

# Pharmaceutical patents and access to HIV/AIDS treatment: the Brazilian experience.

Constance Marie Meiners (Min of Health, BR)

Julien Chauveau (Inserm-U379, FR)

Stephane Luchini (GREQAM/EHESS, FR)

Jean Paul Moatti (Inserm-U379, FR)

Toronto, August 2006.

# HIV/AIDS Pandemic

- Only 15% of people in need of ART in the developing world have access to it (WHO, 2005).
- High cost of medicines remains a major barrier to access to treatment.
- **Q: What is the impact of patent protection on the dynamics of ARV prices?**

# Pharmaceutical Patents

- Dubious role:
  - Medical therapy innovation through heavy investments on R&D;
  - Monopoly power puts upward pressure on drug prices.
- Industry's claim:
  - large sunk costs and high uncertainty level (regulation and market acceptance).

# ARVs Market Structure

- Therapeutic Classes:
  - NRTIs: nucleoside reverse transcriptase inhibitors;
  - NNRTIs: nonnucleoside reverse transcr. inhibitors;
  - PIs: protease inhibitors;
  - Fusion Inhibitors.
- Oligopoly:
  - 27 ARVs launched btw 1987 and 2005;
  - 8 pharmaceutical companies;
  - Top 10 ARVs = 86% market share (6 Co's).

# The Brazilian Programme

- Strategies:
  - Free and universal access to ART;
  - Local production;
  - Import of raw materials from India/China;
  - Centralised procurement;
  - Compulsory license threat.
- Spillover effects
- Challenges:
  - Resistance to treatment + patented drugs.

## ARV Provided by the Brazilian National STD/AIDS Programme (2005)

Active Principle	Introd.	Active Principle	Introd.
<b>1. NRTI</b>		<b>3. PI</b>	
Zidovudine (AZT)*	1991	Saquinavir (SQV)	1996
Didanosine (ddI)*	1993	Ritonavir (RTV)*	1996
Lamivudine (3TC)*	1996	Indinavir (IDV)*	1997
Stavudine (d4T)*	1997	Nelfinavir (NFV)	1998
AZT/3TC*	1998	Amprenavir (APV)	2001
Abacavir (ABC)	2001	Lopinavir/RTV (LPV/r)	2002
Tenofovir (TDF)	2003	Atazanavir (ATV)	2000
Didanosine EC	2005	<b>4. Fusion Inhibitors</b>	
<b>2. NNRTI</b>		Enfuvirtide (T-20)	2005
Nevirapine (NVP)*	1998	<b>* Locally produced drugs</b>	
Efavirenz (EFV)	1999		

Sources: Ministry of Health, Brazil, 2005; Orsi, F. et al. Intellectual property rights, anti-aids policy and generic drugs, 2003; INPI Patent database.

# Method

- Transactions: (Inserm-U379/ORS-PACA)
  - ETAPSUD/ANRS Database;
  - 188 effective transactions (Brazil);
  - Period: 1998 - 2002;
  - Standardised source prices and quantities.
- Patent Status:
  - Literature and informal consultations.

# Method

## ■ Statistical Analysis:

– Unit: Log of Price per Daily Dosis (PDD);

– Explanatory Variables:

\* year of transaction;

\* quantity purchased;

\* number of suppliers;

\* drug characteristic;

\* therapeutic class;

\* nature of producer;

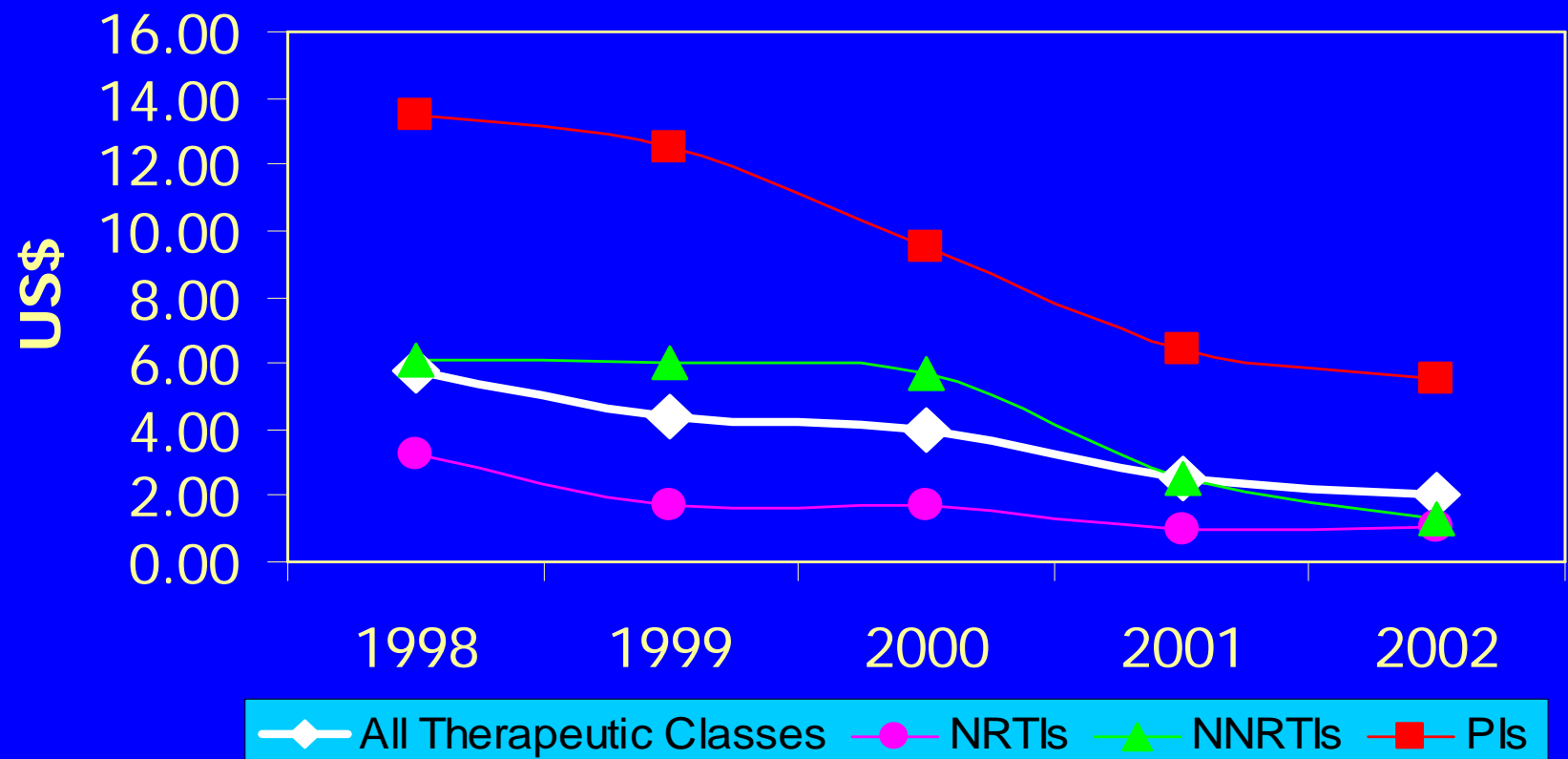
\* line of therapy;

\* patent status;

\* age of drug.

# Results

Evolution of Average PDD (Current US\$)  
by Therapeutic Class: Brazil 1998-2002



## Average PDD (Current US\$) per ARV: Brazil 1998-2002

T. Class	Drug	T. Line*	Price	Patent Status
NRTI	AZT	1st	1.31	off-patent
	d4T	2nd	1.02	off-patent
	3TC	1st	2.14	off-patent
	ddI	2nd	2.37	off-patent
	ddC	off-guideline	0.90	off-patent
	ABC	neither	4.07	on-patent
NNRTI	EFV	1st	4.94	on-patent
	NVP	2nd	3.69	off-patent
	DLV	neither	1.60	on-patent
PI	LPV/r	1st	9.60	on-patent
	NFV	2nd	10.98	on-patent
	SQV	2nd	15.86	on-patent
	APV	neither	8.46	on-patent
	IDV	off-guideline	7.86	off-patent

\* Only 1st and 2nd Therapy Lines



## Multiple Linear Regression on Log of PDD: Brazil 1998-2002

Estimated variable: ln(PDD)	s	$\beta$	t	sig.
(constant)	0.305		4.518	0.000
<b>Year of transaction (1998)</b>				
Year 1999	0.151	<b>-0.185</b>	-3.370	0.001
Year 2000	0.165	<b>-0.286</b>	-4.868	0.000
Year 2001	0.168	<b>-0.500</b>	-7.848	0.000
Year 2002	0.181	<b>-0.432</b>	-7.058	0.000
<b>Drug Characteristic (Branded ARV)</b>				
Generic ARV	0.204	<b>-0.236</b>	-2.828	0.005
<b>Therapeutic Class (NRTIs)</b>				
NNRTIs	0.185	<b>0.232</b>	4.235	0.000
PIs	0.215	<b>0.570</b>	7.390	0.000
<b>Patent situation in Brazil (off-patent)</b>				
ARV with patent granted	0.225	<b>0.217</b>	2.899	0.004
<b>Age of Drug (5 years or more)</b>				
Recent approval by FDA (< 5 years)	0.158	<b>0.120</b>	1.751	<b>0.082</b>
<b>R<sup>2</sup></b>		<b>0.74</b>		

# Main Conclusions

- **Generic competition** enforced by local production of drugs has been a key determinant of ARV price decrease;
- **Increasing patent protection** poses an important threat to the sustainability of ART access in developing countries;
- Yet, patents are considered an important element to encourage R&D;
- So, **the challenge remains in securing access to top ART in the long run.**

# Policy Recommendations

- Use of TRIPS flexibilities:
  - Careful examination;
  - Parallel importing;
  - Voluntary and compulsory licenses;
- Investments on human capital, local manufacturing capacity and R&D;
- Differential Pricing;
- Centralised Procurement Strategy;
- S&T Cooperation;
- Mobilisation of Public Opinion.

Thank you!

[constance.meiners@saude.gov.br](mailto:constance.meiners@saude.gov.br)