

WHO-WIPO-WTO Trilateral symposium

Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines : Learning from the Past, Illuminating the Future

Access to Medicines: Achievements and Ongoing Challenges

Kees de Joncheere,

Director WHO Essential Medicines and Health products

Geneva, October 28, 2015



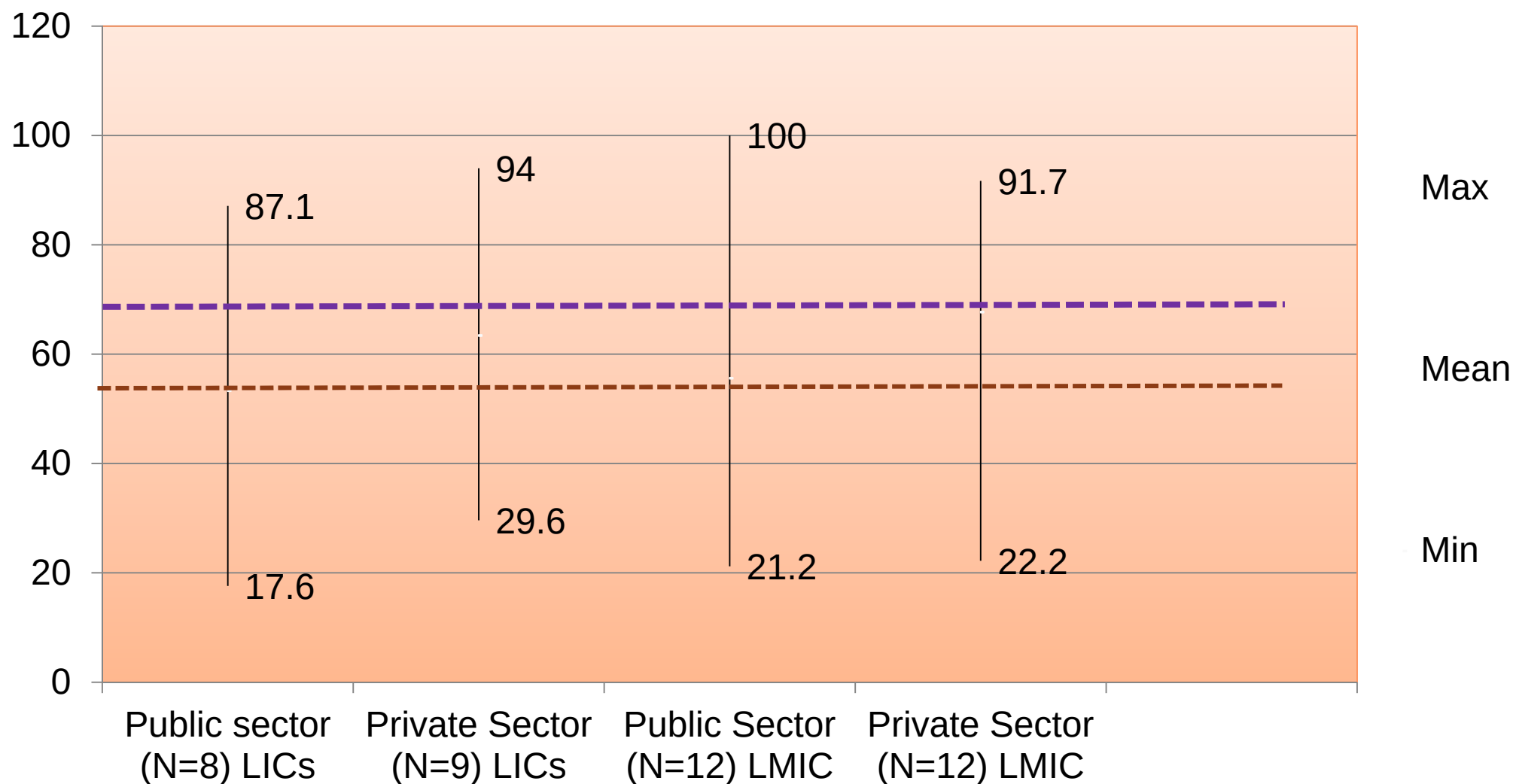
**World Health
Organization**

Overview

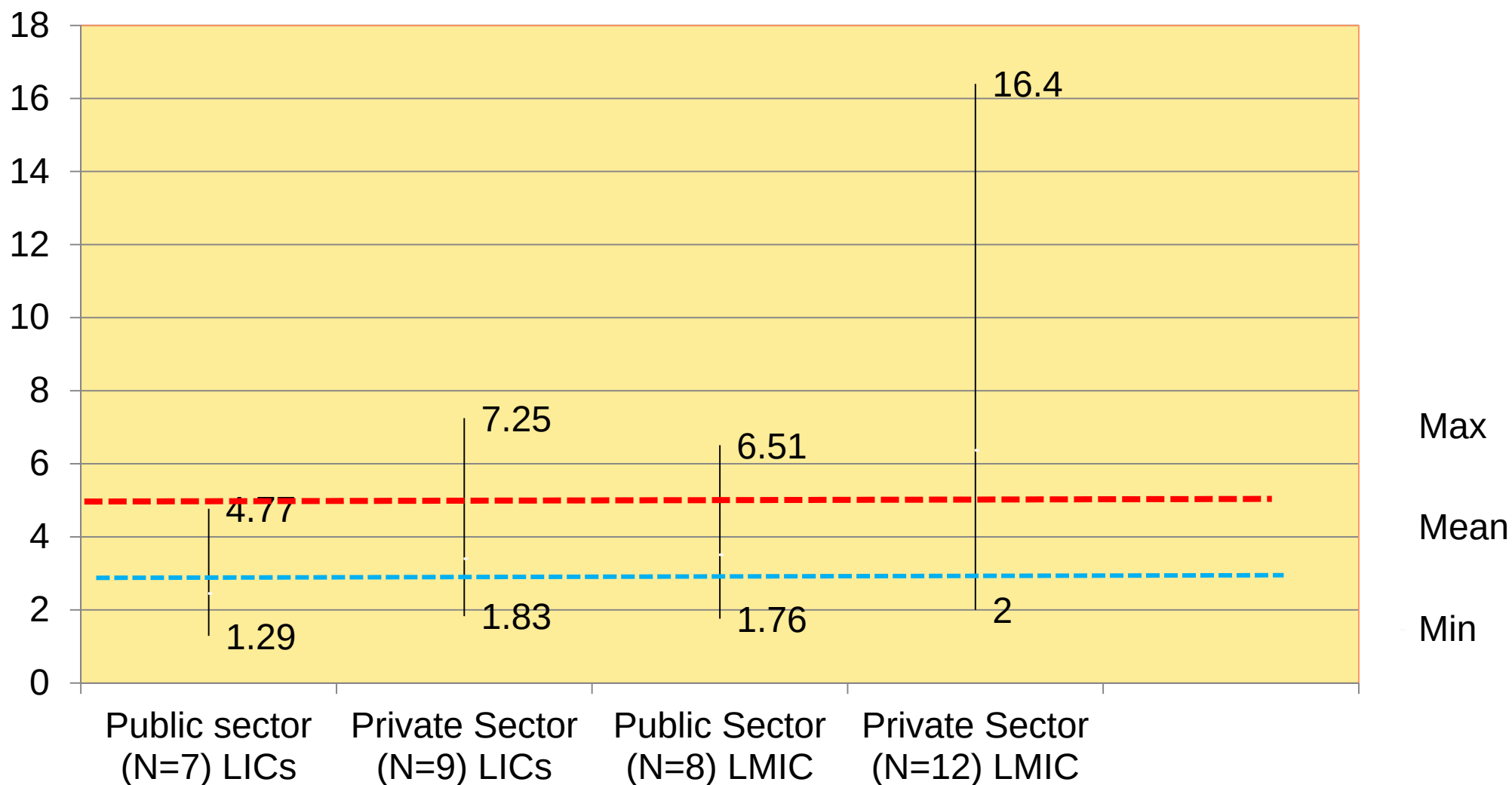
- Access to medicines : important but uneven progress
- Some new challenges
- New goals



Availability of selected generic medicines in public and private health facilities in low- and lower-middle-income countries, 2007–2013 (WHO/HAI Surveys)



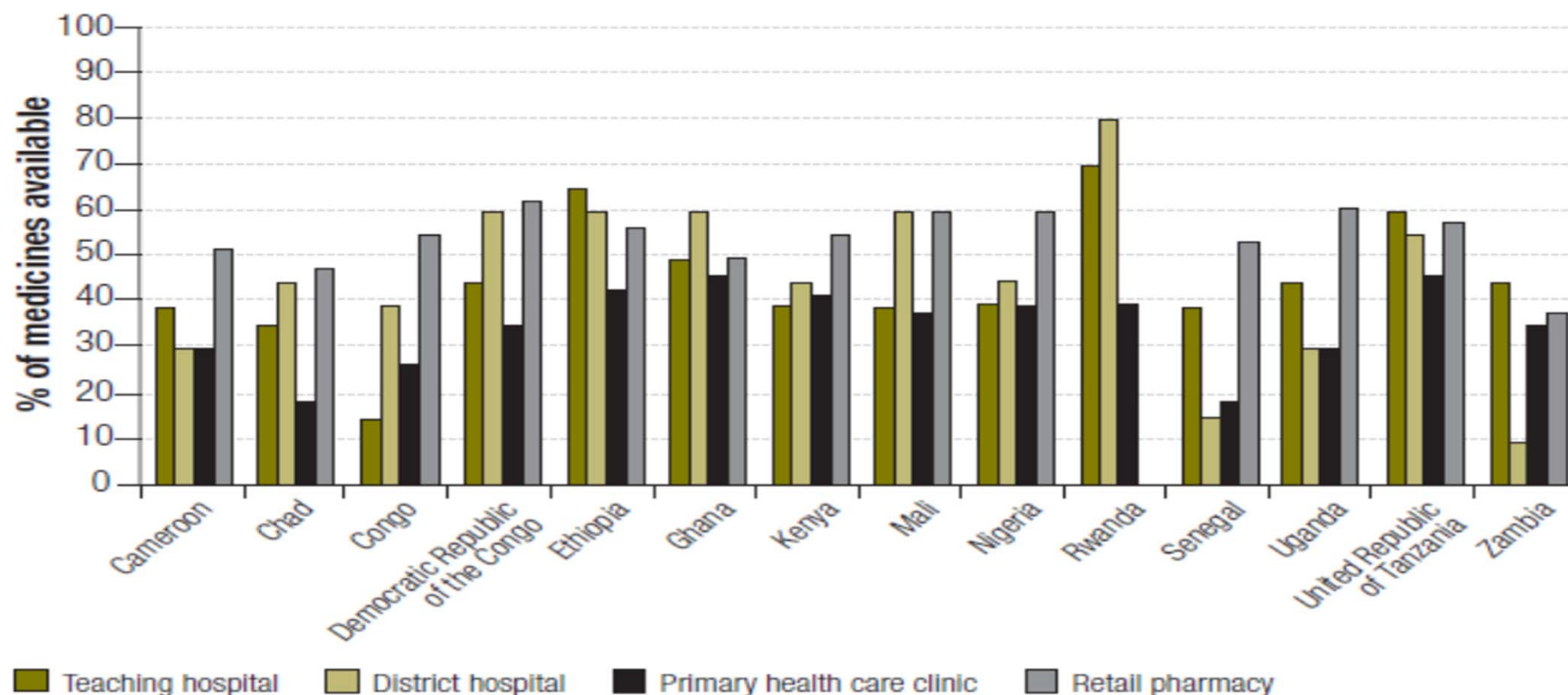
Ratio of consumer prices to international reference prices for selected lowest priced generic medicines in public and private health facilities in LICs and LMICs, 2007–2013
(WHO/HAI Source)



CHALLENGES

AVAILABILITY OF MEDICINE FOR CHILDREN

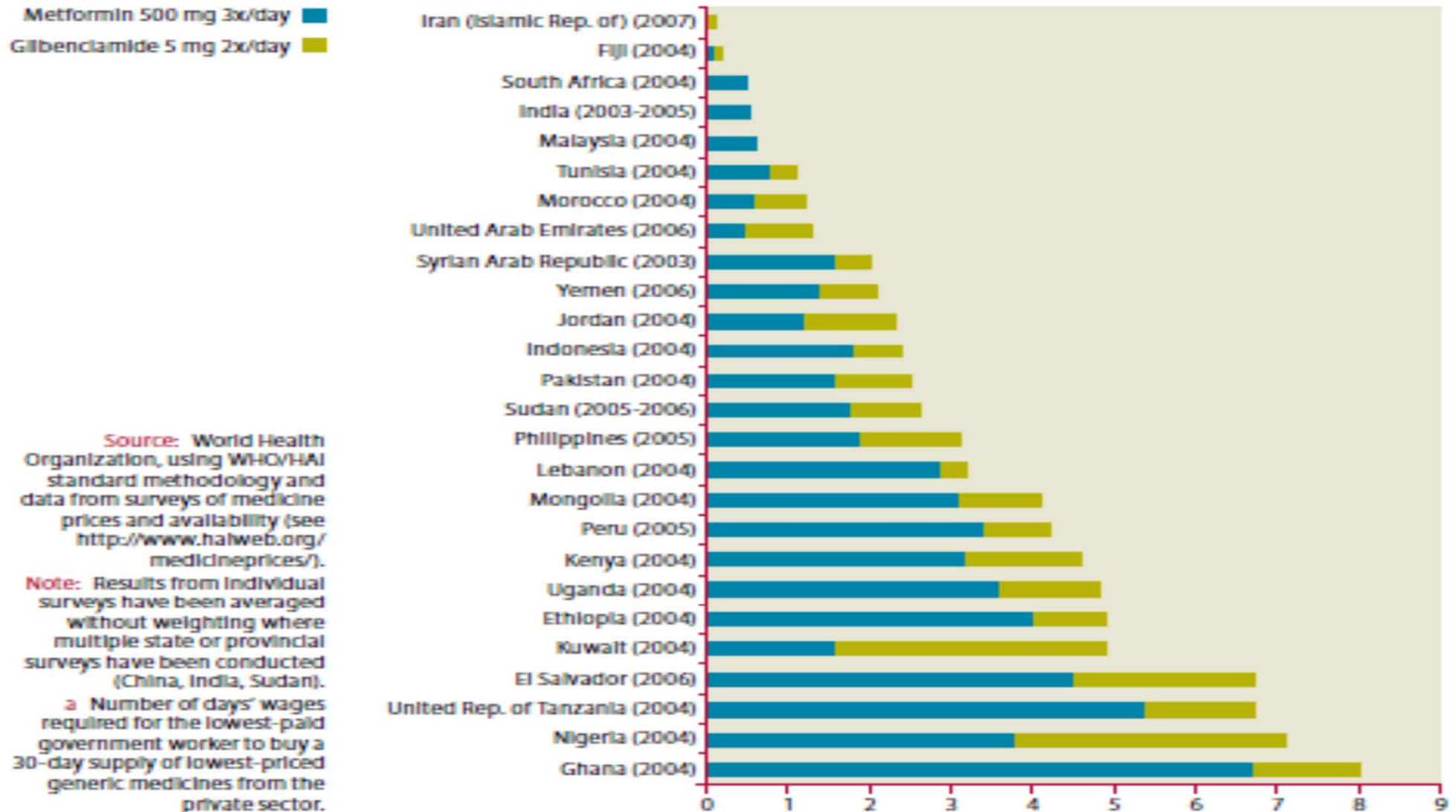
Fig. 2. Proportion of 20 survey medicines available from public and private sector facilities, in 14 countries in central Africa^a



^a In Rwanda there were no data for retail pharmacies.

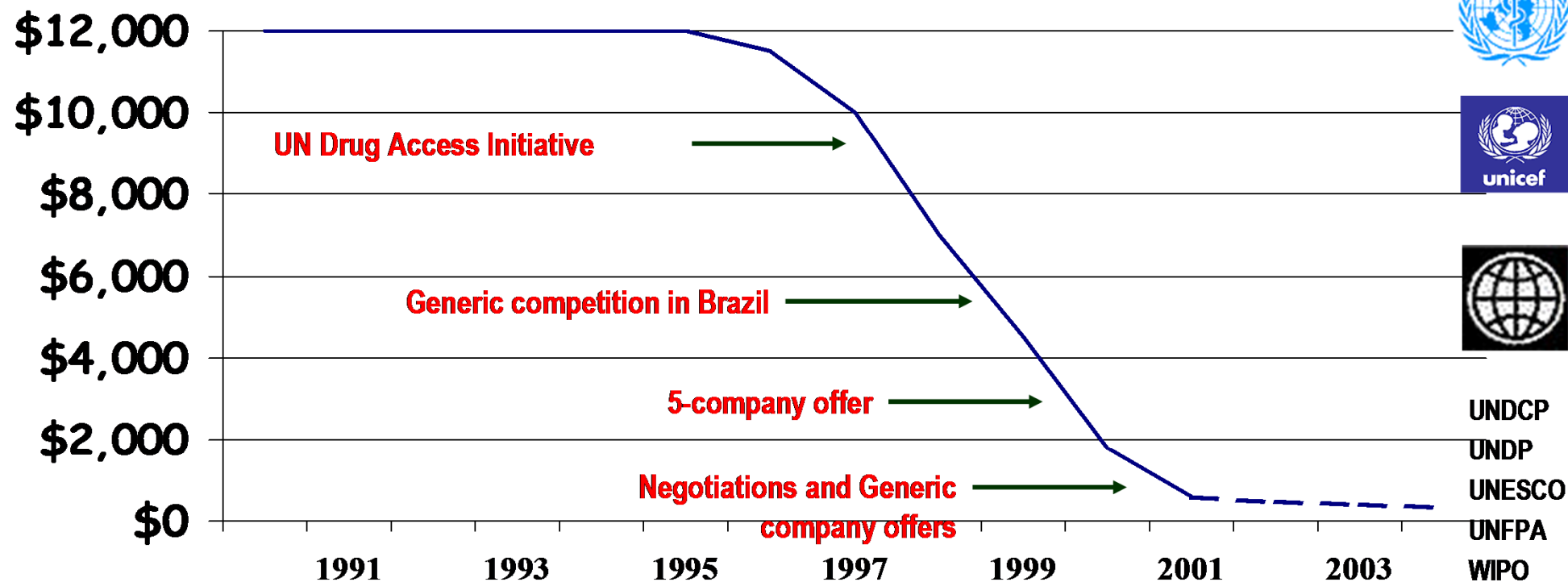
Low public sector availability leads patients to the private sector, where medicines are unaffordable

Affordability of treatment for diabetes (*days' worth of wages^a*)

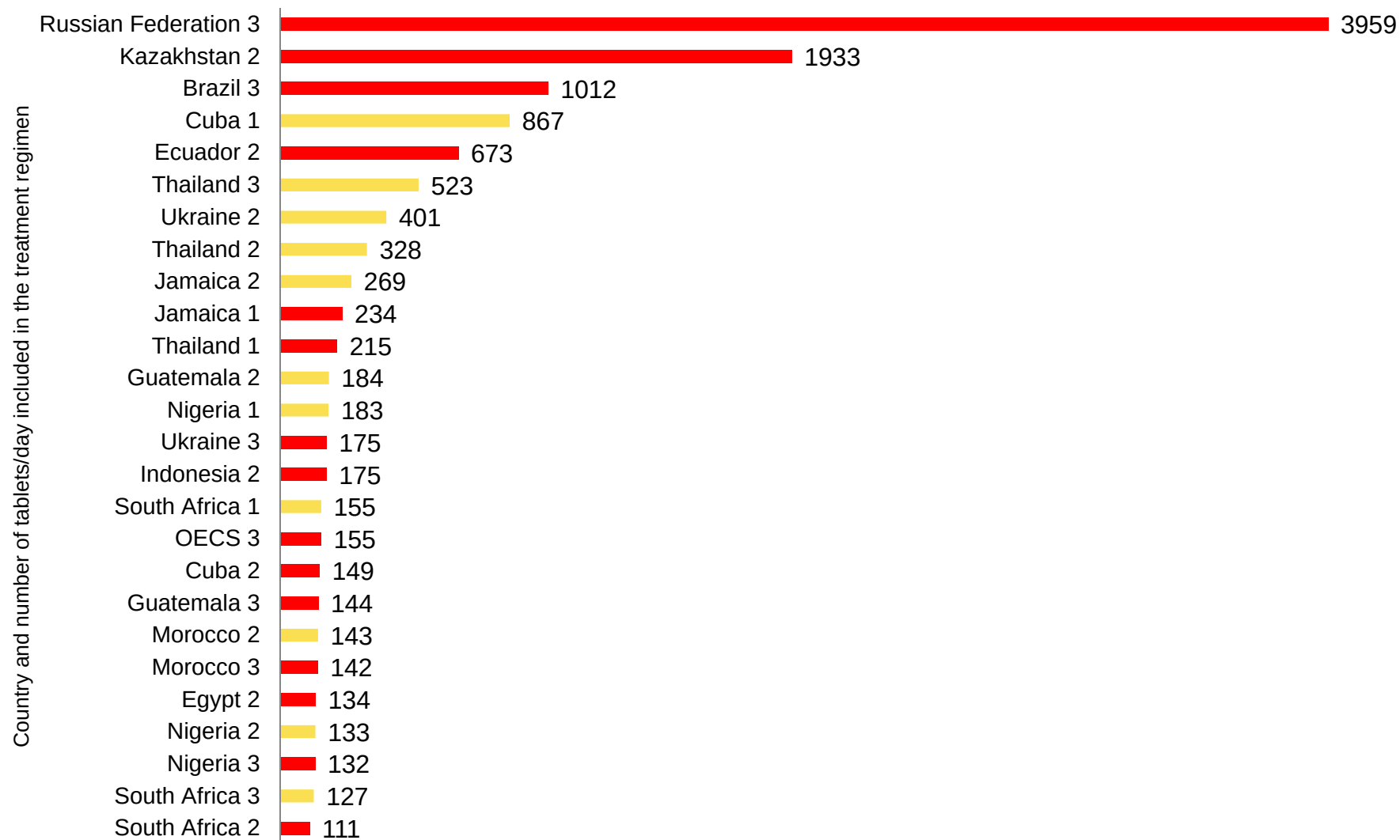


Advocacy, corporate responsiveness, & market forces have reduced antiretroviral prices 95% in 2 years

Annual cost per person for triple therapy (US \$)



Prices paid (US\$/patient-year) for the WHO-recommended first line regimen (tenofovir + emtricitabine or lamivudine + efavirenz)

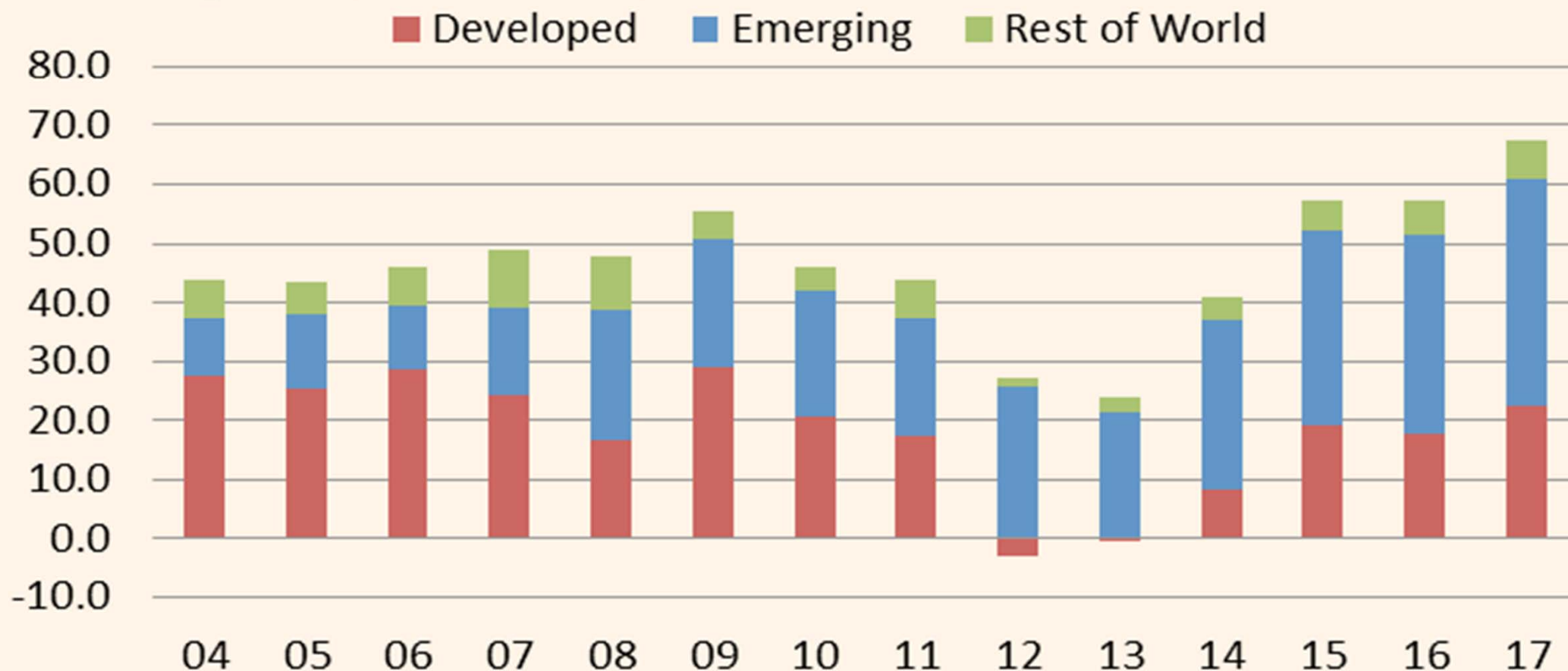


- Some new challenges



Annual growth in spending on medicines

Absolute growth, constant US\$bn



Source: IMS Health Market Prognosis, September 2013

Breast cancer drug turned down for NHS use due to high cost

Decision on Herceptin-style drug which costs £90,000 but can prolong lives by nearly six months heavily criticised

The Guardian April 23 2014



February 10, 2015 7:06 pm

Healthcare: The race to cure rising drug costs

David Crow and Andrew Ward

Critics question whether big pharma's premium pricing model can endure



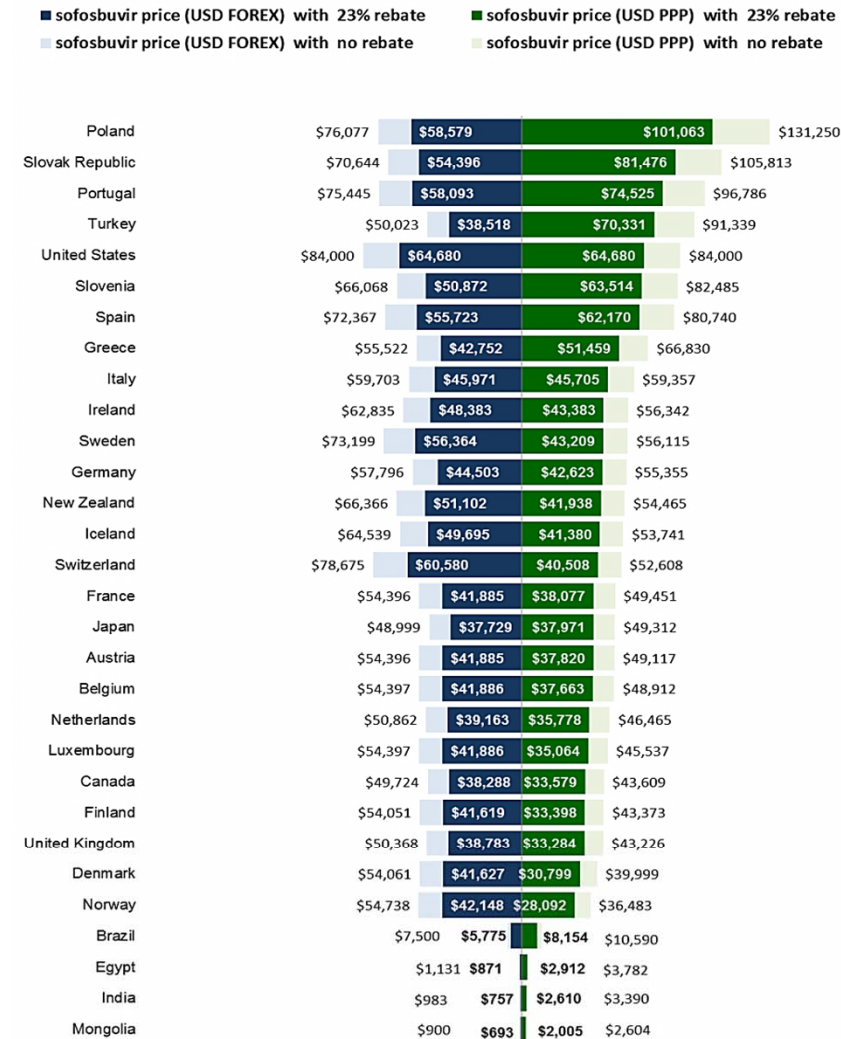
Since contracting hepatitis C 25 years ago, Lucinda Porter's biggest fear has been that she would infect someone else with the deadly virus. "Whenever I cut myself and saw the smeared blood, I would panic," she says.

Financial Times

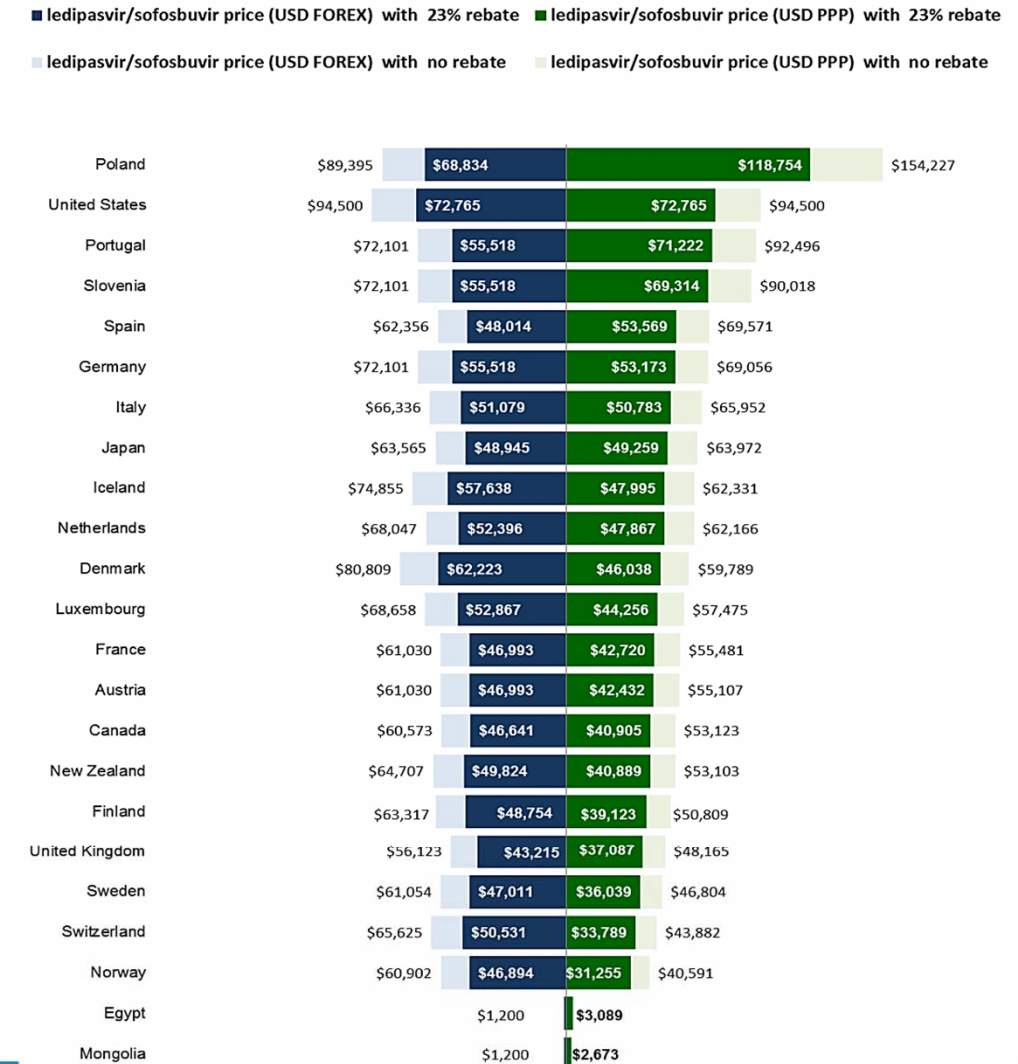


HIGH PRICED MEDICINES

(a)



(b)



Challenges with NCD medicines

- **Oral medicines available as generic multisource products** (Metformin, Aspirin, Hydrochlorothiazide, Tamoxifen) – cheap on the international market but not always available where patients need them, problems with quality-assurance
- **Inhalers for asthma, and insulin** – available but more expensive and more sophisticated to produce and to use. For insulin, limited number of manufacturers, domination of the market by few pharmaceutical companies and specific conditions for distribution.
- **Many new cancer medicines**, often unclear or marginal benefits, invariably high priced
- **Opioid analgesics: efficacious and at affordable costs, necessary for palliative care**, not largely available due to legislative/regulatory barriers – WPC atlas only 15% of patients in need receives PC.

What do NCD medicines cost without tariffs, taxes and mark-ups?

Product	Units per month	Median Unit Cost	Monthly cost	Source
<i>Glibenclamide 5mg tab</i>	30	\$ 0.0067	\$ 0.201	MSH 2013
Metformin 500mg tab	60	\$ 0.0178	\$ 1.068	MSH 2013
Insulin NPH 100IU/ml 10ml	1	\$ 6.70	\$ 6.70	MSH 2013
Salbutamol inh 100mcg 200 doses	1	\$ 1.08	\$ 1.08	ADF 2011
Beclometasone inh 100mcg 200 doses	1	\$ 1.28	\$ 1.28	ADF 2011
Aspirin (ASA) 100mg tab	30	\$ 0.0028	\$ 0.084	MSH 2013
Simvastatin 20mg tab	30	\$ 0.0235	\$ 0.705	MSH 2013
Hydrochlorothiazide 25mg tab	30	\$ 0.0041	\$ 0.123	MSH 2013
<i>Atenolol 50mg tab</i>	30	\$ 0.0118	\$ 0.354	MSH 2013
Tamoxifen 20MG tab	30	\$ 0.0998	\$ 2.994	MSH 2013

Main sources: MSH International Drug Price Indicator Guide 2013 and ADF Catalogue 2011

WHO Essential medicines list 2015: 77 applications and a few big challenges

- Cancer drugs: 29 applications – 16 included, several under patent, and high priced
- New effective HCV drugs included : under patent, voluntary licensing agreements and tiered pricing
- New TB drugs (4+1) included
- Price not a criterium for exclusion
- Affordability as a consequence



Fair pricing - policy options

- **High income countries** : ‘Value-based pricing’, HTA , price/volume agreements; pay for performance; risk-sharing agreement; reference pricing schemes, ...
 - Need for increased transparency on R&D and costs of production
- **LMIC** :
 - Differential pricing
 - Voluntary licensing agreements
 - Local production/import
 - TRIPS flexibilities, including compulsory licenses; patent oppositions ...

- New goals



Historic crossroads: NCDs included in the 2030 Agenda for Sustainable Development



SUSTAINABLE DEVELOPMENT GOALS



SDG's

<https://sustainabledevelopment.un.org/>

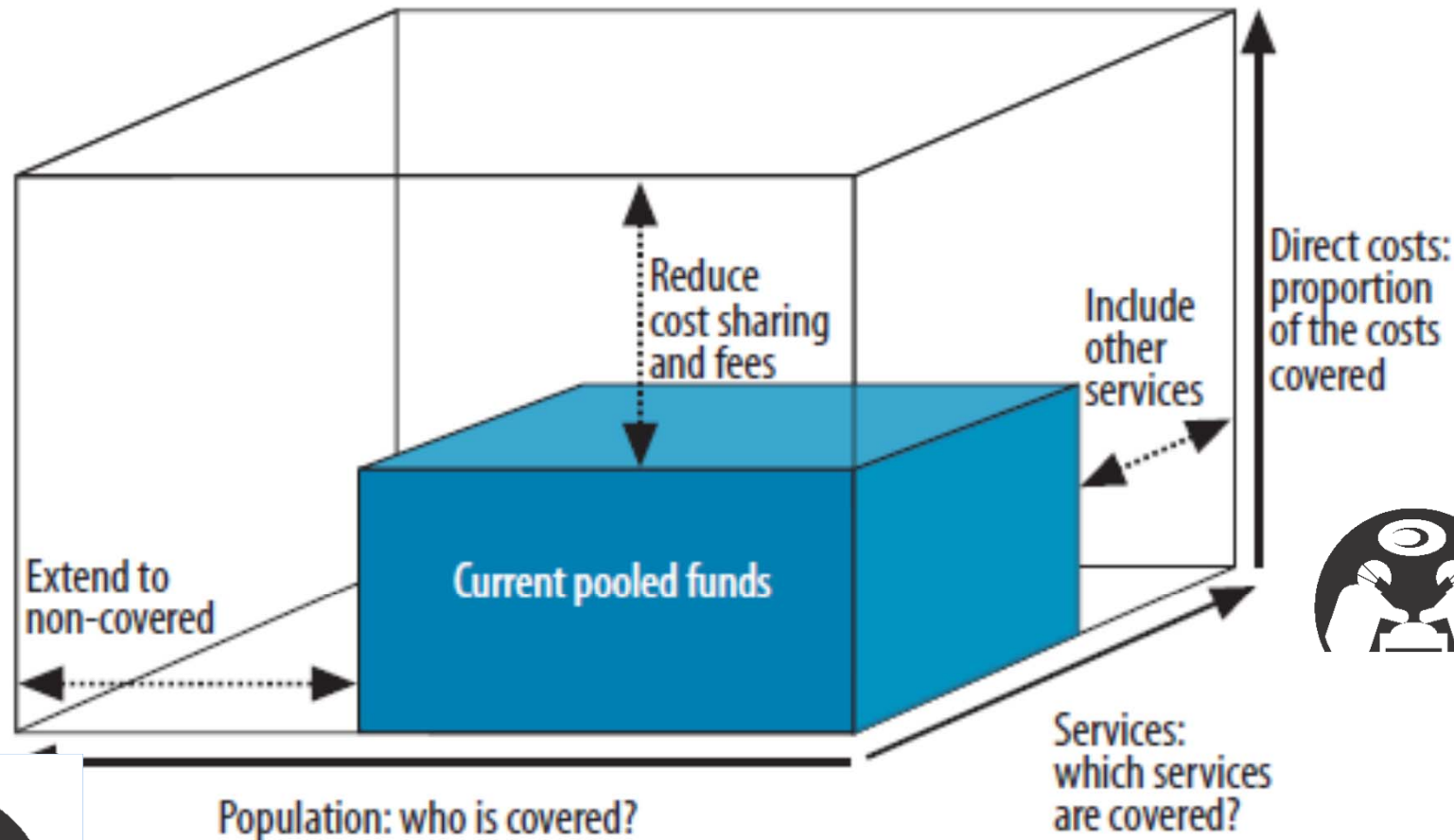
- Disease specific targets : HIV/AIDS, TB, malaria, reproductive + maternal and child health, NCD's ...
- **3.8** Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and **access to safe, effective, quality and affordable essential medicines and vaccines for all**

SDGs

<https://sustainabledevelopment.un.org/>

- **3.b** Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all

Three Dimensions to Consider When Moving Towards Universal Coverage



Health systems financing: the path to universal coverage. Executive Summary
The World Health Report, WHO/IER/WHR/10.1, 2010



Medicines Patent Pool : Progress to date (May 2015)

What next ? Hep C medicines ?

6 patent holders with signed agreements

10 generic manufacturers working with the MPP

12 antiretrovirals licensed to the MPP

117 countries receiving first-line ARVs from MPP generic partners

6m patient-years of treatment as a result of MPP's agreements

US\$ 79m saved from 2012-2014

2.18bn treatment doses delivered through MPP generic partners



Source: Courtesy of MPP
 **World Health Organization**

TRIPS Transition Periods for LDCs

- **2021:** LDCs not required to provide the intellectual property protection covered by TRIPS until 2021 (in all fields: copyright, trademarks, enforcement, patents etc. - except national and MFN treatment); recently extended from 2013 to 2021
- **2016:** Doha Declaration created extended grace period for LDCs specifically for patent and test data protection and their enforcement for pharmaceutical products until 1 January 2016; further extension currently under negotiation in TRIPS Council