

Medicines and Health Products- Access, Sustainable Development Goals and Universal health Coverage.



World Health
Organization



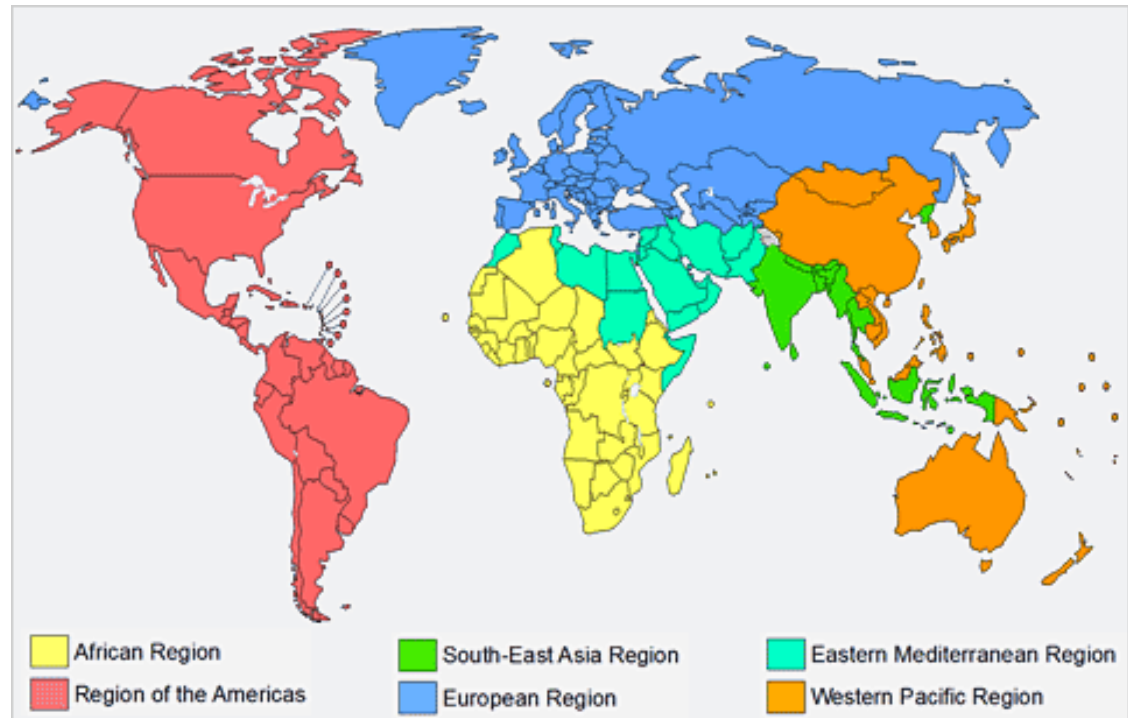
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www.who.int

The World Health Organisation



- UN specialized agency for health
- 194 Member States
- 800+ Collaborating Centers
- 7000 public health experts including doctors, pharmacists, nurses, epidemiologists, scientists, managers, administrators
- 147 country offices
- 6 regional offices,
- 1 headquarters



Constitution of the World Health Organization:

Mandate

- The objective of WHO is the attainment by all peoples of the highest possible level of health
- WHO's prime function is to act as the directing and coordinating authority on international health work

Activities

- **Technical support** to countries on health related issues
- Monitor and assess **global health trends** hand-in-hand with national and regional agencies
- Set universal **norms and standards** to facilitate delivery and reduce errors

GOAL 3



UNIVERSAL HEALTH COVERAGE



All people and communities can use the health services they need, of sufficient quality to be effective, without exposure to financial hardship

- 3.8 achieve universal health coverage (UHC), 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

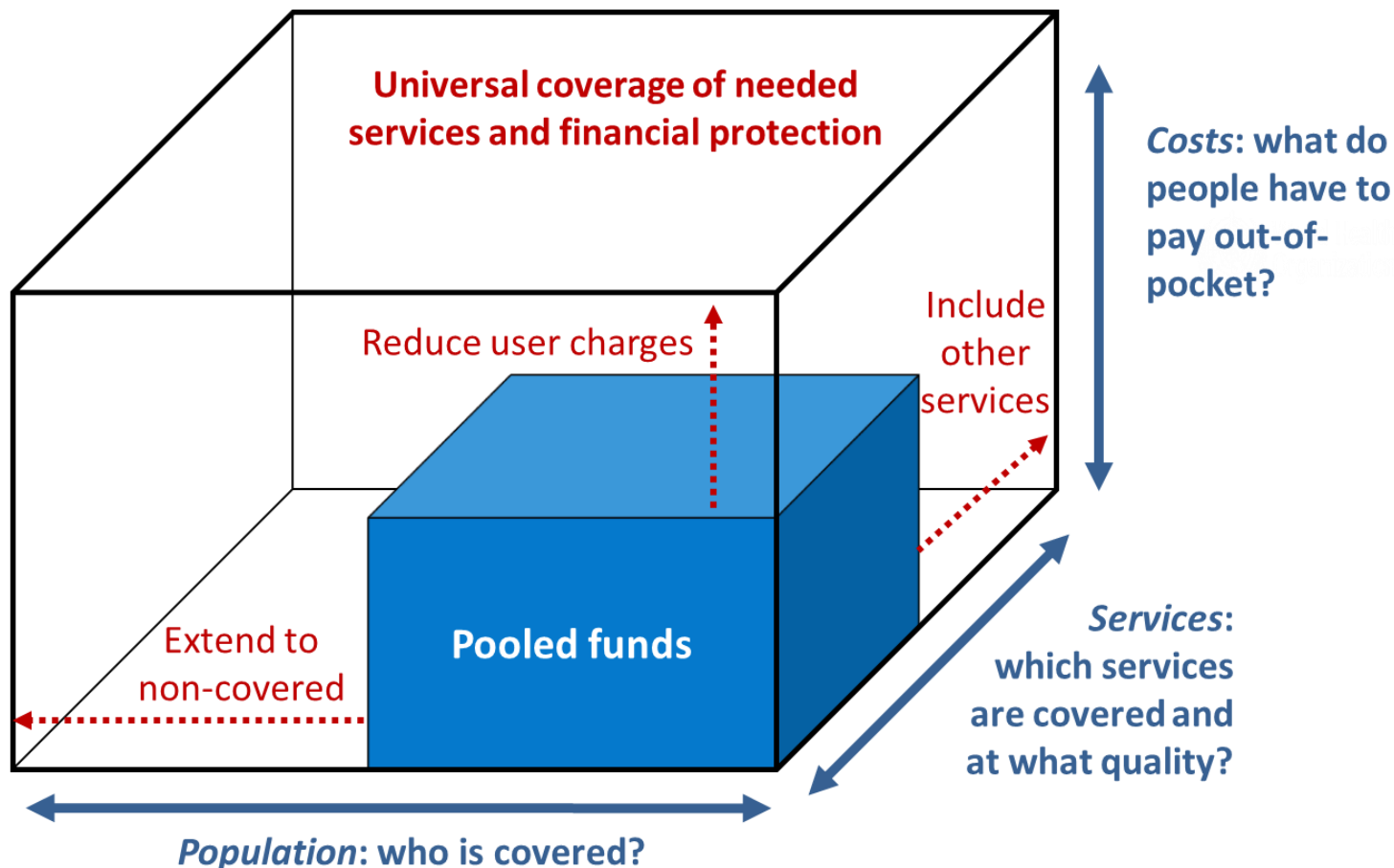
3.8.1 Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population)

3.8.2 Proportion of population with large household expenditures on health as a share of total household expenditure or income

3.B.1 Proportion of the population with access to affordable medicines and vaccines on a sustainable basis

3.B.2 Total net official development assistance to medical research and basic health sectors

The three dimensions of UHC



Lancet Commission estimated US\$77.4-\$151.9 billion (\$13-\$25 per capita) to finance basic package of 201 essential medicines

"Health is a human right. No one should get sick or die just because they are poor, or because they cannot access the services they need." – Dr Tedros

Essentials of Universal Health Coverage



Health financing for universal coverage



Service delivery and safety



Health workforce



Essential medicines and health products



Health systems governance



Health statistics and information systems

"Together for a healthier world"

Dr Tedros Adhanom Ghebreyesus

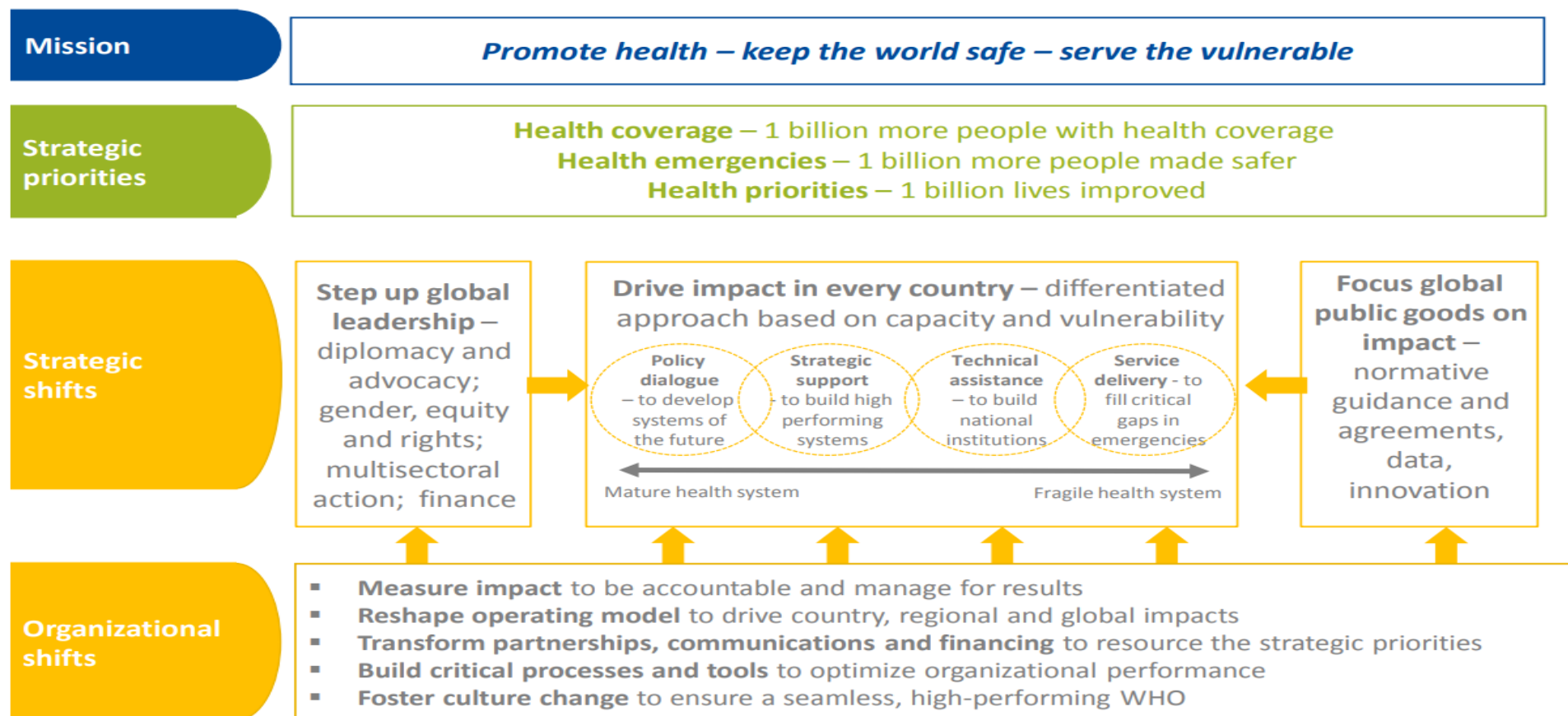


Vision

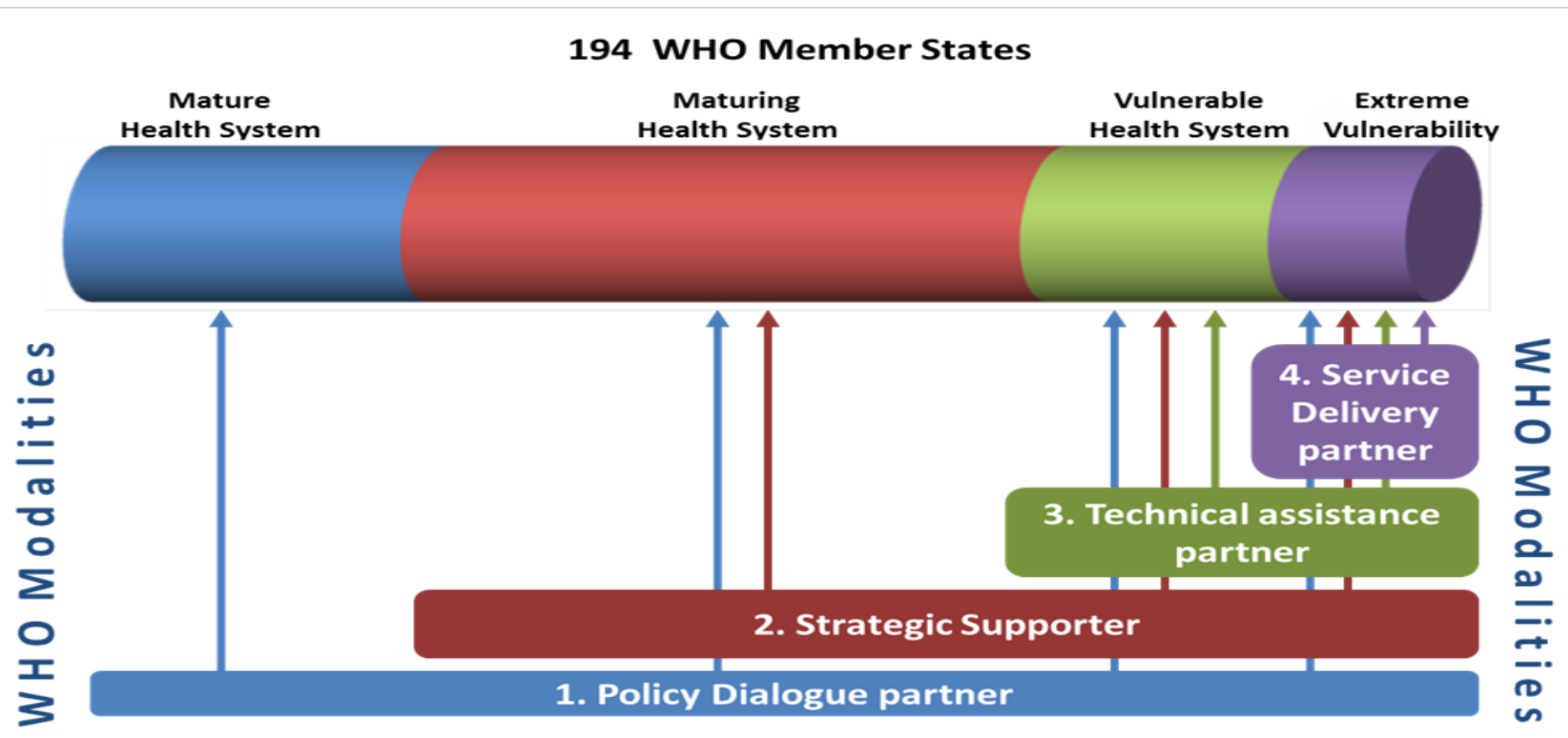
I envision a world in which everyone can live healthy, productive lives, regardless of who they are or where they live. I believe the global commitment to sustainable development – enshrined in the Sustainable Development Goals – offers a unique opportunity to address the social, economic and political determinants of health and improve the health and wellbeing of people everywhere.

Achieving this vision will require a strong, effective WHO that is able to meet emerging challenges and achieve the health objectives of the Sustainable Development Goals. We need a WHO – fit for the 21st century – that belongs to all, equally. We need a WHO that is efficiently managed, adequately resourced and results driven, with a strong focus on transparency, accountability and value for money.

WHO Global Program of Work 2019-2023



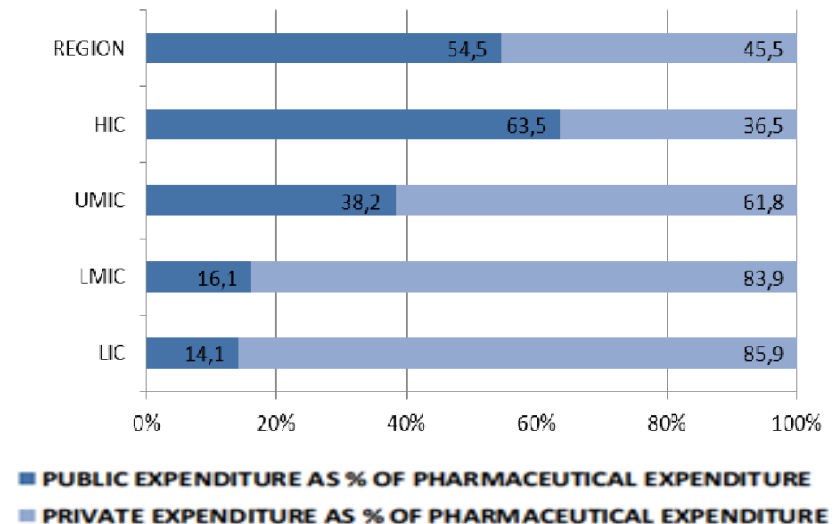
Contributing to impact at country level



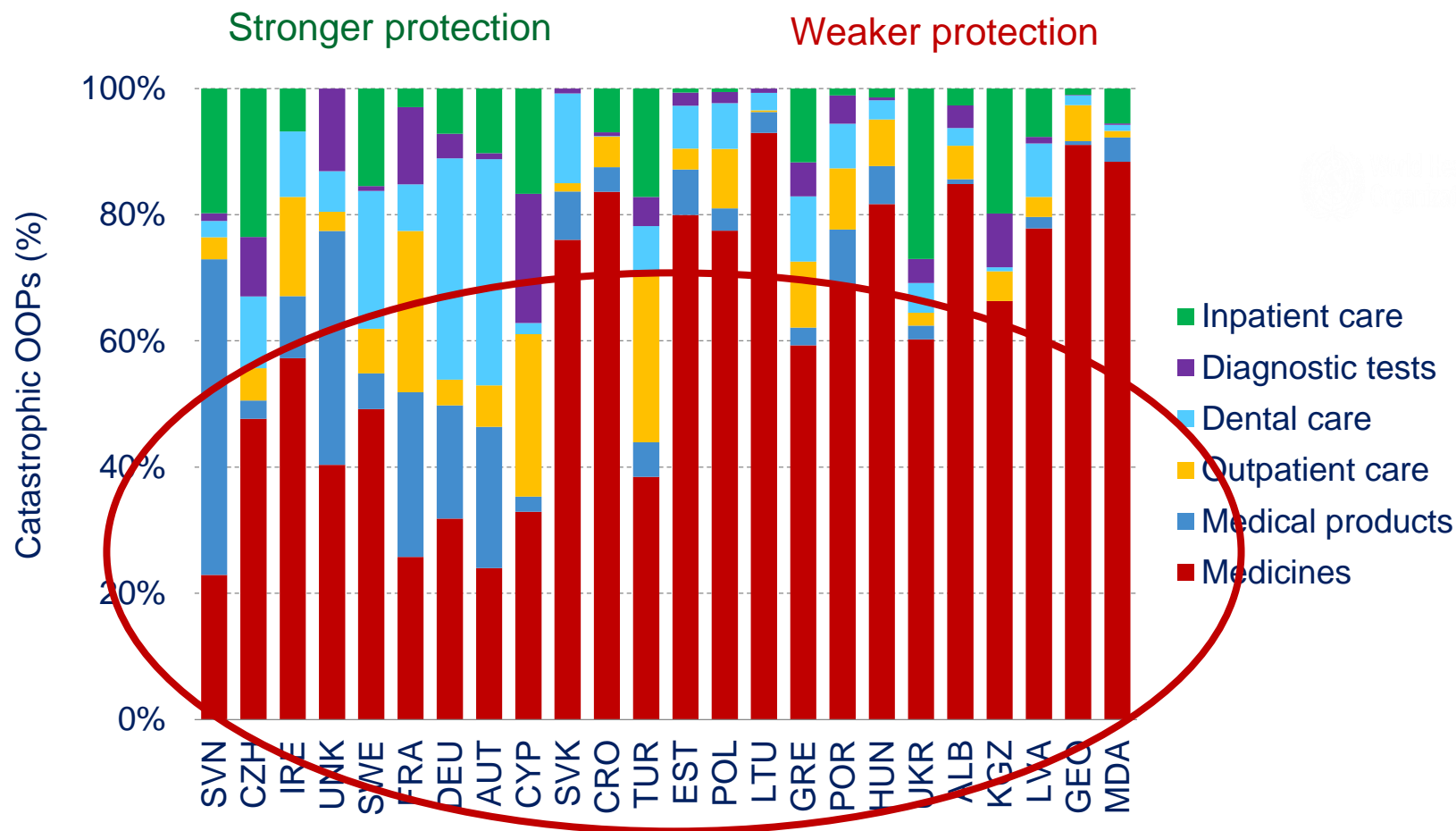
All countries share problems in universal access to medicines

- **Inadequate financing** to ensure **universal access** to essential medicines
- **Inefficiencies** in procurement and managing supply chains
- **Limited pricing policies/negotiating capacity** to get lowest possible prices for quality products
- **Substandard quality** medicines due to limited regulatory capacity and enforcement
- Wide-spread **inappropriate prescribing and use** - leading to drug resistance and suboptimal health outcomes
- Out of pocket spend is up to 80-90% of total pharmaceutical spend in some countries

Private health expenditure as a percentage of total pharmaceutical expenditure in WHO European Region, 2013

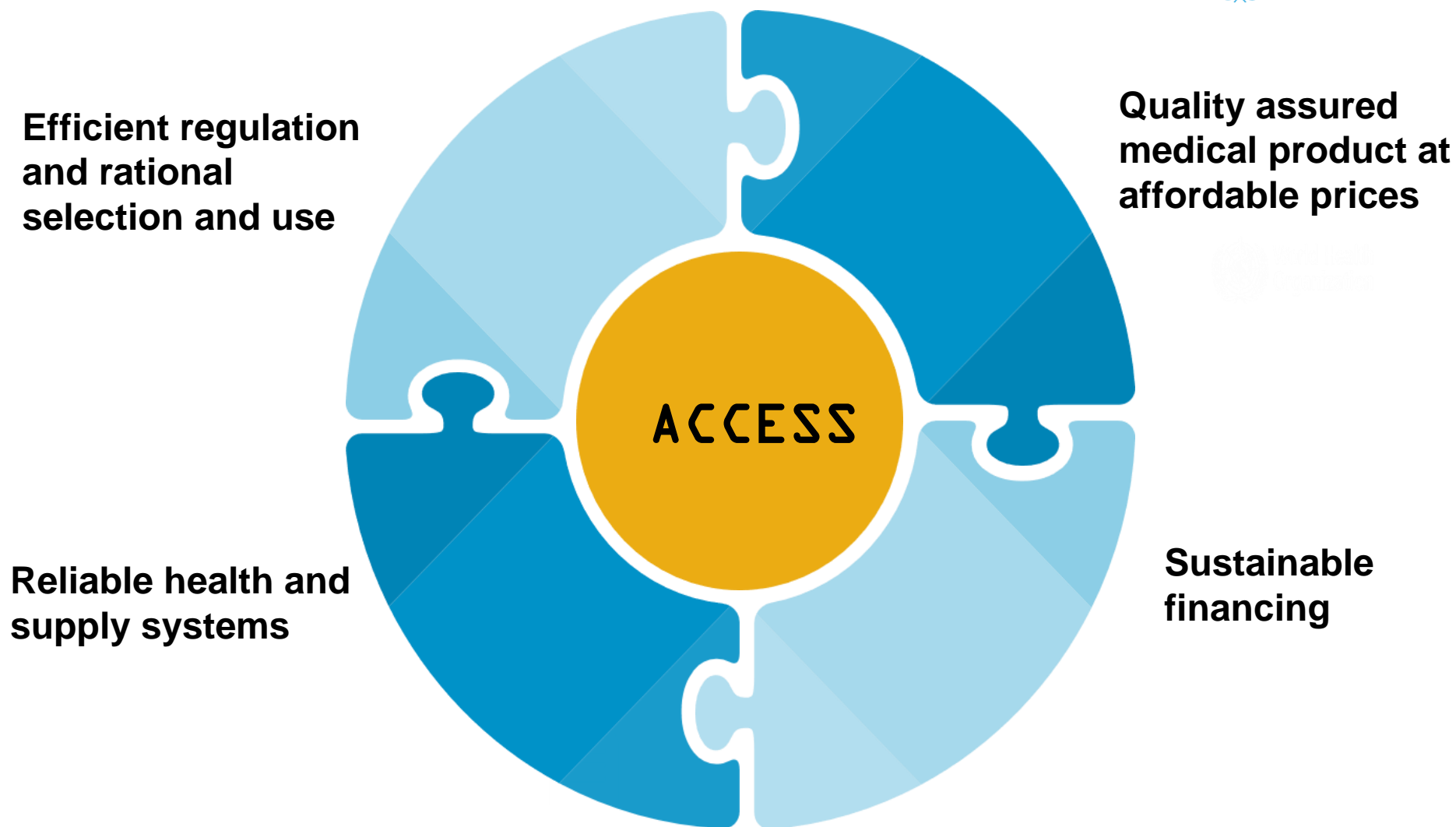


Medicines are the main driver of catastrophic spending among poor households



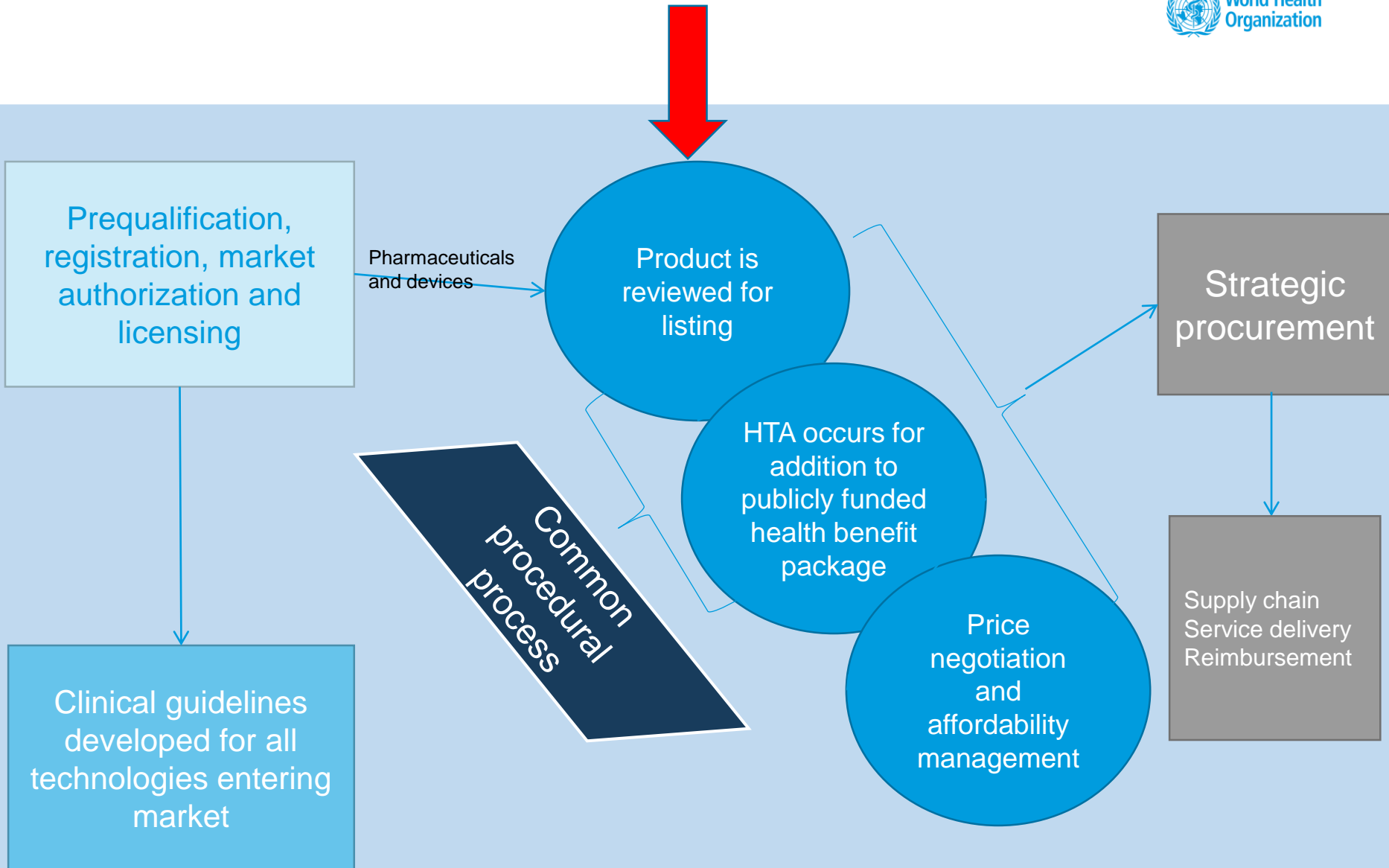
Ensuring access to medicines and health products requires efficient regulation, policies and regulation in all steps of the value chain



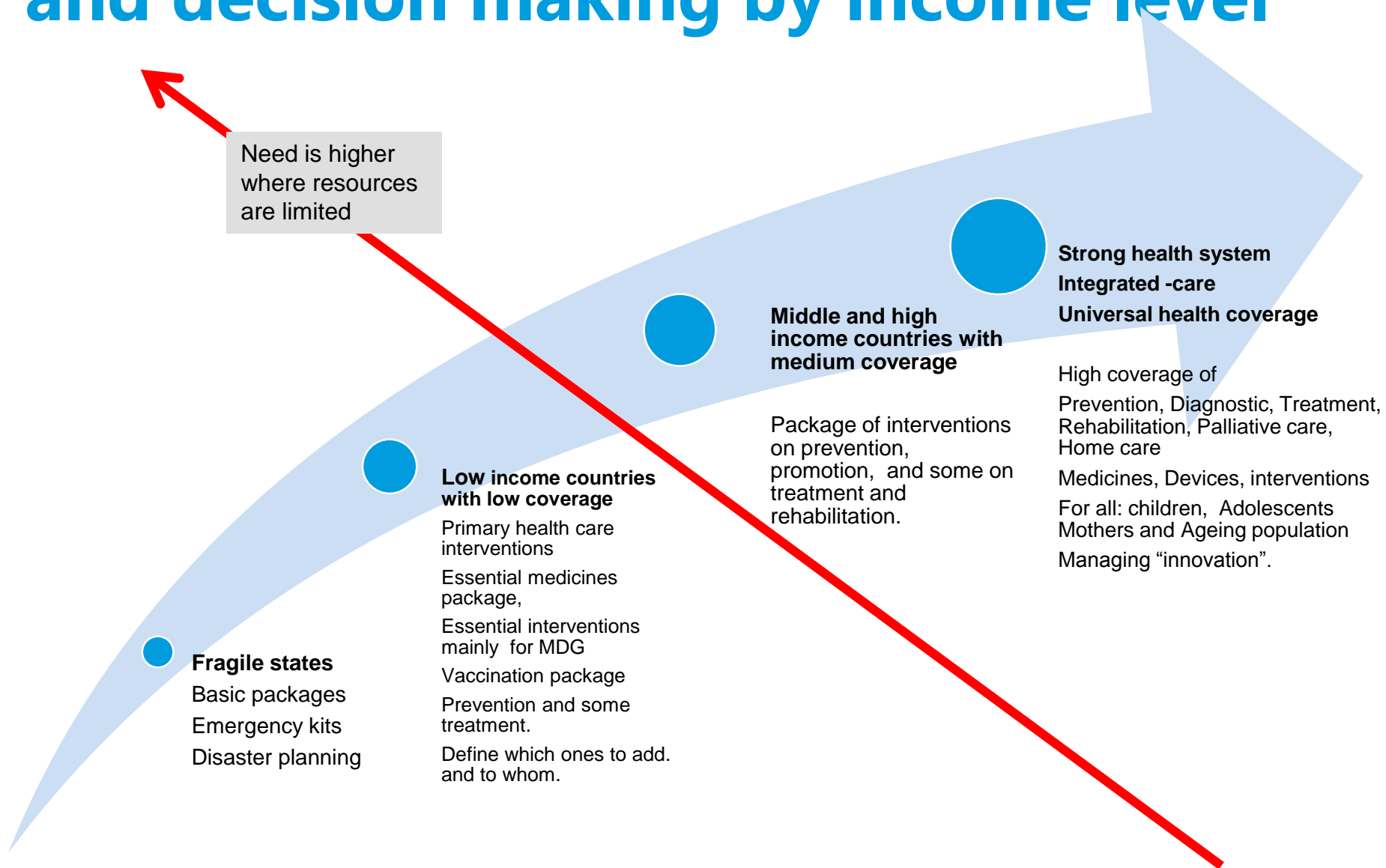




World Health Organization



Spectrum of need for priority setting and decision making by income level



WHO Access priorities



1. Provide leadership on ATM policies

2. Setting product quality norms, standards, and their implementation

3. Providing technical support and building institutional capacity on health product regulation and ATM policies

4. Articulating ethical and evidence based policy options

5. Shaping markets through PQ

6. Monitoring and evaluation of ATM including enhancing data systems

Developing policy options to promote access to medicines and health products

Establishing stronger national pharmaceutical systems and capacity

Responding to evolving health product needs



Access to medicines and vaccines

Report by the Director-General

1. The Executive Board, at its 144th session in January 2019, noted an earlier version of this report.¹ The draft road map has been revised and a new Appendix 2 has been added to indicate the linkage between the Thirteenth General Programme of Work, 2019-2023 and the activities, actions, deliverables and milestones set out in the road map. The milestones have been updated to reflect the global goods planning process, and information has been added on the Organization's mandate with regard to the actions required by the road map and on the distribution of road map activities across the programme budget. The revised draft also reflects issues raised by the Executive Board relating to providing health products for primary health care, monitoring access, optimizing the use of biosimilars, addressing the challenges faced by small island States, and supporting countries transitioning from donor funding.²



Activity: Evidence-based selection and fair and affordable pricing

Action – Support processes for evidence-based selection, including health technology assessment and their implementation¹

Deliverables
Normative guidance for the selection of essential health products and the use of these in the development of national selection processes, including model lists for essential medicines, diagnostics, medical devices and vaccines.
Capacity development for evidence-based selection and priority-setting using various tools, including health technology assessment in collaboration with relevant partners.
Information and knowledge exchange through global and regional platforms to support country decision-making processes on evidence-based selection and health technology assessment of essential health products.

Transparency Resolution

1. URGES Member States in accordance with their national and regional legal frameworks and contexts:

- (1) to take appropriate measures to publicly share information on the net prices² of health products;
- (2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;
- (3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;
- (4) to facilitate improved public reporting of patent status information and the marketing approval status of health products;
- (5) to improve national capacities, including through international cooperation and open and collaborative research and development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including health products for the diseases that primarily affect them, as well as for product selection, cost-effective procurement, quality assurance, and supply chain management;

Pricing of cancer medicines and its impacts

A comprehensive technical report for the World Health Assembly Resolution 70.12 Operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer



WHO GUIDELINE ON COUNTRY PHARMACEUTICAL PRICING POLICIES

Guideline development group comprising external experts

Systematic review team: The Utrecht WHO Collaborating Centre for Pharmaceutical Policy and Regulation

WHO Steering Group comprising personnel from the technical unit and members from WHO departments and regional offices whose work deals directly with the topic of the guideline.

External review group [To be established]

5.	Recommendations	
5.1	Regulation of mark-ups in the pharmaceutical supply and distribution chain	
5.2	Tax exemptions/reductions for pharmaceutical products	
5.3	Application of cost-plus pricing formulae for pharmaceutical price setting	
5.4	Use of external reference pricing.....	
5.5	Promotion of the use of generic medicines.....	
5.6	Use of health technology assessment.....	
6.	Guideline use and adaptation – key principles and general considerations	
6.1	Key principles for policy planning and implementation.....	
6.2	Overarching considerations for policy selection.....	
6.3	Health system and pharmaceutical sector considerations for policy implementation.....	
7.	Research priorities and guideline update	

Examples of requests from Member States

- Investment case for HTA
- Political economy, advocacy, governance
- How to set up HTA “institution”
- Identifying and co-ordination of stakeholders
- Horizon Scanning
- National Essential lists
- Defining “benefit package” linking health products and money
- Global vs. local evidence (decisions, lists)
- Affordability and budget impact
- Disinvestment
- Pricing and procurement technical assistance
- Norms and standards on procurement
- Market shaping

HTP Activity – Access (examples)



- Implementation of National Lists of Essential Medicines and Diagnostics, Priority Medical Devices and Assistive Technology
- Appropriate Institutionalisation of Health Technology Assessment
- Facilitate a package of pricing and reimbursement policies to prioritize and sustain access and reduce OOPP for monopoly as well as competitive (generic) situations
- Facilitate voluntary country collaboration
- Horizon scanning, HTA, PPRI network, Fair Pricing initiative (WHO HQ)
- Develop strategic procurement
- Collaboration initiatives (Nordic Forum, BeNeLuxA)
- Enhancing the role of community pharmacists
- WHO Euro workshops

HTP Activity- Regulation (examples)

- Developing evidence - assessments of regulatory systems worldwide (more than 50 NMRAs assessed in all 6 regions) (**Benchmarking**)
- Providing direct technical support (capacity building, tools and guidance) to regions and countries based on their **Institutional Development Plans**.
- Stimulating/initiating collaboration regulators from various countries on regulatory activities. Promoting and facilitating communication among national/regional regulatory systems using ICDRA, specific network meetings (e.g. WHO Annual Pharmacovigilance Centres meetings, and International Regulatory Cooperation for Herbal Medicines, etc.).
- Promoting regulatory collaboration and harmonization, regulatory **convergence and work sharing**.

A photograph of five children sitting in a row, smiling and hugging each other. From left to right: a girl in a blue shirt, a boy in a light blue shirt, a girl in a white shirt, a boy in a blue and white shirt wearing a red beanie, and a girl in an orange shirt. They are sitting in front of a wooden door.

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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