

Access to Medicines in the Context of the Right to Health

An overview and WHO
Perspective



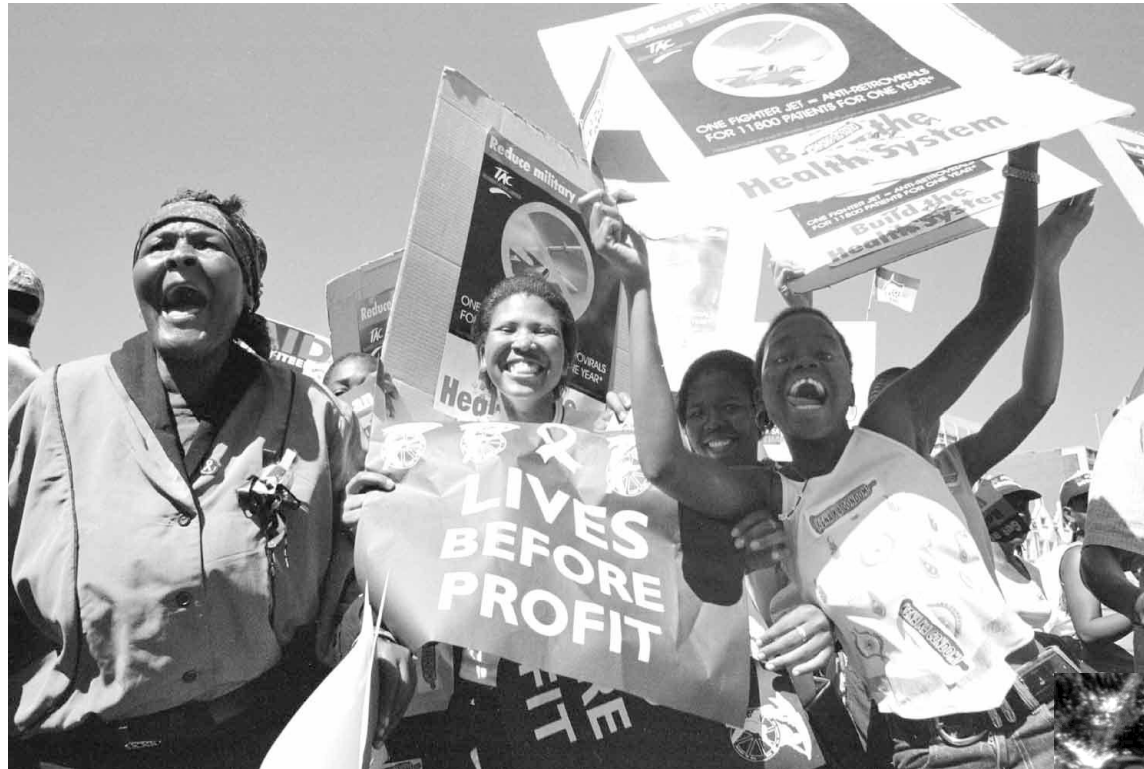
Zafar Mirza

Public Health, Innovation and
Intellectual Property
Department of Essential Medicines and
Health Products

WORLD HEALTH ORGANIZATION

Human Rights Council
SOCIAL FORUM
18 February 2015
Room XII, Palais des Nations,
Geneva

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.**



The Presentation

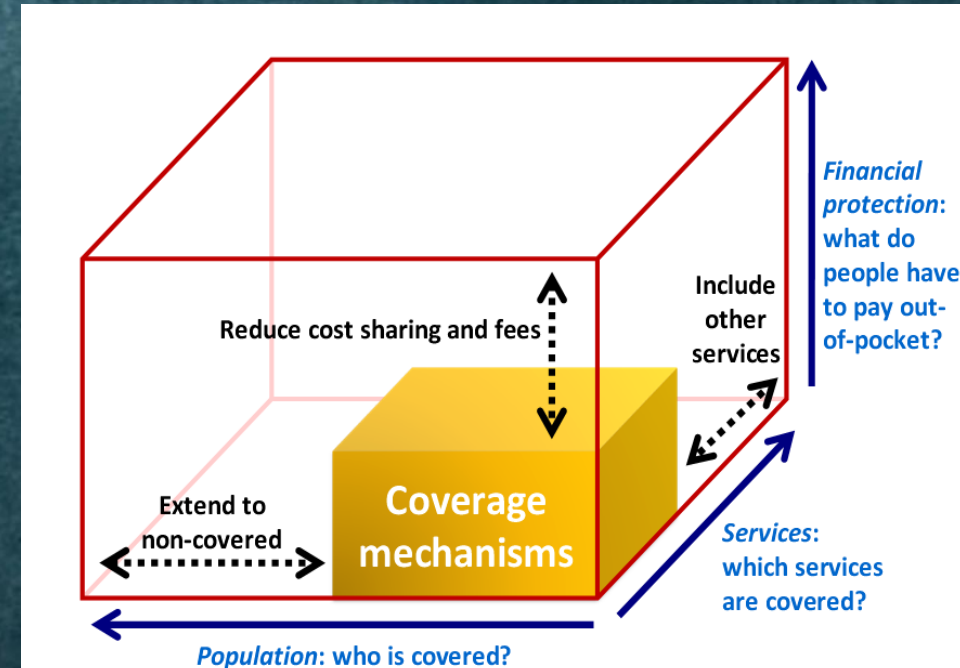
- 1: UHC and health systems and equitable access to medicines
- 2: Access to medicines and the human right to health
- 3: The complex construct of access to medicines
- 4: Access to *quality* medicines – the role of NRAs
- 5: Issues in access to existing medicines Generic medicines
Patent medicines
- 6: Issues in R&D innovation for new essential medicines
- 7: Issues in access to vulnerable populations:
during emergencies; women, children and elderly; access to controlled medicines;

Universal Health Coverage & Access to medicines



Universal health coverage is one of the most powerful social equalizers among all policy options. It is the ultimate expression of fairness. If public health has something that can help our troubled, out-of-balance world, it is this: growing evidence that well-functioning and inclusive health systems contribute to social cohesion, equity, and stability. They hold societies together and help reduce social tensions.

If health is a basic human right then universal health coverage is imperative which is not possible without equitable access to medicines.



Leadership priorities



World Health Organization

Our leadership priorities give focus and direction to our work. They are areas where it is vital for WHO to lead—the key issues which stand out from the body of our work.

WHO values

WHO has been at the forefront of improving health around the world since 1948.

Health:

is a state of complete physical, mental and social well-being, not just the absence of disease or infirmity

is the fundamental right of every human being, everywhere

is crucial to peace and security

depends on the cooperation of all individuals and States

should be shared: extending knowledge to all peoples is essential



WHO directs and coordinates international health by:

providing leadership on matters critical to health

shaping the health research agenda

defining norms and standards for health

articulating policy options for health

providing technical support and building capacity to monitor health trends

Health Systems



THE WHO HEALTH SYSTEM FRAMEWORK

SYSTEM BUILDING BLOCKS

SERVICE DELIVERY

HEALTH WORKFORCE

INFORMATION

MEDICAL PRODUCTS, VACCINES & TECHNOLOGIES

FINANCING

LEADERSHIP / GOVERNANCE

ACCESS

COVERAGE

QUALITY

SAFETY

OVERALL GOALS / OUTCOMES

IMPROVED HEALTH (LEVEL AND EQUITY)

RESPONSIVENESS

SOCIAL AND FINANCIAL RISK PROTECTION

IMPROVED EFFICIENCY

THE SIX BUILDING BLOCKS OF A HEALTH SYSTEM: AIMS AND DESIRABLE ATTRIBUTES

Access to Medicines as part of the human right to health

Universal Proclamations

WHO Constitution – 1947

Preamble

“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures”

Universal Declaration of Human Rights – 1948

Article 25

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”

International Covenant on Economic, Social and Cultural Rights – 1966

Article 12

“The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”

Access to Medicines as part of the human right to health obligations and violations

- A well established principle – "progressive realization of the right to health"
- 2 immediate obligations (ICESCR)
 - Concrete steps must be taken towards progressive realization (article 2.1)
 - The benefits of such steps should be equally available to all citizens without discrimination of any kind (article 2.2)

Access to Medicines as part of the human right to health

- ICESCR Article 12.2d – access to health facilities, goods and services
- 1978 Alma Ata Declaration on PHC - “the attainment of the highest possible level of health is a most important world-wide social goal”. The provision of essential drugs as one of the 8 listed components of PHC
- In 1990 the UN Commission on ESCRs developed the concept of the RTH of the legally binding ICESCR – non-binding general comment
 - GC 3 : confirmed essential primary care as a core state responsibility
 - GC 14 : right to medical services in Article 12.2 (d) of ICESCR includes the provision of essential drugs as defined by the WHO Action Program on Essential Drugs

Access to Medicines as part of the human right to health

UN Special Rapporteur*

Reports by the UN Special Rapporteur on the Right to Health with relevance to access to essential medicines^a

Intellectual property and access to medicines. Doc.E/CN.4/2004/49/Add.1

The human right to medicines. Doc.A/61/338, pp.10–18 (2006)

The responsibilities of pharmaceutical companies. Doc.A/61/338, pp.19–21 (2006)

Health systems and the right to the highest attainable standard of health. Doc.A/HRC/7/11 (2008)

Guidelines for pharmaceutical companies. Doc.A/63/263 (2008)

Mission to GlaxoSmithKline. Doc.A/HRC/11/12/Add.2 (2009)

*first UN Rapporteur for right to health appointed in April 2002

The Nature of Challenges in Access to Medicines

Health system approach	vs	Vertical disease approach
Supply side	vs	Demand side
Structural issues	vs	Functional issues
Public sector	vs	Private sector
Patented medicines	vs	Generic medicines
Communicable diseases	vs	Non-communicable diseases
Locally manufactured	vs	Imported
Government funded	vs	Donor funded
Medicines	vs	Other health technologies
Single supply system	vs	Multiple supply systems
Quality medicines	vs	SSFFC medicines
Modern medicines	vs	Traditional medicines
Rational use of medicines	vs	Inappropriate use

The Complex construct of access to medicines

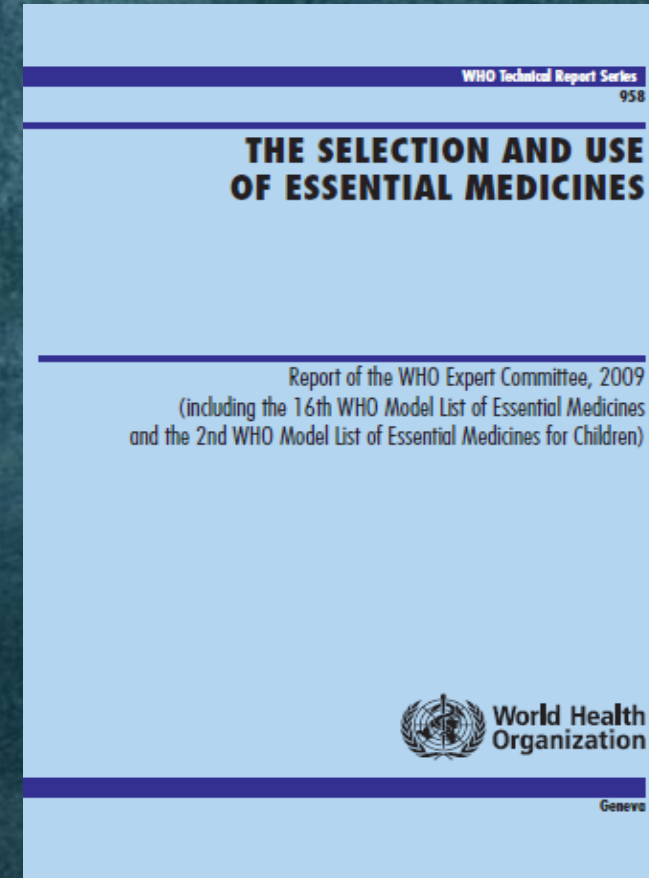
People everywhere have **access** to the **essential medicines** they need; that the medicines are **safe, effective**, and of **good quality**; and that the medicines are **prescribed** and **used rationally**.

For Optimal Access to Medicines...

- ♦ ...medicines need to exist in the first place (R&D, Innovation)
- ♦ ...should be appropriately selected
- ♦ ...should be available at the appropriate level of health care facilities
- ♦ ...people and governments should be willing and able to afford the prices
- ♦ ...quality of medicines should be assured during production and maintained during storage and supply
- ♦ ...medicines are prescribed and dispensed by trained health professionals, and
- ♦ ...patients should use medicines as they are advised

Selection of Essential Medicines

- First edition 1977
- Revised every two years
- Now contains 462 medicines including children's medicines
- Uses HTA approaches
- Patent status NOT considered in selection
- Over time has contained 5% to 10% patent protected medicines



Access to Medicines ; Indicators of the problem

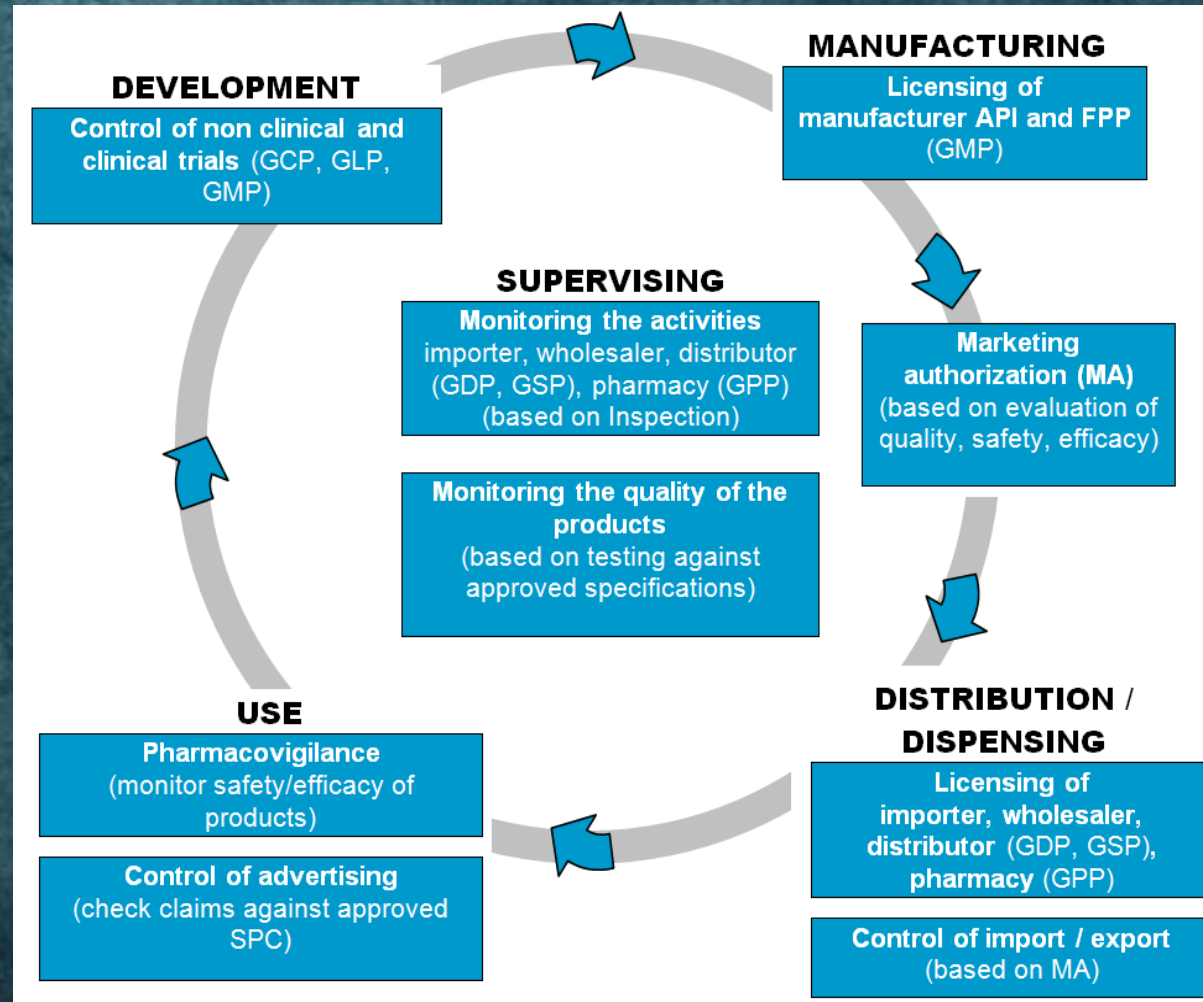
- Between 20 % and 60 % of the health budget in LMIC goes to medicines/technologies expenditures
- In LMIC countries, up to 80 to 90 % of medicines and medical products are purchased out-of-pocket as opposed to being paid for by health insurance schemes
- Average availability of selected generic medicines in LMICs:
 - public sector less than 42 %
 - private sector almost 72 %



Medicine Prices, Availability,
Affordability & Price Components

Access to **Quality** Medicines ;

- Access is meaningless or even harmful if quality of medicines is not ensured
- WHO guidelines in the area of quality assurance of pharmaceutical products include recommendations in major regulatory areas:
 - Research and development;
 - Manufacturing: GMP inspection, product assessment and registration, quality control, laboratory services;
 - Distribution: international trade in pharmaceuticals;
 - Use and supervision;



Issues in access to existing medicines: Generic Medicines

Most medicines are not patent protected and patients still don't have access to them!

Commodity by life stage	Examples of key barriers	Recommendations	Potential 5-year impact
Maternal health commodities			
1. Oxytocin – post-partum haemorrhage (PPH)	Often poor quality	1, 4, 5	15,000 maternal lives saved
2. Misoprostol – post-partum haemorrhage	Not included in national essential medicine lists	5	
3. Magnesium sulfate – eclampsia and severe pre-eclampsia	Lack of demand by health workers	1, 9, 10	55,000 maternal lives saved
Newborn health commodities			
4. Injectable antibiotics – newborn sepsis	Poor compliance by health workers	1, 9, 10	1.22 million neonatal lives saved
5. Antenatal corticosteroids (ANCs) – preterm respiratory distress syndrome	Low awareness of product and impact	9	466,000 neonatal lives saved
6. Chlorhexidine – newborn cord care	Limited awareness and demand	2, 5	422,000 neonatal lives saved
7. Resuscitation devices – newborn asphyxia	Requires trained health workers	1, 9, 10	336,000 neonatal lives saved
Child health commodities			
8. Amoxicillin – pneumonia	Limited availability of child-friendly product	2, 7, 9, 10	1.56 million lives saved
9. Oral rehydration salts (ORS) – diarrhoea	Poor understanding of products by mothers/ caregivers	2, 5, 7, 9, 10	1.89 million lives saved
10. Zinc – diarrhoea			
Reproductive health commodities			
11. Female condoms	Low awareness among women and health workers	1, 7	Almost 230,000 maternal deaths averted
12. Contraceptive implants – family planning/ contraception	High cost	1, 7	
13. Emergency contraception – family planning/ contraception	Low awareness among women	2, 7	

Issues in access to **patent protected medicines**

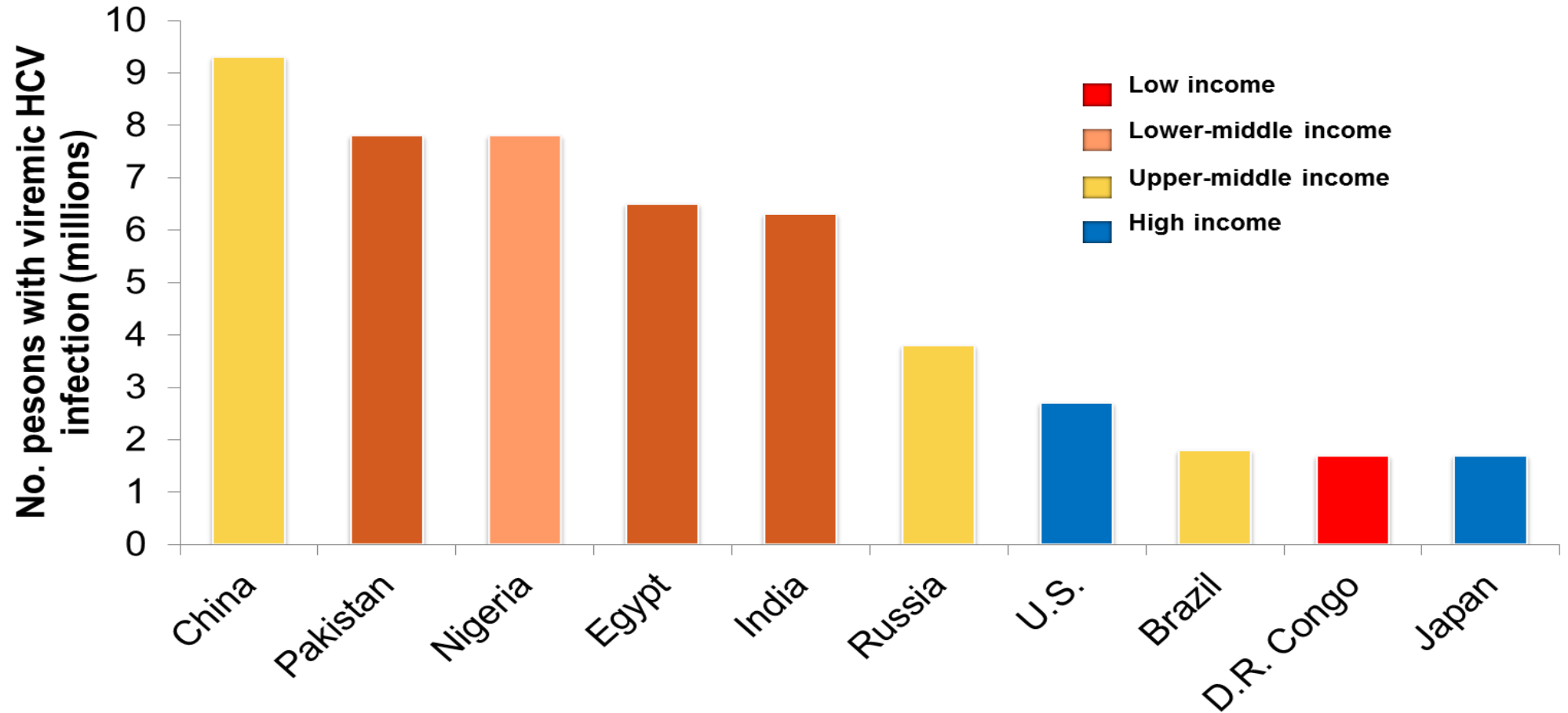
- Monopoly prices are generally unaffordable for people in developing countries:

Example of Hepatitis C

- 350 000 to 500 000 people die each year from hepatitis C-related liver diseases.
- Antiviral medicines can cure hepatitis C infection, but access to diagnosis and treatment is low.
 - \$1000/tablet,
 - \$84,000 for 12 week course



Countries with greatest no. of HCV infections



Adapted from Gower E et al. J Hepatol (2014)

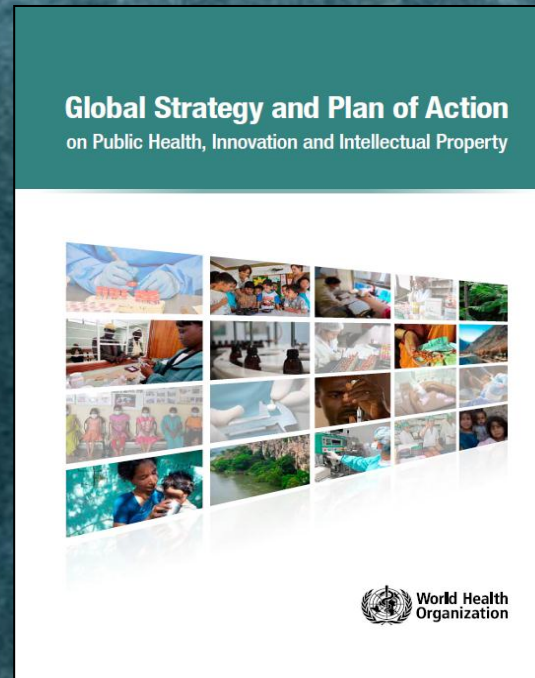
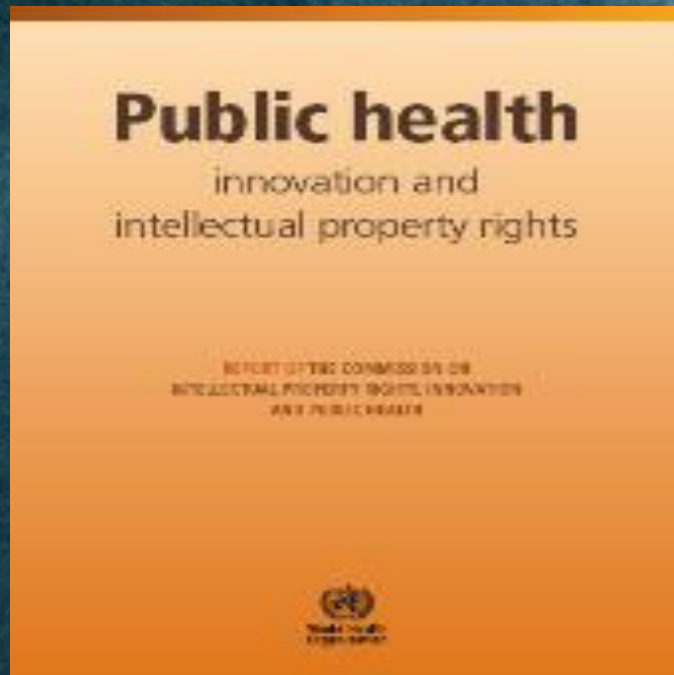
Innovation + Access

Market Failure in Health R&D

- The determinant of investment in R&D is not public health need but return of investment
- Diseases exclusive to or predominant in the developing world do not get enough R&D financing because of lack of market-demand

- 2-3% of total health R&D is for neglected diseases
- Only 37 out of 850 new medicines between 2000-2011 were for neglected diseases;
- No vaccine, medicine or diagnostic is available for Ebola infection
- Only 1 drug in a new class of anti-TB medications has been developed in 40 years i.e. Bedaquiline
- Only 2 new classes of antibiotics were developed in decades
- 17 neglected diseases need new treatments to be developed or existing to be improved;

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



Issues in Access to Medicines for **Vulnerable populations**

- Drug donations during **emergencies**, a huge public health issue
- **Access to controlled medicines**: 5.4 million cancer pain patients remain untreated due to lack of access to morphine; 93.8% of all (licit) morphine consumption by 21.8% of the world population; 80% epileptic patients in Africa do not have access to phenobarbital;
- **Access to paediatric forms of essential medicines** is an important issue. "off-label" use of adult medicines for children is very common with its attendant risks.

Rights-based approach in medicine programmes

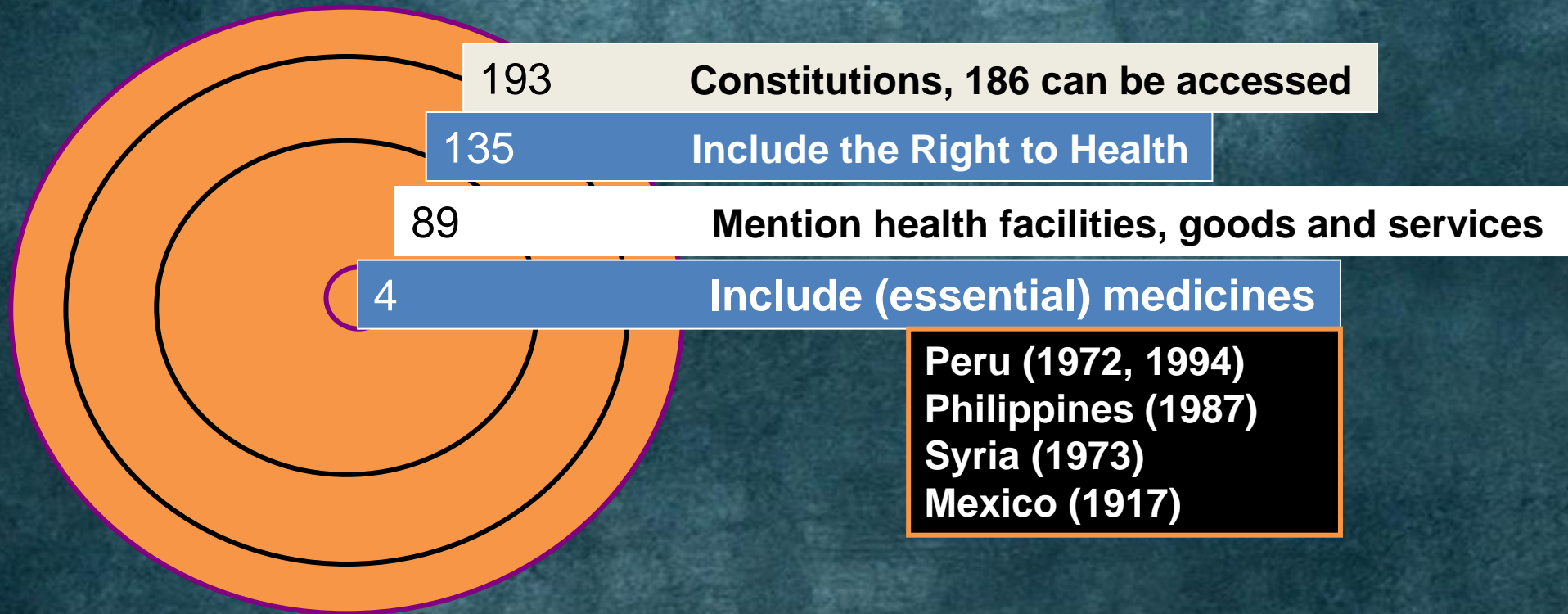
- WHO includes country constitutional commitment as indicator for access to essential medicines

Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation

Five practical points to check

1. Which medicines are covered by the right to health?
2. Have all beneficiaries of the medicine programme been consulted?
3. Are there mechanisms for transparency and accountability?
4. Do all vulnerable groups have equal access to essential medicines? How do you know?
5. Are there safeguards and redress mechanisms in case human rights are violated?

Right to health and access to medicines in National Constitutions



Is access to essential medicines as part of the Right to Health enforceable through the courts?

Hogerzeil HV, Samson M, Vidal Casanova J, Rahmani L (*Lancet* 2006)

Objective

To identify and analyze court cases from low- and middle income countries, in which individuals/groups have claimed access to essential medicines on the basis of human right treaties signed by the State

Results

71 cases from 12 countries • 59 won, 12 lost • half deal with HIV/AIDS; others with leukaemia, diabetes, renal dialysis • 38% public interest cases • 20% supported by NGOs • 93% of successful cases from Latin America (rest from India, South Africa, Nigeria)

THANK YOU

Thank you



WORLD TRADE
ORGANIZATION



WIPO
WORLD INTELLECTUAL PROPERTY
ORGANIZATION



World Health
Organization

Promoting Access to Medical Technologies and Innovation

Intersections between public health, intellectual property and trade



www.who.int/phi/promoting_access_medical_innovation/en/

www.who.int/phi/publications/category/en/

Zafar Mirza
World Health Organization
mirzaz@who.int