Improving access to safe and quality essential medicines and medical devices

The role of pharmacy

2024

International Pharmaceutical Federation

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Contents

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Executive summary

The right to health is a fundamental human right of every individual to enjoy the highest attainable standard of physical and mental health, regardless of any socioeconomic, demographic and health identifiers. Universal health coverage is an imperative goal that hinges on the realisation of equitable and affordable access to safe, effective, and quality medicines and medical devices for all.

Access to essential medicines and medical devices is vital for managing health conditions, preventing diseases, and improving well-being. These medicines and devices are considered essential for addressing public health priorities as timely access can be life-saving, and without them, health disparities worsen. While essential medicines lists do not encompass all medications, they serve as a foundation for promoting equitable access to healthcare and addressing the most pressing health needs within a population.

During the COVID-19 pandemic, challenges around equitable access increased, exacerbated by disruptions in the supply and competition for resources, disproportionately affecting vulnerable populations. These challenges include political and regulatory variations, marketing decisions, and supply chain disruptions that contribute to disparities in healthcare outcomes globally, necessitating international collaboration and regulatory harmonisation to improve access.

In this context, the International Pharmaceutical Federation (FIP) aligned its development goals with the Sustainable Development Goals (SDGs) of the United Nations (UN), which assert health as a fundamental human right. FIP Development Goal (DG) 18 (Access to Medicines, Devices and Services) sets out clear strategies to widen access to medicines, devices, and services. This reference document aims to strengthen collaboration among healthcare professionals, patients, policy makers, and other health stakeholders to improve access and address issues in access such as medicine affordability, availability, quality and safety.

Specifically, it aims to provide a comprehensive overview of the important contributions that pharmacists, pharmaceutical scientists and educators can make in ensuring availability, affordability, and appropriate use of safe and quality essential medicines and medical devices. Pharmacists, as the most accessible healthcare professionals, can help to ensure global access to essential medicines. For instance, pharmacists play an integral role in improving the affordability and availability of medicines. They ensure uninterrupted medicine supply and collaborate with healthcare providers for optimal usage. They can monitor shortages, advice on suitable alternatives and ultimately alert authorities to shortages, price changes, or supply chain issues and advocate for patients by assisting them in navigating healthcare systems, understanding their rights, and accessing support programmes for affordable medication. Pharmacists are also critical in ensuring access to safe and quality medicines by detecting medication interactions and allergies, educating patients on proper medication usage, and managing waste disposal to mitigate environmental risks and enhance the efficacy of medicines.

In addition, pharmacists implement strategies for safe and optimal medicine use, actively monitoring patients, engaging in proactive discussions, contributing to antimicrobial stewardship and deprescribing, improving transitions of care, conducting medication reconciliation, participating in education campaigns, and ensuring evidence-based information dissemination for patient-centred care and positive health outcomes. For example, in antimicrobial resistance pharmacists can ensure the use of correct protocols and guidelines, sequencing of agents and sparing agents for alternative lines of therapy and therefore ensure safe access to medicines at each stage of the disease as needed.

However, there is a significant disparity in pharmacy workforce between low- and high-income countries, underscoring the need for targeted initiatives to bridge this gap.[1] FIP DG 18 which aims to create a competent, agile, and well-distributed workforce aligns with the imperative to address these imbalances and maximise the impact of pharmacists in enhancing healthcare accessibility globally. Various barriers, including under-resourced healthcare systems, regulatory challenges, and the conflict between intellectual property rights and the right to health, hinder progress towards equitable access to medicines. Also, in light of the latest technological developments, it is important that pharmacists can use appropriate digital tools and participate in initiatives that improve access in geographically or otherwise isolated communities.

Pharmacy organisations play a crucial role in advocating for improved policies, with pharmacists leveraging their expertise to contribute to enhancing access globally, striving towards equitable healthcare for all. Moreover, they support policy implementation. Through active engagement with stakeholders and collaboration across sectors, pharmacists make substantial contributions towards addressing disparities in access and advancing the objective of universal health coverage.

This document outlines the importance of access to essential medicines and medical devices, the role of pharmacists, as well as the role of FIP in improving access and addressing the challenges and issues that exist around it.

1 Introduction

1.1. Access to essential medicines and medical devices as an imperative for promoting health

1.1.1 Access: Key to the sustainable development of nations

"The right to the highest attainable standard of health" is one of a set of internationally agreed human rights standards.[2] This right underscores the importance of ensuring that healthcare, including the access to safe, effective, quality, and affordable essential medicines and medical devices, is not just a privilege but an entitlement that governments and international bodies are obligated to uphold. Furthermore, it implies a clear set of legal obligations on states to ensure appropriate conditions for the enjoyment of health for all people. The right to health is a fundamental human right recognised in the Universal Declaration of Human Rights (UDHR)[3] and the International Convention for Economic and Social Rights (ICESR).[4] Since then, many other frameworks address the right to health. All UN Member States have ratified at least one treaty recognising health as a human right, in all regions.[2]

In an increasingly interconnected world, ensuring that people have timely and affordable access to essential medicines and medical devices with proven outcomes is pivotal to promoting health, reducing inequalities, and fostering economic growth. Enhancing access to medicines and medical devices stands at the nexus of health and sustainable development, offering profound benefits for individuals, communities, and societies at large. Improving access has surged to the forefront of global priorities, capturing the attention of governments, international organisations such as the World Health Organization (WHO), and others.[5] Multiple reports and initiatives have been launched by decision-makers, encompassing both legislative and soft-law processes. Furthermore, the matter has found its place on the agenda of the World Trade Organization (WTO), emphasising its global relevance.[6]

The realisation of access to essential medicines and medical devices stands as a crucial bridge between the foundational principles of human rights and the global aspirations as outlined by the United Nations (UN) and Member States in a joint mission of achieving the Sustainable Development Goals (SDGs) as set out in the 2030 Agenda.[7] Under its theme, ''Leave No One Behind'', the SDGs call for action from all countries to bring peace, prosperity, and a world free from poverty, hunger, and disease.

Namely, SDG 3 aims to ensure healthy lives and promote well-being for all at all ages. The goal and related targets touch on access to medicines as a crucial component for sustainable development. Specifically, the relevant target within SDG 3 is target 3.8: "Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all." This target highlights the importance of not only ensuring access to essential medicines but also making them affordable and of high quality.

The COVID-19 pandemic, the migration crisis, and ongoing global conflicts and natural disasters have all served as stark reminders that equitable access to medicines is under formidable threat, challenging healthcare systems worldwide. The urgency to address this issue has never been more evident, and concerted efforts on both national and international levels are required to ensure that essential medicines reach those in need.

1.1.2 Access: Integral to achieving universal health coverage

Universal health coverage (UHC), which includes access to medicines, is seen as a fundamental driver of sustainable development because it contributes to healthier populations, economic productivity, poverty reduction, and reduced inequalities.[8] It aims to ensure that all individuals and communities can access essential healthcare services without suffering financial hardship. The fundamental principle of UHC is to provide equitable access to high quality healthcare services, including prevention, promotion, treatment, rehabilitation, and palliative care, without discrimination or exclusion based on financial or social status.[9] Improving lives through access to medicines and medical devices is

integral to achieving UHC. It ensures that healthcare services are comprehensive, equitable, financially protective, and sustainable, all of which are key objectives of UHC. To advance UHC goals, policy makers and healthcare stakeholders must prioritise not only access to healthcare services but also access to the essential tools for diagnosis, prevention, and treatment, such as medicines and medical devices.

The WHO maintains a list of essential medicines that address the most prevalent health needs within populations. The WHO Model Lists of Essential Medicines are updated every two years by the Expert Committee on Selection and Use of Essential Medicines. The list includes medications considered essential for addressing public health priorities, such as treating common diseases, preventing epidemics, and improving overall health outcomes. By focusing on essential medicines and devices, countries can allocate resources more efficiently, ensuring that limited healthcare budgets are directed towards medications that provide the greatest public health benefit. Additionally, maintaining a list helps streamline procurement processes, facilitates medication availability, and promotes rational prescribing practices. While essential medicines lists do not encompass all medications, they serve as a foundation for promoting equitable access to healthcare and addressing the most pressing health needs within a population.[10]

In 2015, 193 countries committed to achieving UHC as part of the third UN 2030 Sustainable Development Goal (SDG), aiming to fulfil this right to health globally. The WHO defines UHC as "all people [having] access to the full range of quality health services they need, when and where they need them, without financial hardship".[9] UHC and access to quality healthcare are at the core of SDG 3. Achieving this goal requires universal access to health services, particularly the skilled workers who provide them and the resources they need to do so.

The United Nations use the UHC service coverage index, an index for essential health services, for comparison. This index estimates coverage of essential health services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, noncommunicable diseases and service capacity.[11] The index is presented on a scale of 0 to 100. From 2000 to 2019, the UHC index increased from 45 to 67 out of 100.[12] This change represents a significant increase in access to medicines, devices and services, yet there is still room for improvement.

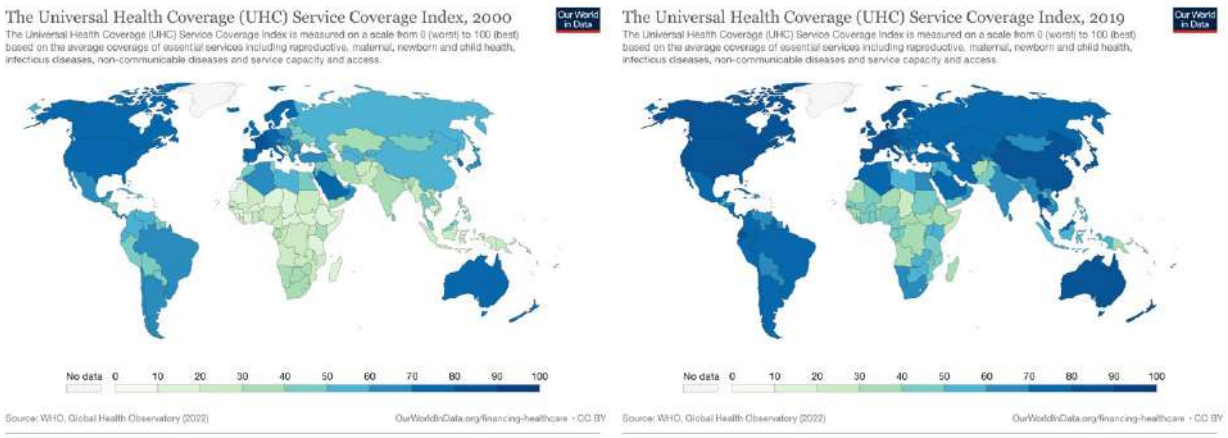

Figure 1. UHC Service Coverage Index from 2000-2019. Reprinted from OurWorldInData.Org (2022)

UHC index from 2000 to 2019

The image above shows the global progress on the UHC index from 2000 to 2019[13]; the darker the blue colour, the higher the UHC index. The progress made is clear, with the Americas, Europe, Northern Asia and Oceania having now close to universal access to healthcare. Much of Central Africa, the Western Pacific and South East Asia has, despite making progress, maintained issues with achieving high healthcare coverage.

In 2019, the WHO launched its five-year strategic plan – the 13th General Programme of Work. This plan focused on a triple billion target: ensuring one billion more people benefit from access to universal health coverage, one billion more people are protected from health emergencies and one billion more people enjoy better health and well-being. They

acknowledged that reaching this goal required addressing the threats to health from a variety of angles and they highlighted 10 of the many issues that (at that time) demanded attention from WHO and health partners in 2019. In spite of the increase of the index, 30% (2 billion people) of the world's population still cannot access essential health services.[9]

There are many areas that require improvement. Firstly, a critical aspect of achieving UHC is ensuring a robust health workforce capable of delivering essential services. Policy makers should focus on not only increasing the number of healthcare professionals but also improving their training and distribution. In many LMICs, there is a shortage of skilled healthcare workers, particularly in rural areas. Investing in education and training programmes, as well as implementing incentives for practitioners in low-resource regions, can significantly bolster the health workforce. Initiatives that educate communities about basic health practices, disease prevention, and the importance of regular check-ups can contribute to a healthier population. Secondly, expensive patented medicines may pose a financial barrier to individuals and healthcare systems. Policies promoting generic alternatives, negotiating fair pricing with pharmaceutical companies, while accounting for the intellectual property issues, can contribute to making essential medicines more affordable and accessible. Thirdly, in the era of advancing technology, integrating digital solutions into healthcare can enhance access, especially in remote areas. And finally, implementing data collection systems to monitor the UHC service coverage index in real-time allows policy makers to make informed decisions. Regular evaluations can identify disparities and guide adjustments in healthcare strategies.

2 Challenges hindering access

In recent years, the introduction of new medicines and treatments has exponentially increased the ability to handle and treat major diseases. According to the World Health Organization (WHO), between 1975 and 2000, the world consumption of pharmaceutical products increased drastically from US$70 billion to US$317 billion, with a consumption of medicines per capita growing from US$17 to US$53. Regardless of the increase in world consumption, more than 80% of all pharmaceutical products are consumed by 15% of the world population located in high-income countries.[14] A study from the Lancet Commission estimated that currently between US$77.4 and US$151.9 billion per year (or $13 to $25 per capita per year) is needed to provide a basic package of 201 essential medicines for all low- and middle-income countries (LMICs).[15]

However, in 2010, the majority of low-income countries (LICs) and 13 out of 47 middle-income countries (one in five countries worldwide), spent less than $13 per capita on pharmaceuticals, with LICs spending an average of US$8.6 per person annually.[14] Most of this funding comes from individuals and households with limited means. This confirms that many people worldwide do not have access to even a limited basket of essential medicines; yet, simultaneously, the world spends at least eight times this amount on medicines. The variation in access to essential medicines may not be solely attributed to individuals lacking access; other factors may play a role. Differences in disease patterns, with a higher prevalence of chronic conditions in high-income countries, could result in increased medication use. Moreover, the presence of an aging population, more prominent in high-income countries, and the prevalence of direct-to-consumer marketing practices in those regions could contribute to observed differences. Better health literacy, and access to screening services in the high-income countries invariably leads to early disease detection and the consumption of medical products over longer periods and across multiple lines of treatment than in LMIC countries (for example in cancer treatment).

There are massive inequities and inefficiencies in financing and governance, linked to an unequal distribution of pharmaceutical consumption across the world. Currently, it is estimated that one-third of the world's people (up to 50% in some regions of Asia and Africa) are unable to receive or purchase essential medicines on a regular basis.[14] Accordingly, more than two billion people in LMICs lack adequate access to essential medicines.[16] The problem is complex and the reasons for this range from high costs to inadequate distribution, with differing views of stakeholder responsibilities to solve it.

During the COVID-19 pandemic, ninety percent of countries reported disruptions to essential health services, according to the Sustainable Development Goals Report 2021.[17] Furthermore, people in vulnerable health and socio-economic circumstances have been impacted disproportionally in recent years.

2.1 Policy environment and access

Assured access to essential and high-quality medicines occurs when there is:[18]

- a public and private sector commitment
- effective and transparent medicine policies, and suitable implementation[14]
- strong and resilient health systems and regulatory authorities
- adequate public financing, and human resources and controls
- efficient supply chain and distribution systems
- Investment in measures to increase health literacy and the ability of patients to self-care
- control on taxes and duties
- ethical promotion and rational use of medicines, as well as control of their quality and safety.

This complex set of activities requires cooperation between governments, intergovernmental and multilateral organisations, NGOs, private sector companies, and academia, amongst others. To implement measures positively and

seek both to remove old obstacles and create new opportunities, the different stakeholders have different roles to play, and their contribution will only be effective if they all work together towards the same goals.

Over the last few decades, strengthened disease management goals from WHO has generated global health partnerships, bringing together the United Nations, national and local governments, universities and philanthropic efforts from organisations and foundations such as the Bill & Melinda Gates Foundation, which has led to significant milestones in the funding, treatment of, and research into the main diseases in LMICs, including HIV/AIDS, malaria and tuberculosis, non-communicable diseases (NCDs) and neglected tropical diseases (NTDs), as well as cross-cutting challenges like women and children's health. Many pharmaceutical companies have embraced this and have become increasingly engaged in access to medicines (ATM) initiatives in LMICs through actions such as improvement of access strategies for existing products and publishing access plans for research and development projects. However, while the 2016 Access to Medicines Index[19] found progress in companies' efforts to improve access in LMICs, it also evidences that their "good practice in making products available and affordable is limited", without consistently targeting the "populations with highest needs in their registration, pricing and licensing actions".

Furthermore, real change requires a shift in the global supply chain towards innovative and sustainable business models, where patient needs, disease priorities, barriers to access, and access behaviours are considered in the decision-making process. Involving a well informed and health literate civil society in the decision-making process can provide clearer insights on their needs and ways to improve their access to healthcare in general.

In the interests of protecting public health, before a medicine is allowed to be sold it needs to be scientifically assessed to determine whether it is sufficiently safe and effective. Only when regulators find this to be the case can a pharmaceutical company obtain a marketing authorisation. However, even once the medicine is authorised for sale, it is not guaranteed that all patients in need of that medicine will immediately have access to it. Access will depend on various factors, including the ability of pharmaceutical companies to market the medicine cost-effectively in a specific country, the willingness of the national health system or insurance company to provide reimbursement, the availability of the medicine on the shelf at local pharmacies when needed, and the patient's ability to afford any costs not covered by the health and insurance systems. The figure below shows some of the main factors that can influence access to medicines, highlighting at what level their impact can be felt.

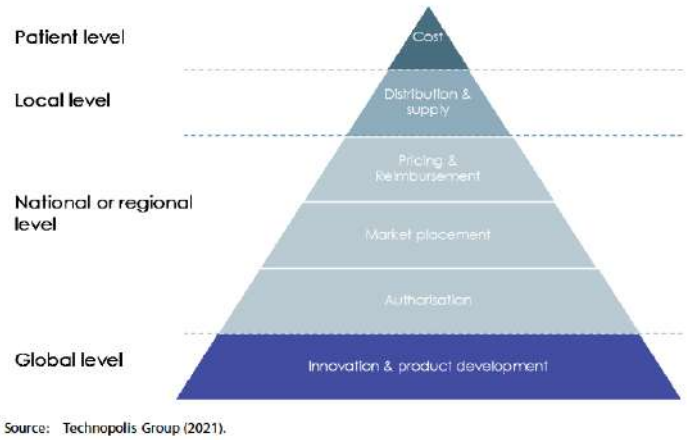

Figure 2. Factors affecting access to medicine at different levels.
Reprinted from de Jongh, T., Velten, L., Schrijver, L., Access to medicinal products, Study for the committee on Environment, Public Health and Food Safety, Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg, 2021

The ability of pharmaceutical companies to cost-effectively market their medicine in a manner that safeguards their rights and shares the costs fairly can influence access to medicines, among many other factors. The availability of medicines in a certain country can depend on whether the marketing authorisation holder chooses to market them there or not, which in turn is heavily influenced by national pricing and other policies.[19]

In addition to this, marketing authorisation and representatives are responsible for ensuring an adequate and uninterrupted supply chain, within the scope of their respective responsibilities. This includes supplying medicinal products to authorised individuals or entities involved in dispensing, with the aim of meeting the needs of patients. This obligation may or may not be determined by the regulations of the country or region but remains an ethical duty. At the same time, regulatory authorities encourage the harmonisation and/or mutual recognition of marketing authorisation procedures at a regional level but also adjustments or modifications in approval procedures. During the marketing of health products, marketing authorisation holders or their representatives must ensure security of supply and address shortages through specific measures including, for example, obligations on marketing authorisation holders to notify regulators on potential or actual shortages and marketing withdrawals, cessations and suspensions in advance.

Using an example from one of the regions, the European Parliament states that access to medicines is highly regulated.[19] Reducing numerous barriers to medicines access stands as a paramount goal for policy makers throughout the European Union. In 2017, the European Parliament proposed a resolution presenting 58 recommendations designed to enhance access to medicines. These recommendations were intended for the consideration of the European Commission and its Member States. The suggested actions span a spectrum of policy areas, encompassing initiatives to foster competitive and equitable pharmaceutical markets, efforts to channel greater pharmaceutical innovation towards unmet needs, and the promotion of heightened coordination among Member States to align policies. Furthermore, in 2022, the European Medicines Agency (EMA) established its Executive Steering Group on Shortages and Safety of Medicinal Products to ensure a robust response to medicine supply issues caused by major events or public health emergencies. It coordinates urgent actions within the EU to manage medicines supply issues and issues related to the quality, safety and efficacy of medicines. It was in accordance with the Regulation (EU) 2022/123) on EMA's Reinforced Role in crisis preparedness and management for medicinal products and medical devices; however, the work on reducing medicine shortages will likely continue beyond crisis situations with planned coordinating activities that aim to prevent shortages or mitigate their effects.

It is crucial to note that regulations may lead to variations in access to medicines both within the country and globally. Every country is individually responsible for the provision of healthcare to its own citizens, and countries differ in how they manage the factors listed in the figure above.

One significant consequence is the divergence in the speed and extent of access to pharmaceuticals between low-, middle-, and high-income countries. This could be due to the need for additional data for specific populations, the comparisons against local standards of care, or national pricing policies that directly influence the decisions of pharmaceutical companies. These factors could affect when a particular medical product will reach patients in a particular geography. Countries with more open regulations, less pricing pressures and larger markets typically get quicker and more extensive access to innovative medicines.

Conversely, it is not necessarily the innovative medicines that have the largest contribution to the disparities in access to medicines. Often, the biggest disparities in health outcomes are due to the differences in access to well-established, essential medicines. The lack of incentives for the production of these generic medicines lead to only a small number of producers who provide the worldwide supply, presenting a clear health security gap, with many nations experiencing delays or limited access to essential medicines, thus exacerbating health inequalities. Shortages of such medicines have recently impacted both developed and developing countries, with examples of basic antibiotic shortages in markets such as Germany and the Netherlands at all-time highs within the last year.

On a global scale, regulatory disparities contribute to differences in healthcare outcomes, highlighting the urgent need for international collaboration to harmonise regulatory frameworks, fostering a more inclusive and accessible healthcare landscape for populations worldwide.

Countries also differ in their approaches to reimbursement of medicines. Increasingly, countries evaluate new medicines on their value for money before deciding whether they should be paid for from national healthcare budgets. As the assessment criteria for this varies between countries, the same medicine can be reimbursed in one country but not in another. Also, the time taken for this decision-making can vary substantially.[20–22]

Even when medicines are marketed and reimbursed in a country, patients could still experience instances where they are not able to get their medicine because of problems in the distribution and supply chain. Although medicines shortages are a growing problem globally, not all countries are equally affected. Availability can be influenced by variations in how countries deal with the risk of shortages, such as by imposing national supply obligations on manufacturers or export bans on specific medicines.

When patients require medication, they typically rely on either a doctor or pharmacist to prescribe it, a process crucial for ensuring proper treatment. However, if access to healthcare professionals is restricted, it inevitably leads to restricted access to essential medicines. Therefore, efforts to improve healthcare accessibility must encompass not only medication availability but also the availability of trained professionals to provide necessary care.

The final hurdle that needs to be overcome before a patient can obtain their medicine is that of cost to the patient. Even if a medicine is mostly reimbursed by the health system or insurance company, patients may still have to cover part of the cost themselves, for instance through co-payments or because their insurance plan has a deductible. If these residual costs are too high, patients may still be unable to access the medicine for financial reasons. The direct costs to patients may vary according to a country's insurance policies and insurance plans.[19]

2.2 Attributes of medicines restricting access

Medicine refers to any substance used in the treatment of illness or injury, and is the most common form of intervention in healthcare.[23] Its significance lies not only in the capacity to address specific health conditions but also in the broader context of public health and well-being. Beyond the conventional view of medicines solely as remedies, they are integral to preventive care, chronic disease management, and overall health maintenance. However, challenges persist in ensuring equitable access to medicines on a global scale. These challenges are rooted in various factors, particularly (although not exclusively) to the following attributes:[24]

- Formulation: Medicines are meant to be taken or used by individuals to treat or manage health conditions. They are designed to be consumed in various forms, such as tablets, capsules, liquids, injections, or topical applications.
- Diversity of use: Medicines encompass a wide range of substances, formulations, and purposes. They can be tailored to treat various health conditions, including physical ailments, mental disorders, infections, and chronic diseases. This diversity reflects the complexity of medical needs across populations.
- Restrictions in access and use: Many medicines are subject to legal and regulatory restrictions. Some medicines, especially those with the potential for abuse or misuse, may be tightly controlled. Governments and health authorities often classify these medicines as prescription-only or controlled substances, limiting their availability without a healthcare provider's authorisation. This control is intended to prevent improper use, safeguard patient safety, and manage public health risks.
- Requirement for healthcare professionals to prescribe: Medicines are frequently required to be prescribed by a qualified healthcare professional. This practice ensures that patients receive appropriate treatment based on their specific health condition, medical history, and other factors. The prescription process involves a healthcare professional's evaluation of the patient's needs, and the chosen medicine is tailored to their individual requirements. This medical oversight helps minimise the risks associated with incorrect self-diagnosis and self-medication, ultimately promoting better health outcomes. However, at the same time, since most medicines will require a prescription, patients will need to see a physician first before getting a prescription and the medicine. The healthcare professional has control over whether to prescribe the medicine or not.
- Complexity of use: Medicines require a certain level of health literacy and the ability to self care in order to use them properly and effectively.

- Potentially dangerous: Medicines, while intended to provide therapeutic benefits, can also pose risks if not used correctly. Incorrect dosages, interactions with other medications, or allergic reactions can lead to adverse effects. Therefore, proper usage and medical guidance are crucial.
- Good Manufacturing Process (GMP): The production of medicines often involves complex processes and precise manufacturing techniques. Developing and producing medicines require specialised knowledge, equipment, and quality control measures to ensure their effectiveness and safety.
- Good Distribution Process (GDP): Many medicines are sensitive to environmental factors such as temperature, humidity, and light. Proper storage conditions are essential to maintain the stability and effectiveness of medications over time. Inadequate storage can lead to degradation and reduced potency.
- Costs: Research, development, testing, and regulatory approval processes contribute to the costs associated with creating new medicines. Additionally, the ongoing production, quality control, and distribution expenses can make medicines relatively costly, which can impact their accessibility, particularly for individuals with limited financial resources.

Further challenges include the structure of healthcare systems, financial support mechanisms, and the focus of healthcare services. Firstly, as highlighted in the previous chapter, differences in health systems among countries can lead to disparities in accessing pharmaceutical services. Secondly, variations in financial systems to support healthcare can affect affordability and availability of medications. Additionally, the emphasis on preventive and promotive care over curative, rehabilitative, and palliative care may impact the prioritisation of pharmaceutical services. Moreover, meeting specific religious or social needs, such as the demand for halal pharmaceuticals, adds another layer of complexity to accessing medicines.

Considering these key features is important when addressing the accessibility of medicines. Ensuring that medicines are affordable, properly manufactured, stored, and used safely is crucial for making healthcare treatments widely available to individuals in need.

2.3 Attributes of medical devices restricting access

Medical devices are defined by the WHO as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.[25] Examples of simple devices include blood pressure monitors, condoms, pregnancy tests and wheelchairs. These are often simpler to manufacture, have a lower risk of misuse and are often easier to transport. Additionally, in many cases a medical professional is not required for use of the device, such as in the case of a wheelchair, although information may be needed. However, they are not without their own challenges when it comes to accessibility. Medical devices, while offering unique advantages, also present certain complexities that impact their availability and utilisation:[24,26]

- Regulatory barriers in accessibility: Factors such as cost, lack of uniformity of regulatory requirements, and distribution networks can limit the reach of medical devices, particularly in resource-constrained regions or underserved communities. Accessibility concerns may arise from disparities in healthcare infrastructure and technological capabilities, hindering the equitable distribution of medical devices.
- Variability in quality and standards: Unlike standardised pharmaceuticals, medical devices can vary significantly in terms of quality, safety, and performance. Ensuring that medical devices adhere to rigorous standards and regulations is essential to prevent substandard or unsafe products from entering the market. This variability in quality can impact user trust and confidence in these devices, affecting their overall accessibility and adoption.
- Maintenance: While many medical devices are reusable and often simpler to manufacture, they still require proper maintenance and training for effective and safe use. Without adequate training and support, users may not fully benefit from these devices, potentially leading to improper handling, reduced device lifespan, or even safety hazards. Addressing these maintenance and training needs is crucial to maximising the accessibility and impact of medical devices.
- Training and addressing specific needs: Medical devices are designed to cater to a wide range of medical requirements, from mobility aids like wheelchairs to diagnostic tools and assistive technologies. While certain

devices may not require direct oversight from a healthcare professional, ensuring that users receive accurate information and guidance on proper usage is essential for achieving the desired health outcomes.

- Human resources: Medical services require the presence of a trained medical professional and can be defined as any service related to the care, treatment or prevention of illness, injury or dysfunction of the human body. These may include dental, vision, mental health and pharmacy among many others. Challenges to increasing access relate to the number of medical professionals, insufficient skills or equipment to provide services and potentially the absence of technology which could provide services without the help of a professional.

Other challenges concern the diverse forms and types of devices, ranging from screening tools to treatment equipment. Furthermore, distinct regulatory frameworks govern pharmaceuticals and medical devices, each with its own set of laws and definitions, which can complicate access to these services. Understanding the precise definitions and classifications of medical devices is essential for navigating regulatory requirements and ensuring proper access.

While medical devices differ from medicines in the above points, there are still difficulties in terms of accessibility. Overcoming challenges related to cost, quality, training, and tailored support is crucial to ensuring that medical devices effectively contribute to improved healthcare outcomes for individuals across diverse settings. These challenges underscore the need for comprehensive strategies to address the complexities of accessing medical devices and promote equitable healthcare delivery.

3 FIP's work on access

3.1 Progress since the first FIP policy statement on access

In 2005, FIP released a statement of policy on improving access to medicines in developing countries.[27] The statement highlighted significant issues in low- and middle- income countries at the time. This included the impact of tuberculosis, malaria and HIV/AIDS. The maps below[28–30] show the progress which has been made since 2005 according to WHO reports; although these diseases are still having a large impact on lives in LIC and LMIC countries, significant progress has been made.

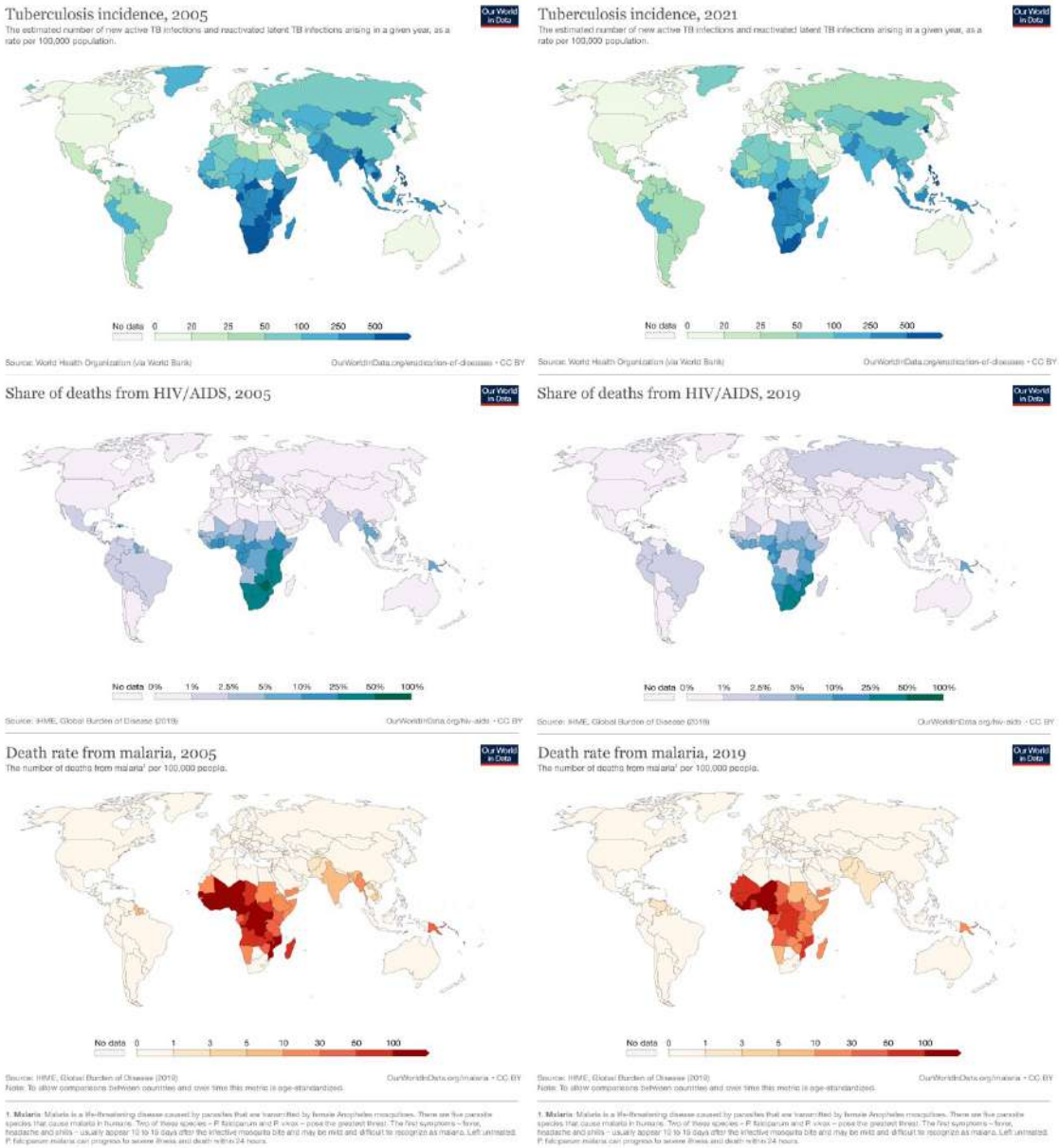

Figure 3. Progress in combatting diseases in low and lower-middle income countries. Reprinted from OurWorldInData.Org (2022)

Despite this positive change, it is crucial that systems and structures continue to develop to provide all nations, particularly LMICs, with the infrastructure and resources needed to tackle these health challenges. The statement remains relevant, however, as global healthcare needs are changing. Emerging diseases such as COVID-19 require different pharmaceutical actions, and global crises such as climate change shift policy focus. For this reason, the statement must be updated to apply to current challenges.

The focus of the 2005 statement on low-middle income countries also no longer aligns with the FIP's objectives, set out in the FIP Development Goals. This updated report expands the scope of FIP's policy statement, relating not only to LMICs but to all countries, and prepares the background information for the production of a statement.

This development will not take away from the focus on providing equal access to safe and effective medicines, devices and services in LMICs, but will add a new focus towards the modern challenges faced by higher income countries, such as the disruption of supply chains caused by multiple factors including inter alia, quality and manufacturing issues, market-related factors, and consolidation of manufacturing in very limited number of production sites. This change is intended to align with FIP Development Goal 18 (Improving access to medicines, medical devices and services).

This change also addresses issues with access in high income countries, where access to medicines, devices and services is, in some cases, restricted. In 2017, it was found that one in four people in the US have trouble affording their prescription medicines[31] and in the UK in 2019, a survey across 402 community pharmacy professionals reported that shortages had been experienced in all 36 categories of medicine.[32] Additionally, in Japan, investigations into manufacturing of generic medicines have found multiple violations of Good Manufacturing Practice (GMP), highlighting a greater need for regulation and monitoring in Japan's pharmaceutical supply chain.[33] Lastly, a European Parliament statement has revealed that, between 2000 and 2018, the number of medicines shortages has increased 20-fold.[34] It is therefore important to acknowledge that, although their problems vary in source and scale, high income countries must also improve their pharmaceutical systems and structures to improve access to medicines, devices, and services.

In order to fully align with FIP DG 18, the 2005 statement will also be updated to consider access not only to medicines, but also to devices and related pharmaceutical services. Medical devices, such as condoms, pregnancy tests and other forms of disease testing play a significant and increasing role in healthcare; allowing people greater control over, and knowledge about, their bodies, which in turn may enable better data and understanding of populations.[25] The new focus on services reflects the expansion of the role of pharmacists. Increasingly, pharmacists are involved in more patient-centred care;[35] this involves providing advice on the use of medicines, as well as providing vaccinations and potentially offering diagnostics.

To summarise, the FIP statement from 2005 covering access to medicines in low- and middle- income countries must be revised. This new reference document will cover access across the globe to all medicines, devices and services, and the ways in which pharmacy has a role to play in enhancing access.

FIP workstream	Additional information is available through the FIP workstream on this topic
Sustainability	FIP workstream on Sustainability Sustainability in pharmacy seeks to increase long-term access to essential medications while minimising any environmental impact. Sustainable approaches help maintain the affordability and availability of medications, particularly in resource-limited settings, and this helps to ensure that people can access their treatments. FIP's work on sustainability can be found on the FIP SustainabilityRx dedicated micro-site. SustainabilityRx is FIP's programme of work that supports the progress and implementation of FIP Development Goal 21 (Sustainability in pharmacy). The programme consists of three main areas of work: economic, environmental, and social sustainability. Sustainability as a concept is ingrained in global development, emphasising the importance of DG21 Sustainability in pharmacy.

3.2 FIP Development Goal 18

FIP aims to improve access to medicines, devices and services as set out in FIP Development Goal 18 (FIP DG 18). The development goal aims to put strategies in place to widen access to medicines and services through a responsive, capable, available and well-distributed pharmaceutical workforce. The goal is also focused on advocacy and contribution to the development and implementation of policies and initiatives addressing affordability and fair pricing of medicines, medical products and devices, and services that aim to ensure equitable access for all, and especially for fragile and vulnerable communities, as well as access to specialised and innovative therapies.[36] This goal is supported by the World Health Organization (WHO) which states that "Universal health coverage can only be achieved when there is affordable access to safe, effective and quality medicines and health products".[25]

FIP workstream	Additional information is available through the FIP workstream on this topic
The FIP Development Goal 18 	FIP workstream on FIP Development Goals Since its launch in 2020, the FIP Development Goals (DGs) programme of work focuses on supporting our members with implementation globally, regionally and locally. The FIP DGs are set to transform pharmacy in alignment with wider global imperatives underpinning the UN Sustainable Development Goals. The DGs can be used as a framework to inform strategic planning and to monitor progress over time, enabled by FIP's Global Pharmaceutical Observatory. They align with FIP's mission to support global health by enabling the advancement of pharmaceutical practice, sciences and education, and are a key resource for transforming the pharmacy profession over the next decade globally, regionally and nationally. Click here for more information on FIP DGs and FIP DG 18.

FIP divides FIP DG 18 into three further areas for improvement: workforce, practice and science. These focus on the people providing access, the systems and structures in place which affect access, and the potential for science to impact access respectively.

The FIP Development Goals Report 2021 provides a snapshot of the areas most deprived of access.[37] FIP member organisations, through their Regional Forums, were surveyed to prioritise the DGs based on their needs. The results of this survey show that globally, out of three tiers of priority to choose from, FIP DG 18 was a "second level" priority goal. Only eight of 21 development goals took a higher priority, including academic capacity, patient safety and sustainability in pharmacy. This report suggests that, on average, insufficient access to medicines, devices and services is important for pharmacy. However, there are disparities: while the Americas, the Eastern Mediterranean region and Europe allocated it as a third level priority goal, it was allocated as a second level priority goal in Southeast Asia and the Western Pacific and a first level priority goal in Africa. These findings complement the results from the UHC index above. The specific countries which assigned access as one of their greatest issues were Algeria, Nigeria, Iceland, Malta, India, Korea, and Malaysia. It should also be noted that this report used data from 49 countries, and as such may not be representative of all countries.

Pharmacists, as the most accessible healthcare professionals, are well positioned to ensure access to essential medicines and medical devices around the globe.[37] In 2017, the median number of pharmacists per 10,000 population was 5.09 globally. There was, however, a significant disparity in this figure between low- and high-income countries, with 0.6 and 7.61 pharmacists per 10,000 people respectively.[38] This disparity underscores the critical need to address discrepancies for improved global access to healthcare. Efforts to address this imbalance should include initiatives to increase pharmacist numbers in underserved regions and to promote collaborative approaches to maximise their impact in healthcare accessibility. This is aligned with FIP DG18's goal to put strategies in place in order to widen access to medicines and services through a responsive, capable, available and well-distributed workforce.[39]

While this reference document leverages on SDG 3.8 as a wider goal, it also aligns to complement with the goals of FIP DG 18. By integrating these diverse perspectives, the document endeavours to provide pharmacists with a comprehensive understanding of how their professional endeavours contribute to both the broader SDG agenda and the specific objectives outlined within FIP DG 18.

3.3 Scope and limitations

This reference document elaborates on the pharmacist's role in access to safe and quality essential medicines and medical devices. It aims to provide a comprehensive overview of the different contributions pharmacists make in ensuring availability, affordability, and appropriate use of safe and quality essential medicines and medical devices. Specifically, it aims to:

- enhance collaboration among stakeholders and healthcare providers to improve access and address issues in access such as medicine affordability, availability, quality and safety;
- empower pharmacists, policy makers, and healthcare stakeholders with actionable insights to enhance the pharmacist's impact on public health; and,
- establish the importance of the pharmacist's role in maintaining and assuring the quality of essential medicines throughout various stages of the supply chain.

Through an examination of successful models and case studies, the document seeks to empower pharmacists, policy makers, and healthcare stakeholders with actionable insights to enhance the pharmacist's impact on public health. Aligning with the SDG target 3.8, the document focuses on essential medicines which is defined by WHO as those that satisfy the priority health care needs of a population.[40] They are intended to be always available within the context of functioning health systems, in adequate amounts, in the appropriate dosage forms, of assured quality and at prices that individuals and the community can afford. The Who Model Lists of Essential Medicines serve as a guide for the development and updating of national and institutional essential medicine lists to support the procurement and supply of medicines in the public sector, medicines reimbursement schemes, medicine donations, and local medicine production. The WHO Expert Committee on the Selection and Use of Essential Medicines is updating its Model List of Essential Medicines in 2023. For simplicity, we will use the simple term "medicines" to describe medicines and vaccines that fall under this definition.

Medical devices[25] are discussed, whilst recognising their diversity. This document is limited to common medical devices utilised by pharmacists such as point-of-care testing kits, nebulisers and inhalers, and medication dispensing systems.

The document also addresses some pharmacist-offered pharmaceutical services related to medicines and medical devices, such as counselling, vaccinations, and medication therapy management. Moreover, the annex section of the document provides a compilation of case studies from various countries, strategically incorporated to vividly illustrate and describe current country situations.

While the contributions of pharmacists to broader medication access are acknowledged, the document confines its scope to the pivotal realm of essential medicines, ensuring a concentrated and targeted approach in line with the overarching global health objectives outlined in the SDGs.

It is also worthy to note that the dynamic nature of the pharmaceutical landscape and evolving healthcare policies may also necessitate frequent updates to keep the document relevant. It may not comprehensively cover every possible scenario of the pharmacist's role in access to essential medicines and medical devices, as there will be diverse challenges that pharmacists face globally.

4 Pharmacists and pharmaceutical scientists improving access to essential medicines and medical devices

According to the WHO framework for health systems[41], a well-functioning health system ensures equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use. To achieve these objectives, the following are needed:

- national policies, standards, guidelines, and regulations that support policy;
- information on prices, the status of international trade agreements and the capacity to set and negotiate prices;
- reliable manufacturing practices when they exist in-country and quality assessment of priority products;
- procurement, supply and storage, and distribution systems that minimise leakage and other waste;
- support for rational use of medicines, commodities and equipment, through guidelines and strategies to improve population health literacy; and,
- ensure adherence, reduce resistance, and maximise patient safety and training.

Monitoring access to essential medicines is closely intertwined with at least two other building blocks: service delivery and governance. WHO describes the value chain of a medicine, identifying steps along the pathway from identification of a new chemical entity to its use in clinical practice (Fig. 4).

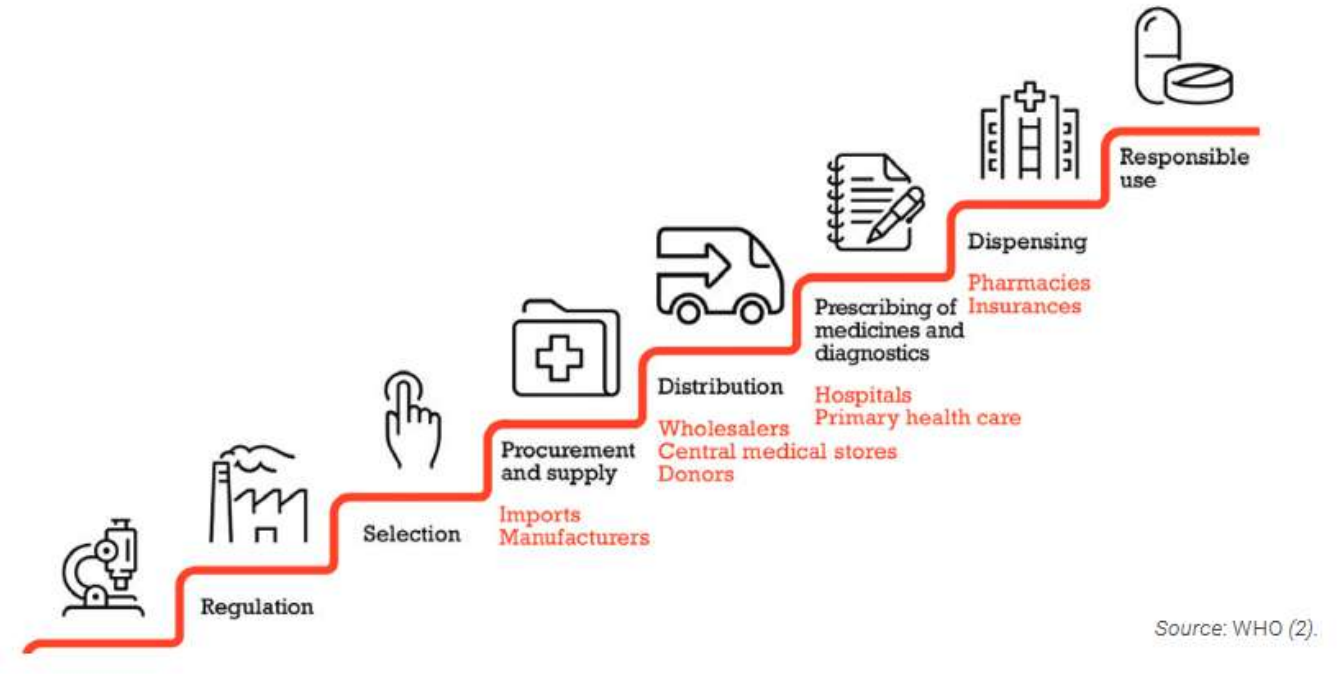

Figure 4. Value Chain of Medicines. Reprinted from UN Toolkit on Synthetic Drugs (n.d.) and 1. United Nations. The Pharmaceutical Value Chain [Internet]. United Nations: UN Toolkit on Synthetic Drugs. Available from: https://syntheticdrugs.unodc.org/syntheticdrugs/en/access/pharmaceutical/index.html

Access to medicines and health products requires attention at all steps along this path.[42] As we can see from the value chain, pharmacists and pharmaceutical scientists are essential in the efforts to improve access to essential medicines in LMICs. When dispensing medicines, pharmacists are instrumental in ensuring patient safety. They can detect potential medicine interactions and allergies, thus minimising risks associated with the use of essential medicines. Pharmacists play a crucial role in patient education, imparting knowledge about the correct usage of medicines, encompassing aspects such as dosage, timing, and potential side effects. Through their efforts to encourage patients to follow their treatment plans diligently, pharmacists enhance the efficacy of medicines while simultaneously mitigating the risk of antibiotic resistance.

Additionally, the responsible management of waste disposal by pharmacists not only fulfils regulatory requirements and mitigates environmental risks but also contributes to resource optimisation, public health protection, and the long-term availability of medicines for patient care. In the case of antibiotics, for example, pharmacists collect unused or waste medicines, reducing the contamination of antimicrobials in the environment.[43] FIP's latest policy statement on environmental sustainability highlights how environmental sustainability includes both mitigation measures, such as reducing pharmaceutical waste, pollution, and greenhouse gas emissions, as well as adaptation measures to climate change.

Regarding medical devices, pharmacists are also commonly involved. For example, in some countries, pharmacists participate in tender processes in hospitals. They can provide clinical input and understanding the compatibility of medical devices with medicines and patient care processes. Pharmacists also play a key role in access and education in the use of medical devices.

WHO identifies four primary components crucial for effective access:

1. rational selection;
2. affordability;
3. sustainable financing; and,
4. the establishment of reliable systems for procurement, storage, and distribution.

This framework underscores the intricate nature of ensuring that individuals can obtain the medicines they need. Furthermore, the multidimensional aspect of access, as expounded by both WHO and Management Sciences for Health (MSH),[44] extends to encompass not only a medicine's availability and affordability but also its accessibility and acceptability to patients. It takes into account cross-cutting dimensions concerning the quality of medicinal products and pharmaceutical services, where pharmaceutical scientists in particular play a crucial role.

Based on the above, this reference document addresses the common challenges under three major areas:

1. affordability;
2. availability; and,
3. quality and safety.

In addition, it considers changes to the workforce in light of new developments.

Pharmacy and pharmaceutical scientists' organisations, at both the national and international levels, assume a pivotal role in all these areas. They bear a responsibility to advocate for improved policies and practices related to access to medicines, ensuring that governments and other stakeholders take effective action. Pharmacists, equipped with a diverse array of technical expertise, are uniquely positioned to contribute to this cause. Their global presence and knowledge base enable them to play a significant role in facilitating and enhancing access to medicines, thereby advancing the overarching goal of providing equitable healthcare for all. The following chapters describe the challenges and show examples of pharmacists' responses to these.

4.1 Affordability

4.1.1 Affordability in the pharmaceutical supply chain and pharmacists' role

Insufficient access to basic life-saving medicines is primarily a result of lacking financial resources but also of inefficient pharmaceutical supply chains. The pharmaceutical supply chain is defined as "the management of product supply from raw material sourcing to active ingredient manufacturing through formulation, packaging and distribution to the patient. It encompasses all related activities across the product lifecycle, including clinical supply, scale-up and transfer as well as outsourcing and product discontinuation. A key requirement is the safe and reliable supply of quality medicines through a supply chain which is responsive to true demand and understands the voice of the customer".[45] In addition, aspects such as environmental, social, and governance criteria should also be taken into account in the context of achieving objectives like antimicrobial resistance (AMR) for antimicrobials. These are the principles and standards related to environmental sustainability, social responsibility, and corporate governance that guide the actions of companies, organisations, and stakeholders involved in the pharmaceutical industry.

Pharmacists often require specific professional training and/or academic education in order for them to take on particular roles in the supply chain. The 2018 FIP Report on the role of the medicines expert in ensuring quality and availability presents case studies which demonstrate that countries seem to recognise that the involvement of pharmacists in the supply chain is desirable, even if there are hurdles to the practical implementation.[45]

In Cameroon for example, legislation requires pharmacists to be involved wherever medicines are procured, stored, or dispensed. Apart from Cameroon, countries like France and Portugal also have strong legislation that guarantees input of pharmacists at all stages of the supply chain. In settings where there is a lack of human resource, pharmacists are put in management positions and supervise supply chain activities. For example, Solomon Islands' geographical complexity makes it unfeasible to employ pharmacists at every point of the supply chain. Instead, they are put in management roles to oversee activities and maximise their impact. There is also a short supply of pharmacists in Lebanon where a lot of Syrian refugees are being cared for. Thus, they are employed instead in head offices of various agencies that respond to humanitarian emergencies.

FIP workstream	Additional information is available through the FIP workstream on this topic
Pharmacists in the supply chain 	FIP's 2018 work has looked into pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability Click here for more information.

In assessing the affordability of medicines, medical devices and medical services, analysing the supply chain and its vulnerabilities for each can provide useful insight. This reference document examines the stages of each supply chain and assesses the factors which contribute to final prices at each stage.

The pharmaceutical supply chain is a complex network of entities and processes. The components of the supply chain which are examined here are: research and development; manufacturing; distribution; price negotiation; and, sale to consumer.

4.1.1.1 Research and development

Some aspects of the supply chain for medicines vary between countries. However, the supply chain always begins with the research and development of medicines. Estimates of the average cost of producing a new medicine range from $1.3 billion to $2.8 billion USD.[46] This significant expenditure is often reported as the main reason for the high price of medicines, restricting UHC.

In 2016, over half of all new medicine patents originated from North America, and most of the remaining patents from Europe.[47] Patent protection is then provided for an exclusivity period, meaning that a company which patents a new medicine is then the only company able to legally manufacture that medicine during that time period. However, the escalating obligations and data complexity needed for marketing authorisation have significantly curtailed the exclusivity period. Originally around 15-20 years (with a five-year medicine development phase), this timeframe has now shrunk to approximately 10-12 years.[48–50] Moreover, obtaining marketing authorisation does not mark the culmination of the process. In many countries, extensive pricing negotiations, often spanning years due to additional data requirements, contribute to delays in product launches. For instance, there is a notable time lag between the launch of a product in Italy and Spain compared to Germany, all occurring within the dwindling 10–12-year exclusivity period. Adding to these challenges, the newly proposed European legislation further reduces exclusivity by two years.[51] This development has prompted many manufacturers to contemplate withholding product registrations in European markets simultaneously with the United States.[52]

This is a way of compensating the pharmaceutical company for the significant investment to develop a medicine. However, this means that newly developed medicines, protected by intellectual property (IP) laws, are very expensive. This is a particular issue with medicines manufactured by one company, a monopoly, or a small number of companies. This is the case in the US, for example, where a few major companies with monopoly control most of the market for a life-saving medicine for diabetes. Patent protection is an issue in this situation, particularly in chronic and life-threatening diseases, as “new and improved” medicines can be introduced at the end of the 20 years of patent protection with new patent protection and a continued monopoly.[53]

Once the patent has expired, the medicine can be made by non-originator pharmaceutical companies. In many cases the price can drop significantly as competition increases. Intellectual property laws therefore contribute to the inability of low-income countries to access innovative medicines.[54,55]

In the pharmaceutical industry, pharmacists and pharmaceutical scientists engage in a rigorous process of medicine development and testing to guarantee the safety and efficacy of new medicines.[45] These industry professionals conduct research assessing potential benefits and risks of a medicine for human consumption. The pre-clinical and clinical trials involve data collection, analysis, and reporting. Through these trials, industry pharmacists ascertain whether a new medicine meets stringent regulatory requirements and upholds the highest standards of safety and quality before it is made available to the public.

4.1.1.2 Manufacturing

Following the development of a medicine, it must then be manufactured. For the 90% by volume of the global pharmaceutical market made up of small-molecule medicines, manufacturing is relatively cheap and simple.[56] For this reason, significant amounts of global manufacturing is outsourced to countries which can produce these medicines at

the lowest costs per unit, such as China and India; an FDA study in 2011[57] found that manufacturing active pharmaceutical ingredients in India could save US and European pharmaceutical companies 30-40% in costs. As a result, these two countries alone produced, in 2021, 50% of the world's ibuprofen, 60% of the world's paracetamol and 90% of the world's penicillin.[56]

Global crises such as the COVID-19 pandemic and the ongoing conflict in Ukraine have highlighted vulnerabilities in the pharmaceutical supply chain; a significant issue being the sourcing of active pharmaceutical ingredients (APIs) from these manufacturers in China and India.[58,59] A study from Washington University found that over 80% of APIs for essential medicines in the US have no domestic manufacturing source,[60] which has raised concerns over the consequences if trade relations with foreign manufacturer's countries were to deteriorate.

Governments are beginning to explore the potential for onshoring pharmaceutical supply chains, to increase security of supply of medicines.[61] Although benefits of this could include higher security, increased health sovereignty, and quality and flexibility in the supply chain, these benefits could come at the cost of higher prices for reliable APIs.

Additionally, the remaining 10% of medicines by volume, known as large-molecule medicines or biologicals, are more challenging to manufacture; they are regulated, tested and controlled differently.[62] These include insulin, vaccines and many treatments for autoimmune diseases and cancers. Biologicals are highly effective and targeted and are being used increasingly as treatments. However, they are also very expensive, ranging from an average of US$10,000 to US$30,000 per year to US$500,000 for the most expensive.[63] As a result, access to these treatments is restricted, even in high income countries.

In the pharmaceutical industry, responsible pharmacists and pharmaceutical scientists play a crucial role in ensuring that manufacturing processes adhere to strict quality standards and regulatory requirements. Their responsibilities typically include ensuring that all manufacturing processes comply with regulatory standards set by government agencies such as the FDA (Food and Drug Administration) in the United States or the EMA (European Medicines Agency) in Europe. This includes adherence to Good Manufacturing Practices (GMP) regulations. Responsible pharmacists are often tasked with maintaining accurate and detailed documentation of manufacturing processes, including batch records, standard operating procedures (SOPs), and validation protocols. They are often responsible for the final approval and release of finished product batches for distribution, ensuring that they meet all quality specifications and regulatory requirements before reaching the market.

4.1.1.3 Price negotiation and distribution

From the manufacturing site, medicines are distributed. Traditionally, there have been at least five means of distributing medicines within countries. The key difference in these methods is the weighting of the role of government and of the private sector.[45] Examples of systems are listed below:

- Central medical stores (CMS): a centralised government unit buys and distributes medicines.
- Autonomous supply agency: similar structure to a CMS but autonomous or semi-autonomous.
- Direct delivery system: medicines are delivered directly from suppliers to districts and major facilities, and the government selects suppliers and negotiates prices (but does not store or distribute medicines).
- Primary distributor or primary vendor system: the government contracts pharmaceutical suppliers and primary distributors. The suppliers send medicines to the distributor which stores and sends medicines to districts and major facilities.
- Primarily private supply: private pharmacies provide medicines for public-sector patients, with government intervention required to ensure equitable access.

There is no clear "best" system from this list and many countries use a combination as appropriate. For example, an effective and reliable private pharmaceutical sector is required for direct delivery or prime distributor systems to function.

The choice of pharmaceutical supply system is relevant to affordability. If the purchasing of medicines is centralised, i.e., a government is responsible for the purchasing of medicines for its entire population, and the population is sufficiently large, medicines can be bought for significantly lower prices due to economies of scale and the resulting high purchasing power. On average, a 15% price reduction can be expected from centralised purchasing, although this effect is nullified if the supplier does not face sufficiently high competition (an HHI index of over 46% provides insufficient competition for purchasing economies of scale to be effective). In some instances, however, massification of purchases can also induce vulnerabilities in the event of failure. This can be through logistical challenges, supply chain disruptions, or other issues that may arise if the centralised process breaks down.[64,65]

Other costs arise from the distribution of medicines and the diligence needed to ensure that medicines are transported and stored safely, and remain effective.[66] Maintaining an effective cold supply chain presents a major difficulty in LMICs due to a number of reasons including power outages, equipment breakage and a lack of trained personnel.[67] Additionally, costs are incurred in achieving regulatory compliance, proper handling of medicines, security, traceability and effective reverse logistics. Pharmacists are commonly involved in all these processes to ensure the safety of the patient, and at the same time strive for efficiency, contributing to reduced costs.

In some countries, governments negotiate with pharmaceutical companies to set maximum prices for certain essential drugs, and in others, they directly subsidise a portion of the cost of medications to make them more affordable for consumers. In numerous low- and middle- income nations, the absence of crucial partnerships among the government, insurance companies, and manufacturers has led to a situation where only a fraction of the population benefits from government-subsidised prices. Pharmacists in government collaborate with pharmaceutical companies to devise pricing strategies, negotiating to align the cost of essential medicines with the government's budget. They also have governmental roles that focus on initiatives such as identifying high-cost medications, advocating for increased subsidies, or negotiating lower costs. In research settings, pharmacists and pharmaceutical scientists conduct health economic assessments to evaluate the cost-effectiveness of various health and medicines interventions. Their findings contribute to informed policy decisions, guiding choices on which medicines to subsidise or exclude from subsidies.

4.1.1.4 Reaching the patient

In essence, the process of medicines reaching consumers from manufacturers to pharmacies is a well-regulated and highly organised system that prioritises the safety, efficacy, and accessibility of essential healthcare products for patients. The distributors are intermediaries who store and transport medicines to various destinations. They often supply medicines to pharmacies across communities, hospitals, and healthcare facilities. Throughout this journey, stringent quality control measures, temperature monitoring, and security protocols are in place to safeguard the integrity and safety of the medicines. Regulatory authorities in each country also oversee various aspects of the supply chain to ensure compliance with safety and quality standards. Pharmacies procure medicines and maintain inventories based on demand and patient needs.

Affordable pharmaceutical products and services are essential for ensuring equitable access to healthcare for all individuals. When medications and pharmacy services are priced beyond the means of certain patients, it creates barriers to access, particularly for those with limited financial resources.[68]

4.1.2 Affordability in clinical or primary health care and pharmacists' role

Once medicines are delivered to pharmacies and hospitals, it is the responsibility of pharmacists to deliver these medicines to patients. This involves multiple essential processes, including medicine selection and administration, and the necessary counselling, follow up and pharmacovigilance.[45]

Within this, there are multiple ways to improve the affordability of medicines and opportunities for pharmacists to take this further. This reference document will first consider some examples of methods for cost reduction through community pharmacists, followed by hospital pharmacists.

FIP workstream	Additional information is available through the FIP workstream on this topic
Primary health care	FIP workstream on Primary health care The FIP primary health care (PHC) programme aims to support and strengthen pharmacy to deliver evidence of impact in PHC in line with the World Health Organization's Astana Declaration, 2018. FIP's vision is a world where everyone benefits from access to safe, effective, quality and affordable medicines and health technologies, as well as from pharmaceutical care services provided by pharmacists, in collaboration with other healthcare professionals while leaving no one behind. The programme supports countries and regions with PHC policies for enabling pharmaceutical policies and systems. We seek to increase the knowledge and skills of the pharmaceutical workforce in delivering PHC and consolidate our programmes of work in a policy framework that is clearly aligned with the Astana Declaration and the WHO-UNICEF Operational Framework for PHC. Click here for more information.

4.1.2.1 Community pharmacists and their role in improving affordability of medicines

Community pharmacists, as the most accessible healthcare professionals[69], are uniquely positioned to reduce costs for health care systems. Pharmacists are often on the frontline of healthcare delivery, working in both public and private healthcare settings. They play a crucial role in maintaining an uninterrupted supply of essential medicines to the patient. They work closely with healthcare providers to ensure that these medicines are in stock and available when needed.

Pharmacists can contribute to monitoring the availability and pricing of medicines in their communities. They can report shortages, price fluctuations, or issues with the supply chain to relevant authorities, facilitating a rapid response to potential problems. They can advocate for patients by helping them navigate complex healthcare systems, understand their rights, and access support programmes that make their medicines more accessible.

FIP workstream	Additional information is available through the FIP workstream on this topic
Pharmacy as a gateway to care 	FIP workstream on Pharmacy as a gateway to care: Helping people towards better health FIP issued a reference document concerning self-care and promoting pharmacists' crucial role in helping people towards better health through the management of minor ailments, supporting the appropriate OTC selection strategies and serving as a gateway for further referral if needed. Click here for more information.

This reference paper focuses on five key areas in which community pharmacists currently, or have the potential to, reduce costs: chronic disease management; adherence monitoring; medicines use review; selection of over the counter (OTC) items; and, management of minor ailments. It will also touch upon the concept of responsible use of medicines. These collectively contribute to optimising healthcare resources, promoting patient adherence, and efficiently promoting better health conditions which, in turn, enhances overall access to medicines by ensuring their appropriate use, reducing costs, and prioritising resources for more critical healthcare needs.

4.1.2.1.1 Noncommunicable disease management

Noncommunicable diseases (NCDs) cause 70% of worldwide deaths, or 41 million annually worldwide.[70] Pharmacists are well positioned to reduce the burden of these diseases on the healthcare system, allowing for significant cost savings. An example is shown by the comparison between treatment of hypertension by usual medical care and pharmacy-run services, showing a cost saving of almost US$650,000 by preventing hospital admissions and emergency department visits.[71] Pharmacists have regular contact with patients, are trained to reduce disease severity, monitor medication therapy to achieve desired clinical outcomes, reduce adverse health events, and make recommendations to patients or prescribers regarding pharmacotherapy where appropriate. Expanding pharmacist roles with respect to NCDs can result in both clinical and cost benefits for patients as cheaper but still high-quality care can be accessed more quickly and easily through a pharmacist.[72]

Pharmacists in primary health care settings can also reduce costs for patients who require medicine for extended periods through guidance towards cost-efficient purchasing strategies. In some countries such as USA, mail orders or 90-day supplies are available. In other countries (most EU countries, for instance) do not allow mail order of prescription medicines but have instead more general "renew prescriptions" options.

4.1.2.1.2 Adherence

Adherence is defined as the degree to which a patient's actions match the agreed recommendations.[73] Pharmacists play an essential role in promoting and monitoring adherence.[74] It is estimated that, in HICs between 20% and 50% of patients do not adhere to their recommendations. This may result in higher rates of disease progression, pharmacotherapeutic failure and hospitalisation. The annual cost of nonadherence in the US alone is estimated to be US$100 billion; pharmacists could help reduce this cost.[75]

Community pharmacists are again well positioned to increase rates of adherence to medicines. They hold a uniquely advantageous position for identifying patients who may not be taking their medicine as recommended and the reasons for this, and are able to provide education and counselling at the point of supply where necessary. Research suggests that pharmacists are able to increase rates of adherence, and thus medical outcomes.[75] It should be noted that, somewhat counterintuitively, affordability of care can be improved through higher rates of adherence as, although short term costs of taking the advised medicine are higher, the patient will save costs on the further care which may be required without adherence.[76]

4.1.2.1.3 Medicine use review

Complementary to community pharmacists' roles in encouraging adherence, it is beneficial for both the patient's safety and the cost of medical care to ensure that the recommended treatment for the patient is appropriate. A medicine use review (MUR) takes the form of a conversation between a pharmacist and a patient with the aim of improving the patient's knowledge, adherence, and use of medicines. These conversations may also allow the pharmacist to determine whether the pharmacotherapy of the patient is appropriate.[75] MURs may help to reduce the health, environmental and, importantly, financial costs of overprescription and polypharmacy, as well as medicine wastage. They have also been found to be effective and cost-effective.[77]

Overprescription or polypharmacy is defined as the prescribing or taking of more medicines than are clinically required.[78] Overprescribing is increasingly recognised as an issue in the pharmaceutical sector; the first international conference on this subject took place in 2022 in Denmark and in 2021 the NHS (National Health Service) in England published its first report on the problem.[79] Meanwhile, an American study found that over 40% of older Americans take

five or more prescription medicines, and almost 20% take 10. Medicine overload is expected to result in the deaths of over 150,000 older people in the US over the next decade if nothing is changed, and a focus on reducing polypharmacy could save the American medical system up to US$62 billion.[80] MURs could alert pharmacists to harmful overuse of medicine, reducing costs both for medical systems and patients. This, in turn, would increase the affordability of medical care.

The other key benefit of MURs is the opportunity for a reduction in medicines wastage. A pharmacist may be able to identify which medicines are not being taken (disposed of, kept at home, or returned) and respond accordingly. It has been estimated that, in 2009, the gross annual cost of NHS primary and community care prescription medicines wastage in England was US$300 million.[75] Avoiding the purchase of prescription medicines which are not taken may save both healthcare systems and patients unnecessary costs. There may also be the result of a fall in the improper disposal of medicines, with benefits for the environment.

4.1.2.1.4 Selection of OTC items

If a patient needs medical care, without a prescription, pharmacists can play a significant role in cost minimisation. This occurs in different forms where the pharmacist may offer advice, including potentially nonpharmacological treatments. Alternatively, if an OTC medicine or product is required, pharmacists can help patients to choose the most cost-effective medicine, including recommending cheaper generic medicines over expensive, brand-name ones. This has a twofold cost saving effect; the patient may receive the most effective medicine at the lowest price, and the medical system supplying the medicine can save through supplying cheaper generic medicines, as well as avoiding visits to general practitioners and emergency departments which result from improper medicine selection. Pharmacists can educate patients about over-the-counter alternatives for minor ailments, reducing the use of reimbursed medicines, and, therefore, the co-payment for the health system. In some instances, generic equivalents of brand-name medicines are often more affordable but contain the same active ingredients and are equally effective.

Pharmacists can also recommend alternative medicines within the same therapeutic class that might be more cost-effective for the patient. They can work with healthcare providers to ensure that the alternative medicine is appropriate for the patient's condition. Pharmacists can also assist patients to save money through providing minor ailment services and thus reducing the burden on the health system.

4.1.2.1.5 Management of minor ailments

Community pharmacists can play a larger role in caring for patients with minor ailments. This would also reduce pressure on GPs and emergency departments, saving the patient money if they would otherwise have had to pay for these services, and relieving pressure from these services. A study from 2014 found that, in the UK, 13% of visits to GPs could have been managed by community pharmacists. Examples include management of colds, hay fever and minor aches and pains. Community pharmacists are ideally positioned for supplying first aid; they usually require no appointment, are the most accessible healthcare professional, are open at convenient times and can provide care without need for payment in certain situations. Additionally, pharmacists can triage patients with serious ailments through to the appropriate services.[75] Allowing pharmacists to care for patients in such a way could present significant saving opportunities for healthcare systems.[81]

4.2 Responsible use of medicines

Responsible use of medicines (RUM) refers to the judicious and ethical utilisation of pharmaceutical products in healthcare. It involves healthcare providers prescribing medicines based on evidence-based guidelines, ensuring that patients receive the right medicines at the right dosages and for the appropriate duration. Patients play a crucial role in responsible use by adhering to treatment plans, understanding potential side effects, and avoiding self-medication or sharing prescriptions. Additionally, responsible use entails minimising the risk of antibiotic resistance by using antibiotics only when necessary and as prescribed. This approach not only maximises the effectiveness of medicines but also promotes patient safety, reduces healthcare costs, and contributes to the overall quality of healthcare delivery. The 2012 report entitled "The benefits of responsible use of medicines from 2012" identified pharmacists as key levers in achieving responsible use of medicines.[82] Pharmacists play a pivotal role in promoting the RUM through their

expertise and patient-centred approach. They educate patients about their medications, ensuring that individuals understand proper dosages, timing, potential side effects, and the importance of adhering to prescribed treatment regimens. Pharmacists also emphasise the importance of not sharing medicines and avoiding self-medication, which can lead to adverse effects and complications. Furthermore, they actively participate in medication therapy management, helping patients manage chronic conditions, monitor treatment progress, and adjust therapies as needed to optimise effectiveness while minimising risks. By fostering open communication, providing clear instructions, and offering personalised guidance, pharmacists empower patients to take an active role in their healthcare and make informed decisions, ultimately contributing to the responsible use of medicines.

4.2.1.1 Hospital pharmacists and their role in improving affordability of medicines

Hospital pharmacists also play a significant role in improving access to medicines through managing affordability. The primary duty of a hospital pharmacist is to supply medicines, although their responsibilities also include the entire process of distribution of medicinal products and the important process of controlling, correcting, and informing patients of the medical products used.[83] The role of hospital pharmacists is also evolving; it has grown from dispensing, and now encompasses important services, such as, in some cases, providing clinical pharmacy services and advising other healthcare professionals about pharmacotherapy.[84]

Hospital pharmacists can present cost saving opportunities for both health systems and patients primarily through improved patient outcomes through rational drug use. By reducing medicine related problems, adverse medicine effects and the length of stay for the patient, among other factors, the cost of medical care can be reduced for both the hospital and the patient. This results from fewer future visits and faster recovery times. Notably, the hospital pharmacist services contribute to savings for the hospital only if the resulting savings are greater than the costs of carrying out the service. Additionally, cost saving opportunities may arise in the selection of the most cost-effective medicines for patients.

One specific example of the ways in which hospital pharmacists can reduce costs for patients is compounding. Compounding, or an extemporaneous preparation, involves changing dosage form or mixing medicines into a new dosage form as required by the patient.[85] These types of medicines are estimated to make up between one and three percent of pharmaceutical prescriptions.[86] Assuming that appropriate procedures are followed, compounded medicines may be more cost effective, or provide specific formulations which are not necessary commercially.

Another example is splitting of doses. Purchasing tablets of larger doses than needed and splitting them (often in half) can present significant cost savings for patients.[87] Hospital pharmacists may facilitate these savings by providing patients with split medicines, as opposed to whole tablets.

Lastly, hospital pharmacists can relieve costs and time expense for patients by accessing needed medicines through prior authorisation assistance. Prior authorisation is a serious obstacle for many patients accessing necessary medicines in the United States.[88] In an American Medical Association survey, it was found that 91% of physicians thought that prior authorisation negatively affected patient outcomes and 91% found that patients had experienced delays receiving necessary care because of prior authorisation.[89] Hospital pharmacists can reduce this burden by working with healthcare providers and insurance companies to streamline the approval process and ensure timely access to needed medicines.

4.2.1.2 Pharmacists' role in improving affordability of medical devices

Pharmacists can play a significant role in improving access to medical devices by providing guidance on product sourcing, selection, use and financing strategies. More specifically, when selecting a product, it should be inexpensive, effective, durable and, if necessary, customised. A pharmacist can then increase durability and effectiveness for the patient by providing relevant guidance on the use of the device, consequently delaying the cost of replacement, and increasing cost-effectiveness.

One of the most common and effective ways pharmacists can improve cost-effectiveness for patients is through education on correct usage. This has a twofold benefit; the patient can maximise their benefit from the device, and the

device may also last longer. For example, those who need the use of inhalers can be assisted by pharmacists and be educated by them on the appropriate use, monitoring inhaler technique and decreasing critical error rates. As a result, the device may be replaced after a longer period of usage. Both factors improve the cost effectiveness of devices.

Moreover, pharmacists also play an important role in educating patients and healthcare workers alike on the proper use and the results of medical devices like testing kits for HIV, COVID, or pregnancy. Point-of-care testing (POCT) services in pharmacies include a range of tests of different purposes and have been shown to result in positive health outcomes. The 2022 FIP statement on the role of pharmacy professionals in POCT[90] details recommendations for different stakeholders to further improve the provision of POCT services in the pharmacies.

FIP workstream	Additional information is available through the FIP workstream on this topic
Point-of-care testing 	FIP workstream on Point-of-care testing (POCT) services in pharmacies Studies have demonstrated the potential health and economic benefits of performing POC tests in pharmacies. The maintenance of good health and the early detection of disease significantly reduces the need for expenditure on healthcare and expands the capacity of healthcare systems to respond to the needs of populations. The 2022 FIP statement deliberates on the role of pharmacy professionals in POCT to ensure access to affordable healthcare services where there may be insufficient workforce capacity across other healthcare professions, and access to healthcare services or clinical laboratories may be limited. Click here for more information.

Furthermore, pharmacists can look for a selection of criteria when helping a patient choose a medical device in order to minimise the cost to the patient. Analogous to medicines, some medical devices may have generic or store-brand alternatives that are more affordable than brand name options. Additionally, pharmacists may know of inventories of second-hand devices, which could be less expensive than new devices, but equally as effective. If there is no device available which fully suits the needs of the patient, such that it will provide an insufficient result or requires the purchasing of further accessories, a pharmacist may also be able to provide a customised device, which is better suited to the needs of the patient.

Finally, pharmacists can help patients understand their health insurance and co-payment plans, specifying which devices are covered, to ensure the most cost effective service for the customer. Pharmacists can help patients understand their financial obligations, including co-payments and deductibles, as well as any other out-of-pocket costs.

4.3 Availability of essential medicines and medical devices

One of the major challenges in guaranteeing access to essential medicines is ensuring their availability in the right place and at the right time.

The availability of pharmacies and pharmacists in an area are vital considerations in the consumer's access to medicines. In Spain, for example, retail pharmacies must have authorisation which is only issued according to a quota system based on geographic location and population.[91] This helps to ensure that even in less populated areas, residents have access to necessary pharmaceutical services.

In this chapter, we explore the different strategies, approaches, and initiatives that improve the availability of essential medicines, with a focus on the role of pharmacists.

4.3.1 Medicine shortages

Over the past decade, pressure on supply has led to shortages of certain medical products, including vaccines. These shortages are detrimental to patient care, to maintaining public health, and to the organisation of healthcare systems. It is a complex issue with many nuances such as regulatory and political factors, manufacturing and quality factors, and supply and demand. Additionally, medicines shortages vary greatly from country to country, and the lack of reliable information at a global level limits the capability for establishing a global coordinated action.

Some of the challenges facing healthcare systems in many regions are twofold. Firstly, there is often a noticeable limitation in the capabilities of national regulatory authorities which can hinder the effective oversight of pharmaceuticals and healthcare products. Secondly, the limited capacity for local production creates a heavy reliance on other nations for the supply of essential medicines and medical supplies, potentially leaving countries vulnerable to disruptions in the global supply chain. These two interconnected issues underscore the need for stronger regulatory systems and a renewed focus on building manufacturing capacity to enhance self-sufficiency and healthcare resilience. It is also essential to have a less complex supply chain, and a resilient API production. The EU is now looking into strategies to decrease the dependency on global supply chains, focussing on critical medicines,[92] and the US has put in place actions to ensure availability of critical medicines in the US.[93]

Recent shortages are particularly notable in the realm of generic products, as previously highlighted. In fact, during exclusivity periods, manufacturers typically bear the responsibility of ensuring access to their medicines in markets where they possess marketing authorisation. Conversely, generic production faces impediments stemming from supply chain challenges and a lack of interest.

In a report by FIP in 2020 regarding shortages of medicines, it was noted that at a European level, pharmacy staff spend 6.6 hours per week dealing with shortages. This is backed by a 2018 study from Canada where a survey revealed that two thirds of pharmacists (67%) deal with medicine shortages daily or several times a day and estimate that managing medicine shortages can occupy up to 20% of their shift.[94] In 2019, European hospital pharmacists stated that the impact that medicines shortages had on patients include delays in care (42%), suboptimal treatment (38%), cancellation of care (27%), and increased length of stay (18%).[95] A European community pharmacy group reported that, despite the efforts of pharmacists, issues of shortages for chronic diseases still persist.[96] In 2023 every pharmacy across the EU spent, on average, almost 10 hours per week dealing with medicine shortages, which is a significant increase in the past decade. They advocate for greater flexibility for pharmacists to address shortages efficiently, along with immediate measures to enhance notification, information dissemination, and fair redistribution of medicines across countries.

Pharmacists can play a crucial role in addressing shortages by reporting supply incidents and, when permitted at the national level, substituting or compounding medicines in short supply. Various countries have implemented effective strategies in this regard. In the upcoming case study section, we explore Spain's Information Center on the Supply of Medicines (CISMED). This digital tool enables Spanish pharmacies to report incidents, aiding national authorities in promptly detecting shortages and facilitating policy actions as necessary. In some countries, shortage reporting systems are being implemented by national associations of pharmacists. A report from FIP provides an overview of eight models for reporting medicines shortages and in some countries, reporting of medicines shortages has been integrated into dispensing software used by all community pharmacies. In France, for instance, reports are sent to the database of the National Council of the Chamber of Pharmacists of France where the information is processed and sent to the health authorities.[97]

In the FIP Statement of policy on medicines shortages,[95] it was recommended that pharmacists should be given greater authority to solve medicines shortages at community or hospital pharmacies when they occur. Their expertise should be sought in the development of national medicine policy decisions, in pharmacy or medicines and therapeutic committees, in committees defining essential medicines lists and antibiotic use policies, and in committees promoting responsible use of medicines or proposing guidelines for managing medicines shortages, including lists of alternative medicines when appropriate. They should also be given authority to dispense alternatives to the prescribed medicines in the event of a shortage.

FIP workstream	Additional information is available through the FIP workstream on this topic
Global medicine shortage	FIP workstream on FIP's work in addressing global medicine shortage Medicines shortages have become a complex global issue, putting lives at risk and creating difficulties for healthcare professionals. There is evidence that these shortages are worsening with time; as a result, there is a growing concern among healthcare professionals about the future of medicines availability worldwide. FIP has been working to address global medicines shortages since 2011, when this problem was highlighted at its 71st World Congress of Pharmacy and Pharmaceutical Sciences. FIP has since produced a number of reports and a statement of policy on this matter. Click here for more information.

4.3.2 Equity in access

Equity in health refers to the absence of avoidable, unfair, or remediable differences in health outcomes, access to health care, and quality of health care among different groups of people. Numerous factors significantly influence health equity and equality, encompassing social and environmental elements, all of which can result in various adverse outcomes for individuals, communities, and even societies. These ramifications not only harm the welfare of the affected populations but also carry wider repercussions for social, economic, and public health outcomes.

4.3.2.1 Improving access in rural areas

Governments have a crucial role to play in promoting the accessibility of healthcare services, including pharmaceutical care, in rural areas. Dispensing medicines in these remote regions is of paramount importance as it addresses critical healthcare gaps. By supporting and incentivising the establishment of pharmacies and healthcare facilities in rural areas, governments can ensure that residents have easier access to essential medicines and professional advice. This not only improves the overall health and well-being of rural populations but also contributes to reducing health disparities between urban and rural areas. Moreover, it can potentially bolster local economies by creating employment opportunities and supporting small businesses in these underserved regions.

Achieving this goal involves implementing regulations governing the establishment of pharmacies based on demographic and geographic criteria. Additionally, ensuring the sustainability of pharmacies in rural areas is paramount, and financial support should be provided to these crucial health establishments.

Therefore, government initiatives to promote dispensing in rural areas are a significant step towards achieving equitable healthcare access for all citizens. One example of this is Spain, where community pharmacies have an evenly distributed network across the entire national territory, in order to ensure that the provision of pharmaceutical services from community pharmacies reaches the entire population of Spain; 98% of citizens have a pharmacy in the place where they live.[98]

4.3.2.2 Intellectual property laws

As mentioned in the Research and development section, intellectual property (IP) laws can play a complex role in improving access to medicines. While these laws are primarily designed to incentivise innovation and protect the rights of creators and inventors, they can also have implications for the accessibility and affordability of medicines. In particular, patents and exclusivity rights can sometimes limit access to affordable medicines.

On a positive note, the intersection of production and intellectual property rights has led to promising collaborations, exemplified by partnerships between the World Trade Organization (WTO), the World Health Organization (WHO), and the issuance of WHO certification licenses. These strategic alliances serve as a catalyst for countries to manufacture globally recognised medicines at a more affordable cost. By navigating the intricacies of intellectual property

regulations and promoting technology transfer, such initiatives empower nations to produce essential medicines in adherence to international quality standards. This not only fosters greater accessibility to life-saving medicines but also bolsters self-reliance in healthcare, ultimately contributing to improved health outcomes on a global scale.

The ability of countries or regions to regulate and prioritise specific therapy areas over others is crucial. Rare diseases, once considered underserved with orphan status, no longer fall into that category, as the market has become somewhat skewed towards them. There is now a noticeable pressure to control these diseases, even with initiatives like the declared US Cancer Moonshot. Examining the impacts of the Inflation Reduction Act in the US and the prospective European pharmaceutical legislation underscores significant developments in the industry. The latter promises to achieve a more equitable and earlier access to medicines for an additional 67 million patients in the EU (a 15% increase compared to February 2024).

An illustrative case is seen in antimicrobials, where the looming threat of imposing restrictions on intellectual property during pandemics, when these medicines are most likely to be utilised, has deterred their development. Additionally, improper usage leading to antimicrobial resistance has further curtailed access. The newly proposed 2024 European legislation aims to incentivise antimicrobial development, including the provision of an extra patent year for manufacturers involved in this sector.

Pharmacists play a role in improving access to medicines through various strategies related to intellectual property laws. These can be divided into three categories: alternatives, advice and advocacy.

Pharmacists can reduce the impact of intellectual property laws on prices of medicines by advising patients on alternative treatments, particularly generic substitutes, which may be cheaper but equally as effective. Generic substitutes become available after the expiration of patent protection. By staying informed about upcoming patent expiries, perhaps through their national associations, pharmacists can prepare to trade cheaper generic substitutes as early as possible. However, in some countries, such as Austria, Bulgaria, Luxembourg and the United Kingdom, generic substitution is not allowed[99] and this has a big impact on access, especially in conditions of shortage. In Bulgaria, there is high penetration of generic medicines in the market but generic substitution rights are still not granted to pharmacists; in instances where the medicine or medical device is prescribed with the trade name, the pharmacist is obliged to dispense exactly the prescribed medicine, and in instances where it is not available in the pharmacy, it must be ordered within the next 24 hours.[100]

Biosimilar substitution is a way in which significant savings in health systems and hospitals can be achieved, thus increasing access. Hospital pharmacists can play a pivotal role in the uptake of biosimilars. In the EU the EMA has guidelines for biosimilar substitution.

Pharmacists can also educate healthcare providers, patients and the public about intellectual property laws and their impacts on medicine prices. They can work alongside patient advocacy groups with their national associations to raise awareness about access barriers due to intellectual property issues. This may increase awareness of the issue, foster informed discussions and enable customers to make financially rational decisions about their choices of medicines.

In addition, pharmacists can advocate to reduce the impact of intellectual property laws. Pharmacists, through their national organisations, can participate in global and local advocacy initiatives, including campaigns by organisations such as WHO and FIP. Pharmacist involvement in advocacy can help shape policies that prioritise patient needs, reduce barriers, and foster equitable access to vital medicines.

4.3.2.3 Equitable solidarity in access vs nationalism

The experience with COVID-19 vaccines and the emergence of "vaccine nationalism" have brought to the forefront the stark global inequalities that require urgent attention. If we are genuinely committed to achieving universal health coverage for all people worldwide in a fair and just manner, it is imperative that these inequalities are actively and comprehensively addressed.

Regional targets for health spending exist, such as the African Union's Abuja Declaration Target to allocate 15% of government spending to health.[101] Governments, the pharmaceutical industry, and other stakeholders should prioritise, collaborate, and commit to more substantial efforts and contributions that could potentially lead to affordable and equitable access for patients. This could be done through creating global (public and private) multi-stakeholder partnerships and platforms to identify roles and responsibilities of each stakeholder and to establish ways to evaluate and monitor the impact, efficacy and effectiveness of actions and interventions. Additionally, acknowledging the common problem in access and the urgent need for solutions sheds light on the need for collaborative efforts and on the potential negative impact of competition among them.

FIP plays a key role in enhancing the development of the pharmacy profession in order to meet the world's healthcare needs and expectations. To address the inequities and inequalities faced, FIP-EquityRx became the public-facing name of FIP's Equity and Equality Programme in 2018, an encompassing programme supporting FIP DG 10's global implementation locally, regionally, and globally. Since the launch of FIP Development Goal 10: Equity and Equality in 2020, FIP has expanded the scope of its equity programme to beyond gender and diversity balances, extending to equity in access to care and all that this encompasses.

The scope of expansion became an even stronger imperative to support equitable access to healthcare for every person, regardless of their social, demographic and healthcare identifiers and their intersectionality. Leaving no one behind, FIP aims to achieve enhanced and equitable access to care for all individuals including children and older people, gender diverse groups, indigenous/cultural groups, people living in rural and remote areas, people with low socioeconomic status, vulnerable population groups as well as pregnant and breastfeeding women, people with disabilities, people with mental illnesses, and people living with rare and under-recognised diseases.

FIP has also expanded the scope of its programme to encompass vaccine equity and life-course immunisation advocacy efforts, highlighting the pivotal role of pharmacy in mitigating vaccine inequities and expanding access to essential immunisation services and vaccine distribution. In a new policy statement released in September 2023, FIP calls for the expansion of vaccination schedules and strategies to ensure access to vaccines for all age groups. In addition, FIP published several toolkits and handbooks, including Give it a shot: Expanding immunisation coverage through pharmacists[102] as well as Vaccination of special-risk groups: A toolkit for pharmacists[103] that provide guidance on ways that pharmacists can contribute to widening access to vaccination and therefore equity to health. FIP also hosted several series of activities and digital events, not only on vaccine equity and access to life course immunisation, but also on gender equity, health literacy, as well as initiatives such as FIPWiSE (Women in Science and Education) which aims to increase women's involvement across different fields in pharmacy and health.

FIP workstream	Additional information is available through the FIP workstream on this topic
FIP's EquityRx programme	FIP workstream on FIP's EquityRx programme The FIP Development Goals are set to transform global pharmacy by providing a systematic and integrated framework that can support the transformation of pharmacy practice, science, and workforce and education. Of the 21 Goals, FIP Development Goal 10 impacts us all. The Equity & Equality Goal calls for clear strategies to address inequalities in the pharmaceutical workforce, widen access and equity of pharmaceutical care services and access, as well as equity in global capacity in pharmaceutical sciences development. FIP-EquityRx – FIP's programme on Equity & Equality in pharmacy – is driving FIP DG 10's global implementation. Click here for more information.

4.4 Quality: safe and effective medicines

Recognising that medicines play a pivotal role in various forms of care, supporting individuals, their families, carers, and health professionals in the safe and quality use of medicines requires leadership to foster a culture of coordination

and collaboration. This involves guidance through policies, guidelines, accreditation standards, and clinical information systems that steer the safe and quality use of medicines, necessitating improvements in the effectiveness and interoperability of digital systems and the use of smart technologies.

Pharmacists, as key stakeholders in the healthcare system, play a pivotal role in implementing strategies to ensure the safe and optimal use of medicines. They are on the front lines, actively monitoring patients for early signs of medicine-related issues and engaging in proactive discussions with those starting new medicines. Pharmacists contribute significantly to the appropriate use of antimicrobials, actively participate in deprescribing initiatives, and play a vital role in reducing harm from high-risk medicines. Their expertise extends to improving the safe and quality use of medicines during transitions of care, facilitating effective information transfer, and conducting medication reconciliation and review when necessary. Additionally, pharmacists contribute to education and awareness campaigns, empowering healthcare professionals to navigate the complexities of prescribing and administering medicines safely. Their commitment to staying informed and up-to-date ensures that individuals receive accurate and evidence-based information. Education, training, and awareness campaigns are essential to support pharmacists in safely prescribing, dispensing, and administering medicines, monitoring their effects, deprescribing when necessary, and involving individuals in decision-making regarding their use of medicines.

4.4.1 Pharmacists' role in assuring patient safety

A review of the pharmacist's role in patient safety conducted by FIP in 2020[104] provides a useful summary of the potential for pharmacists to ensure that access to the medicines they provide is safe and effective throughout the medicines use process. Pharmacists have a key role in:

- Ensuring the safe, high quality and appropriate supply of medicines;
- Warranting the appropriateness of prescriptions at initiation of treatment;
- Safeguarding safety in transitions of care between hospitals/other healthcare units and the community;
- Confirming the accurate and appropriate supply of medicines;
- Ensuring information about medicine products is provided in an accessible way to patients, thus ensuring they are using their medicines in the correct way; and,
- Identifying and resolving clinically significant, potentially harmful medication-related problems.

Continuously reducing harm and promoting the safe and optimal use of medicines necessitates health professionals to stay current with the development and appropriate utilisation of both existing and emerging medicines and health technologies.

Within hospital settings, pharmacists assume a multifaceted responsibility by contributing to quality control through their involvement in the medication management process.[105] They collaborate closely with healthcare teams to conduct comprehensive checks, ensuring that medicines are accurately prescribed, prepared, and administered to patients. Hospital pharmacists are the final checkpoint in in-patient settings, before a medicine reaches the patient, meticulously reviewing dosages, potential interactions, and appropriate administration routes, and optimising pharmacotherapy to uphold the highest standards of patient safety and care.

Assessment of the implementation of the FIP Basel statements, the preferred future of hospital pharmacy globally, shows there are discrepancies between countries regarding the levels of implementation of the statements. For example, one survey question (out of 76 questions), with 66 respondents, asked whether hospital pharmacists should take responsibility for all medicines logistics in hospitals, such as meticulously reviewing dosages, potential interactions, appropriate administration routes and optimising pharmacotherapy. Only 59% of respondents strongly agreed with this statement, part of the 98% of respondents who agreed with the statement to a degree. Interestingly, the other 75 questions in the same survey have agreement rates higher than 90%. This shows the difference in attitudes to changing responsibilities of hospital pharmacists around the world. This should be taken into consideration when discussing pharmacists' roles in different contexts.

Collaborative efforts among all stakeholders are imperative to minimise the risks associated with the use, overuse, underuse, and misuse of medicines. Specific examples include actively monitoring individuals for early signs and symptoms of medicine-related harm or misuse, enquiring about symptoms or side effects from those starting new medicines, ensuring the judicious use of antimicrobials to combat resistance, monitoring and addressing inappropriate polypharmacy, deprescribing unnecessary medicines, mitigating harm from high-risk medicines, and enhancing the safe and quality use of medicines during transitions of care and in all settings.

FIP workstream	Additional information is available through the FIP workstream on this topic
Patient safety	FIP workstream on patient safety Related to reducing medication harm, FIP has the following work stream on patient safety. This is a high priority for pharmacists across our profession who are responsible for ensuring that, when a patient receives and uses a medicine, it will not cause harm. On a global level, FIP works closely with the World Health Organization on its patient safety programme and has been closely involved in advancing and advocating for global patient safety. FIP also prepares tools for pharmacists practising in different settings and countries across the globe. This work is in line with the ambitions of the FIP Development Goal 19 (Patient safety) and contributes to the delivery of the DG. Click here for more information.

Despite the crucial role pharmacists play in promoting the safe and optimal use of medicines, they face an additional challenge in combating the global issue of substandard and falsified medicines. The following sub-chapter will therefore deliberate on this issue.

4.4.2 Pharmacists' role in minimising substandard and falsified medical products

The world is going through rapid change; technological progress, radical progress in matters of communication and access to information, as well as the increasing power of multi-nationals, are transforming the global landscape, including the pharmaceutical industry.

Unfortunately, some of these developments have encouraged the production and sale of medical products which do not meet the required safety standards, whether due to the manufacturing process or inappropriate storage, or due to the criminal manufacture and fraudulent distribution of sub-standard or falsified medicines. The prevalence of these illicit products poses a significant threat to patient safety and public health.

According to the WHO's Global Surveillance and Monitoring System (GSMS) for substandard and falsified (SF) medical products, around one in ten medicines is either of a sub-standard quality or falsified in countries with low or medium income.[106] This observation is not limited to the most expensive medicines or the most well-known brands, but also concerns patented and generic products.

FIP believes that pharmacists are key personnel in combatting SF medical products as they are the final member of the pharmaceutical distribution chain. If given proper training, pharmacists in the community and hospital settings can swiftly identify SF medical products that may have penetrated the supply chains. They are also trained to report these instances to the proper authorities, as well as educate and advise patients who have been exposed to them.[107]

Pharmacists are at the forefront of efforts to detect and prevent the distribution of SF medicines, emphasising the importance of maintaining the integrity of the pharmaceutical supply chain. Through their vigilance and commitment, pharmacists contribute to ensuring that patients receive genuine, high-quality medicines. They actively engage in initiatives to enhance the traceability and authentication of pharmaceutical products, working collaboratively with regulatory authorities and other healthcare professionals to address this critical issue.

Pharmacists ensure that products are safe, effective and of quality, as well as providing advice and expertise.[108] Pharmacists diligently carry out the task of verifying the expiration dates and quality of medicines before dispensing them to patients.[109] This involves an inspection to ensure that the medicines are safe, effective, and suitable for use. Pharmacists are therefore critical in ensuring the safe and adequate supply and rational use of all medicines; they play a pivotal role in maintaining and assuring the quality of medicines throughout various stages of the supply chain.

The ongoing efforts of pharmacists in combatting the infiltration of substandard and falsified medicines underscore their dedication to safeguarding the well-being of patients and maintaining the integrity of the healthcare system. The profession's commitment in the fight against fake medicines is manifested in the FIP Statement of policy on counterfeit medicines.[110] The statement acknowledges that limited access to affordable medicines creates an environment that is conducive to the distribution of counterfeit products, which perpetuates inequity in the quality of healthcare among the world's population.

It is a policy of FIP to urge national governments to put in place, with adequate funding and within the overall national quality assurance system for medicines, effective measures to detect and prevent the circulation of counterfeit medicines. This includes the development of appropriate analytical methods and training programmes for pharmacists on the detection of counterfeits, and maintaining reasonable margins for pharmacists and wholesalers in order to ensure professional and reliable practice.

FIP workstream	Additional information is available through the FIP workstream on this topic
Substandard and falsified (SF) medical products	FIP workstream on Minimising substandard and falsified (SF) medical products FIP has been speaking out against SF medical products for over 20 years. We believe that pharmacists, pharmaceutical scientists and educators can be a vital asset in assuring the safety of patients through their active participation in the fight against SF medical products. Click here for more information.

5 Capacity building for improved access to pharmaceutical expertise

The pharmacist's role extends far beyond traditional dispensing and encompasses a wide array of functions, such as preventive care, health promotion, screening for common conditions, and the treatment of common ailments following established clinical protocols. Pharmacists also take on responsibilities like monitoring treatment adherence and managing related side effects, all while collaborating closely with other healthcare providers as needed.

Furthermore, the rapid advancements in information and health technology offer unprecedented opportunities to revolutionise the way we deliver healthcare in the future. For example, digital technology has a great potential in the early detection of shortages. In some countries, pharmacists have developed digital tools that allow them to notify in an automated manner and in real-time incidences of supply of certain medicines to their authorities.

Given the scarcity of healthcare professionals, especially in LMICs, task shifting, and more efficient utilisation of existing human resources have become critical imperatives. The expanded role of pharmacists is seen within this broader context. Pharmacists do not confine themselves solely to their pharmacies but rather step into the realm of influencing the social determinants of health upstream. Pharmacists also actively engage in interdisciplinary teams, working to reshape and redesign healthcare services as part of the recovery and reform agenda.

Embracing these innovations and harnessing their full potential should be a top priority in the short to medium term. This holistic approach to healthcare reform, encompassing the redefined roles of pharmacists and the integration of cutting-edge technology, holds the promise of creating a more resilient, accessible, and effective healthcare system for all.

5.1 New roles for pharmacists in light of new developments in public health

Expanding the role of community pharmacies within healthcare systems offers a multifaceted approach to improving access to medicines and healthcare services. It enhances accessibility, convenience, and overall healthcare outcomes and offers significant cost reduction. It is also notable that pharmacists are well positioned to expand their responsibilities to provide a wider range of services[111] as they are comparatively highly accessible and suitably skilled.

Community pharmacies serve as vital health hubs within communities, offering not only curative, rehabilitative, and palliative care but also playing a significant role in preventive and promotive healthcare. Some examples are the provision of hormonal contraception without prescription and the administration of vaccines, both of which have far-reaching implications for patients and healthcare systems. In Canada, pharmacists have the authorisation to prescribe medications for the treatment of uncomplicated urinary tract infections (UTI) in some provinces. A study on pharmacist prescribing and care in patients with uncomplicated UTI in the community showed that pharmacist-led management is effective and safe, and patient satisfaction appears very high. These changes have reduced the time and resource expense for patients and healthcare systems of otherwise needing to consult a physician.[112]

In the case of vaccinations in particular, community pharmacies enabling higher rates of vaccination in turn reduces the cost for patients and healthcare systems of needing to treat the ailments being vaccinated against.[113,114] The involvement of pharmacists in logistics, advocacy, pharmacovigilance and vaccination (as vaccinators) is crucial in national immunisation programmes.

This not only streamlines processes but also promotes preventive healthcare and empowers patients to take control of their health. This expanded role supports more efficient healthcare delivery, reduces the burden on physicians, and contributes to better health outcomes for individuals and communities alike.

FIP also continuously advocates and monitors how the contribution of pharmacists to vaccination strategies evolves around the world. A report released in December 2023 highlights the recent developments and success stories of pharmacy-based vaccination globally. It also describes some of the challenges faced in introducing vaccination services by pharmacists.[115]

FIP workstream	Additional information is available through the FIP workstream on this topic
FIP's Transforming Vaccination Programme	FIP workstream on FIP's Transforming Vaccination Programme FIP's work on vaccination is based on the conviction that improving vaccination coverage and promoting a life-course approach to vaccination are global imperatives to which pharmacists can greatly contribute. Of the 21 FIP Development Goals launched in September 2020, vaccination is linked to 17 goals, which clearly indicates the high priority vaccination holds not only for pharmacy and FIP, but also for global health. In particular, Development Goal 16, focusing on communicable diseases, is overtly linked to the prevention of this group of diseases, in which vaccination plays a prominent role. Click here for more information.

During the COVID-19 pandemic, the UK government expanded the healthcare workforce legally able to administer vaccines, with similar programmes introduced around the world. Now that the urgency of providing COVID-19 vaccinations has lessened, the usefulness of pharmacists in increasing the number of vaccinations is being widely acknowledged. In the US, for example, it has been found that pharmacists provided more recommended routine vaccinations than physicians. In 2021, FIP highlighted the impactful contributions of pharmacists in delivering vaccines in the US, UK, Australia, Canada, Germany, Ireland, and Switzerland.[116] In Malaysia, focus was directed on pharmacists as vaccine administrators and they also had certified training on immunisation for pharmacists (CTPIP). Pharmacists were also able to tap into point-of-care testing, such as in Portugal where pharmacists implemented rapid antigen testing for SARS-CoV-2 in community pharmacies with NHS referral.

Pharmacists across the world significantly adapted their roles for the COVID-19 pandemic. In Wuhan, China, for example, pharmacists were reassigned from their normal stations to assist in field hospitals.[117] Hospital pharmacists globally offered services beyond their specialties to help with soaring demand for emergency care, while simultaneously working under the pressure of intensive care medicine shortages.[118] Pharmacies in Japan and Ireland extended working hours, and in Malta, pharmacists helped streamline their dispensing services and were given the authority to dispense medicines without a doctor's prescription.[116] Pharmacists have been widely praised by ministers and heads of state for their services in response to the pandemic.

With expanding roles of pharmacists, the profession continues to shift from transactional dispensing of medicine to a more comprehensive and patient-centred means of care,[35] with a positive impact on access.

5.2 New roles for pharmacists in light of new technologies

The global post-COVID-19 landscape has had a profound impact on the accessibility of medicines worldwide. Innovative solutions emerged to support patients in home isolation or quarantine during both pandemic and endemic phases of COVID-19 within their communities.

Technology stands at the forefront of revolutionising access to medicines and medical devices, with a particular focus on the integral role of community pharmacists in delivering innovative solutions. The integration of advanced technologies aims to address pandemic-related challenges and contribute to sustained improvements in healthcare accessibility. In this context, e-pharmacy platforms serve as a cornerstone for improving medicines access, allowing

patients to conveniently order prescriptions online, with community pharmacists efficiently processing and dispensing medications. These platforms also facilitate contactless transactions, minimising exposure risks during pandemics and ensuring a seamless experience for patients in home isolation.

Pharmacists are at the forefront of these efforts, offering services through e-pharmacy, home delivery, and tele-pharmacy. These services aim to enhance patients' comprehension of their treatment, improve medication adherence and compliance, and facilitate access to essential medical devices such as blood pressure monitors, glucose monitors, pulse oximeters, and thermometers.

The post-COVID-19 landscape emphasises increased reliance on remote monitoring devices integrated with telehealth platforms. These devices facilitate real-time data transmission to pharmacists and healthcare providers, enhancing chronic condition management. Mobile health applications play a crucial role in supporting patients in home isolation, providing medication reminders, educational resources, and personalised health information. Digital medication adherence tools, such as smart pill dispensers and reminder apps, can be integrated into e-pharmacy and tele-pharmacy services, improving treatment outcomes.

Efficient logistics and tracking systems enabled by technology enhance home delivery services. Pharmacists utilise route optimisation algorithms and real-time tracking to ensure timely and secure delivery of medications, particularly crucial during pandemic and endemic phases when reducing physical contact is essential. Tele-pharmacy services enable virtual connections between community pharmacists and patients, allowing for video consultations, secure communication channels, medication counselling, and guidance on medical device usage. This approach enhances patient understanding and promotes medication adherence.

Moreover, digital technology holds significant potential in the early detection of shortages. In certain countries, pharmacists have developed digital tools enabling automated and real-time notification of supply incidents for specific medicines to authorities. This underscores our profession's dedication to aiding national authorities in promptly identifying supply issues and actively contributing to policy-making efforts aimed at preventing shortages.

Furthermore, data analytics and artificial intelligence (AI) support pharmacists in identifying trends, predicting medication needs, and tailoring interventions for individual patients. Collaboration platforms for healthcare providers, facilitated by technology, enhance communication through shared electronic health records and secure messaging systems, ensuring holistic and coordinated care, even in home isolation scenarios.

From e-pharmacy and home delivery services to tele-pharmacy and remote monitoring, these technological advancements are poised to improve patient comprehension, medication adherence, and overall access to essential medicines and medical devices. This shift towards technology-driven healthcare solutions reflects a commitment to patient-centric and efficient care delivery in both pandemic and endemic phases of public health challenges.

FIP workstream	Additional information is available through the FIP workstream on this topic
FIP's Technology Advisory Group	FIP's Technology Advisory Group The FIP Technology Advisory Group brings together experts from within FIP membership to exchange views on current activities, problem areas, best practices, and more, in technology. The group provides technical insights for FIP's collaborations with partners like the World Health Organization in the realm of health technology. Its objectives encompass exploring global initiatives and developments in health technology, understanding their impact on pharmacists, and identifying emerging opportunities for pharmacy advancement. It actively facilitates the gathering and sharing of best practices related to health technology development and implementation, with a specific focus on its application to pharmacy. FIP has produced a number of reports, statements and other resources for pharmacists on digital health and the impact of technologies on pharmacy. Click here for more information.

6 Conclusions

In essence, access to medicines is an integral part of the broader sustainable development agenda, contributing to various goals that collectively aim to create a healthier, more equitable, and sustainable world. Pharmacists are uniquely positioned to not only improve access but also to address the challenges and issues that could impede equitable access to essential medicines and devices. Pharmacists can advocate for improved policies and leverage their expertise to enhance global access to medicines, striving for equitable healthcare for all. Their efforts can help ensure the availability, affordability, and quality of medicines, alongside advocating for patients and supporting policy implementation. Additionally, as key stakeholders in the healthcare system, pharmacists play a pivotal role in implementing strategies to ensure the safe and optimal use of medicines, actively monitoring patients, engaging in proactive discussions, contributing to antimicrobial stewardship and deprescribing, improving transitions of care, conducting medication reconciliation, participating in education campaigns, and ensuring evidence-based information dissemination for patient-centred care and positive health outcomes. Through active engagement with stakeholders and collaborative efforts across sectors, pharmacists can make substantial contributions towards addressing disparities in access to medicines and advancing the objective of universal health coverage. Pharmacists' efforts and contributions embody the essence of compassionate healthcare provision and highlight the vital role of pharmacists in shaping a healthier and more equitable world.

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7 Annex: Case Studies

7.1 Malaysia

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7.1.1 Current situation and evolution of access to medicines

The Malaysian National Medicines Policy (MNMP) is an official document by the Malaysian Government that was granted Cabinet approval in 2006. This policy prioritises medium- and long-term goals for the Malaysian pharmaceutical sector and is reviewed from time to time to maintain its relevance. This document is a directive to ensure systematic and holistic governance of medicines to achieve better health outcomes for Malaysians. The objectives of the MNMP are to promote equitable access to medicines and rational use of safe, effective and affordable essential medicines of good quality to improve health outcomes of the nation. In an effort to ensure its success, a comprehensive planning and strategy implementation through a transparent framework, supported by the aspirations and commitments of the Government and all stakeholders towards common goals, is vital to strengthen the country's pharmaceutical sector. MNMP was developed in parallel with the general objective of the medicine policy proposed by the World Health Organization (WHO). The components under this policy are:

- governance in medicines
- quality, safety and efficacy of medicines
- access to medicines
- quality use of medicines
- partnership and collaboration for the healthcare
- industry.

Access to medicines in Malaysia faces multifaceted challenges. Firstly, the high cost of pharmaceutical products, driven by patents and intellectual property rights, particularly affects newer and patented medicines. Prolonged patent terms contribute to sustained high prices, and addressing this issue involves implementing transparency mechanisms and negotiating with pharmaceutical companies. Geographical disparities, especially in rural and remote areas, lead to limited healthcare facilities, impacting access to essential medicines, especially for vulnerable populations. Challenges in the efficiency and sustainability of the medicine supply chain, encompassing logistics, storage, and distribution, further hinder continuous availability. Moreover, the National Health & Morbidity Survey highlights limited health literacy among Malaysian adults, emphasising the need to empower communities and individuals to enhance understanding and management of medications for improved health outcomes. The outlined challenges underscore the importance of examining and potentially revising Malaysian regulations concerning access to medicines.

7.1.2 Regulations impacting access to medicines

The list of legislation under the Pharmaceutical Services Programme (PSP), MOH, includes the Poisons Act 1952, the Sale of Drugs Act 1952, the Pharmacists Registration Act 1951, the Medicines (Advertisement & Sale) Act 1956, and the Dangerous Drugs Act 1952, and their respective subsidiary acts.

The legislation is reviewed periodically to ensure that the provisions continue to meet current practices and needs. Amendments to legislation are proposed to provide better oversight of pharmaceutical practices, products, and advertising. Issues faced in the strengthening of legislation include policies that are unclear and uncertain, and the difficulty of getting consensus from all stakeholders.

7.1.3 Role of pharmacists and local pharmacy organisations in addressing access to medicines

Pharmacists and local pharmacy organisations play an important role in ensuring availability and accessibility of safe and effective medicines in Malaysia. Pharmacists are key healthcare professionals involved in the dispensing and

management of medications, contributing directly to the accessibility of medicines. They have a significant impact on patient outcomes by ensuring proper medication use, offering counselling, and monitoring for potential drug interactions or adverse effects.

Pharmacists are generally responsive to the evolving healthcare landscape and regulatory changes, adapting their practices to meet the needs of patients. They play a role in implementing public health initiatives, campaigns towards improving health literacy, particularly on the use of medicines, and can quickly respond to emerging health issues, ensuring the availability of necessary medicines.

Periodical engagements amongst all stakeholders are organised to ensure pharmacists are well informed about the latest developments in the pharmaceutical industry and are aware of new medications and treatment protocols. Local pharmacy organisations contribute to awareness by organising educational programmes, workshops, and campaigns to inform both pharmacists and the public about the importance of access to medicines.

Component 5 of the MNMP focuses on enhancing partnership and collaboration within the healthcare industries in Malaysia. This involves implementing pragmatic partnerships and collaborations among stakeholders, adhering to best practices and standards, strengthening relevant policies, resources, and infrastructure, and promoting smart partnerships to enhance competitiveness.

In Malaysia, the public and private health sectors operate independently, leading to disparities in service delivery and resource allocation. This results in an imbalance of burden on facilities and human resources, particularly in the public sector. Healthcare expenditure is increasing due to rising demand and the escalating cost of services.

Key challenges in the healthcare sector include affordability, distribution, and regulatory compliance. Ensuring access to affordable medicines, especially for chronic conditions, establishing efficient distribution networks particularly in rural areas, and keeping up with evolving regulations and standards pose challenges for pharmacists and local pharmacy organisations.

7.1.4 Examples of regulations, innovations, and interventions supporting access to medicines

1. Inter-ministry pooled procurement

To optimise the expenditure and savings to the Government, and in line with the “Do More with Less” policy, the Ministry of Health Malaysia implemented the pooled procurement of medicines with MOHE and MINDEF as these Ministries are also involved in procurement for their respective health facilities and have the same aspiration to achieve quality goals for health care.

2. Exercising the rights of government for selected HIV and hepatitis medications

In 2003, Malaysia became the first country in Asia to issue a government-use licence (The Rights of Government) for antiretrovirals to treat HIV. The health authorities initiated the measure after considering various options and consultations with all the relevant stakeholders and agencies. Subsequently, Malaysia also exercised The Rights of Government for the hepatitis medication sofosbuvir in 2017.

3. Value-added services (VAS)

The MOH has implemented VAS such as Integrated Medicine Dispensing System (Sistem Pendispensan Ubat Bersepadu, SPUB); Pharmacy Appointment System; Drive-Through Pharmacy; Medicines by Post (Ubat Melalui Pos, UMP) and Locker4U, to help patients to refill their prescriptions every month at their own convenience, in order to address the geographical disparities that exist in the country. The MOH also has plans to expand the services to outsource the supply of follow-up medications to community pharmacies (Ubat@Komuniti).

4. Know Your Medicines Programme

Know Your Medicines Programme (Program Kenali Ubat Anda) has been introduced as a national project to raise awareness on the quality use of medicines. Activities conducted under this programme include exhibitions and talks, radio and television interviews, mass media promotion, and home visits.

With the adoption of the Health White Paper (HWP) by the Malaysian Parliament in June 2023, Malaysia is on its way to transforming its healthcare system. The role of the Malaysian Ministry of Health as a provider and purchaser of healthcare services will be progressively decentralised to improve service delivery and the checks and balances function. The public sector agencies will continue to play the role of service provider, while the responsibility of purchasing healthcare services from both the public and private sectors will be undertaken by the strategic purchaser. The health transformation in Malaysia aims to establish comprehensive institutional, administrative, and governance frameworks. These arrangements will facilitate the diversification of funding sources, contributing to the creation of a dedicated health fund. Healthcare reform is needed not only to prepare the system for the future, but also to enable Malaysians to live in better health and ensure the prosperity of the nation.

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7.2 South Africa

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7.2.1 Current situation and evolution of access to medicines

South Africa has a two-tiered healthcare system, with the government-administered public sector funded largely from the fiscus, with some user charges, and the private sector funded through insurance schemes by users and their employers.

Medicine provided in the public system is procured in terms of a limited Essential Medicine List (EML), mostly via limited competitive bids (tenders). Most medicines provided in the public sector are generics. Access in the public sector is hampered by poor infrastructure, an inadequate pharmaceutical workforce, long queues at health facilities and medicine stockouts. Pharmacists in the public sector are directly involved in the process of selecting medicines, as well as in the operation of the procurement and distribution system. However, at primary care level (clinics), much of the dispensing is done by nurses, with some use of pharmacy support personnel.

In the private sector, a wider variety of medicines are provided, based on the reimbursement rules of each medical scheme and the benefit option chosen by the member. Although generic utilisation in the private sector is high, some innovator products are also reimbursed. A non-discriminatory single exit price model is applied in the private sector, with regulated maximum dispensing fees and maximum annual increases in the price paid by pharmacies. Although medicines access is somewhat easier in the private sector, it is constrained by higher prices. Pharmacists in the private sector are responsible for most dispensing in community pharmacies and hospitals but make extensive use of support personnel. An important access-enhancing role is the assistance they provide to patients trying to navigate their insurance systems.

The stark division between the sectors is meant to be addressed by the government's universal health coverage plan, introducing a National Health Insurance Fund which would procure health services, including medicines.

7.2.2 Regulations impacting access to medicines

The South African pharmaceutical sector is primarily regulated by The Medicines and Related Substances Act, together with the laws governing health professions, such as the Pharmacy Act. The national medicines regulatory authority, created by the Medicines Act, is the South Africa Health Products Regulatory Authority (SAHPRA). Pharmacists' professional activities are governed by the Pharmacy Act and the regulations and codes of conduct, including Good Pharmacy Practice standards, issued by the South African Pharmacy Council.

There is also a ministerially appointed Pricing Committee which advises on the private sector pricing system.

Government policy in relation to medicines is ostensibly based on the National Drug Policy, which was issued in 1996, but has not been updated or revised.[1] More recent policy positions have the potential to significantly alter the pharmaceutical system in South Africa, such as the planned introduction of National Health Insurance. The key objectives of the NDP were:

Health objectives:

- ensure the availability and accessibility of essential drugs to all citizens;
- ensure the safety, efficacy and quality of drugs;
- ensure good dispensing and prescribing practices;
- promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information; and,
- promote the concept of individual responsibility for health, preventive care and informed decision-making.

Economic objectives:

- lower the cost of medicines in both the private and public sectors;
- promote the cost-effective and rational use of drugs;
- establish a complementary partnership between government bodies and private providers in the pharmaceutical sector; and,
- optimise the use of scarce resources through co-operation with international and regional agencies.

National development objectives:

- improve the knowledge, efficiency and management skills of pharmaceutical personnel;
- re-orientate medical, paramedical and pharmaceutical education towards the principles underlying the NDP;
- support development of the local pharmaceutical industry and the local production of essential medicines; and,
- promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomic and other areas of the pharmaceutical sector.

7.2.3 Role of pharmacists and local pharmacy organisations in addressing access to medicines

Although there are a range of voluntary pharmacy professional associations in South Africa, which have addressed issues of pharmaceutical systems' design and quality, they have not been intimately engaged in the struggle for access to medicines. Instead, that locus of struggle has been dominated by civil society organisations, usually organised around a specific disease or disease category. Examples include the Treatment Action Campaign, which has campaigned for access to antiretroviral medicines and tuberculosis treatment. The Cancer Alliance has focused on access to cancer testing and comprehensive care. Other health rights organisations include Section27 and a local chapter of Médecins Sans Frontières (Doctors without Borders). The Stop Stockouts Project (SSP) has focused on medicines shortages in the public sector. Some of these civil society efforts have been bolstered by individual pharmacists and supported by pharmacy associations, who have engaged politicians, for example. There have been some academic publications related to medicines access in South Africa.[2,3,4]

In 2017 the national Minister of Health appointed a task team called “The forum to promote transparency and multi stakeholder engagement regarding medicine availability”. The Forum meets on a regular basis and reports via its Chairperson to the Minister on medicine availability in the country. Most pharmacy organisations, including the pharmaceutical industry associations, have at least one representative on the Forum.

7.2.4 Examples of regulations, innovations, and interventions supporting access to medicines

Although South Africa’s initial post-apartheid amendments[5] to medicines legislation have popularly been portrayed as directly related to the struggle for access to affordable, generic antiretrovirals, their intent was to enhance access to medicines more broadly. The intention to address patent barriers to access has been less successfully addressed. Although South Africa announced new intellectual property (IP) policies in 2018,[6] aimed at introducing patent examination and enhancing patentability standards, starting with pharmaceuticals, these have never been enacted. South Africa’s patent Act is still more restrictive than the minimum stipulated in the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). No compulsory licences have been issued for any medicines, but South Africa has benefitted from several voluntary licences, including those negotiated by the Medicines Patent Pool.

As mentioned above, the main medicine pricing intervention in the private sector has been the single exit price (SEP), comprising of a fixed ex-factory price with a logistics fee component (and value added tax) for medicines sold to all purchasers other than the state. There is some evidence of a positive impact on medicine pricing in South Africa.[7]

South Africa implemented mandatory offers of generic substitution by pharmacists in May 2003, making it a legal requirement to inform patients of the availability of generic alternatives to allow them to make an informed choice.[8]

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7.3 Egypt

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7.3.1 Current situation and evolution of access to medicines

In Egypt, the healthcare system includes both public and private sectors. Public healthcare is provided through government-run facilities, and there are also private hospitals and clinics. Urban centres, like Cairo and Alexandria, generally have a better healthcare infrastructure compared to rural areas.

Pharmacies are widespread, with over 80,000 pharmacies, even in remote areas, but the availability of specific medicines can vary. In some cases, there might be shortages or limited stock, impacting timely access. The government has implemented various programmes to address these issues, aiming to improve distribution networks and ensure a consistent supply of essential medicines.

The affordability of medicine remains a significant a concern for many Egyptians. While there are subsidies in place for certain medications, some individuals still face challenges in covering healthcare costs. Health insurance coverage is expanding, but not everyone is covered, leading to financial barriers for some seeking medical treatment.

In recent years, there have been efforts to enhance healthcare infrastructure and increase the number of healthcare professionals with more than 350,000 licensed pharmacists, but achieving equitable access across different regions is an ongoing challenge. Overall, while progress is being made, there are still areas in Egypt where improvements are needed to ensure universal and affordable access to medicine.

Several factors contribute to the issues surrounding access to medicine in Egypt:

1. Geographical disparities: Rural areas often face challenges in terms of healthcare infrastructure. Limited access to healthcare facilities and pharmacies in remote regions can impede the availability of medicines.

2. Economic factors: Affordability is a significant barrier; while there are subsidies for some medications, not all drugs are covered. Many people, especially those with lower incomes, may struggle to afford essential medicines, even with government assistance.

3. Supply chain challenges: Inefficient distribution systems and occasional shortages can affect the availability of medicines. Logistical issues in transporting drugs from manufacturers to pharmacies may lead to delays or stockouts.

4. Healthcare infrastructure: Varied quality of healthcare facilities and the availability of trained professionals impact the overall healthcare system. Insufficient healthcare infrastructure, particularly in rural areas, can limit access to both medical facilities and medicines.

5. Regulatory processes: Regulatory hurdles and delays in the approval of new medications can affect their timely availability in the market, impacting patient access to newer and potentially more effective treatments.

6. Education and awareness: Limited health education and awareness in some communities may lead to inadequate utilisation of available healthcare services and resources, including medicines.

7. Health insurance coverage: While health insurance is expanding, not everyone is covered. A lack of comprehensive health coverage can leave individuals without financial protection for medical expenses, hindering their ability to access necessary medications.

Addressing these multifaceted challenges requires a comprehensive approach involving improvements to infrastructure, economic policies, healthcare education, and regulatory processes to ensure equitable access to medicine for all Egyptians.

7.3.2 Regulations impacting access to medicines

In Egypt, the pharmaceutical sector is governed by a comprehensive regulatory framework overseen by the Egyptian Drug Authority (EDA). The registration and approval of pharmaceutical products involves a rigorous process to assess their safety, efficacy, and quality before market entry. The government actively intervenes in drug pricing, implementing subsidies for essential medications to enhance affordability. Pharmacies must obtain licenses from the Ministry of Health and Population, ensuring adherence to specific standards and providing access to approved and safe medicines. The import and distribution of pharmaceuticals are closely regulated to prevent issues such as counterfeit drugs and guarantees the safe delivery of medications. The promotion of pharmaceutical products, including TV and social media campaigns, is strictly controlled to prevent misleading information and ensure ethical marketing practices. Egypt encourages the use of generic medications to improve affordability, supported by regulatory measures. Clinical trials for new drugs require approval from regulatory authorities to uphold ethical standards, patient safety, and the reliability of trial results. Intellectual property rights are considered crucial for pharmaceutical innovation, and Egypt adheres to international agreements while balancing the need for affordable access to medicines.

While these regulations aim to safeguard public health and ensure the availability of safe and effective medicines, ongoing efforts are necessary to address challenges, such as improving regulatory efficiency, enhancing access in underserved areas, and adapting to evolving healthcare needs.

7.3.3 Role of pharmacists and local pharmacy organisations in addressing access to medicines

Pharmacists in Egypt play a multifaceted role in healthcare, serving as accessible healthcare professionals who go beyond dispensing medications. They contribute significantly to patient care by offering advice on proper medication usage, addressing concerns about side effects, and fostering patient education and adherence. In community health, local pharmacy organisations develop initiatives such as health screenings and vaccination programmes. Pharmacists act as frontline guardians of medication safety, preventing adverse interactions and guiding proper storage. They play a vital role in improving patient adherence, conducting counselling and follow-ups to enhance understanding and commitment to treatment plans. Pharmacy organisations also advocate for policies supporting the profession and contribute to healthcare outcomes through lobbying and supporting regulations. Pharmacists engage in continuing education to stay updated on healthcare advancements, ensuring the delivery of high-quality information and services. With widespread accessibility in communities, pharmacies provide essential medications and advice, particularly crucial in both urban and rural areas. Pharmacists collaborate with other healthcare professionals, contributing expertise to comprehensive and integrated patient care.

The impact of pharmacists and local pharmacy organisations is multifaceted, ranging from direct patient care to broader community health initiatives and advocacy efforts. Their contributions are integral to the overall functioning and effectiveness of healthcare systems.

7.3.4 Examples of regulations, innovations, and interventions supporting access to medicines

The Egyptian Drug Authority (EDA) oversees stringent drug registration and approval processes, ensuring safety, efficacy, and quality standards. Government pricing regulations set price ceilings and subsidies to enhance medication affordability, and policies encourage the use of generic medications. The Ministry of Health and Population regulates pharmacy licensing, ensuring standards for safe medication dispensing. Digital health integration, including electronic prescriptions, enhances healthcare efficiency, and innovations like telemedicine, health apps, and community pharmacist engagement improve access and education. Public health campaigns address concerns, and community health initiatives go beyond dispensing. Collaboration with NGOs and international agencies addresses health challenges, continuous education for healthcare professionals ensures updated services, and emergency preparedness strategies maintain stable medication supplies during crises. These measures collectively enhance access, affordability, safety, and efficiency in Egypt's healthcare system, requiring ongoing collaboration and adaptation to emerging challenges for sustained success.

Several lessons can be gleaned from the efforts to address access to medicine in Egypt:

1. Holistic approach: Comprehensive approaches that consider economic, geographic, and cultural factors are crucial. Solutions should address the interconnected nature of healthcare access issues.

2. Regulatory agility: A balance between stringent regulations to ensure safety, and flexibility to adapt to emerging healthcare needs is essential. Regulatory frameworks should be responsive to the evolving landscape of healthcare.

3. Community involvement: Engaging communities in healthcare initiatives and decision-making processes fosters a sense of ownership and can lead to more effective health interventions.

4. Digital transformation: Embracing digital health initiatives enhances efficiency and accessibility in healthcare. Telemedicine, electronic health records, and health apps can play a pivotal role in overall healthcare delivery.

5. Health literacy: Promoting health education and literacy is fundamental. It empowers individuals to make informed decisions about their health, fostering a culture of proactive healthcare-seeking behaviour.

6. Collaboration: Collaborative efforts between government bodies, healthcare professionals, NGOs, and international organisations are vital for creating synergies, pooling resources, and addressing complex healthcare challenges.

7. Emergency preparedness: Establishing robust strategies for maintaining the supply chain of medicines during emergencies is critical. This lesson is particularly relevant in ensuring continuous access to essential medications during unforeseen events.

8. Affordability measures: Implementing policies to enhance the affordability of medicines, such as price regulations and subsidies, is crucial for ensuring that healthcare is accessible to diverse socio-economic groups.

9. Innovative interventions: Embracing innovative interventions, such as telemedicine and community health initiatives, can broaden the reach of healthcare services and improve overall health outcomes.

10. Continuous monitoring and adaptation: Regular evaluation and adaptation of policies and interventions are necessary. The healthcare landscape evolves, and continuous monitoring ensures that strategies remain effective and responsive.

These lessons learned from Egypt's experiences in addressing access to medicine can provide valuable insights for other regions and countries facing similar challenges. They underscore the importance of a multifaceted, adaptable, and community-centric approach to achieving meaningful improvements in healthcare accessibility.

Building on the lessons learned, here are recommendations for further enhancing access to medicine in Egypt:

1. Strengthen regulatory efficiency: Streamline and expedite regulatory processes for drug registration and approvals to ensure timely access to new and essential medications.

2. Promote digital health integration: Continue to invest in and expand digital health initiatives to enhance healthcare efficiency, accessibility, and data management.

3. Community empowerment: Foster community engagement and education programmes to empower individuals to take an active role in their health, including understanding the importance of medication adherence.

4. Expand telemedicine services: Invest in and expand telemedicine services to increase healthcare accessibility, particularly in remote or underserved areas.

5. Enhance health literacy: Develop and implement comprehensive health literacy programmes to improve public understanding of health issues, treatment options, and the proper use of medications.

6. Address geographic disparities: Implement targeted strategies to address healthcare disparities between urban and rural areas, ensuring that all populations have equitable access to healthcare services and medicines.

7. Encourage public-private partnerships: Foster collaborations between public entities, private organisations, and NGOs to leverage resources and expertise in addressing healthcare challenges.

8. Invest in healthcare infrastructure: Continue efforts to improve healthcare infrastructure, particularly in rural areas, to ensure the availability of healthcare facilities and pharmacies.

9. Incentivise generic medication use: Implement policies that encourage the use of generic medications to enhance affordability, without compromising quality and safety.

10. Regularly assess emergency preparedness: Establish and regularly update emergency preparedness plans to ensure a stable supply of medications during crises, such as pandemics or natural disasters.

11. Support continuous education for healthcare professionals: Promote ongoing education and training programmes for healthcare professionals, ensuring they stay abreast of the latest medical advancements and best practices.

12. Monitor and evaluate policies: Establish a system for continuous monitoring and evaluation of healthcare policies and interventions to assess their effectiveness and make informed adjustments as needed.

By implementing these recommendations, Egypt can further advance its efforts to improve access to medicine, ensuring that healthcare services are not only available but also optimised for the diverse needs of its population.

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7.4 Netherlands

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7.4.1 Current situation and evolution of access to medicines

In the Netherlands all citizens are required to have health insurance. The Health Insurance Act describes the basic healthcare, including medicines. Almost all medicines (except OTC) are reimbursed through health insurance. The health system (insurance) is based on solidarity; access to basic health care in primary and secondary care settings, as well as medicines, is guaranteed by reimbursement through the health insurance.

7.4.2 Regulations impacting access to medicines

The Health Insurance Act provides a package of healthcare services established by law, and this covers the basic package of care. The Health Insurance Act in the Netherlands mandates basic health insurance coverage for all residents, encompassing GP care, hospital services, and medications. It establishes fundamental entitlements to healthcare and requires individuals to purchase this mandatory insurance. The law ensures that healthcare providers cannot exclude anyone from basic health insurance. Additionally, it outlines the funding structure for basic health insurance, covering medication, access to healthcare providers, and hospital admissions. This mandatory basic insurance is applicable to both adults and children residing or working in the Netherlands, and the healthcare package remains uniform for everyone.

7.4.3 Role of pharmacists and local pharmacy organisations in addressing access to medicines

Due to budget cuts, health insurers have introduced interventions to decrease prices of medicines. Currently there are tender systems from different health insurers and prices of generic medicines have fallen. This is one of a number of reasons for medicine shortages and hampers access to medicines. Prices of medicines are too low for the pharmaceutical industry, causing disinterest in the Dutch market.

On the other hand, there are also issues with innovative medicines with a very high price. New, innovative medicines are expensive, and are less likely to be available because they are placed in a ‘negotiation lock’. During this period the government negotiates pricing with the manufacturer; the average waiting time is now two years (600 days).

7.4.4 Examples of regulations, innovations, and interventions supporting access to medicines

During the COVID-19 pandemic the number of patients admitted to hospital intensive care units (ICU) rose sharply. It was anticipated that this could lead to shortages, specifically for medications used in ICU. Pre-emptively the Dutch Association of Hospital Pharmacists and the Ministry of Health decided to create a Dutch National Medication Coordination Centre (LCG) that was to monitor, coordinate and assure the availability of 14 selected medicines that were deemed essential for ICU care. Options for interventions included (forced) redistribution of stocks to hospitals in anticipated need, guaranteed purchases through import, and the compounding of medication in hospital pharmacies with a GMP-licence. In addition, collaboration with the Associations of Medical Specialists was set up to make rapid changes in treatment protocols possible in case a shortage was predicted. During the pandemic IL-6 receptor blockers were added to the list of medications to be coordinated. The result was that critical shortages did not cause interruptions to the care of patients in Dutch ICUs.

Having a national coordination point, and therefore a single ‘centre of command’, is essential when major events take place. It greatly reduces the time spent by healthcare professionals ‘on the floor’ who can now focus on their clinical tasks. Having the centre run by professionals (i.e., hospital pharmacists) who have hands-on experience was crucial to take rapid action, give credible advice, and minimised the interruption of normal processes in the hospitals and the regular supply chain.

The concept has now been adopted for medication shortages in critical care areas and in specialised medical care settings not related to the pandemic. The centre contributes to efforts that have been initiated at the European Union level to tackle critical medication shortages in which the European Medicines Agency now has an enlarged mandate.

The Netherlands, though small, is a well-connected country with 17 million inhabitants and around 90 hospitals. In larger settings a regional approach may be more appropriate, with the regional centres connecting at national level.

As mentioned, control by healthcare professionals greatly reduces administrative burdens and delivers results, even when medication shortages seem to be increasing.

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7.5 Australia

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7.5.1 Current situation and evolution of access to medicines

Australia has national programmes that provide access to medicines through the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS).[1] Under the schemes, the Australian government subsidise the cost of most prescription medications, making them affordable for the population.

The PBS started in 1948 as a limited scheme, offering a restricted list of medicines available for free to Australians. Over time, there have been efforts to improve and streamline the process of accessing medicines. The PBS has, over the years, evolved to include a much broader range of medicines, and the government regularly reviews and updates the list of subsidised medicines.

As of 2023, the PBS is available to all Australian residents who hold a Medicare card. In general, patients may pay up to AUD$30 for PBS subsidised medicines while the Australian government pays the remainder of the cost. Australians who hold concession cards, for example veterans who have the Department of Veterans' Affairs Gold, White or Orange Card, will only pay up to AUD$7.30 for most PBS medicines.

One challenge with access to medicines in Australia is the limited availability of certain specialised or newer medicines. These medicines may not be subsidised by the PBS, making them potentially costly for patients who need them.

7.5.2 Regulations impacting access to medicines

The Therapeutic Goods Administration (TGA) is the regulatory body responsible for overseeing the approval, registration, evaluation, and monitoring of therapeutic goods in Australia.[2] Therapeutic goods include prescription medicines, non-prescription medicines, complementary medicines, medical devices, vaccines, blood products and biologics. The PBS further regulates the pricing and subsidy of medicines to enhance affordability. A notable change in policy documents was the review of Australia's National Medicines Policy, which was first published in 2000. The policy was revised and delivered to the Australian Government in December 2022.[3] One of the key reasons for the need to refresh the National Medicines Policy has been the significant transformation in healthcare, including advancements in medicines such as biologics and precision medicine, and the integration of digital technologies, all of which have occurred over the past two decades.

The central pillars of the 2022 National Medicines Policy are: equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford; medicines meet the required standards of quality, safety and efficacy; quality use of medicines and medicines safety; and, collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.

The 2022 National Medicines Policy is intended to be the guiding policy framework for the accessibility of medicines for all Australians. The policy, designed to address evolving healthcare needs, emphasises a patient-centric approach by promoting timely access to innovative and affordable medications. By fostering a collaborative environment between pharmaceutical manufacturers, healthcare providers, and regulatory bodies, the policy aims to streamline the approval process for new medicines, ensuring that cutting-edge treatments reach patients efficiently. Additionally, the policy places a strong emphasis on equity, striving to reduce disparities in access to medicines across different demographic groups. The 2022 National Medicines Policy identifies a set of fundamental principles intended to guide and direct all partners to work collaboratively, cooperatively and transparently in achieving the 2022 National Medicines Policy aim through the co-design and development, implementation and evaluation of its related policies, strategies, programmes and initiatives.

The fundamental principle of "Equity and Access" within the National Medicines Policy underscores a commitment to ensuring that all Australians, regardless of their diverse backgrounds, circumstances, or health vulnerabilities, have equitable and timely access to effective and high-quality medicines. The policy is designed to eliminate health inequities experienced by various vulnerable population groups, such as Aboriginal and Torres Strait Islander people, those from

culturally and linguistically diverse backgrounds, children, older individuals, people with disabilities, residents of rural and remote areas, those with low socioeconomic status, individuals with rare diseases, those with mental illness, LGBTQI+ individuals, and pregnant and breastfeeding women, among others. By prioritising cultural safety and recognising the compounded health experiences of these groups, the National Medicines Policy strives to foster a healthcare system that is inclusive, responsive, and oriented towards achieving positive health outcomes for all members of the Australian community.

7.5.3 Role of pharmacists and local pharmacy organisations in addressing access to medicines

Pharmacists and pharmacy organisations play important roles in ensuring access to medicines in Australia. Key organisations in pharmacy advocacy within Australia include the Pharmacy Guild[4] and the Pharmaceutical Society of Australia (PSA).[5]

1) Impact: The Pharmacy Guild, as the representative body for community pharmacy owners, engages in negotiations with pharmaceutical suppliers and government bodies to facilitate a fair and efficient distribution of medicines. The Pharmaceutical Society of Australia, as a professional organisation for all pharmacists, has a broad impact on access to medicines through advocacy efforts, educational initiatives, and continuous professional development. This, in turn, positively influences patient outcomes and facilitates access to medicines.
2) Responsiveness: The responsiveness of pharmacists and pharmacy organisations in Australia is generally high. Pharmacists in Australia are well-trained professionals that are informed about the latest development in the pharmacy industry. Pharmacy organisations in Australia are recognised for their proactive approach and quick response to changes in the healthcare landscape. They provide training programmes and resources to assist pharmacists in adapting to new requirements, ensuring high standards of service. They actively develop guidelines and resources to support pharmacists in delivering quality patient care, contributing to improving access to medicines.
3) Awareness: Pharmacists and pharmacy organisations in Australia demonstrate a strong awareness of issues related to access to medicines. The professional pharmacy organisations are always informed about regulatory developments, advocating for policies that support fair reimbursement for pharmacy services, and actively participating in policy discussions about the availability of medicines. The pharmacy organisations often communicate these insights to their members, fostering a collective awareness within the pharmacy community.
4) Challenges: Challenges related to access to medicines in Australia can include supply chain issues, shortages of certain medicines, and concerns about pharmacy viability, particularly in rural and remote areas.

7.5.4 Examples of regulations, innovations, and interventions supporting access to medicines

A significant policy intervention by the Australian government that supports access to medicines is the 60-day dispensing instead of 30-day dispensing. Under this new regulation, prescribers can now prescribe, and pharmacists can dispense double the maximum medication quantity for patients with stable conditions on the PBS.

The first stage of the 60-day dispensing commenced on 1 September 2023 and included about 100 medicines. Upon full implementation on 1 September 2024, more than 300 medicines subsidised by the PBS will be eligible for the 60-day dispensing. It is expected to impact approximately six million Australians, potentially saving patients up to AUD $180 annually.[6] Over a four-year period, the estimated cumulative savings for patients exceeds AUD $1.6 billion.[6]

One of the challenges associated with the policy change was in technological readiness. For example, the clinical software vendors faced initial difficulties in adapting their systems to support the transition from 30-day to 60-day dispensing. Some clinical software was not fully ready to accommodate the new regulation, which led to operational disruptions and delays in implementation.

Additionally, challenges extend to the supply chain, where pharmacists needed to cope with a large increase in supply of medicines. Pharmacists needed to actively reach out to wholesalers to ensure adequate and timely provision of medicines. The demand for double the maximum medication quantity required a robust and responsive supply chain to prevent potential medicine shortages.

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7.6 Spain

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7.6.1 Current situation and evolution of access to medicines

The Spanish health system (SNS) has universal access, is free of charge and covers essential services. The SNS provides citizens with a variety of services, including outpatient pharmacy services, which include medicines and pharmaceutical products on prescription or dispensed through community pharmacies. By providing comprehensive coverage at an affordable cost to citizens according to their socio-economic status and state of health, it ensures equitable access to medicines fssor the population. In turn, the principles and substantive criteria established by the Law on Guarantees and Rational Use of Medicines and Medical Devices ensure the quality of provision throughout the SNS in a decentralised framework, fulfilling the main objective that all citizens continue to have access to the medicine they need, when and where they need it, under conditions of effectiveness and safety. The pharmacy model in this healthcare system, based on its extensiveness and accessibility, as well as public investment in pharmaceutical services has vastly contributed to achieving this objective.

In Spain, pharmacists guarantee access to medicines. Spain differentiates between hospital pharmacists, responsible for the custody, storage and dispensing of medicines for hospital dispensing, and community pharmacists, in charge of the custody, storage and dispensing of all other medicines in a community pharmacy. Spain now has a widespread network of community pharmacies, consisting of 22,220 pharmacies throughout the country, with a ratio of one pharmacy for every 2,137 inhabitants.[1] There has been a trend over the last few years to limit the dispensing of new medicines in community pharmacies. This can be seen in the data on new active ingredients included in the official Nomenclature of the National Health System's pharmaceutical provision for 2010-2022:

- In 2010, 44.44% of new medicines were authorised as medicines for hospital use and the remaining 55.56% for dispensing in community pharmacies (25.93% for hospital diagnosis and 29.63% for prescription or dispensing in community pharmacies).
- In contrast, in 2022, out of the total number of new medicines, 53.06% were authorised for hospital use and 46.94% were authorised for dispensing in community pharmacies (24.49% for hospital diagnosis and 22.45% for prescription or dispensing in community pharmacies).

This trend moves new medicines away from community pharmacies by limiting their funding to when they are dispensed to patients in hospital pharmacies, making them less accessible to patients.

Medicines shortages are also an issue. Prior to the pandemic, an upward trend in medicine shortages was observed, peaking in 2019. However, the situation reached pre-pandemic levels, and according to the Spanish Medicines Agency (AEMPS), there are currently around 900 presentations of medicines experiencing shortages. Data reported by the Spanish Medicines Supply Information Center (CisMED) show that there has been an increase in medicines shortages in 2023. Supply shortages are multifactorial and, as observed, these situations exist in other countries nearby, which suggests that this is a global problem.

7.6.2 Regulations impacting access to medicines

Royal Legislative Decree 1/2015 of 24 July 2015, approving the revised text of the Law on guarantees and rational use of medicines and health products[2] is the regulatory text which states that: ‘the custody, storage and dispensing of medicines for human use shall correspond exclusively to community pharmacy open to the public and legally authorised, and in specific circumstances, to the pharmacy services of hospitals and primary care centres.’ According to Law 14/1986 of 25 April 1986 on General Health, article 103.4, "Only pharmacists may be owners and proprietors of pharmacies open to the public"[3]. Therefore, access to medicines is guaranteed by competent pharmacists.

Law 16/1997, of 25 April 1997, on the Regulation of Community Pharmacies[4] determines, on a basic principle, that the planning of pharmacies will be established considering the demographic density, characteristics and geographical dispersion of the population, in order to ensure the accessibility and quality of the service and the sufficiency in the supply of medicines, in accordance with the health needs of each territory. However, every Spanish region currently applies these basic criteria in terms of population and distance. Most of the regions have established a minimum distance between pharmacies of 250 metres, with rare exceptions (e.g., Navarra).

It is also important to stress that Royal Legislative Decree 1/2015 contains a series of supply guarantees, namely that pharmaceutical manufacturers, wholesalers, importers, community pharmacies, hospital pharmacy services, health centres and other healthcare facilities are obliged to supply or dispense the medicines and health products requested of them under the legal and regulatory conditions established; laying down the principle of continuity in the provision of services to the community as a guiding principle for the functioning of the actors in the medicinal product chain. In addition, this regulation includes guaranteeing supply as the main function of the entities that carry out the distribution activity, which is in turn reflected in Royal Decree 782/2013, of 11 October, on the distribution of medicinal products for human use. On the other hand, the reform of European pharmaceutical legislation now in progress, aims to improve European patients' access to safe and affordable medicines, as well as to support the innovation efforts of the European pharmaceutical industry in order to increase its autonomy (as of today, there is a high dependence in Europe on active ingredients and certain medicines from countries outside of EU) and its competitiveness in the international arena. Hopefully, this reform will come with measures to prevent medicines shortages and provide Member States with tools to mitigate or combat them in a coordinated way (e.g., through a solidarity mechanism).

In Spain, every practising pharmacist must be registered as a member of the Provincial Pharmacy Chamber (Colegio Oficial de Farmacéuticos (COF)) of their corresponding province. In larger regions, there are Regional Councils that bring together the different COFs in the region. All these organisations also form part of the Consejo General de Colegios Farmacéuticos de España (CGCOF), which is the umbrella organisation for all pharmacists regardless of their area of practice in Spain.

They operate at local, regional, or national level, and the actions and initiatives they undertake are on behalf of, and for the registered pharmacists in their organisation, as well as for the protection of consumers and users of the services provided by its members.

7.6.3 Role of pharmacists and local pharmacy organisations in addressing access to medicines

Access to medicines has an impact on all pharmacists, as well as on patients. It is the task of the CGCOF to develop and implement strategies and action plans at a national level with the support of the registered member, which can be implemented in collaboration with the health authorities.

One of the roles undertaken by CGCOF is to cooperate with the Public Authorities in the promotion of public health and disease prevention, and to collaborate with the Health Administration at a national level in the formulation of health policy on pharmaceutical care and the rational use of medicines and health products, through collaborative actions in education and information on these products.

Community pharmacists provide a range of professional pharmacy care services on a regular or even daily basis, either directly or indirectly affecting patients' access to their medication.[5]

These include, among others, dispensing, the minor ailment indication service, pharmaceutical compounding, the substitution of medicines in the terms and situations legally permitted, health education and information, and the therapeutic adherence service.

Medicine shortages have a major impact on the daily practice of community pharmacists as they are unable to provide medication to many patients. In many cases, the pharmacist finds alternatives to the treatments that are experiencing shortages.

7.6.4 Examples of regulations, innovations, and interventions supporting access to medicines

The General Pharmaceutical Council has implemented different tools to respond to this problem. The following are worth noting:

- CisMED (Medicines Supply Information Centre) is a tool created to generate information on medicines that are in short supply in EU pharmacies, and recognised by the European Commission and referenced in OECD documents as good practice. CGCOF shares weekly reports with the national competent authority on these shortages, allowing them to detect possible supply problems and to act accordingly.

- FarmaHelp is a free resource provided to pharmacies. If a patient requests a medicine that is not available in that pharmacy, the pharmacy can ask nearby pharmacies, via the FarmaHelp online platform, whether they have the medicine available so that the patient can collect it at that pharmacy.

In this regard, under the coordination and guidance of the General Council, pharmacists inform patients of the current situation and keep them informed of any new developments regarding the medicines they are requesting.

All pharmacists, together with the COFs and the General Council, tackle this challenge and seek ongoing solutions, while maintaining exemplary coordination, as evidenced by the proper functioning of the tools which, in many cases, have proven to resolve situations that would otherwise have made it difficult for patients to access their medication. However, there are other challenges that require regulatory change in order to be solved. One of the challenges facing pharmacists in Spain is that they are not able to substitute dosage or dosage form on a general basis. In this respect, and as a very useful tool to tackle shortages, pharmacists in Spain would welcome greater flexibility (namely, exceptional measures introduced by the Spanish Medicines Agency in the next section). In addition, another challenge is the price difference of medicines in EU Member States which tends to favour their marketing in countries with higher prices.

At the European level, on 26 April 2023, the European Commission (EC) adopted a proposal for a new Directive[6] and a proposal for a new Regulation,[7] revising and replacing the existing general pharmaceutical legislation. Among others, it aims to ensure patient access to affordable medicines so that citizens of the EU can benefit from equal access to safe, modern, and affordable therapies, as currently not all patients in Europe have quick access to innovative therapies and may not even have access to the prescribed medication due to shortages. One of the goals is to encourage the production of medicines in Europe to avoid heavy reliance on countries outside of EU for the supply of medicines, active ingredients and other ingredients or products necessary to produce medicines. On 24 October, the EC adopted a package of measures to prevent shortages of essential medicines in the EU, for the forthcoming winters:[8]

- Implementation of a European Voluntary Solidarity Mechanism for Medicines (October 2023);
- A list of essential medicines (end of 2023) with the aim of monitoring essential medicines along the supply chain and preventing or mitigating possible shortages.

In Spain, as well as in many other EU countries, pharmacists faced a shortage of paediatric amoxicillin in extemporaneous oral suspension form during the winter of 2022. The Spanish Medicines and Health Products Agency granted pharmacists exceptional permission to dispense amoxicillin as tablets and to explain how to dose and administer it for use in children. Such clearances are very important to ensure that all patients have access to critical medicines. In addition, the General Council has implemented initiatives and/or tools aimed at improving or facilitating patients' access to their medication.

Tools to mitigate the impact of shortages:

- CisMED (Medicines Supply Information Centre), is a digital communication infrastructure between community pharmacies, Pharmacy Chambers and the General Pharmaceutical Council that generates real time information on medicines experiencing shortages. CisMED operates as follows: through its management programme, participating pharmacies send information to their Provincial Pharmacy Chambers on medicines not supplied upon request to their usual distributor; next, the COFs consolidate the information provided and send it back to the General Council to consolidate the COFs' information at national level; finally, valuable information is obtained about the situation of medicines supply incidences at pharmacy level, contributing to the early detection of potential shortages.
- In 2022, almost 10,000 pharmacies participated on a voluntary basis in CisMED, one in three being located in rural areas. CisMED is notified on more than 5,000 medicines that could not be supplied to the pharmacies by any of their suppliers, due to shortages. Overall, 403 presentations of medicines were classified as experiencing supply shortages, which amounts to an increase of 150%. All therapeutic groups were affected, mainly those for the nervous system, where 20% were affected, and cardiovascular medicines, at 19.9%. This information is shared with the Spanish Medicines Agency on the basis of a collaborative agreement.
- FarmaHelp is a free digital tool from the Spanish Pharmacy Representative Bodies which enables community pharmacists to contact nearby pharmacies should a patient need a medicine which it is not available. Its main

objective is to connect the network of community pharmacies to help both pharmacists and patients find and fight against shortages.[10, 11]

- By December 2023, more than 9,910 pharmacies were connected to FarmaHelp to help patients locate medicines experiencing lack of supply and, between May and October, a total of 18,732 medicine requests could be solved, meaning that more than 18,000 patients benefited from this system and were able to continue with their treatment. This is part of a new initiative to make medicines more accessible to patients.
- Collaborative dispensing:[12] The COVID-19 pandemic led to the adoption of temporary solutions to provide continuous pharmaceutical care to the population during an unprecedented health crisis. In this regard, the fifth additional provision of Law 2/2021 of 29 March was implemented on urgent prevention, containment, and coordination measures to deal with the health crisis caused by COVID-19. These measures allowed, on a temporary basis, public health authorities in six autonomous regions to set up collaboration mechanisms between hospital pharmacy services and community pharmacies. As a result, hospital medicines were dispensed in community pharmacies close to the patient's home to ensure access and continuity of treatment during the lockdown, as well as avoiding unnecessary travel to the hospital to pick up the medication. To evaluate the outcome of the initiative, both patients and professionals were surveyed. All patients surveyed reported their willingness to continue this way in the future, preferring to have the medicine delivered by their usual community pharmacy and to maintain the possibility of contacting the hospital pharmacy service if necessary. In addition, all professionals interviewed expressed their satisfaction towards collaborative dispensing and stated that, compared to other possible alternatives for delivering the medicine to patients at home, it was the most appropriate for most patients. This service is currently available in six autonomous regions and, in June 2023, a new subsection was introduced in article 3 of the Law on Guarantees, whereby the temporary provision was permanently included in the regulations, consolidating collaborative dispensing.

Policy recommendations to respond to today's challenges include:

- It is important to increase patients' access to novel medicines in community pharmacies, thereby addressing the trend for these medicines to be only available through hospitals and primary care centres, often far from patients' residence or place of work.
- Enabling community pharmacists to provide the full range of medicines in pharmacies, including innovative and specialised medicines (e.g., biologics, including biosimilars) can increase equity in patient access, reducing direct and indirect costs to patients and potentially improving follow-up and adherence to these typically expensive treatments.
- Member States should allow pharmacists to substitute scarce medicines with the available alternative, as part of a shared decision-making process with prescribers and patients or, where appropriate, in accordance with national protocols. Likewise, Member States may encourage and promote pharmaceutical compounding to help mitigate shortages of medicines for which there are no suitable alternatives available on the market.
- Community pharmacy reporting systems may contribute to information gathering that could be relevant for national competent authorities on shortages. These systems, such as CisMED, provide a valuable complementary tool to mandatory reporting by other actors in the supply chain such as manufacturers, as is the case in many European countries. By detecting early signals and providing warnings of potential shortages, a more complete picture for health authorities can be provided of medicines shortages at the pharmacy level.
- Promoting the rational use of medicines should be at the heart of any policy to improve the affordability of medicines for health systems. This can be done by adequately remunerating cost-effective health services that are shown to improve health outcomes and adherence to treatment, and mitigate risks related to medicines use.

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