

TRIPS & Access to Medicines

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A 2 K Annual Workshop

**BIBLOTHECA ALEXANDRIA
28 September 2009
Alexandria**



This Presentation

- Globalization and Trade
- World Trade Organization
- Health Related Trade Agreements in WTO
- Intellectual Property Protection
- TRIPS Agreement and how it effects access to medicines
- TRIPS flexibilities
- Doha Declaration
- Free Trade Agreements
- WHO work in this area

Globalization

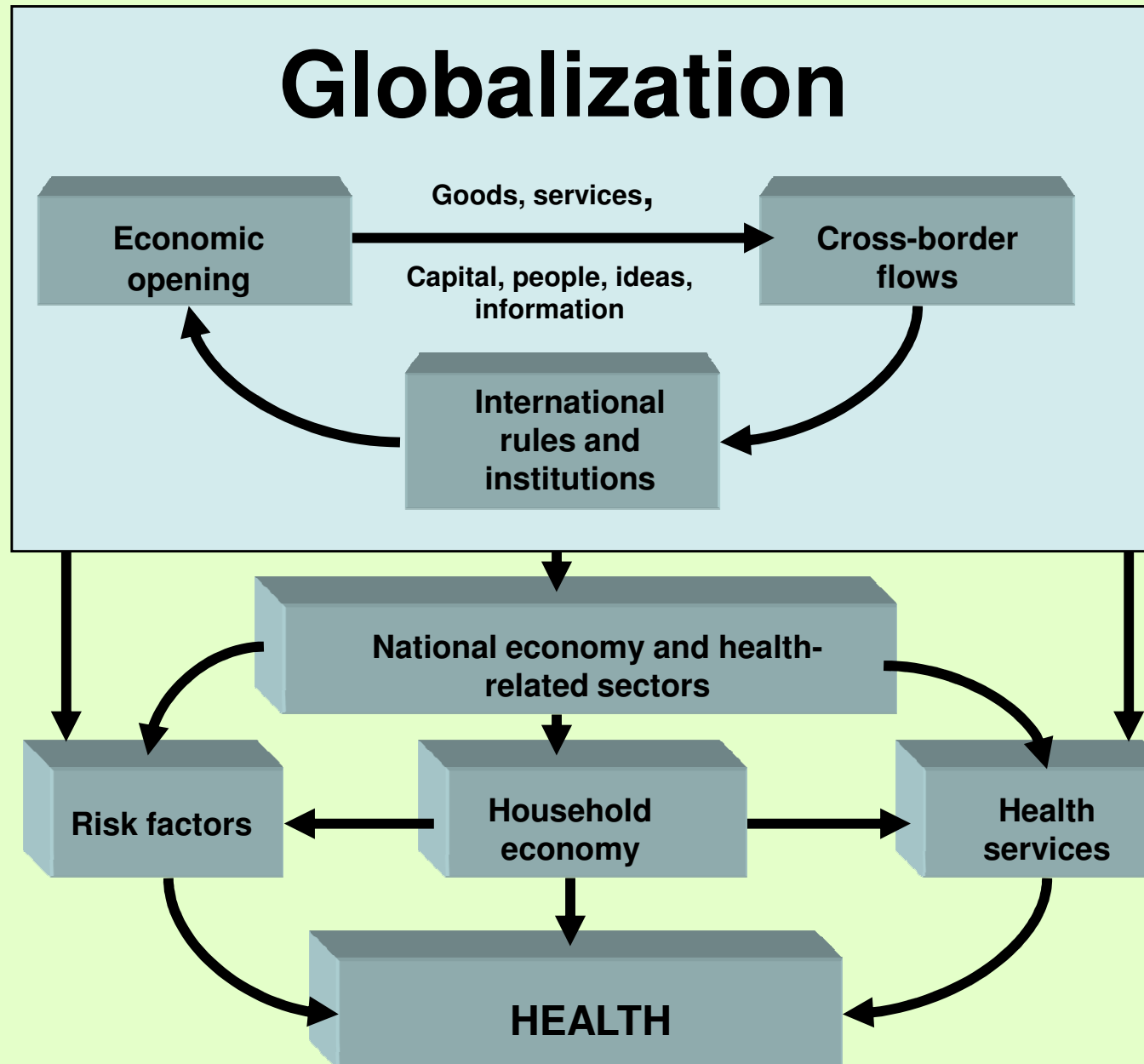
Communication Revolution

Political

Economic

Social

Globalization



Trade

- Voluntary exchange of goods and services
- Imports and exports
- Theory of comparative advantage



Leading Exporters & Importers in the World

2005 figures

#	Exporters	Value Bln USD	Importers	Value Bln USD
1	Germany	969	USA	1732
2	USA	904	Germany	773
3	China	762	China	660
4	Japan	594	Japan	514
5	France	460	UK	510
6	The Netherlands	402	France	497
7	UK	382	Italy	379
8	Italy	367	The Netherlands	359
9	Canada	359	Canada	319
10	Belgium	334	Belgium	318

Modern history of International Trade

- Post world war II scenario
- GATT in 1947
- Seven rounds of international trade negotiations
1947-1986
- Uruguay round – 1986 -1994
- Establishment of WTO, 1st January 1995



World Trade Organization

- A multilateral trade negotiation forum with 152 countries as members.
- Promotes free trade
- Basic Principle: Trade without discrimination
 - Most Favored Nation Treatment
 - National Treatment
- Dispute Settlement Mechanism



Important WTO Agreements

Single Undertaking

Goods

- ▶ GATT
- ▶ Agreement on Agriculture
- ▶ Agreement on Application of Sanitary & Phytosanitary Measure
- ▶ Agreement on Technical Barriers to Trade

Services

- ▶ General Agreement on Trade in Services - GATS

Intellectual Property

- ▶ Agreement on Trade Related Aspects of Intellectual Property Rights

- ▶ Understanding on rules and procedures governing dispute settlement
- ▶ Trade policy Review Mechanism

Trade in Health

Goods

- ▶ Medicines; Vaccines and other health technology

Services

- ▶ Movement of health professionals; patients; health related investments and supply of health care services across countries

Intellectual Property

- ▶ Patents; trade marks; copy rights on health related products and services

- ▶ Understanding on rules and procedures governing dispute settlement
- ▶ Trade policy Review Mechanism



Important Health Related WTO Agreements

Goods

- ▶ **GATT**
- ▶ **Agreement on Agriculture**
- ▶ **Agreement on Application of Sanitary & Phytosanitary Measure**
- ▶ **Agreement on Technical Barriers to Trade**

Services

- ▶ **General Agreement on Trade in Services - GATS**

Intellectual Property

- ▶ **Agreement on Trade Related Aspects of Intellectual Property Rights**

- ▶ **Understanding on rules and procedures governing dispute settlement**
- ▶ **Trade policy Review Mechanism**

Intellectual Property Protection & Rights

what is it ?

- Way of encouraging innovation & creativity
- Grant of conditioned legal monopoly
 - Must be innovative
 - Time limited
 - revealing knowledge; know-how
- IP protection takes many forms
 - Patents
 - Trade marks
 - Copy rights
- Patent rights

TRIPS – Agreement on Trade Related Aspects of Intellectual Property Rights

- One of the new areas in the multilateral trade
- Three industries pushed it in WTO discussions: pharmaceutical; software; motion pictures
- Before WTO era countries were deciding about the IPR protection according to their level of development
- Developed countries of today developed their industries by extensive copying of innovations made elsewhere

Short introduction to TRIPS

- Set-up a minimal criteria for patent protection – implementation through national legislation
- In case of pharmaceuticals it means:
 - more stronger: both process and product patents
 - more longer patent term: 20 years
 - a number of public health protective flexibilities and safeguards are also provided in the agreement
 - FTAs are undermining these safeguards – TRIPS plus approaches

Short introduction to TRIPS

- The national patent laws are required to be amended

[there is a need for MoH and ministries of trade to work together]

- Reverse engineering is no more possible:

Reverse engineering: case of India

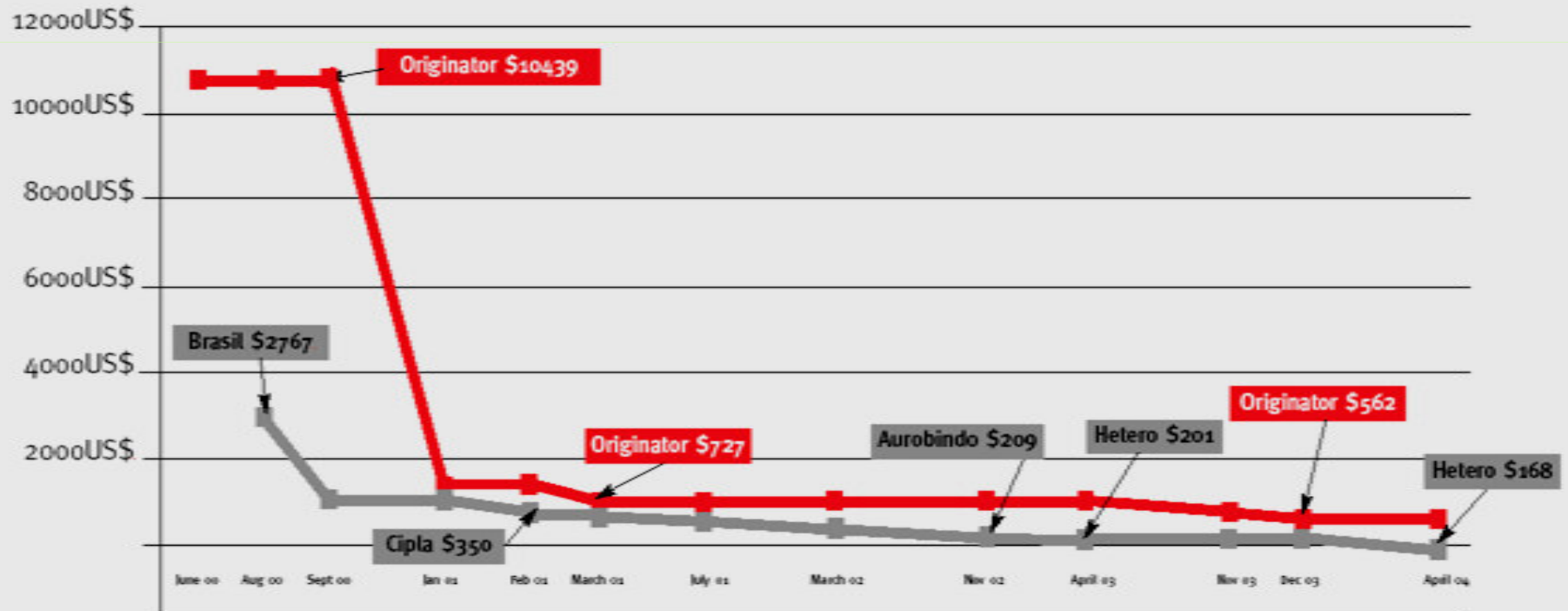
	Medicines	Introduced in Int. market	Introduced in Indian market	Time lag in years
1.	Salbutamol	1973	1977	4
2.	Mebendazole	1974	1978	4
3.	Rifampacin	1974	1980	6
4.	Naproxen	1978	1981	4
5.	Bromhexin	1976	1981	6
6.	Ranitidine	1981	1985	4
7.	Captopril	1981	1985	4
8.	Norfloxacin	1984	1988	4

The role of generics in lowering drug prices

The Effects of Generic Competition

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.

May 2000-April 2004



Public Health related Aspects of IPRs

New drugs are to be developed, but even if they are developed would they be accessible to the poor

- THE CHALLENGE :**
1. Unaffordable medicine prices
 2. Irrational Use of medicines
 3. Unfair health financing mechanisms
 4. Unreliable medicines supply
 5. The quality of medicines
 6. New medicines are needed

New drugs for existing & neglected diseases	New drugs to replace existing ineffective or unsafe drugs	New drugs for newly emerging diseases
<ul style="list-style-type: none"> <input type="checkbox"/> 95% investments in R&D are for 20% people <input type="checkbox"/> 1% drugs in last 25 years for tropical diseases and TB, makes 11% GBD <input type="checkbox"/> e.g. vaccines for HIV/AIDS, treatment of hepatitis B, Cystic fibrosis are urgently needed 	<ul style="list-style-type: none"> <input type="checkbox"/> More effective drugs need to be developed for HIV/AIDS <input type="checkbox"/> TB, Malaria have become drug resistant to existing drugs <input type="checkbox"/> safer drugs are needed to replace toxic treatments available for trypanosomiasis and leishmaniasis etc. 	<ul style="list-style-type: none"> <input type="checkbox"/> more than 20 diseases have emerged in last 10 to 15 years e.g. ebola virus; new strains of Cholera; SARS etc <input type="checkbox"/> all these new diseases require new treatments to be developed

TRIPS Flexibilities

- **Government Use**

allow government agencies to use an invention, for public, non-commercial purposes.

- **Compulsory License**

permit 3rd parties to use an invention, without the patent holder's consent on grounds of public interest.

TRIPS Flexibilities

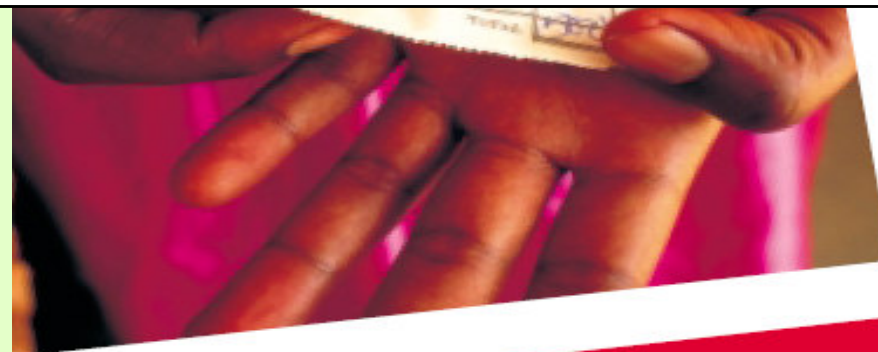
- **Parallel Imports**

import at a lower price and resale of patented product in another country

- **Exception to Rights**

allow for limited use of a patent in specific circumstances;
Bolar exception

A GLOBAL CAMPAIGN FOR ACCESS TO MEDICINES



CUT THE COST

Patent Injustice: How World Trade Rules Threaten the Health of Poor People

**MILLIONS HAVE
A DRUG PROBLEM.
THEY CAN'T GET ANY.**



Doha Declaration

on TRIPS & Public Health

- Adopted by consensus at the WTO's 4th Ministerial Conference in Doha, Qatar, on 14 November 2001.
- To respond to the concerns that have been expressed that the TRIPS Agreement might make some drugs difficult to obtain for patients in poor countries.

Doha Declaration

on TRIPS & Public Health

- It reaffirms the members' rights to use fully the provisions of the TRIPS Agreement, which provide flexibility for this purpose.

Free Trade Agreements

TRIPS Plus

Undermine TRIPS flexibilities

- Restrict issuing of C.L., parallel imports
- Patent extension beyond 20 years
- Data exclusivity

WHO Work in this area

WHA52.19 May 1999 ... monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, ... to maximise the positive and mitigate the negative impact of those agreements ...

WHA55.14, 2002 ... ensure that WHO's Medicines Strategy address ... the impact of international trade agreements on access to Medicines

WHA56.27, 2003 ... to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the TRIPS Agreement

WHA57.14 (22 May 2004 ... to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health

WHO Work in this area

Commission on Public Health, Innovation and Intellectual Property



Intergovernmental working group on Public Health and Intellectual Property



Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

Public health

innovation and
intellectual property rights

REPORT OF THE COMMISSION ON
INTELLECTUAL PROPERTY RIGHTS, INNOVATION
AND PUBLIC HEALTH



Conclusions

- Trade is part of economic globalization.
- It has emerged as an important determinant of health.
- There are international trade agreements in WTO which have a direct impact on public health.
- Strong and prolong patent protection has an effect on access to new essential medicines.
- TRIPS flexibilities needs to be understood and they must be fully incorporated in the national patent law.

If you are interested to know more

Log on to

www.who.int/phi

THANK YOU

