Chapter 7

The Pharmaceutical System and Its Components

Regulation and Management and Associated Challenges

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Key Messages

- The pharmaceutical system is an integral subset of the health system which must have in place mature regulatory structures and robust supply systems to ensure that it supports national efforts to advance universal health coverage.
- Health technologies are life-enhancing and lifesaving commodities that require the products to be safe, quality-assured, efficacious, and used appropriately to achieve the desired health outcomes.
- Governments are responsible for establishing strong national regulatory authorities (NRAs) that are the gatekeepers of the supply chain of medical products, and are responsible for ensuring the quality, safety, and efficacy of medicines. The World Health Organization (WHO) has developed a global benchmarking tool to facilitate country efforts in strengthening NRAs.
- Managing the supply of health products and technologies has four key areas: selection, procurement, distribution, and use. Each needs to function well to ensure equitable access to health products.
- Pharmaceutical system challenges in low- and middle-income countries (L&MICs) include lack of well-functioning NRAs, inappropriate selection and use of essential medicines, substandard and falsified products, inadequate pharmaceutical workforce, lack of good pharmacy practice, insufficient understanding of intellectual property protection, and innovation processes.

7.1 Introduction

Medicines account for 20–30% of global health spending, more so in L&MICs. They constitute a major part of the budget of whosoever is paying for health services [1]. Their impact on health financing places them in a central position in discussions, strategies, and plans for universal health coverage (UHC) [2]. Currently, the majority of people in L&MICs pay for medicines out-of-pocket, often leading to financial hardship [1]. Unaffordability commonly results in people not taking their medication as prescribed or not at all, which in turn leads to poor health outcomes. With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the threat of financial burden has become even greater, as is the need to accelerate progress toward UHC.

Box 7.1 Health Technologies

According to WHO, health technology is "the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives" [3]. Health technologies equip health care providers with tools for prevention, diagnosis, treatment and rehabilitation, and attainment of internationally agreed health-related development goals.

This chapter discusses the pharmaceutical system as part of the health system and describes health products and technologies (see Box 7.1). While focused on medicines and vaccines, which are essential for a well-functioning health system, the content also applies to other health products, such as medical devices, health applications and software, wearables, and other durable and nondurable commodities. Table 7.1 gives an overview of definitions of various types of health technologies, specifically health products commonly used in health care. This chapter also highlights the regulatory and management challenges of the pharmaceutical system, while Chapter 21 discusses how to improve health system performance by strengthening the pharmaceutical system.

7.2 The Pharmaceutical System and Its Components

Equitable access to health products is a key condition and an indicator for countries' progress toward UHC [12]. Ensuring access to health products depends on a well-functioning health system, in particular its components of governance, information, financing, workforce, and service delivery. It requires robust regulatory and supply systems which take into account the countries' contexts, address the needs of vulnerable populations, and foster innovation [13]. Access to health care, including essential medicines, is a fundamental human right [14]. Realization of this right involves various combinations of public and private financing and service provision arrangements [15].

A *pharmaceutical system* may be defined as a subset of the health system which "consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes" [16].

A pharmaceutical system thus includes, but is not limited to, the NRA or equivalent body, the Central Medical Store or equivalent procurement and purchasing unit(s), and all related agencies or units in charge of financing medicines and their appropriate use. It needs to have functional or collaborative links to other bodies that influence its performance, such as professional orders or associations, social insurance systems, and patent offices. Those in charge of each component of the pharmaceutical system, or related functions (e.g., selection, financing, regulation, quality assurance, services planning, and monitoring) are *collectively* responsible for the system's performance on access to medicines.

A well-functioning pharmaceutical system, as an integral component of the health system, should ensure reliable access to quality-assured, safe, and efficacious essential medicines and health technologies that are available in sufficient quantities and are affordable to the population [17]. This requires effective regulatory and procurement systems, as well as legal provisions for access to medicines, governance arrangements, and efficient

Table 7.1 Common types of health technologies used in health care provision

Product	Description
Medicines	Medicines may be defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [4].
Vaccines	Vaccines are a heterogeneous class of prophylactic medicinal products containing antigenic substances capable of inducing specific, active, and protective host immunity against an infective agent or toxin, or against other important antigenic substances produced by infective agents [5].
Advanced therapy medicinal products (ATMPs)	ATMPs are medicines for human use that are based on genes, tissues, or cells. They offer groundbreaking new opportunities for the treatment of disease and injury [6].
Homeopathic medicines	Products are prepared following a well-defined procedure, starting from substances derived from the mineral, herbal, and animal worlds. The techniques of preparation of these drugs include the dilution of the raw material, in hydroalcoholic solutions or in other excipients, and the potentization of the product into different grades [7].
Traditional and complementary medicines (T&CMs)	T&CM products include herbs, herbal materials, herbal preparations, and finished herbal products that contain parts of plants, other plant materials, or combinations thereof as active ingredients. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g., animal and mineral materials) [8].
Biological medical products (biotherapeutic medicines)	Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small-molecule drugs. They may be developed using genetically engineered bacteria, yeast, fungi, cells, or even whole animals and plants [9].
Blood products	Any therapeutic substances derived from human blood, including whole blood, blood components, and plasma-derived medicinal products [10].
Medical devices	An article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological, or metabolic means [11].

management of resources. Weak governance and inefficient practices leave health systems vulnerable to corruption and mismanagement, and can have a detrimental effect on health budgets, patients' health and wellbeing, and trust in public institutions [18].

7.2.1 The Pharmaceutical System as Part of the Health System

Health system strengthening interventions must address interconnections between system components [19]. In particular, complex relationships between medicines and health governance, financing, human resources, health information, and service delivery should be given sufficient consideration. Otherwise, populations' access to medicines is addressed mainly through fragmented, often vertical approaches usually focusing on supply, unrelated to the wider issue of access to health services and interventions [20].

National medicines policies are recommended by WHO to express and prioritize the medium- to long-term goals set by governments for pharmaceutical systems, and to identify the main strategies for attaining them [21]. A holistic approach to the national medicines policy is required to ensure that the elements are interlinked and should be aligned with the national health policy and other related development policies, such as higher education, industry, trade, and others.

In discussing the pharmaceutical system, this chapter focuses on two main areas: regulation and management. The relationship between health technologies and the health system underscores aspects concerning their regulation and management through robust supply systems and policies in order to ensure quality, safety, and efficacy of products. The chapter also highlights major challenges faced by pharmaceutical systems in low- and middle-income countries (L&MICs).

7.3 Regulation of Health Products and Technologies

Governments are responsible for establishing strong NRAs with a clear mission, sound legal basis, realistic objectives, appropriate organizational structure, adequate number of qualified staff, sustainable financing, access to up-to-date, evidence-based technical literature, equipment and information, and capacity to exert effective market control. NRAs must be free of conflicts of interest and accountable to both the government and the public, and their decision-making processes should be transparent. Monitoring and evaluation mechanisms should be built into the regulatory system to assess attainment of established objectives. NRAs can fall into different categories, such as stringent regulatory authority (SRA), WHO listed authority (WLA), and regional regulatory system (RRS), which are elaborated in Box 7.2.

7.3.1 Main Functions and Assessment of NRAs

National regulatory authorities are the gatekeepers of the supply chain of medical products, and are responsible for ensuring the quality, safety, and efficacy of medicines. The range of health products regulated by NRAs varies depending on the level of development of the NRA, local context, and historical factors, but may include medicines, vaccines, blood and blood products, medical devices including diagnostics, traditional or herbal medicines, and veterinary medicines [24].

The WHO has developed a global benchmarking tool (GBT) to facilitate country efforts in strengthening NRAs. The WHO GBT enables WHO and NRAs to identify strengths and areas for improvement; to facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps; to prioritize IDP interventions; and to monitor progress and achievements [25]. The GBT has been considered a game-changer because it is the first globally accepted tool for assessing and strengthening

Box 7.2 Key Terms Related to NRAs

Stringent Regulatory Authority

The concept of an SRA was developed by WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria to guide medicine procurement decisions, and is now widely recognized by the international regulatory and procurement community [22]. An SRA is defined as a regulatory authority which is:

- a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration, and the Ministry of Health, Labour and Welfare of Japan (represented by the Pharmaceuticals and Medical Devices Agency); or an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada; or
- a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein, and Norway.

WHO Listed Authority

The interim definition of a WLA is "A regulatory authority or a regional regulatory system which has been documented to comply with all the indicators and requirements specified by WHO for listing based on an established benchmarking and performance evaluation process" [23].

Regional Regulatory System

An RRS is defined by WHO as "a system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory or legal framework." Examples of an RRS include the European Medicines Agency and the African Medicines Regulatory Harmonization Initiative.

NRAs [26]. The tool proposes nine main functions for an NRA and a set of indicators to measure its performance (Table 7.2).

7.3.2 Other Regulatory Functions

Several additional aspects of a pharmaceutical system are regulated by Ministries of Health or other agencies, including pricing/reimbursement, registration/licensing of pharmacy personnel, control of narcotics, psychotropic substances, and precursors, good pharmacy practice, and international cooperation. The modalities and competent authorities for managing these important functions vary among countries. While these important functions may fall outside the scope of an NRA, they have a strong impact on the pharmaceutical sector.

7.4 Managing Supply of Health Products and Technologies

This section presents the four key areas of pharmaceutical management: selection, procurement, distribution, and use (Figure 7.1).

Table 7.2 The WHO nine NRA functions with a summary of each function based on the GBT [25]

NRA function	Description
01– National regulatory system	Provides the framework that supports WHO recommended regulatory functions
02 – Registration and marketing authorization	A procedure for approval of a medical product for marketing after it has undergone a process of evaluation to determine the safety, efficacy, and quality of the product and the appropriateness of the product information
03 – Vigilance	The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medical product-related problems
04 – Market surveillance and control	Plays a crucial role in ensuring medical products' consumer safety since its objective is to ensure compliance of the products placed on the market with preset criteria for quality, safety, and efficacy (i.e., verify compliance with marketing authorization and good practices guidelines)
05 – Licensing establishments	Premises, facilities, establishments, and companies throughout the supply chain should possess a license to operate, issued by the NRA
06 – Regulatory inspection	Ensures that operations at pharmaceutical establishments are carried out in accordance with approved standards, norms, and guidelines and are in compliance with the national medical products legislation and regulations
07 – Laboratory testing	Ensures that the NRA is able to assess the quality of medical products by performing quality tests on them in certain situations
08 – Clinical trial oversight	Aims at protecting the safety and rights of humans participating in clinical trials, ensuring that trials are adequately designed to meet scientifically sound objectives, and preventing any potential fraud and falsification of data
09 – NRA lot release	Applies for the regulatory release of specified biological products to ensure the quality, safety, and efficacy of biological products through a regulatory release system

7.4.1 Selection

Selection of essential medicines takes into consideration national disease burden and clinical need, thereby improving access through streamlined procurement and distribution of quality-assured medicines, supporting rational or appropriate prescribing and use, and lowering costs for the health care systems and for patients. Since 1977, WHO has regularly provided guidance for the selection of essential medicines [28]. In 2021, WHO published its twenty-second model essential medicines list and eighth model essential medicines list for children. The concept of essential medicines is closely linked with health insurance and essential health services packages. High-cost medicines such as those for the treatment of cancer may also be included in essential medicines to improve access to lifesaving products. Box 7.3 summarizes the main elements of the concept of essential medicines.

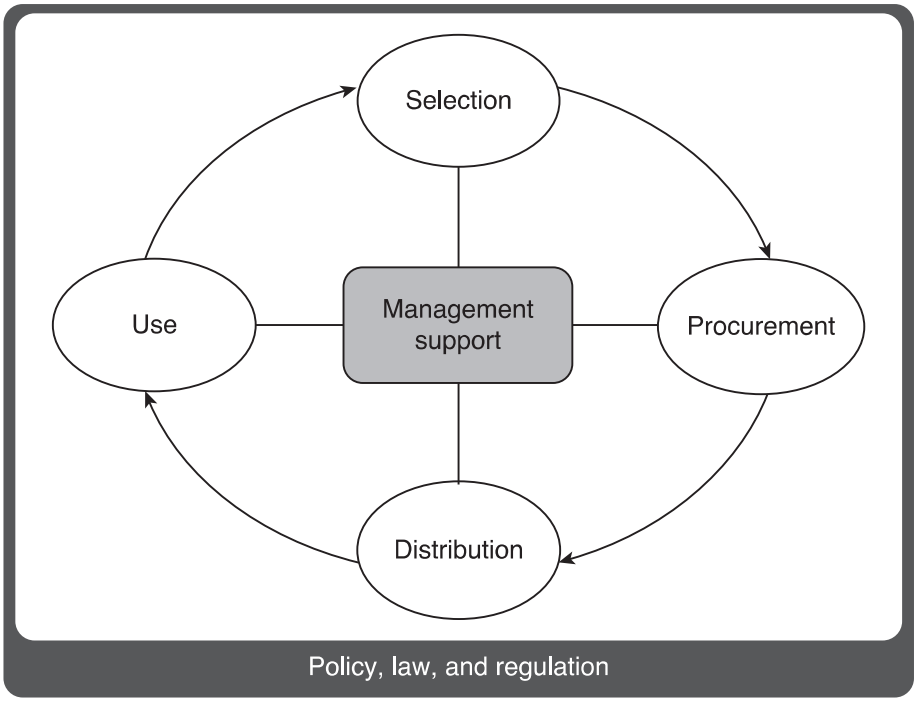

Figure 7.1 Pharmaceutical management framework [27].

Box 7.3 The Essential Medicines Concept [29]

Essential medicines are:

- those that satisfy the priority health care needs of the population;
- selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford.

7.4.2 Procurement

Procurement practices are a major determinant of availability and cost of pharmaceutical products [27]. Procurement involves efforts to quantify medicines' requirements, selecting appropriate procurement methods, and prequalifying suppliers and products. It also involves managing tenders, establishing contract terms, assuring medicines' quality, obtaining the best prices, and ensuring adherence to contract terms. Procurement methods need to be strengthened to ensure that procurement is linked to national medicines lists and prescribing patterns. Pooled procurement is often considered a valuable option to redress the imbalance in market leverage between supply and demand and to serve public health goals (Box 7.4) [30].

7.4.3 Distribution

A well-managed distribution system focuses on measures that ensure product integrity and quality throughout the distribution chain of the products [27]. The distribution system

Box 7.4 Potential Benefits of Pooled Procurement [30]

Existing pooled procurement models that consolidate purchasing across national boundaries have demonstrated the following benefits:

1. reductions in unit purchase prices;
2. improved quality assurance;
3. reduction or elimination of procurement corruption;
4. rationalized choice through better-informed selection and standardization;
5. reduction of operating costs and administrative burden;
6. increased equity between members;
7. augmented practical utility in the role of the host institutions (regional or international) administering the system; and
8. increased access to essential medical products within each participating country.

should allow countries to maintain a constant supply of medicines, keep medicines in good condition throughout the process, maintain cold chain where required, minimize medicine loss due to spoilage and expiry, maintain accurate inventory records, rationalize medicine storage points, use available transportation resources efficiently, and reduce theft and fraud.

7.4.4 Use

Medicine use is appropriate when patients receive the medicines they need, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost both to them and the community [31]. Some of the key interventions advocated for improving use of medicines include establishment of a multidisciplinary national body to coordinate policies on medicine use, use of clinical guidelines, development and use of national essential medicines lists, establishment of drug and therapeutics committees in districts and hospitals, inclusion of problem-based pharmacotherapy training in undergraduate curricula, continuing in-service medical education as a licensure requirement, supervision, audit and feedback, use of independent information on medicines, public education about medicines, avoidance of perverse financial incentives, use of appropriate and enforced regulation, and sufficient government expenditure to ensure availability of medicines and staff [32]. An aspect related to the use of medicines, especially after their authorization, is to monitor long-term efficacy and safety throughout their use in health care practice. This requires the NRA to operate a *pharmacovigilance* system (Box 7.5).

7.4.5 Ensuring Equitable Access to Health Products

The most common causes of death and disability in L&MICs can be prevented, treated, or alleviated with cost-effective essential medicines and health technologies. Still, hundreds of millions of people do not have regular access to essential medicines, despite having developed national essential medicines lists [34]. Among those who do have access, many are given the wrong treatment, receive too little medicine for their treatment, or do not use the medicines correctly. The need to expand access to medicines and health products is highlighted in the Sustainable Development Goals (SDGs) in at least seven targets, including two specific to SDG 3 (3.8 and 3.b) [12].

Box 7.5 Pharmacovigilance System

A pharmacovigilance system is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problem [33]. Before a medicine is authorized for use, evidence of its safety and efficacy is limited to the results from clinical trials, where patients are carefully selected and followed up very closely under controlled conditions. After authorization, the medicine may be used in a large number of patients, for a long period of time, and with other medicines. Also referred to as *postmarketing surveillance*, it is the identification and collection of information regarding medicines after their approval for use in a population.

Several initiatives have been developed to present comprehensive frameworks for access to medicines. Table 7.3 provides a summary of three frameworks. The frameworks overlap on several aspects ("affordability" and "availability") and include components such as "architecture" or "reliable health systems." Limitations of these frameworks have been identified as: adopting a supply-side approach to address demand-side constraints; a focus on products rather than services (except for WHO-MSH 2000); and limitation of the governance of the pharmaceutical sector [20].

7.5 Major Pharmaceutical System Challenges in L&MICs

There are growing concerns about the resilience of health systems and their ability to respond to the challenges of UHC and health emergencies and other emerging threats to health [37]. Efforts to strengthen the resilience of health systems to cope with these challenges should include strengthening of pharmaceutical systems [16].

7.5.1 Lack of Well-Functioning Regulatory Authorities

Many countries still lack a well-functioning regulatory system. According to the WHO regulatory systems strengthening database, among its 194 Member States, only 50 countries (26%) have mature regulatory agencies, while 144 countries have suboptimal regulatory systems. Fifty-one percent of countries are at the lowest level, while 23% are at the second lowest level of maturity [24].

Inappropriate selection of essential medicines may lead to their inappropriate use and inefficiencies in the health system. It may lead to delayed inclusion of new medicines, limitation of physicians' ability to prescribe drugs, a potential impact on new drug research and development programs, and other challenges [38]. Fragmentation in the procurement process for pharmaceuticals and lack of coordination capabilities often result in significant waste of resources. Weak distribution systems may enable product diversion to the black market and proliferation of counterfeit and substandard products [39].

7.5.2 Inappropriate Use of Medicines

Inappropriate use of medicines is a major problem of present-day medical practice, and its consequences include the development of bacterial resistance to antibiotics, ineffective treatment, adverse effects of drugs, and economic burden on the patient and society. Inappropriate use of medicines may take many different forms – for example, polypharmacy, overuse of antibiotics and unnecessary injections, failure to prescribe in accordance

Table 7.3 Domains and determinants covered in existing frameworks for access to medicines

Domains	Specific determinants	Cross-cutting determinant
Access to Medicines Framework 1 – WHO-MSH 2000 (Centre for Pharmaceutical Management 2003)		
Availability	Medicines' supply – type and quantity	Quality of products and services
	Medicines' demand – type and quantity	
Affordability	Prices of medicine products and services	
	User's income and ability to pay	
Acceptability	Characteristics of products and services	
	User's attitudes, expectations of products and services	
Accessibility	Medicines' supply location	
	User location	
Access to Medicines Framework 2 – WHO (2004) [35]		
Rational use	Rational therapeutic choices	Quality of medicines
	Improved medicines' use by consumers	
Affordable prices	Medicines' pricing policies	
Sustainable financing	Resource mobilization	
	Pooling	
	Reduction of OOP expenditures	
Reliable health and supply systems	Medicine procurement and supply	
	Regulation	
	Human resources	
Access to Medicines Framework 3 – Frost and Reich (2010) [36]		
Availability	Manufacturing	Architecture: organization relationships at national and international levels
	Forecasting	
	Procurement	
	Distribution	
	Delivery	
Affordability	Government affordability	
	Nongovernmental agency affordability	
	End-user affordability	
Adoption	Global adoption	
	National adoption	
	Provider adoption	
	End-user adoption and appropriate use	

with clinical guidelines, and inappropriate self-medication. However, despite the global problem of inappropriate use, few countries are monitoring use of medicines or taking sufficient action to correct the situation [40]. It is estimated that over half of all medicines are prescribed, dispensed, or sold inappropriately [31]. Furthermore, half of all patients fail to

Box 7.6 Key Definitions Related to Substandard and Falsified Medicines [45]

Substandard medical products, also called "out of specification," are authorized medical products that fail to meet either their quality standards or specifications, or both.

Unregistered/unlicensed medical products have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products deliberately/fraudulently misrepresent their identity, composition, or source.

take their medication as prescribed or dispensed [41]. In 2012, the Information Medical Statistics Health Institute estimated a global annual loss of US$500 billion that could be avoided by more responsible use of medicines, and identified nine underlying factors, including nonadherence, delayed medicine use, medication errors, antibiotic misuse/overuse, suboptimal generic use, mismanaged polypharmacy, medicine shortages, substandard/counterfeit medicines, and misuse of expensive therapies [42].

7.5.3 Substandard and Falsified Products

Poor access to quality health products is often filled by substandard or falsified products. The growth of e-commerce has also contributed to this trend by making it easier to purchase medicines online, often from unauthorized sources [43]. Box 7.6 highlights the differences between substandard, unregistered/unlicensed, and falsified medical products.

Substandard and falsified medical products are a significant threat to public health, promote drug-resistant infections, and waste valuable resources [44]. NRAs and law enforcement agencies need to be strengthened to comply with international standards in manufacturing and quality assurance of medicines and should collaborate with international agencies to address this important threat to public health.

7.5.4 Weak Collaboration among Stakeholders

The pharmaceutical sector is complex and involves numerous stakeholders, such as the pharmaceutical industry and its shareholders, patients and patient organizations, health professionals, consumer organizations, civil society, wholesalers, hospitals, academia, national and regional competent authorities, and others. Lack of multistakeholder collaboration negatively affects transparency and accountability in the pharmaceutical sector and may hinder progress toward the goal of access to medicines [46]. Global initiatives such as WHO's Good Governance for Medicines program and the Medicines Transparency Alliance have adopted a multisectoral approach in promoting good governance in the pharmaceutical sector [47].

7.5.5 Inadequate Workforce

The shortage of pharmacists and pharmaceutical personnel has implications for the functioning of a health system. The availability of trained human resources in the pharmaceutical sector is of critical importance in meeting national and global health goals, and thus requires

special attention [48]. The particular importance of an adequate pharmaceutical workforce is often overlooked by policymakers when addressing the human resources for health needs.

Competent pharmaceutical professionals are required for the development, production, distribution, and appropriate utilization of medicines, as well as supportive functions such as regulation, operational research, and training. Over the period 2006–2012, the density of pharmacists has increased substantially in many low-income countries, but their baseline remains low compared with those of high-income countries [49]. Pharmacy workforce capacity varies considerably between countries and regions and generally correlates with population- and country-level economic indicators. Countries and territories with lower economic indicators tend to have fewer pharmacists and pharmacy technicians, which has implications for inequalities regarding access to medicines and medicine expertise.

7.5.6 Lack of Good Pharmacy Practice

There is increasing recognition that providing consumers with medicines alone is not sufficient to achieve treatment goals. To address medication-related needs, pharmacists should accept greater responsibility for the outcomes of medicines use. Pharmacy practice is evolving to provide patients with enhanced medicines-use services. Good pharmacy practice is the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care [50]. Remuneration of pharmaceutical services is a challenge to achieving good pharmacy practice [51].

7.5.7 Insufficient Understanding of Intellectual Property Protection and Innovation Processes

The current patent protection system under the auspices of the World Trade Organization (WTO) has introduced enhanced global minimum standards for intellectual property protection. The WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement has a significant impact on the pharmaceutical sector, and more specifically on medicine prices, and may hamper access to medicines by the poor [52]. Policymakers may sometimes lack a clear understanding of the innovation processes that lead to new technologies and the ways in which these technologies are monopolized and disseminated, which may hinder innovation and equitable access to vital medical technologies. Furthermore, the complex interplay between the distinct policy domains of health, trade, and intellectual property, and of how they affect medical innovation and access to medical technologies, requires a clear understanding, inter-ministerial collaboration, and expertise at the national level in L&MICs [13].

TRIPS flexibilities, including compulsory licensing, are inbuilt public health safeguards that have been further enhanced and affirmed through the Doha Declaration on TRIPS and Public Health and multilateral developments since 1995, and will remain valid until 2033. To maximize the benefits that can be accrued though the use of these flexibilities, a precondition is to have these incorporated in the national legislation, which unfortunately is still not the case in many L&MICs [53]. Box 7.7 defines some of the key related terms.

In light of the high cost of innovative health products, health technology assessment (see Chapter 13) is used by some countries for the systematic evaluation of properties, effects, and/or impacts of health technology, to inform policymaking and selection of health products.

Box 7.7 Key Definitions: Innovations and Intellectual Property

Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of their creation for a certain period of time [54].

Compulsory licensing is the practice of authorizing a third party to make, use, or sell a patented invention without the patentee's consent [55].

Parallel import refers to genuine products first put on the market in another country and imported through a channel parallel to the one authorized by the rights holder [13].

7.6 Conclusions

The capacity of many L&MICs to assess and approve health products remains limited, due to inadequate resources, overburdened staff, and incoherent policy frameworks. Innovative strategic approaches are needed globally to increase harmonization among countries and encourage regulatory recognition and reliance. At the time of writing, the COVID-19 pandemic presents a major threat to public health and our way of life. One of the main challenges has been ensuring access to important health products, including treatments, vaccines, personal protective equipment, *in-vitro* diagnostics, and others. The pandemic has highlighted that in both rich and poor countries the pharmaceutical systems may not be fully integrated into health systems or adequately prepared to respond. Stakeholders should continue to collaborate at global and national levels to strengthen pharmaceutical systems and increase preparedness for delivering health technologies where needed in a timely manner.

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