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FIP STATEMENT OF POLICY
Improving access to safe and quality essential medicines and medical devices: The role of pharmacists

Preamble

The International Pharmaceutical Federation (FIP) statement of policy on improving access to medicines in developing countries was revised in 2005. The issue of access to medicines[1] and medical devices has since grown to become a high priority in all countries, particularly following the COVID-19 pandemic. This issue is well reflected in the FIP Vision (updated in 2019), which is of 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.[2] Equitable access to healthcare is crucial to improving public health and achieving universal health coverage (UHC)[3] as it enables people to receive timely and appropriate care regardless of their socio-economic status.

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This 2024 update of the FIP policy statement emphasises **improved access to safe and quality *essential* medicines and medical devices**.[4] It aims to address current global challenges and provide pertinent recommendations to enhance healthcare access worldwide. By addressing disparities in access to health care, including essential medicines and medical devices, pharmacists, policymakers and other healthcare professionals can work towards reducing health inequities and improving overall health outcomes for populations worldwide.

[1] Certain countries use the term "drug," whereas others prefer "medicine" to refer to the same substance. For the purpose of this statement FIP uses the term “medicines”.

[2] FIP Strategy 2019-2024. Available from: https://www.fip.org/files/content/about/vision-mission/FIP-strategic-plan-2019-2024.pdf

[3] WHO Universal Health Coverage (UHC) definition: UHC means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care.

[4] WHO Model List of Essential Medicines, 20th List (April 2017). Available from: https://www.who.int/publications/i/item/eml-20

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Introduction

The right to health is a fundamental human right, encompassing every individual's entitlement to the highest attainable standard of physical and mental health and well-being. Ensuring equitable access to safe, effective, and quality medicines and medical devices for all is a key principle of UHC.

It is critical in advancing both human rights and United Nations Sustainable Development Goals (SDGs) objectives. However, challenges persist, including differing regulatory requirements, supply chain disruptions, manufacturing capacity constraints and detrimental pricing strategies, all of which contribute to increased medicines shortages worldwide and exacerbate healthcare inequities and inequalities. FIP aligns its goals with the SDGs and UHC principles and, in this context, strives to improve access to medicines and medical devices by focusing on workforce, practice, and science in pharmacy.

Pharmacists play a vital role in ensuring access to essential medicines and medical devices, but a significant disparity in the number of pharmacists and pharmacies, their roles, and the structure of healthcare systems between low- and high-income countries represent challenges that need to be tackled through targeted initiatives. Pharmacy organisations advocate for improved policies and, through active engagement and collaboration, pharmacists contribute significantly to addressing disparities in access to medicines and medical devices and to advancing UHC objectives.

AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT:

A. Governments and policymakers, in collaboration with FIP member organisations, should undertake to deliver the following objectives:

A1. Policy and regulation

1. Ensure access to medicines and medical devices is always accompanied by access to pharmacists and appropriate pharmaceutical expertise.
2. Legislate appropriately to encourage regulatory systems within which pharmacists and other healthcare providers can use their skills to ensure the appropriate management and supply of quality medicines and medical devices to their populations.

3. Consider legislative changes that empower pharmacists to provide accessible substitutes[5] when a prescribed medicine is not available, to improve access to medicines and medical devices.
4. Guarantee that the security of supply of medicines and medical devices is central to every law that ensures patients have access to essential medicines and medical devices at all times, even in the event of public health emergencies and major events.
5. Establish processes to gather data, disseminate information, and prevent and manage shortages in medicines and medical devices.
6. Establish robust recall systems for both medicines and medical devices.
7. Promote regulations that ensure transparent and fair pricing, and reimbursement policies for medicines and medical devices. (Guaranteeing the affordability of medicines for patients and contributing to health systems' financial and fiscal sustainability is a key component to ensuring equitable access to medicines and medical devices.)

A2. Access and equity

1. Actively pursue the SDG #3 related to equitable access to essential medicines and medical devices.
2. Optimise national regulatory systems to ensure equitable access to medicines and medical devices for all, irrespective of socioeconomic status or geographical location.
3. Encourage harmonisation of regional regulatory and legal systems to support equitable access to medicines and medical devices, and pharmaceutical expertise, independent of national borders.
4. Establish incentives to encourage pharmacists and other healthcare professionals to practise in all healthcare settings, including geographically isolated areas.

A3. Healthcare infrastructure

1. Strive for a national health policy ensuring financial protection through UHC.
2. Establish optimal financial processes and mechanisms to ensure the economic viability of all sectors involved in the lifecycle of medicines and medical devices, from development to administration.
3. Ensure the sustainability of the healthcare supply chain, addressing both economic and environmental factors.
4. Implement proper pharmaceutical and medical devices waste management practices to support environmental sustainability,

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[5] FIP Statement of Policy on Medicines Shortages. 2020. Available from: https://www.fip.org/file/4786

reduce wastage, meet social and governance goals, and promote efficient resource use.

A4. Collaboration and coordination

1. Work closely with academia and other relevant research organisations to utilise data and evidence and inform policies on access to medicines and medical devices.
2. When necessary, enhance the collaboration of industrial, hospital and community pharmacists to provide, where applicable and appropriate, access to highly specialised medicines.

A5. Quality assurance

1. Ensure global leaders are appropriately briefed with accessible, accurate, reliable, evidence-based information on access to medicines and medical devices.
2. Promote the use of World Health Organization and national therapeutic guidelines to ensure appropriate and rational use of medicines and medical devices.
3. Develop or update international, regional and national priority lists of essential medicines and medical devices.
4. Minimise the risk of substandard and falsified (SF) medical products through stringent quality control measures at each point of the supply chain and post-marketing surveillance (e.g., pharmacovigilance).

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B. Patient organisations, in collaboration with FIP member organisations, should:

1. Advocate for policy changes that promote greater access to medicines and medical devices, such as increased funding for research and development of new medicines, and promote pricing and reimbursement policies that enhance access to medicines.
2. Increase patients' literacy on medicines and medical devices and their use.
3. Increase awareness of the importance of access to medicines and medical devices and educate patients, healthcare providers, and policymakers about the impact of limited access to medicines and medical devices.
4. Collaborate with the medicines and medical devices industry to increase patient and public engagement and involvement in clinical trial designs and recruitment.
5. Empower patients to take an active role in their health care and advocate for equitable access to medicines and medical devices.

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C. The medicines and medical devices industry, in collaboration with FIP member organisations, should:

1. Improve transparency regarding pricing structures and costs within pharmaceutical markets for government/policy makers/health professionals/public.
2. Make sure all patients across the world have timely and equitable access to safe, effective, and affordable medicines, with a focus on maintaining fair pricing and affordability in low- and middle-income countries.
3. Develop affordable medicines as substitutes, for example, biosimilars or generics, especially for diseases affecting low- and middle-income countries.
4. Partner with governments and non-governmental organisations to ensure equitable access to safe medicines and medical devices.
5. Develop context-specific patient access programmes considering capacity to pay, medication adherence, and enabling treatment without delay.
6. Invest in research and development, including neglected diseases and unmet medical needs, to create new medicines and improve existing treatments.
7. Support local production of medicines and medical devices in low- and middle-income countries through technology transfer, sharing of intellectual property, training, and investment in facilities.
8. In line with legal requirements or conditions, donate medicines and medical devices to aid disease prevention and treatment in low- and middle-income countries, particularly during emergencies in cooperation with national competent authorities.
9. Improve supply chain management to ensure efficient and effective supply of medicines and medical devices to those in need.
10. Notify regulators of potential or actual shortages, and of marketing withdrawals, cessations, and suspensions well in advance.
11. Work with patient groups and/or national patient safety networks to increase disease and treatment literacy.

D. Pharmacists should:

D1. Patient education and empowerment

1. Educate and empower patients so they possess the necessary knowledge to participate in decision-making regarding their health. Equip patients with accessible health and medicines

information to enable informed decision-making and rational medicines use.[6]
2. Deliver information to patients about shortages and access to alternatives using appropriate channels of communication.

D2. Collaboration and advocacy

1. Collaborate with other healthcare professionals to deliver essential medicines and medical devices across various healthcare settings (e.g., collaborative dispensing of hospital medicines in community pharmacies).
2. Share information with their governments and health professional colleagues on the barriers to access to medicines and medical devices, and work with them to devise strategies at local, national, and international levels on ways to overcome those barriers.
3. Collaborate with governments to develop policies supporting underserved areas and populations, such as patients with rare diseases or who are culturally and linguistically diverse.

D3. Regulatory compliance and ethical practices

1. Employ regulatory tools to detect, prevent and report the distribution of SF medical products, safeguarding the integrity of the pharmaceutical supply chain.
2. In accordance with the FIP Code of Ethics for Pharmacists,[7] avoid corrupt or unethical behaviour that may impede access to medicines and medical devices. Prioritise the interests of individual patients and of public health over commercial interests. Advocate for ethical practices that ensure equitable access to quality and safe essential medicines and medical devices, and oppose the manufacture and distribution of substandard products and predatory pricing practices.
3. Take a leadership role in advocating medicines and medical device safety.
4. Exercise their practice in the sole interest of their patients.

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[6] FIP Statement of Policy on Strategic development of medicines information for the benefit of patients and users of medicines. 2023. Available from: https://www.fip.org/file/5632

[7] The International Pharmaceutical Federation (FIP). Ethics and the pharmacist: Privacy and confidentiality. The Hague, Netherlands. Available from: https://www.fip.org/file/5591

D4. Supply chain and waste management[8]

1. Support the establishment of effective supply chains for quality and affordable medicines and medical devices, from research to supply, to improve equitable patient access.
2. Be actively involved in processes, such as formulary development, that support equitable access to medicines and medical devices.
3. Actively participate in handling pharmaceutical and medical wastes.

D6. Responsible use

1. Work closely with patients, other healthcare providers, and government to ensure that treatment options are both clinically appropriate and cost-effective, balancing efficacy with affordability to improve access to medicines and medical devices.[9]
2. Encourage responsible use of medicines and medical devices in their practices or places of work.

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E. AGAINST THIS BACKGROUND, FIP COMMITS TO:

1. Collaborate closely with organisations promoting equitable access to medicines and medical devices, such as the United Nations, WHO, governments, and international patient and industry organisations (e.g., the International Alliance of Patients Organizations, the International Federation of Pharmaceutical Manufacturers and Associations, etc.).
2. Encourage collaboration with other healthcare professionals to enhance access to care and facilitate transfer of knowledge and information on medicines and medical devices.
3. Promote the global adoption of the recommendations in this document and a set of harmonised criteria to promote access at national, regional, and international levels.
4. Advocate for a regulatory and policy framework that enables pharmacists to exercise their professional competence and responsibility to increase access to medicines and medical devices and ensure timely access for patients.
5. Develop evidence-based policies and competency development programmes targeting pharmacists' roles in mitigating the impact of medicines shortages in industry, hospital, healthcare facility and community settings.

[8] FIP Statement of Policy on environmental sustainability within pharmacy. 2023. Available from: https://www.fip.org/file/5618
[9] FIP's work and advocacy related to promoting responsible use of medicines. Available from: https://www.fip.org/what-we-do

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