Access to Medicines and Health Products (MHP) Division

Member State Information Session

Update of the Road map for access to health products

1 July 2024

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75 HEALTH FOR ALL

Access Road Map

- May 2018 decision WHA71(8), requested the DG to elaborate a road map report, outlining WHO's work on access to medicines and vaccines for 2019–2023, including activities, actions and deliverables.

- A report was drafted and revised based on consultations with Member States and other stakeholders and submitted to the seventy-second World Health Assembly (A72/17).

- The Roadmap presents a comprehensive outline of the work of WHO
- Update to reflect:
  - WHO transformation
  - GPW14
  - Lessons learnt including from COVID-19 pandemic
  - Changes in the global health outlook
  - Emergency preparedness, response and resiliance
  - New mandates

Selected achievements

New standards were issued for ensuring **quality and safety of lifesaving therapeutics** such as oxygen and for biologicals such as cell and gene therapies.

The number of **globally recognized names** assigned to pharmaceutical substances grew by 500 names annually and comprising around 12 000 names.

Lists of essential medicines and essential in vitro diagnostics; priority lists of medical devices and technical specifications for assistive products were updated, providing important **guidance for procurement and reimbursement decision-making**.

Access to safe blood, improved regulation and organization of national blood transfusion programmes and plasma fractionation programmes was achieved through technical cooperation and capacity-building.

Procurement and supply chains have been strengthened with technical support provided for assessments, policy updates and establishment of pooled procurement mechanisms.

Gains were made in building capacity on **pricing policy, transparency and information exchange**.

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Selected achievements

WHO's **prequalification** lists were expanded and new pathways to prequalification listing developed.

Local production and technology transfer of health products was strengthened with extensive global and regional capacity-building events, and the establishment of the COVID-19 Technology Access Pool (C-TAP), the mRNA Technology Transfer Hub and Global Training Hub in Biomanufacturing.

WHO contributed to **enhancing regulatory systems** in countries by benchmarking and providing specialized technical support.

The **WHO Listed Authority Policy** initiative was launched and the first three WLAs were listed to replace the previously used concept of Stringent Regulatory Authorities.

Safety surveillance systems were strengthened to support and safeguard the uptake of new or innovative products and efforts to improve the prevention, detection, and response to substandard and falsified medical products were intensified.

Regulatory preparedness for public health emergencies was strengthened ensuring that countries can respond more swiftly and effectively to public health emergencies, enhancing global health security.

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MHP Key Challenges: 2024-2025

Institutionalize
programmes

Institutionalize initiatives & programmes beyond COVID-19

- *C-TAP to H-TAP*
- *mRNA TT programme*
- *Biomanufacturing training*

Empower Regional & Country offices to facilitate timely support to Member States

Coordinate Internal & external partners to advance with cross-cutting work

Accelerate
outputs

Accelerate outputs by integrating lessons learned from COVID-19

Adapt PQ & EUL processes for medicines, diagnostics, vaccines & other health products

Ensure equitable and timely access to novel health products

Visualize
outcomes & impact

Increase visibility of outcomes & impact to increase accountability and trust & to showcase values

Proactive communication with media and stakeholders

Gap analysis to visualize country needs

Develop measurable indicators and consolidate a result framework

Monitor indicators for country support to evaluate effectiveness

e.g. Alignment of WHO guidelines and PQ procedures has improved timely access

5

No country in the world can address these challenges alone

$30.5 billion

Global estimated spend on substandard and falsified medicines in LMICs[1]

2.5 billion

2.5 billion people globally need one or more assistive products[2]

2 billion people

Experiencing financial hardship due to out-of-pocket health spending[3] a majority of which includes cost of health products

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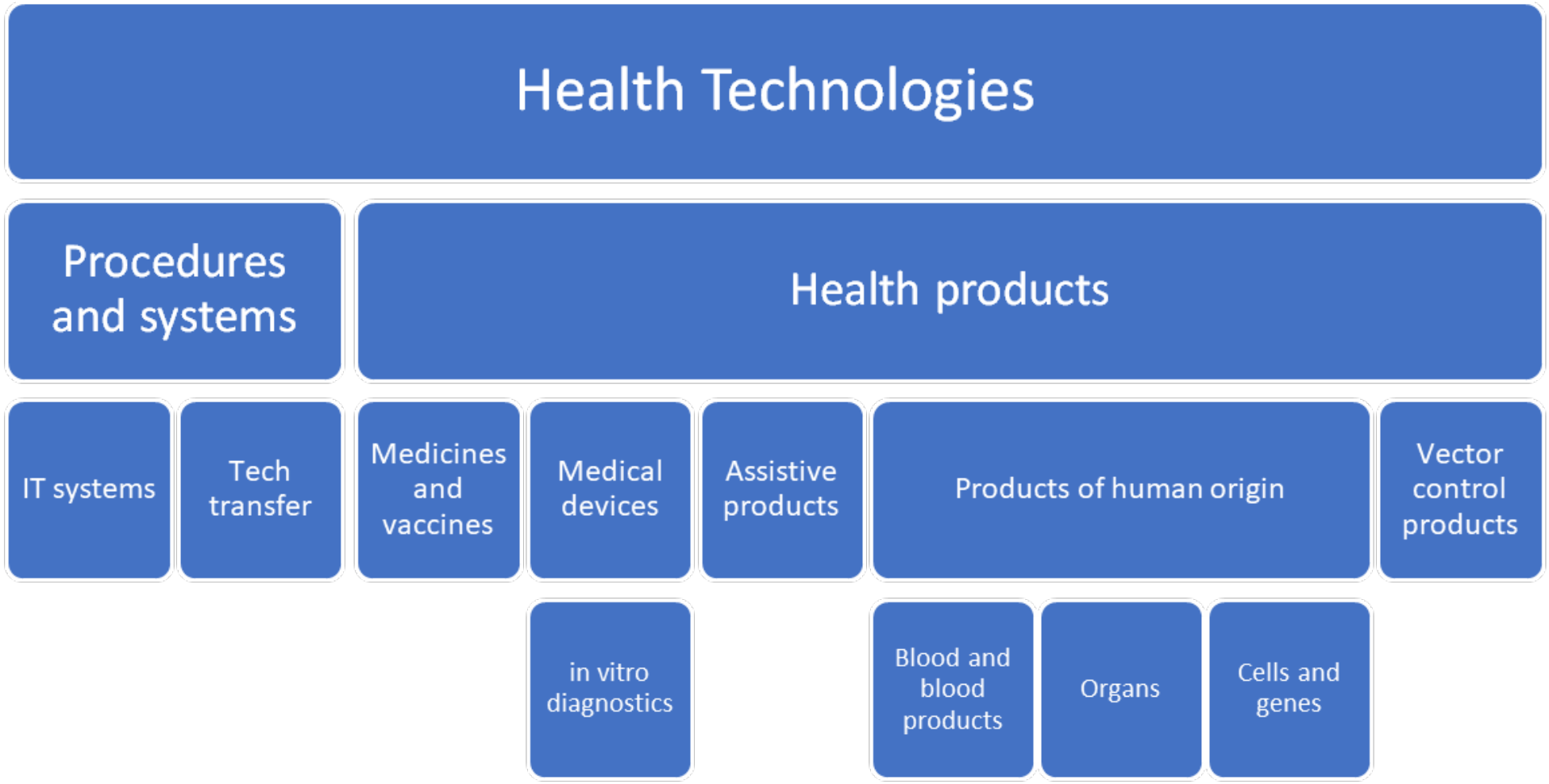
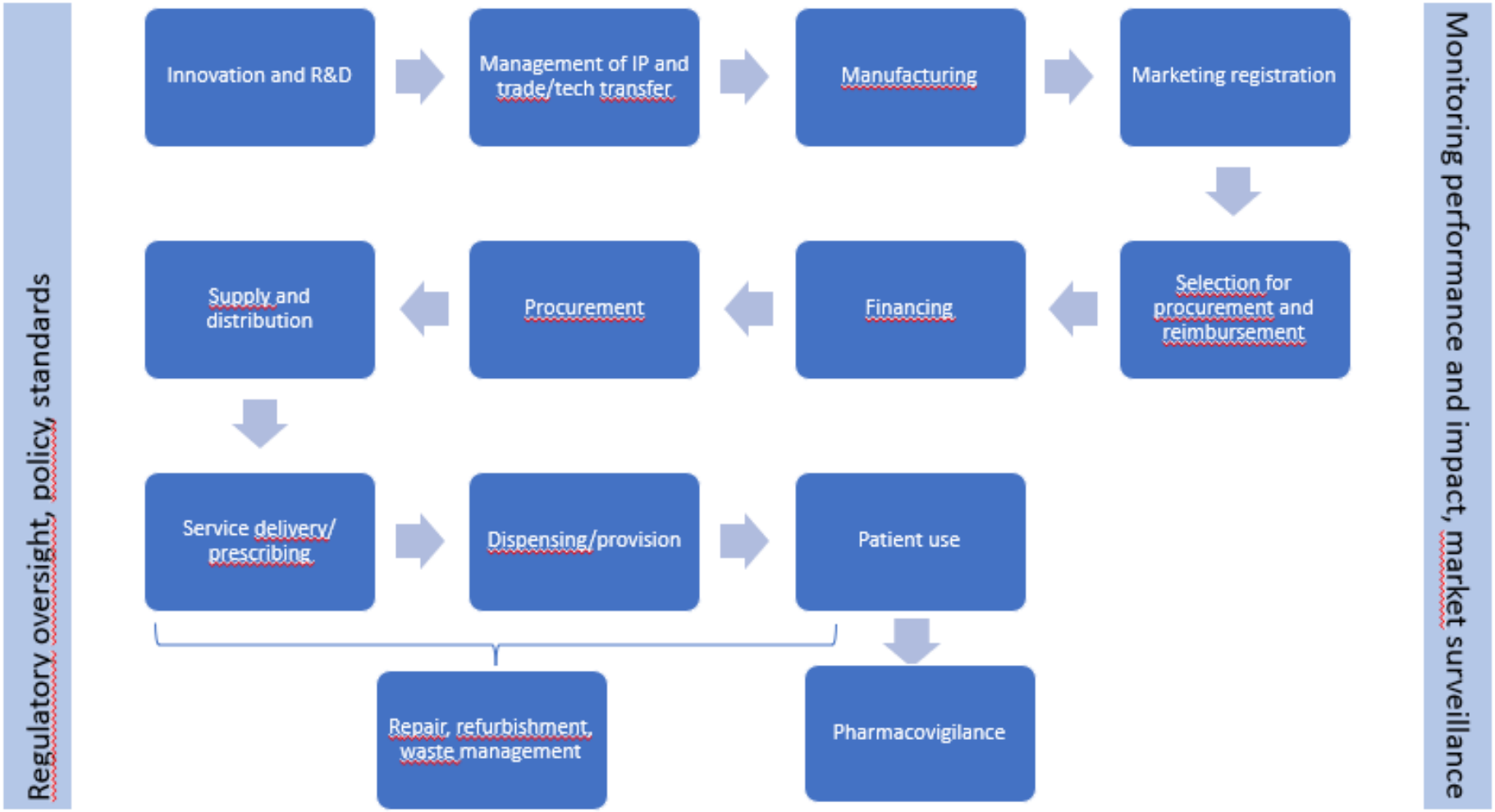
[1] https://www.who.int/publications/i/item/WHO-MVP-EMP-SAV-2019.04
[2] https://www.who.int/news-room/fact-sheets/detail/assistive-technology
[3] https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)

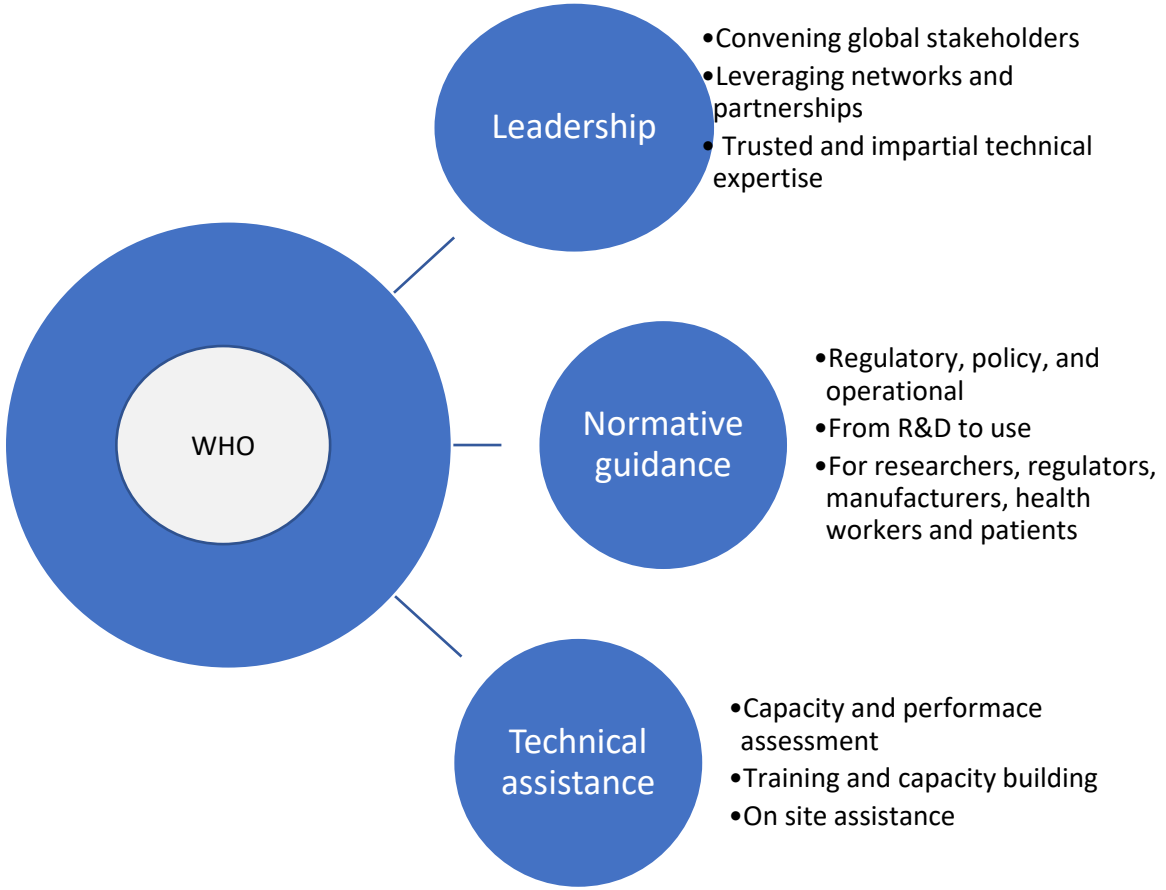
Scope


Health Technologies
Procedures and systems
Health products
IT systems
Tech transfer
Medicines and vaccines
Medical devices
Assistive products
Products of human origin
Vector control products
in vitro diagnostics
Blood and blood products
Organs
Cells and genes

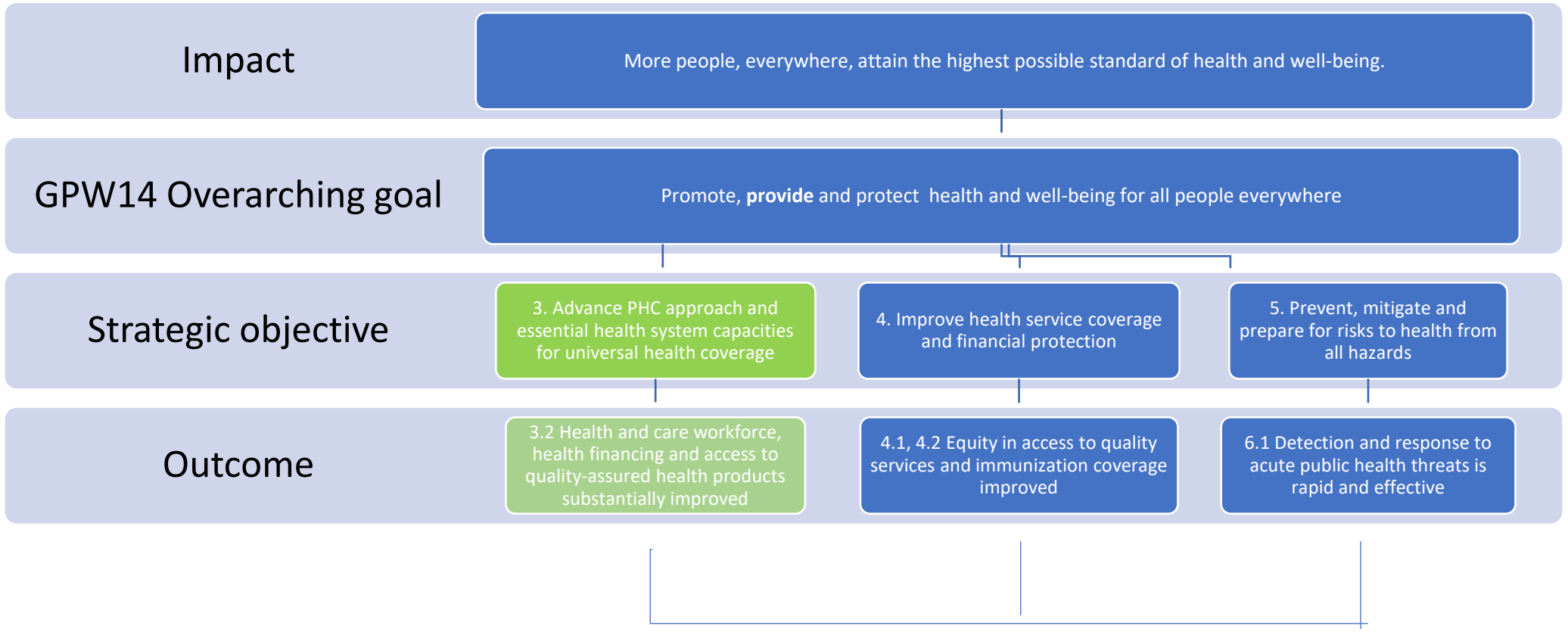
Core components in the access value chain



WHO's role in supporting Member States to improve access to safe, effective and quality assured health products



Access to health products within the GPW14



Access to health products in the WHO Road Map 2025-2030 (draft):

3 strategic objectives proposed to achieve GPW14 outcomes and impact:

Ensure **safe, effective and quality-assured** health products

- Regulatory systems strengthening
- Reliance and convergence
- Prequalification and risk-based assessment
- Regulatory market surveillance

Improve **equitable access** to health products

- Public health driven R&D and innovation
- Application and management of intellectual property
- Local production and end-to-end development
- Selection
- Pricing and affordability
- Procurement and supply
- Service delivery and use

Strengthen **cross-cutting areas** across the access pathway

- Product identification
- Environmental sustainability
- Monitoring

WHO Access Road Map (2019-2023) https://iris.who.int/bitstream/handle/10665/330145/9789241517034-eng.pdf?sequence=1

Timeline and next steps