



REPUBLIC OF SOUTH AFRICA



Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

***Topic 4: Overview of the Use of Patent-Related Flexibilities
and the Main Constraints thereon within the Region***

**Durban, South Africa
January 29 to 31, 2013**

Public health related aspects of intellectual property rights

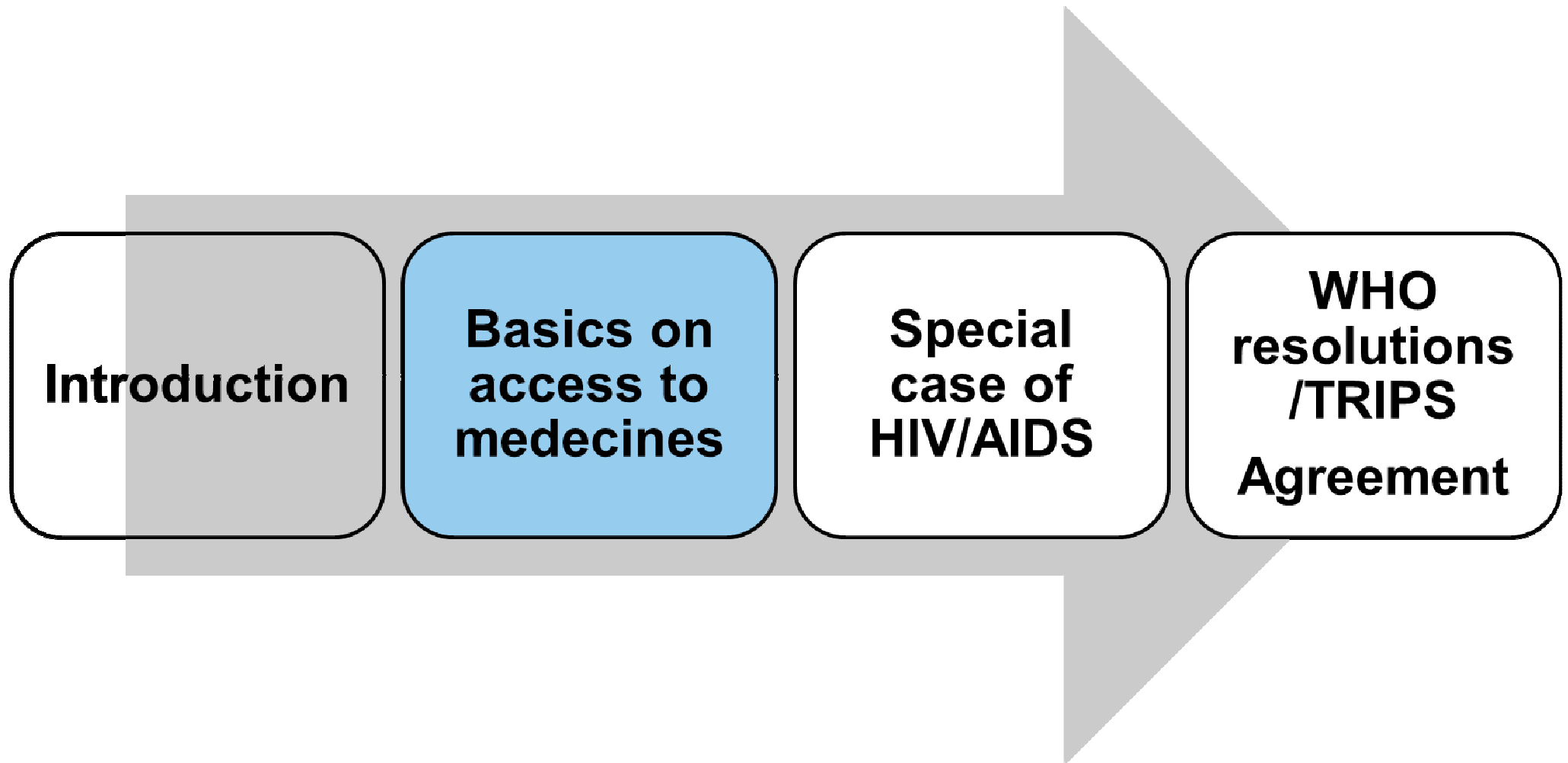
Regional Seminar on Patent-Related Flexibilities

Dr. Peter Beyer

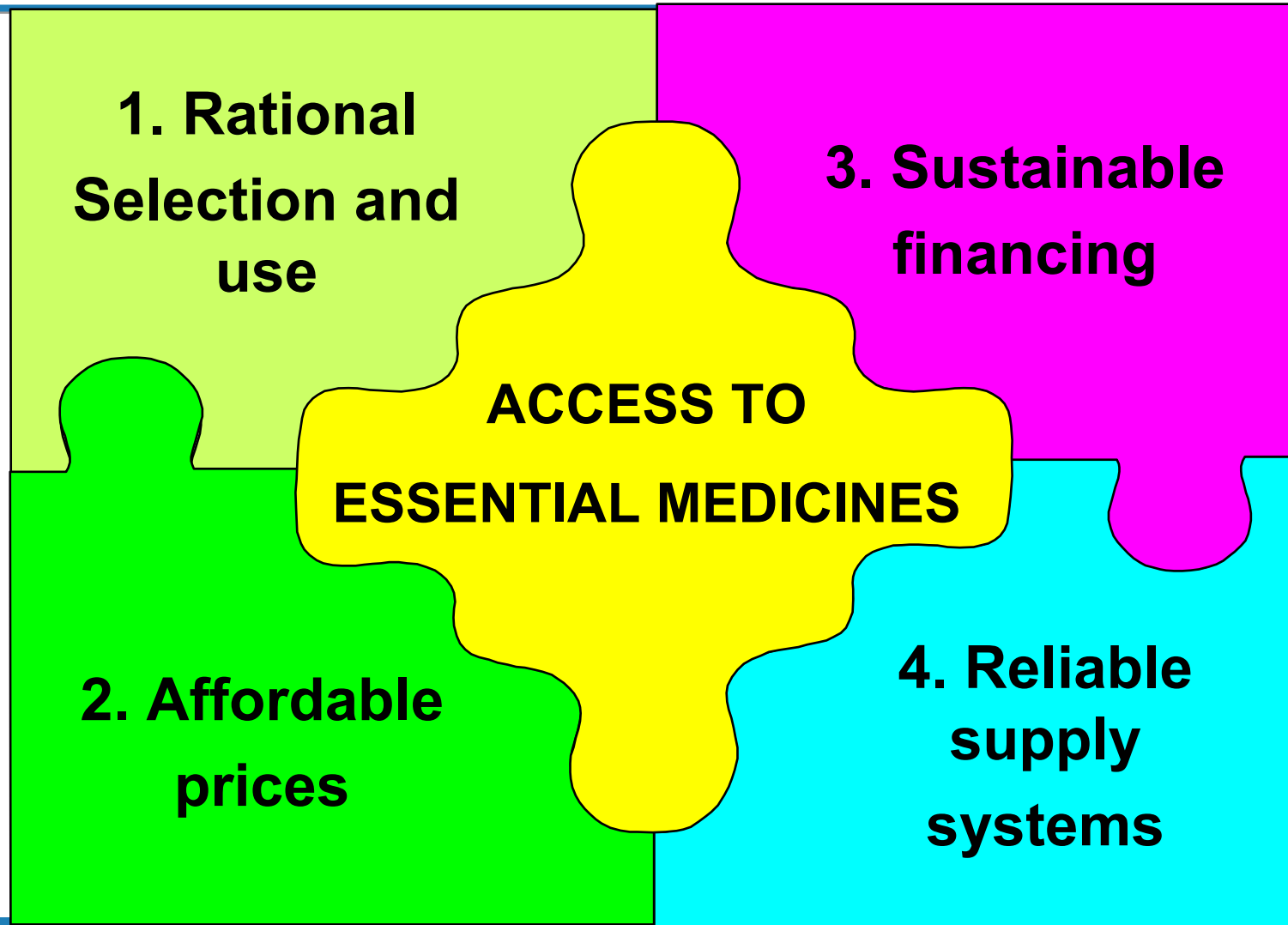


**World Health
Organization**

Outline



Framework for access to medicines

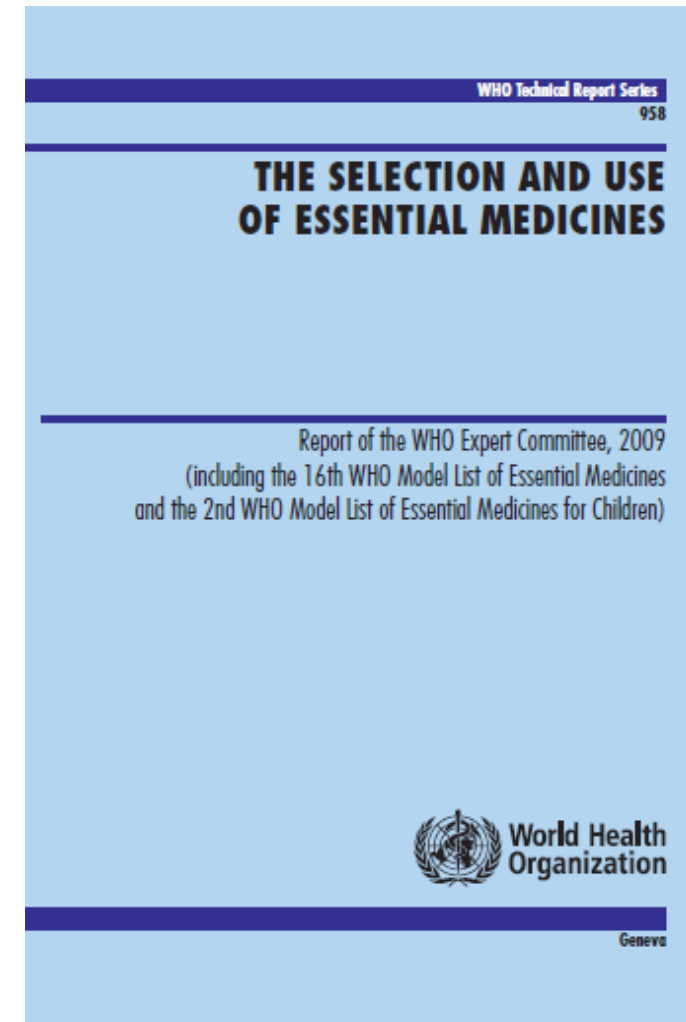


Rational selection of medicines

WHO Essential Medicines List

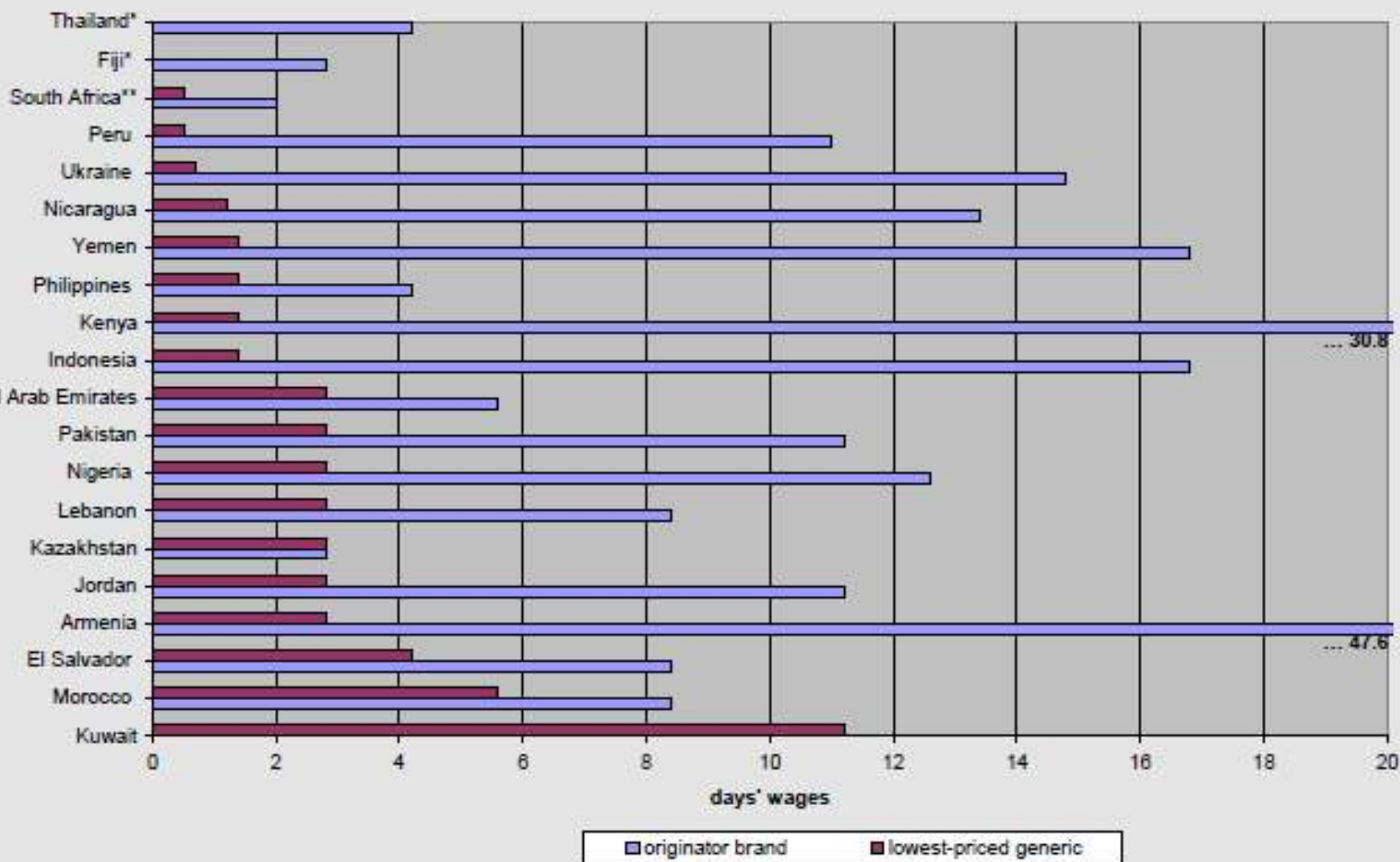
- 1977 - First edition
- Revised every two years
- Now contains more than 400 medicines including children's medicines
- Patent status NOT considered in selection

www.who.int/selection_medicines/en/index.html



Affordability: no. of days wages, lowest paid govt. worker, to buy 7 day course ciprofloxacin 500mg tab twice daily, private sector

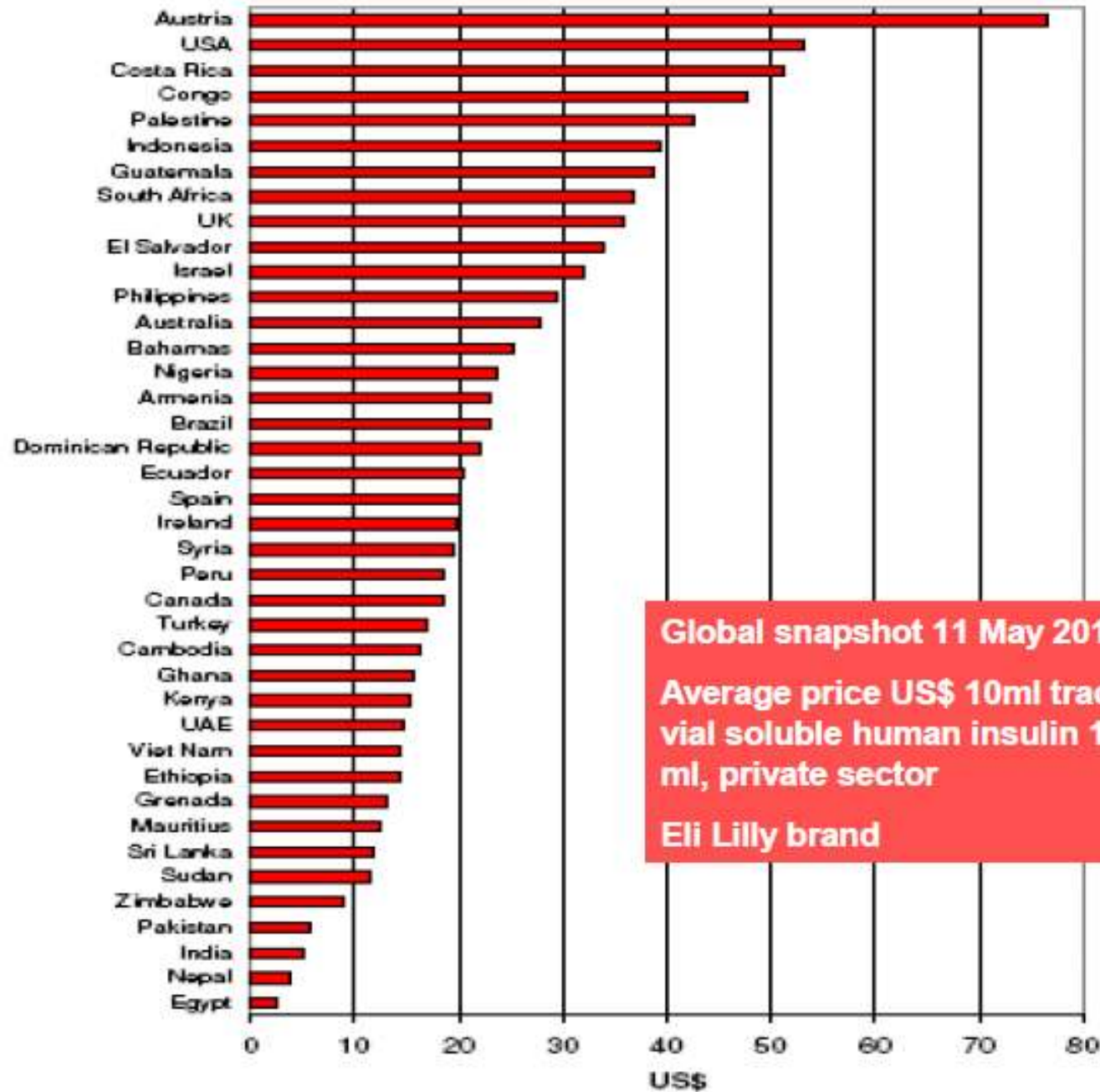
Affordable Prices



Source:
Health Action
International
www.haiweb.org



Affordable Prices



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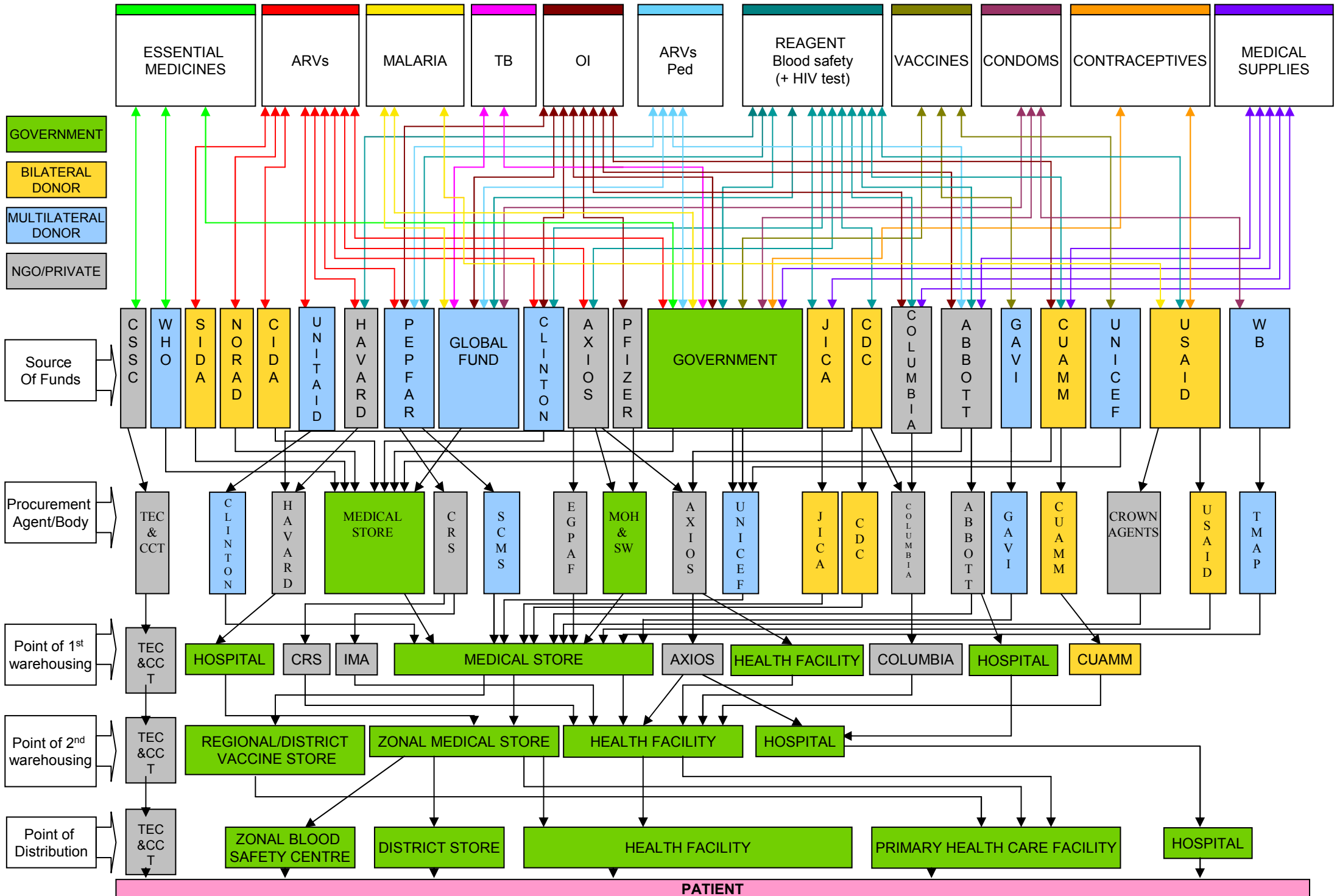
Health Action International,
www.haiweb.org/



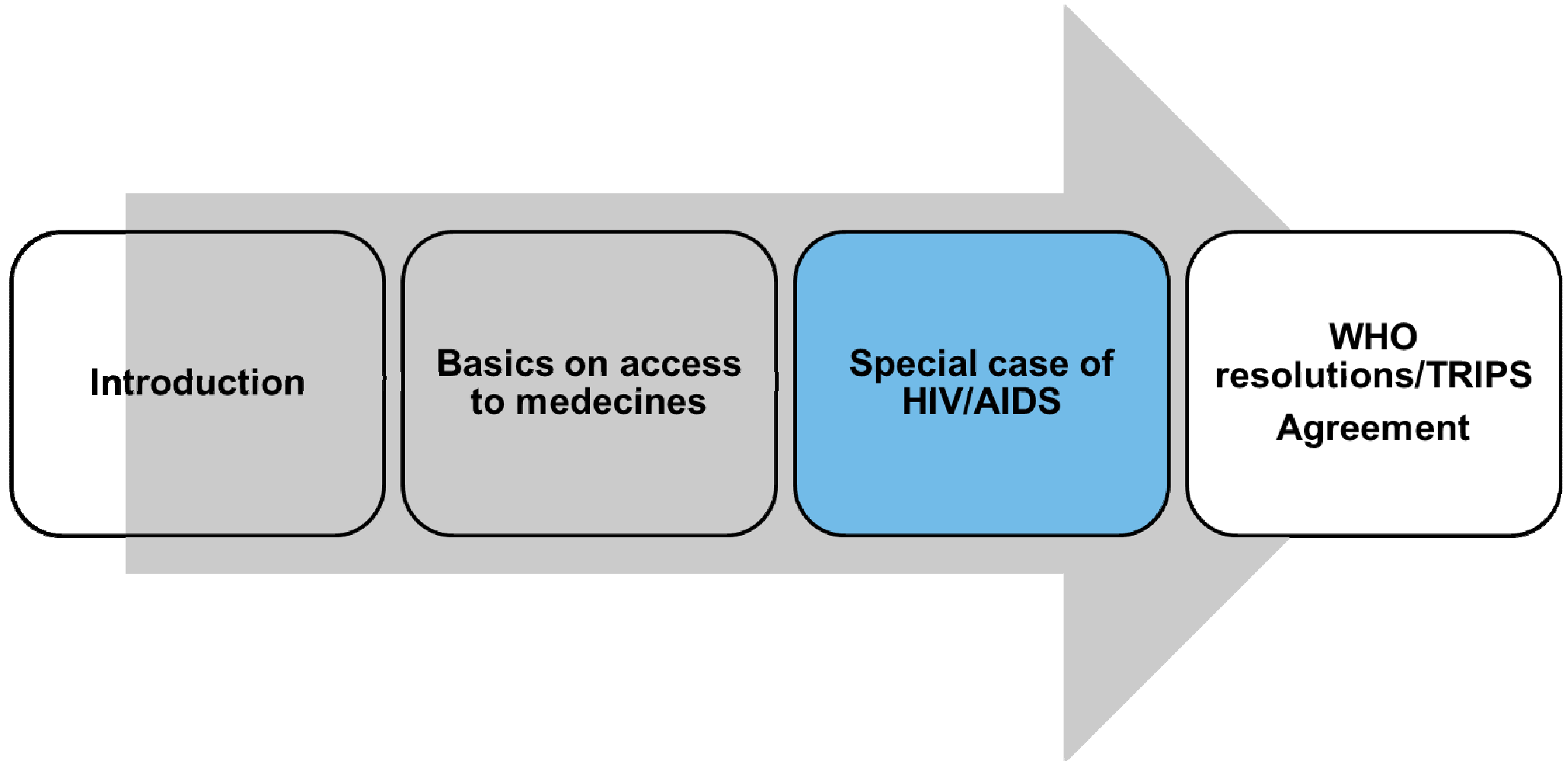
Medicines supply systems in TANZANIA. 2007



United Republic of Tanzania



Outline



The case of HIV/AIDS

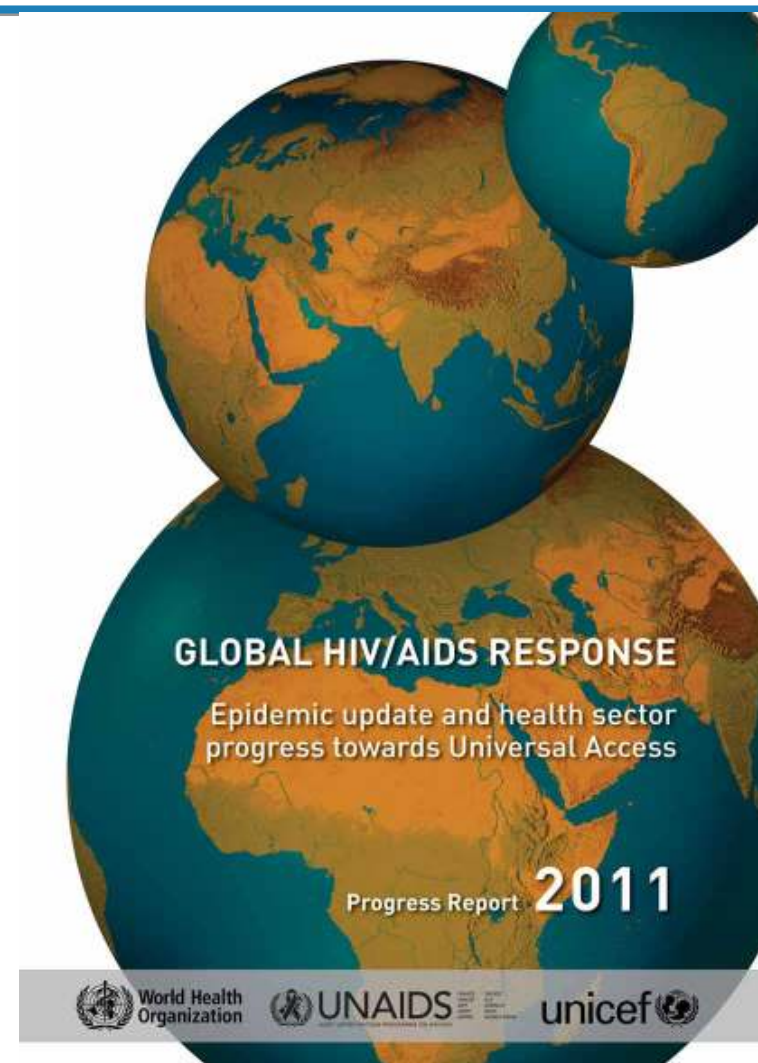
**Access to antiretroviral (ARV) therapy
in low-& middle-income countries:**

2003: 400.000 patients

2011: 8 million patients

**In need of treatment: 15 million (target
2015 - UN Political Declaration on
HIV/AIDS)**

**May increase with future revisions of
treatment guidelines**



Prices and sources of ARVs

2000: first-line ARVs cost over US \$10.000 per person/year

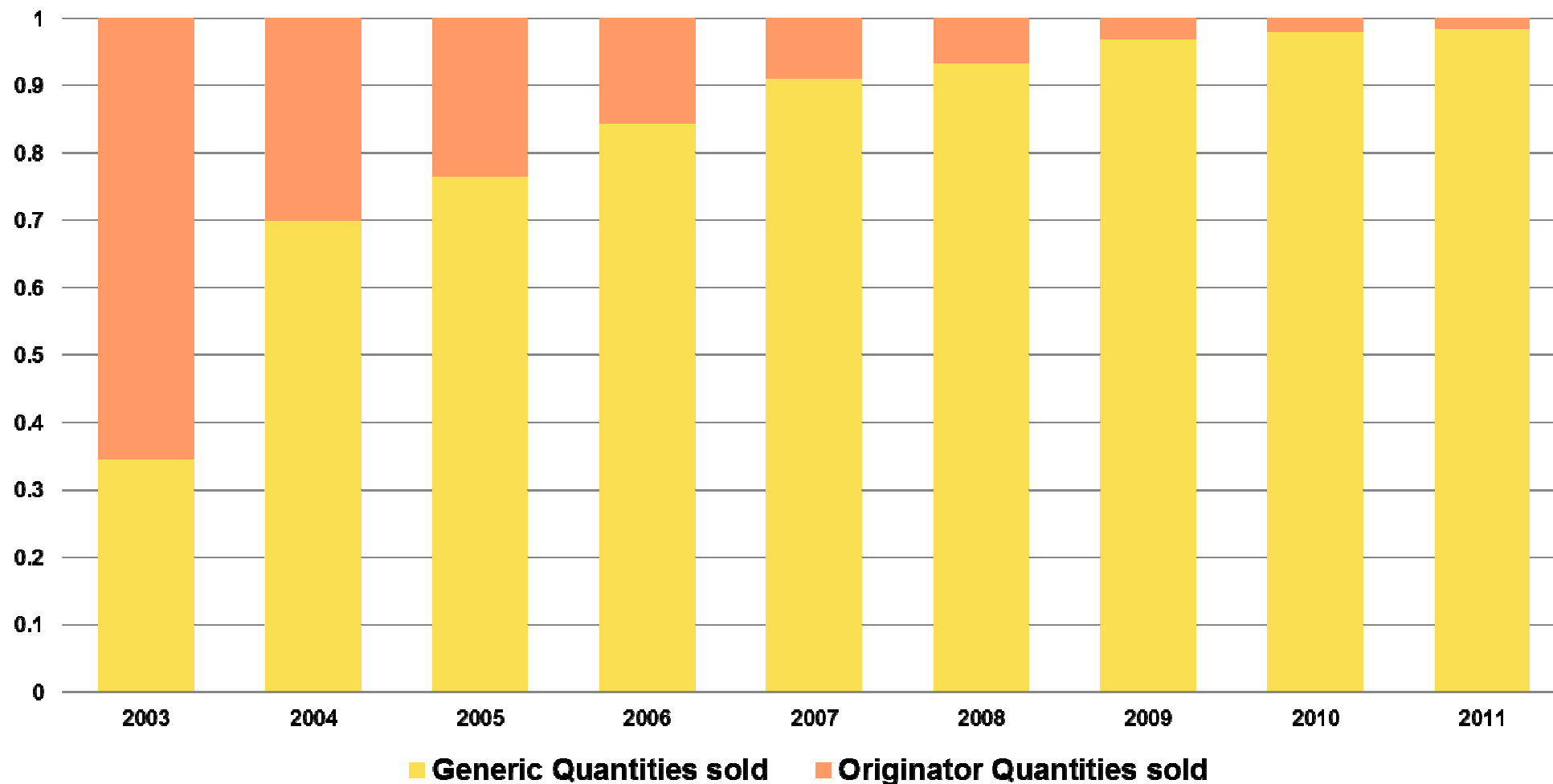
2010: median price of ten most widely used first-line regimens is about US \$121 per person/year

Price reductions are the result of:

- Competition with and among generic producers
- Increasing market size due to the financial engagements of donors and national governments in financing procurement of HIV/AIDS treatment in developing countries

WHO, UNAIDS, UNICEF, Global HIV/AIDS response: epidemic update and health sector progress towards universal access: progress report
2012

Generic vs. originator ARVs in quantities sold (%) (WHO Global Price Reporting Mechanism)



Prices and sources of ARVs

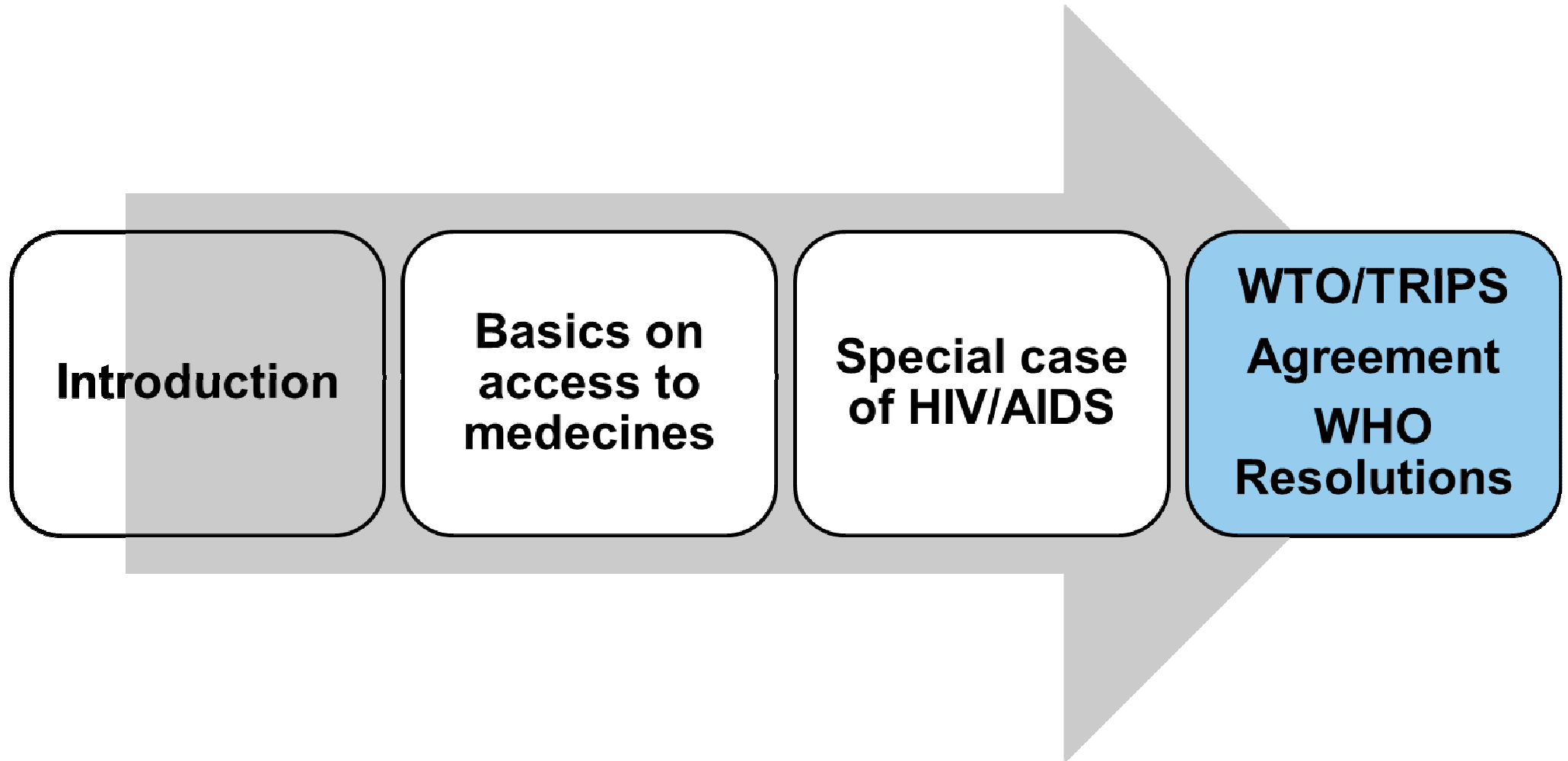
The role of Indian generic antiretroviral producers:

- 80% of the donor-funded developing country market
- In 2008: 87% of ARV purchase volumes; paediatric market 91% of purchase volume

Possible as many of the current ARVs are not patented in India

Brenda Waning, Ellen Diedrichsen, Suerie Moon, A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries, J Int AIDS Soc. 2010; 13: 35.

Outline



Global strategy and plan of action on public health, innovation and intellectual property

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;¹

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health

WHA 62.16	2009	GSPA PH, innovation & IP
WHA 63.28	2010	Establishment of CEWG on financing of R&D

WTO/TRIPS Agreement & Public Health

- TRIPS sets up the minimum criteria for patent protection countries have to implement through national legislation
- With regard to pharmaceuticals requires:
 - both process and product patents (previously no harmonization)
 - minimum patent term: 20 years (previously no harmonization)
 - protection of undisclosed information against unfair commercial use and disclosure (some precedents in Paris Convention)
- TRIPS provides for a number of public health-related flexibilities and safeguards



What kind of options do countries have?

TRIPS provides for public policy options/flexibilities that can help increase the availability of essential medicines, including:

- choices on grounds for compulsory licences/government use**
- limited exceptions to exclusive rights (research/Bolar exemption)**
- possibility to allow for parallel importation**
- discretion as to how to apply patentability criteria (novelty, inventive step and industrial applicability)**
- discretion as to how to provide for test data protection**
- pre-grant and post-grant opposition procedures**



How have flexibilities been used?

Research exemption

- **E.g. Switzerland:** research exemption, allowing all research and experimental projects access to information about the patented invention and its possible uses, including for research with a commercial background as its final purpose

Bolar exemption

- **E.g. South Africa/Egypt:** starting manufacturing on a non-commercial scale during patent period for purpose of market authorization; not considered a patent infringement



How have flexibilities been used?

Compulsory licenses

- **E.g. Brazil:** threat to use compulsory licensing lead to significant price reductions of key antiretrovirals; compulsory license for efavirenz in 2007

Government use

- **E.g. Indonesia:** in 2012 issued government use declarations for seven treatments for HIV/AIDS and Hepatitis C



How have flexibilities been used?

Pre-grant opposition procedures

- **India:** patent applications for antiretrovirals were rejected based on pre-grant oppositions

Patentability criteria:

- **India:** applications were rejected for lack of innovative step as known substances are not considered novel under the Indian Patent Act (paediatric formulations, heat stable versions)



Conclusions and Outlook

- Intellectual property is one determinant for access to medicines
- Prices of ARVs continue to decrease globally, but not for all treatment regimens - continued challenge for scaling up treatment coverage
- Financial commitment at governmental level is needed to sustain supplies of ARVs



Conclusions and Outlook

- Successes in increasing access to ARVs rely on Indian generics – will this be possible in the future?
- WTO/TRIPS agreement provides flexibilities to increase access to medicines
- Pharmaceutical companies are increasingly using non-exclusive license agreements in the area of HIV/AIDS
- Countries need to identify strategies to deal with access to high priced medicines



Public Health & Intellectual Property

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**WHO Department of Public Health,
Innovation and Intellectual Property:**

<http://www.who.int/phi>