What drives access to quality medical products for all?

1 Research and Development (R&D)

Communicable diseases (e.g. malaria, addressing antimicrobial resistance, measles, HIV)

Non-communicable diseases (e.g. cardiovascular diseases, cancers, chronic respiratory diseases, diabetes)

Basic research and discovery | **Early pre-clinical development** | **Clinical development**

Push and pull incentive mechanisms, including intellectual property rights, market size and expected revenues

2 Regulatory Systems

Pre-clinical trials → **Clinical trials** → **Production and scaling up**

Market surveillance → **Pharmacovigilance** → **Life-cycle management**

Pre-market | **Registration** | Approval | **Post-market**

Establish, evaluate and maintain quality, safety and efficacy

Good Manufacturing / Clinical / Distribution / **Practice**

3 Financing

Supply side

Manufacturer price

Wholesaler price (mark-ups)

Demand side

- Health technology assessment (evaluation of benefits and costs of a new medical product)
- Price negotiations with the manufacturer
- Taxes and tariffs
- Reimbursement schemes (e.g. health insurance)
- Socio-economic status of patient
- Financial viability of the health system

4 Supply and Distribution

Production capacities

Transport system

Stock and storage management

National regulations

5 Healthcare Facilities, Equipment and Personnel

Facilities and equipment

Healthcare providers, including their technical knowledge and social skills

Treatment guidelines

6 Patients' Health-Seeking Behaviour and Adherence

Supply side

- Form, dosage, colour and taste of product
- Type and communication skills of providers

Demand side

- Patient literacy
- Guiding social and cultural norms and values
- Stigma of disease or health condition
- Preference for other medical products (e.g. traditional medicine)

Access to quality medical products for all

Substandard and falsified medical products

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Access to quality medical products[1] is a complex health and development challenge. It depends on the physical availability and financial affordability of a product as well as its geographical accessibility and sociocultural acceptability.

At the same time, access is subject to both supply (i.e. products and health systems' services) and demand (i.e. people's needs and resources).

Whether a patient will gain access to a product can be assessed along the pathway of a product. We have identified six key steps on this pathway – from research and development to ultimately the use of the product by the patient. These key steps are interlinked but do not necessarily have a chronological order (see graphic and explanation).

Access barriers to quality medical products can be different depending on disease and product. We need to adapt approaches accordingly.

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The pathway of quality medical products

1) Research and Development (R&D)

Physical availability of a new quality medical product depends first on R&D. Different incentive mechanisms, including intellectual property rights, market size and expected revenues, are needed to stimulate R&D. Only when quality medical products successfully pass through research, early development and clinical development, is there a chance that they will ultimately reach and benefit patients.

2) Regulatory Systems

If successful at clinical trial stage, a product is then evaluated by national or regional regulatory authorities to ensure that it meets standards for efficacy, safety and quality – it is approved if the benefits outweigh the risks.

3) Financing

In many countries, before introduction into the national list of essential medicines or into reimbursement schemes, products undergo cost-benefit analyses. If the products are evaluated as cost effective, they may be reimbursed by financing schemes which may positively affect the product's affordability. But affordability also depends on the purchasing power of patients and their families, and on the supply side on the price set by manufacturers.

4) Supply and Distribution

Further along the access pathway, geographical accessibility of products is influenced by available local infrastructure and logistics. Inefficiencies in existing supply chains and distribution channels can compromise geographical accessibility of a medical product.

5) Healthcare Facilities, Equipment and Personnel

Access to medical products also depends on factors such as availability of health facilities, qualified healthcare providers and medical equipment.

6) Patients' Health-Seeking Behaviour and Adherence

Medical products must be acceptable to patients and providers. This can depend on factors such as cultural norms and beliefs, whether it is a generic or branded product, or on product features, including form, dosage, taste and colour.

[1] The term «quality medical products» refers to both medicines and medical devices (including vaccines, diagnostics and in vitro diagnostics).