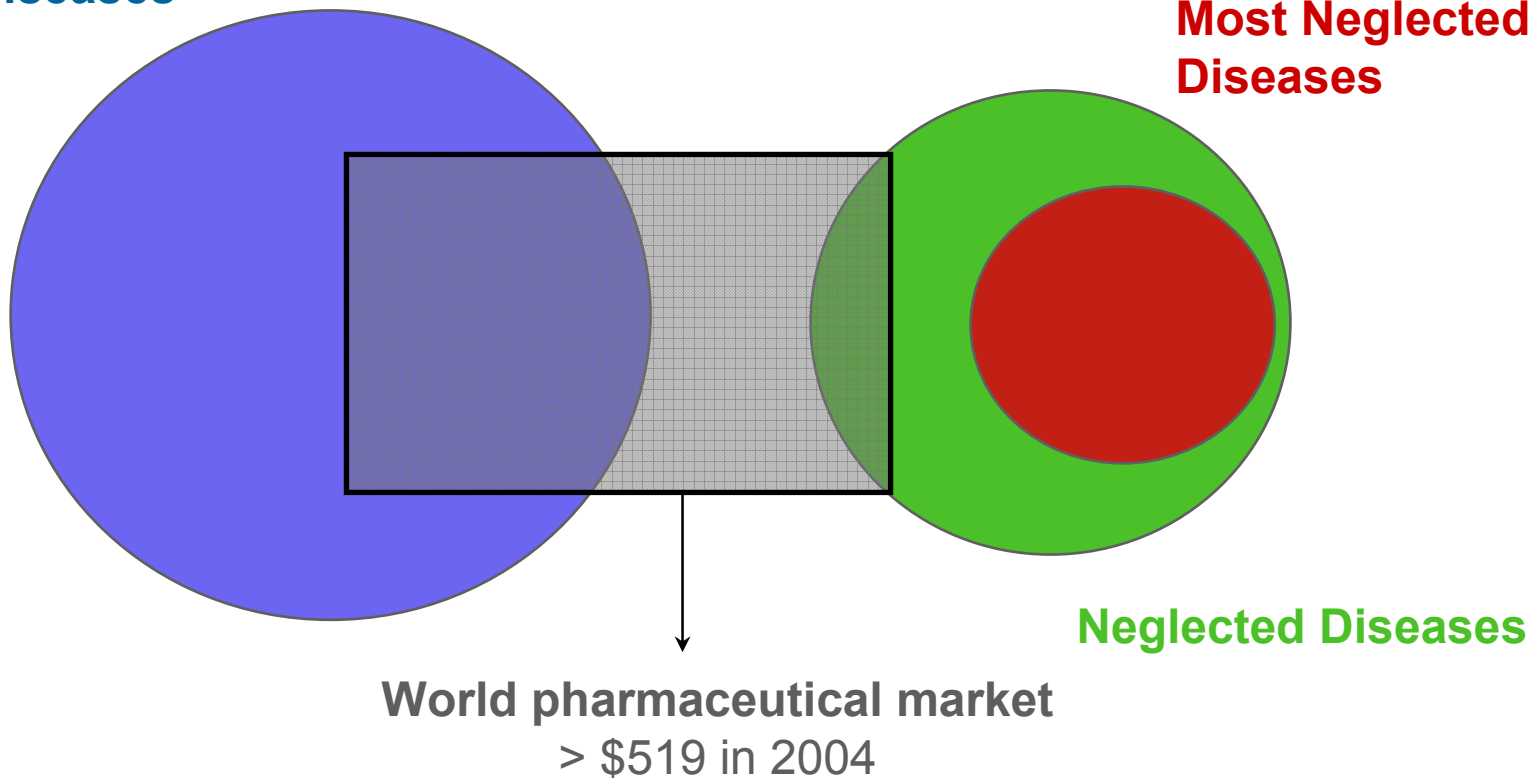
Innovation in France '81-'01



- Major Therapeutic innovation previously no treatment was (7)
- Product is an important therapeutic innovation with certain limitations (69)
- Product has some value does no fund.change the present practice (203)
- Product has minimal additional value, (414)
- Product may be a new molecule but has no additional therapeutic value mostly me-too product (1584)
- Product without evident benefit but with potential or real disadvantages (67)
- Editors postpone their judgements until better data is available (116)

Global pharmaceutical market neglects

Global Diseases



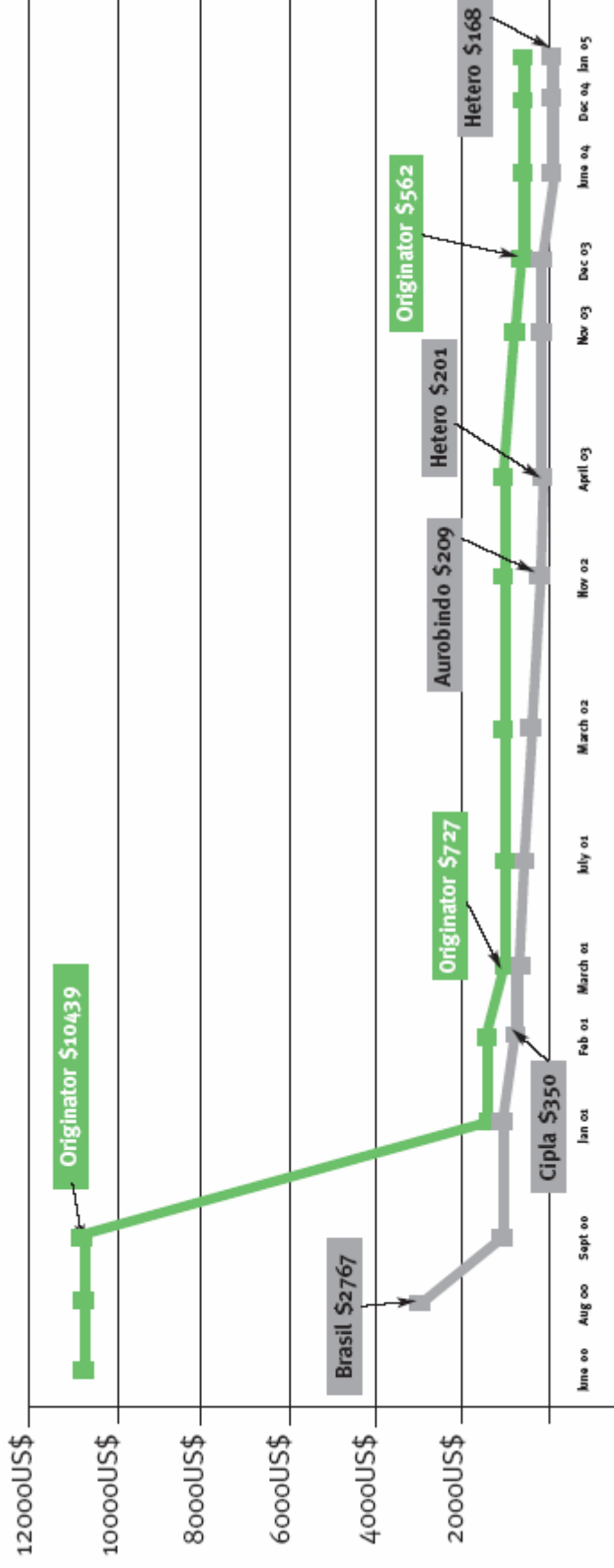


Costs are high

- High prices => Lack of Access
- R&D priorities set to satisfy profitable markets not health needs

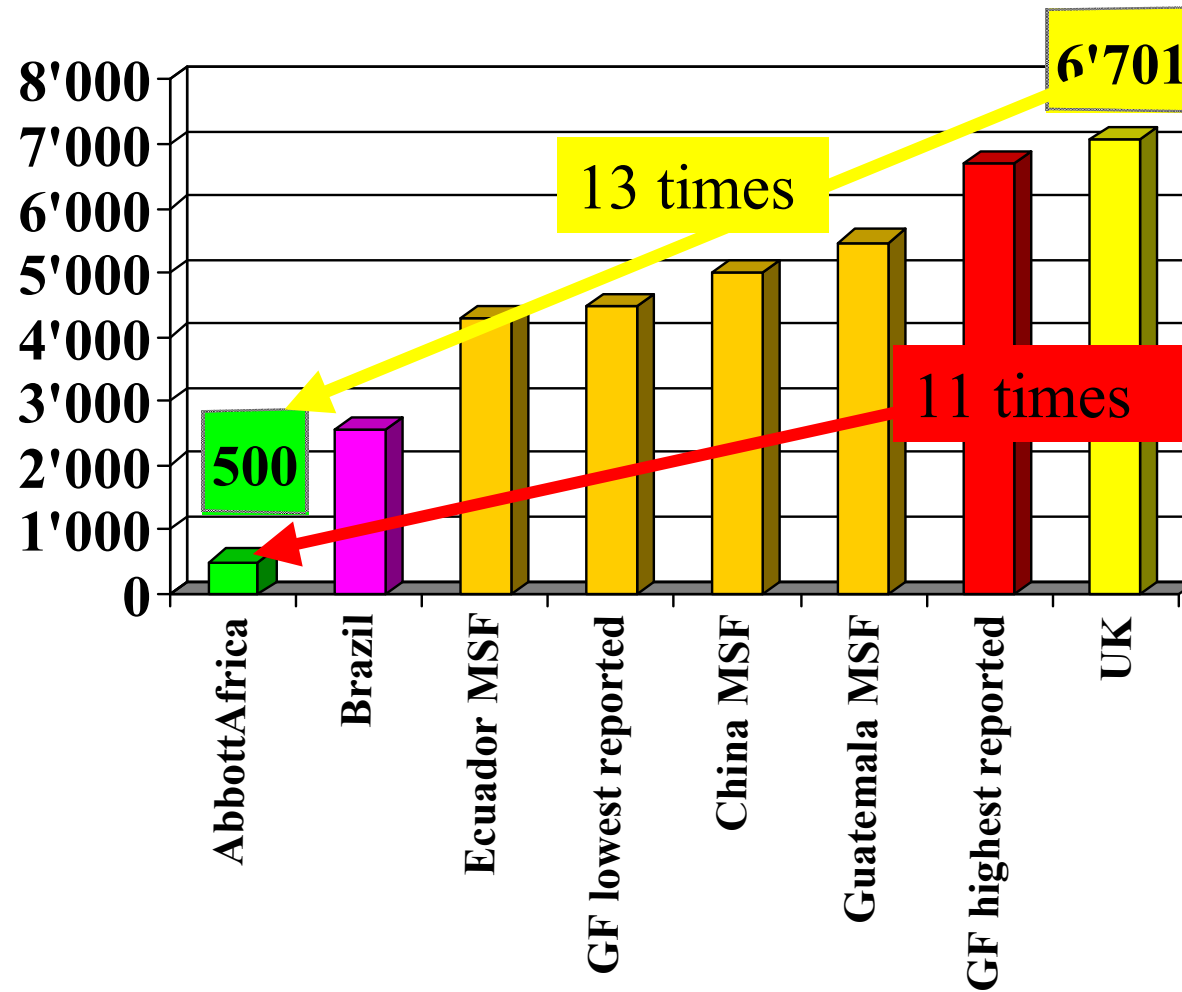
The Effects of Generic Competition

May 2000-Jan 2005



Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year. Generic competition has shown to be the most effective means of lowering drug prices. During the last four years, originator companies have often responded to generic competition.

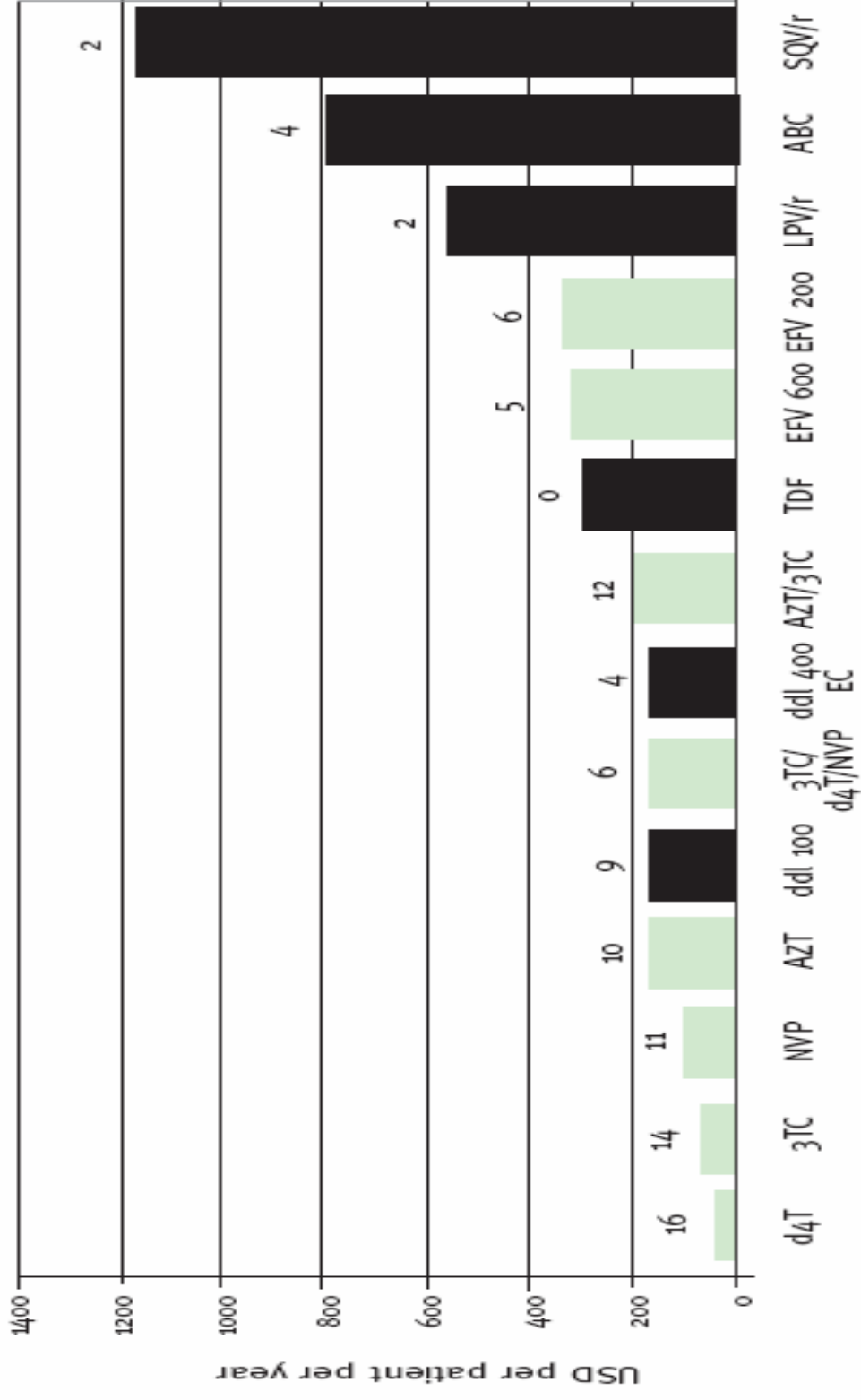
Price variability: Lopinavir/ritonavir (Kaletra®) in different countries (yearly price 2004-5 in USD)



Patents and high drug prices

Manufacturer	Country of distribution	US\$ Price per unit (200 mg) June 2000
Biolab (Thailand)	Thailand	0.29 (April 2002 0.15)
Cipla	India	0.64 (June 2002 0.10)
Bussie (Colombia)	Guatemala (neg.)	3.00
Pfizer	Thailand	6.20
Vita	Spain	6.29
Pfizer	South Africa	8.25
Pfizer	Kenya	10.50
Pfizer	Spain	10.57
Pfizer	Guatemala (neg.)	11.84
Pfizer	USA	12.20
Pfizer	Guatemala	27.60

Prices of medicines recommended as 1st and 2nd line by WHO in January 2005





	No. of sources (WHO PQ)	Differential price originator/generic	GF lowest reported	GF highest reported
AZT	10 (3)	221 / 140	131	234
d4T	16 (2)	55 / 26	44	1190
3TC	14 (3)	69 / 55	66	168
NVP	11 (4)	438 / 80	58	263
EFV 600	5 (0)	347 / 347	347	821
ABC	4 (1)	887 / 706	796	934
TDF	0 (0)	300 / ---	6752	6752
EC ddI	4 (0)	279 / 163	204	1810
SQV+r	2 (1)	1043 / 1226	2723	5102
LPV/r	2 (1)	500 / 1971	4468	6700



Essential Medicines

- WHO: Essential Medicines are “those that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts in appropriate dosage forms and at a price the individual and the community can afford”



- Governments need to take responsibility and action
- Ensuring that new Essential Medicines are available and affordable cannot be left to the market
- Health R&D is a global public good that requires policies to ensure
 - R&D priorities are set according to health needs
 - New financing mechanisms to meet those needs
 - Access to innovations are assured (e.g. patent pool)
 - IP does not hamper access to compounds, knowledge and research tools