

# *Global Health Policy Forum on Access to Medicines*

## **WHO views**

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**World Health  
Organization**

# Overview

- Access and UHC
- GSPOA and Innovation
- Prequalification
- Availability and affordability
- Next steps



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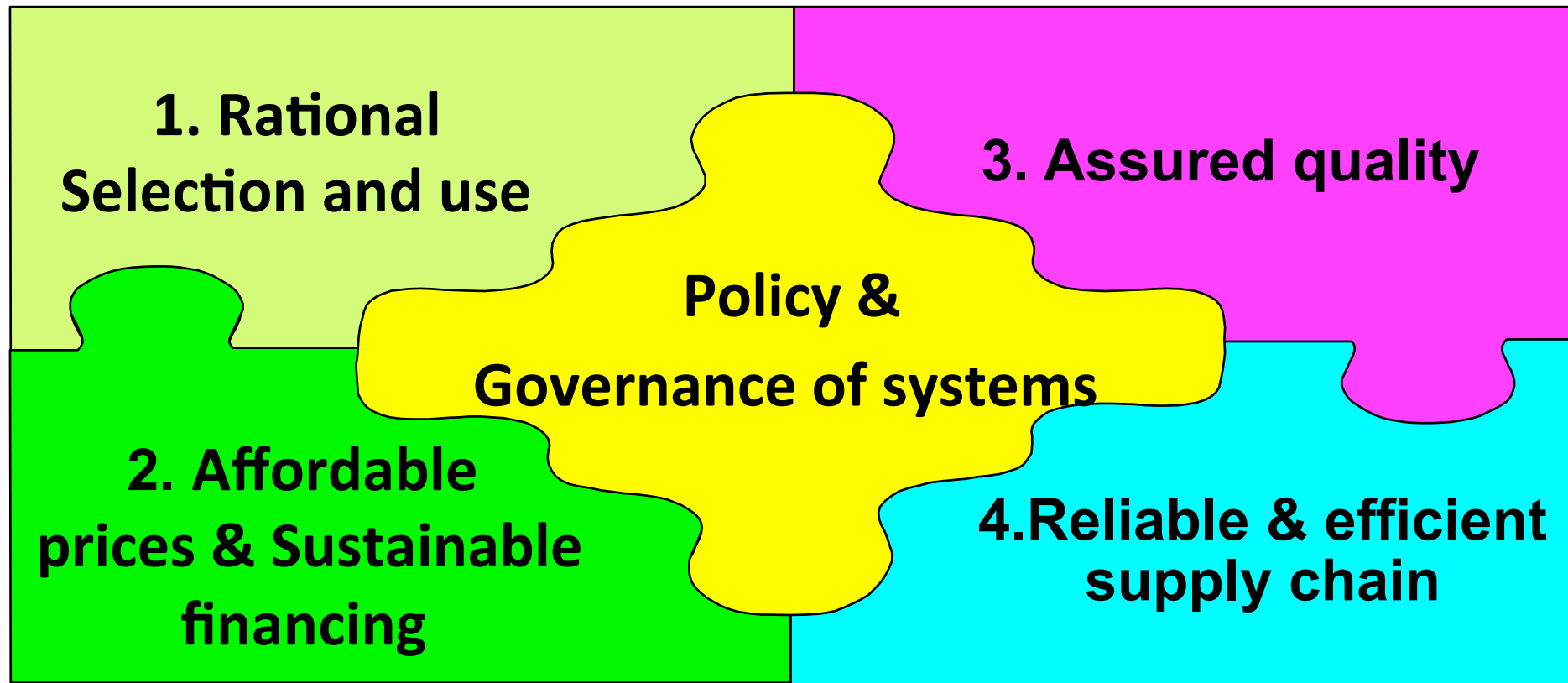


# Universal health coverage (UHC)

*The goal of universal health coverage is to ensure that all people obtain the health services they need without suffering financial hardship when paying for them.*

- A strong, efficient, well-run health system that meets priority health needs
- Affordability – a system for financing health services to avoid financial hardship
- **Access to essential medicines and technologies to diagnose and treat medical problems.**
- A sufficient capacity of well-trained, motivated health workers to provide the services needed

# Access to quality assured medicines as part of health services coverage



# WHO Strategy on access to medicines

- Based on the principles of
  - Evidence-based selection of a limited range of medicines
  - Efficient procurement of quality assured medicines
  - Affordable prices
  - Effective distribution networks
  - Rational/responsible use of medicines
- Despite sustained efforts problems remain with low availability and affordability of essential medicines in many low- and middle-income countries
- Problems with medicines are key issues identified as inefficiencies in health systems

# Ten leading causes of inefficiency

## World Health Report 2010, Chapter 4

**1. Medicines: underuse of generics and higher than necessary prices for medicines**

**2. Medicines: use of substandard and counterfeit medicines**

**3. Medicines: inappropriate and ineffective use**

4. Health-care products and services: overuse or supply of equipment, investigations and procedures

5. Health workers: inappropriate or costly staff mix, unmotivated workers

6. Health-care services: inappropriate hospital admissions and length of stay

7. Health-care services: inappropriate hospital size (low use of infrastructure)

8. Health-care services: medical errors and suboptimal quality of care

**9. Health system leakages: waste, corruption and fraud**

10. Health interventions: inefficient mix/ inappropriate level of strategies

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# Global Strategy on Public Health, Innovation and Intellectual Property

- Not all needed medicines are currently available – neglected diseases, medicines in appropriate formulations for children are examples
- Aim of the Global Strategy is to promote new thinking on innovation and access to medicines
- also .... to provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries
- Public health R&D and innovation agenda is also addressed through EU funded initiatives like the Priority Medicines for Europe project (2013)



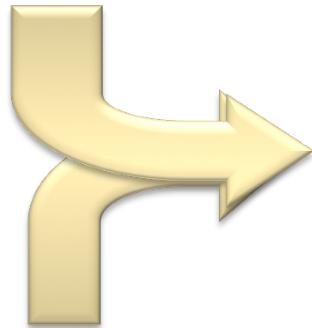
# WHO and Intellectual Property Protection

- The Global Strategy and Plan of Action (GSPA-PHI) confirms and expands the WHO mandate in public health & intellectual property:  
  
"**... the WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (...), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. "**
- WHO is supporting enhanced local production capacity for pharmaceuticals and other health care products through technology transfer (education, training, licensing, etc.)
- Benefits of this investment may be both to industry and health policies improving skill development, employment opportunities and increasing access to medicines in countries; however products produced must be of good quality

# Framework for Local Production for Improving Access

## INDUSTRIAL POLICY

- Competitive
- Reliable
- Innovative
- Productive
- Responsible
- Strategic



## HEALTH POLICY

- Access  
(Availability  
Affordable)
- Quality
- Supply
- Rational Use

## SHARED GOALS HEALTH + INDUSTRY

- Strategic selection of essential medical products
- Pricing of local products that governments & people can afford.
- Strict compliance to quality standards
- Health security
- Innovation.



## Government Support

Direct support to reduce the cost of manufacture

Indirect support of local production for improving access



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# Medicines of assured quality

- Prequalification program is flagship WHO activity
- Provides evaluation and inspection activities, and supports national capacity building for sustainable manufacturing and monitoring of quality medicines.
- Evaluation of the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing and clinical sites.
- Prequalification of sources of active pharmaceutical ingredients and quality control laboratories of pharmaceuticals
- Key output is identification of suppliers of quality assured medicines for HIV, TB, malaria and reproductive health products. Information used by agencies like UNAIDS and UNICEF to guide procurement

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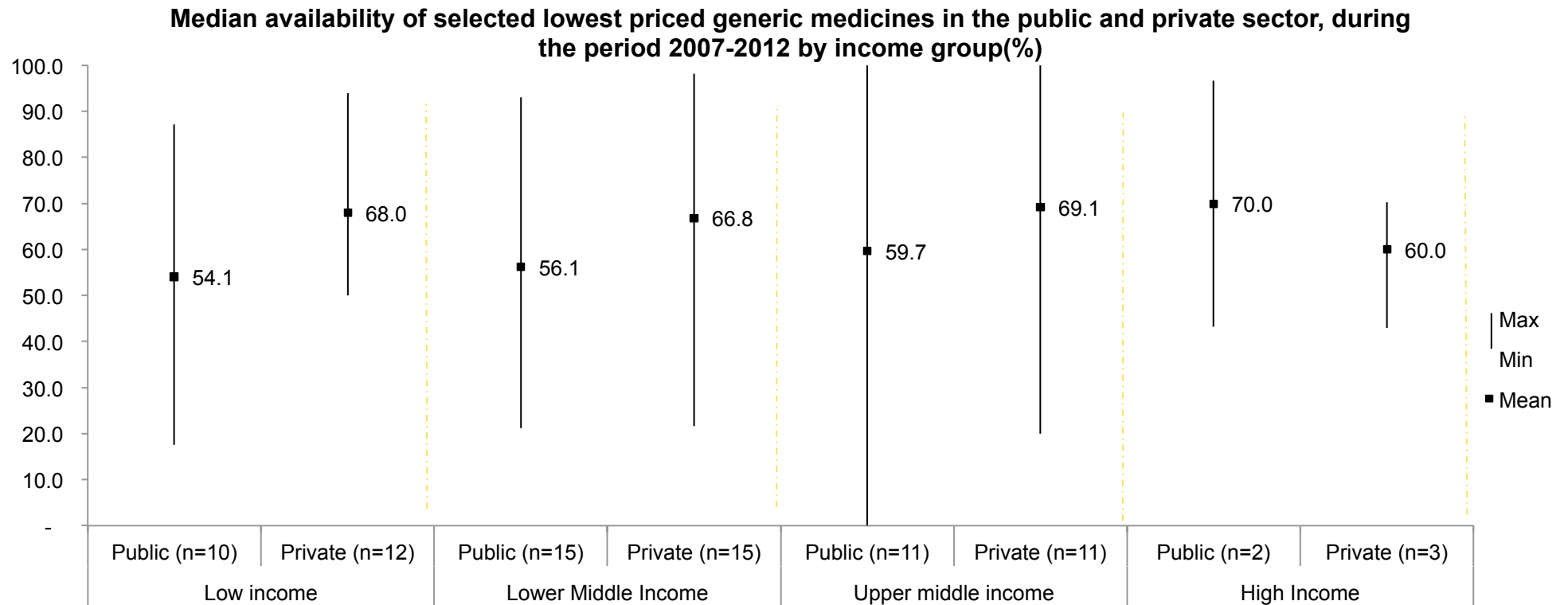


# Availability of medicines

- Evidence of often poor and variable availability of medicines with regional or urban/rural differences in availability
- Availability is generally better in the private sector
- Even when available there may be problems of poor quality medicines – substandard and counterfeit medicines
- WHO Global Action Plan for the prevention and control of NCDs 2013-2020 sets a target of 80% availability of affordable essential medicines required to treat major non-communicable diseases in both public and private facilities
- Available data suggest there is a long way to go to reach these targets



# Low and variable availability of medicines



Source: World Health Organization/Health Action International, using data from medicine price and availability surveys undertaken from 2007 to 2013 using the WHO/HAI methodology (<http://www.haiweb.org/medicineprices>). n=number of countries. Baskets of survey medicines differ between countries.



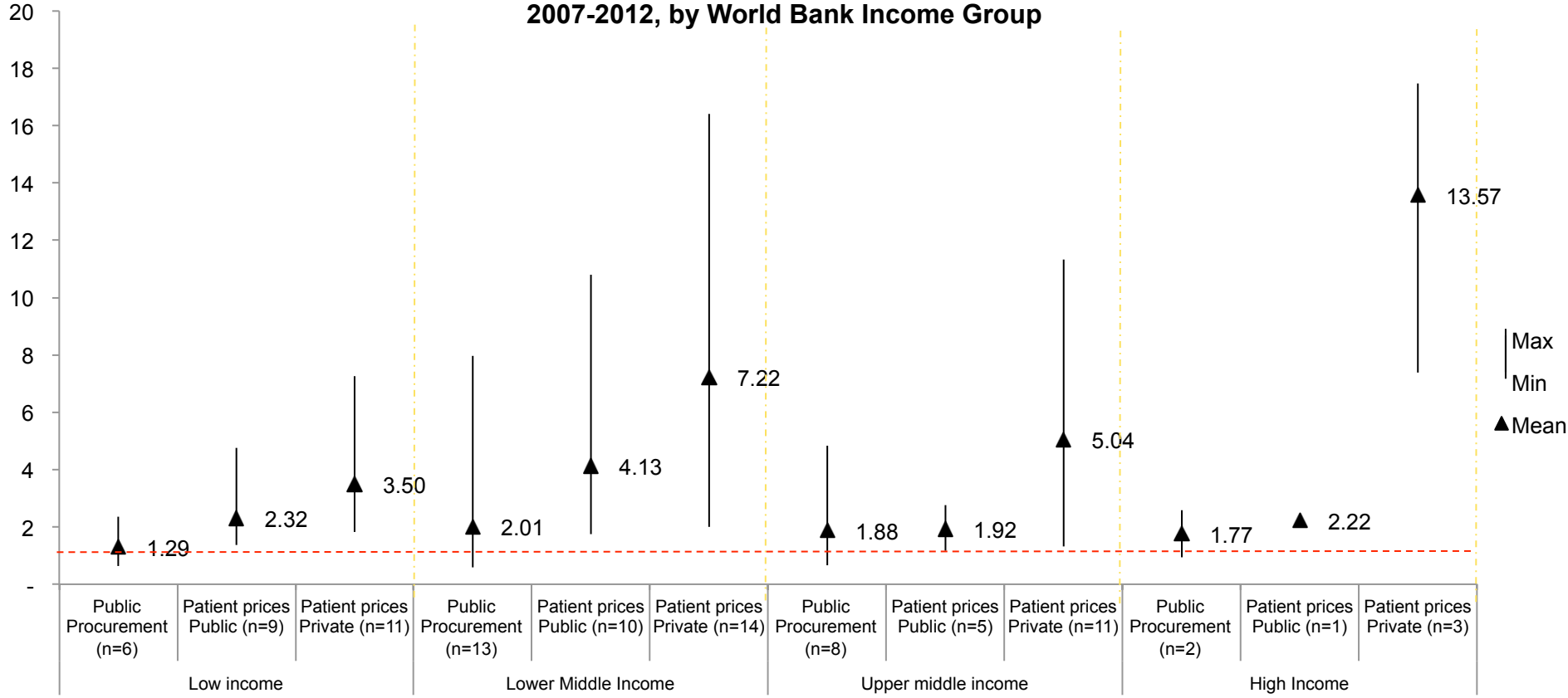
# Affordability of medicines

- In low and middle-income countries much of the health expenditure is out-of-pocket (OOP)
- Aim of UHC is to avoid high OOP expenses that put care out of the reach of many patients and impoverish families
- While availability of medicines is higher in the private sector, also the costs of medicines are higher
- Taxes, government tariffs and mark-ups applied to medicines reduce affordability
- One measure of affordability is how many days wages are required to purchase a course of medicines or one month of treatment



# Variability in prices of medicines (affordability)

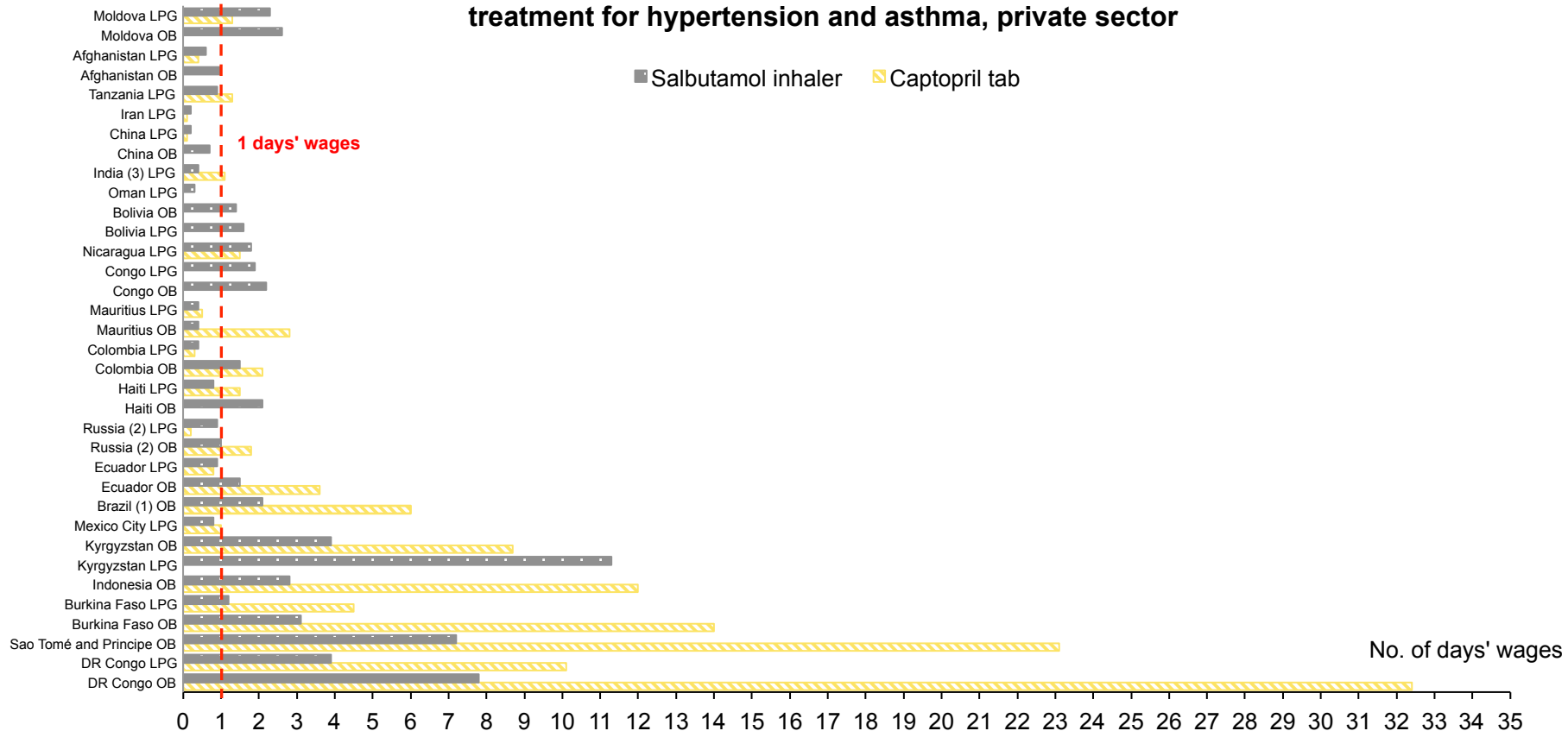
Ratio of public procurement prices and consumer prices (in the public and private sector) to international reference prices for selected lowest priced generic medicines, during the period 2007-2012, by World Bank Income Group



Source: World Health Organization/Health Action International, using data from medicine price and availability surveys undertaken from 2007 to 2013 using the WHO/HAI methodology (<http://www.haiweb.org/medicineprices>). n=number of countries. Baskets of survey medicines differ between countries. Data are unadjusted for differences in MSH reference price year used, exchange rate fluctuations, national inflation rates, variations in purchasing power parities, levels of development or other factors

# Affordability to patients

Number of days' wages needed by the lowest-paid unskilled government worker to pay for 30 days' treatment for hypertension and asthma, private sector



Source: World Health Organization/Health Action International, using data from medicine price and availability surveys undertaken from 2007 to 2013 using the WHO/HAI methodology (<http://www.haiweb.org/medicineprices>). n=number of countries. Captopril 25mg tab x2/day; Salbutamol 100mcg/dose inhaler, 200 doses (1) Rio Grande do Sul State, (2) Tatarstan Province, (3) NCT Delhi, (4) Shaanxi Province

# Generic medicines policies

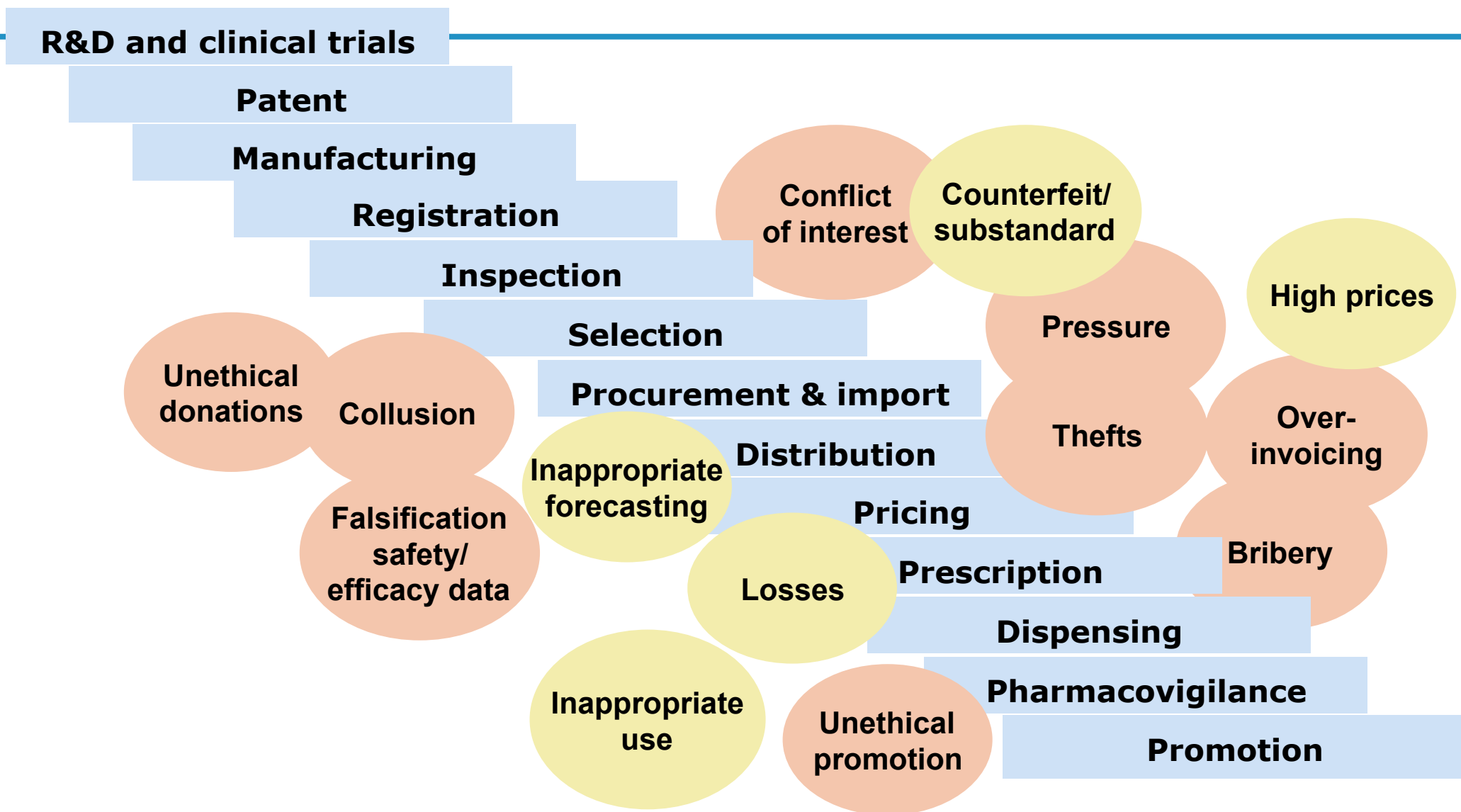
- Use of generic medicines can improve the availability and affordability of essential medicines
- Underuse of generics has been identified as one of the leading causes of health system inefficiency
- Effective quality assurance systems are needed to ensure the quality of generic medicines in circulation and to promote a competitive generics market
- Education campaigns are also needed to reassure prescribers and the public that low price does not equal low quality



# Effective distribution networks

- Supply chains for medicines are long and complex, if these are compromised access to good quality medicines will be compromised
- Pharmaceutical systems need to be strengthened; these require appropriate policies that are effectively implemented and enforced
- Efficient systems and good record keeping are needed to avoid stock-outs of essential medicines
- To minimise vulnerability to corruption and corrupt practices that waste limited health resources, it is important to have transparent processes, institutional checks and balances, codes of conduct for public employees in place

# Inefficiencies and unethical practices can occur throughout the medicines supply chain



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# Responsible use of medicines

- Need to understand what doctors prescribe and what medicines patients take to treat illnesses (requires in-country studies)
- Assess whether prescribing is in line with best-practice treatment guidelines (WHO supports development of treatment guidelines)
- Health care professionals and patients/consumers need accurate information about medicines (WHO Essential Medicines and Health Products Information Portal is one source)
- Promotional practices of pharmaceutical industry need to be monitored (WHO has developed criteria for ethical promotion)
- Concerns about antimicrobial resistance have given a renewed focus to the responsible use of medicines



# Access to medicines – unfinished agenda

- Despite some improvements towards MDGs, problems with access to key essential medicines remain
- Patients with HIV, TB, malaria untreated or sub-optimally treated
- MDR-TB poses significant threats to management of TB
- Unmet needs of mothers and children for essential medicines and reproductive health commodities
- Global challenges of non-communicable diseases; poorest countries are dealing with double burden of communicable and NCDs
- Providing access to cancer therapies and other high cost medicines
- Managing responsible use of antimicrobials to deal with problems of antimicrobial resistance

# Access to medicines – a renewed focus

- Medicines related resolutions to be considered by the World Health Assembly 2014
  - Access to medicines
  - Strengthening regulatory systems
  - Palliative care
  - Antimicrobial resistance
  - Health Technology Assessment
- WHO will continue to play an important role supporting Member States to deal with the ongoing and complex issues regarding essential medicines



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# Thank you

