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
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:
  o WHO transformation
  o GPW14
  o Lessons learnt including from COVID-19 pandemic
  o Changes in the global health outlook
  o Emergency preparedness, response and resilience
  o 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**.
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.
### 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

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e.g. Alignment of WHO guidelines and PQ procedures has improved timely access
No country in the world can address these challenges alone

$30.5 billion
Global estimated spend on substandard and falsified medicines in LMICs¹

2.5 billion
2.5 billion people globally need one or more assistive products²

2 billion people
Experiencing financial hardship due to out-of-pocket health spending³, a majority of which includes cost of health products

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]
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

Leadership
- Convening global stakeholders
- Leveraging networks and partnerships
- Trusted and impartial technical expertise

Normative guidance
- Regulatory, policy, and operational
- From R&D to use
- For researchers, regulators, manufacturers, health workers and patients

Technical assistance
- Capacity and performance assessment
- Training and capacity building
- On site assistance
Access to health products within the GPW14

Impact
More people, everywhere, attain the highest possible standard of health and well-being.

GPW14 Overarching goal
Promote, provide and protect health and well-being for all people everywhere

Strategic objective
3. Advance PHC approach and essential health system capacities for universal health coverage
4. Improve health service coverage and financial protection
5. Prevent, mitigate and prepare for risks to health from all hazards

Outcome
3.2 Health and care workforce, health financing and access to quality-assured health products substantially improved
4.1, 4.2 Equity in access to quality services and immunization coverage improved
6.1 Detection and response to acute public health threats is rapid and effective
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

- Drafting: May, June
- Internal consultation: June, July
- MS consultation: July
- Stakeholder consultation: September
- Finalization: October, November