FIP STATEMENT OF POLICY AND CALL TO ACTION

Pharmacist's authority in pharmaceutical product selection: Therapeutic interchange and substitution

Note: a glossary with the definitions of key terms used in this statement is provided as an annex.

Executive summary

The International Pharmaceutical Federation (FIP) recognises the selection of pharmaceutical products, including therapeutic interchange and substitution, as a core component of medicines optimisation and a critical contributor to safe, effective, equitable and sustainable healthcare systems. As healthcare professionals ideally positioned at the centre of patient care, pharmacists play a central role in ensuring that patients receive appropriate, high-quality medicines while supporting continuity of care, health system resilience and responsible use of resources.

While pharmacists are responsible for safe and effective pharmaceutical product selection, specialised roles — for example, pharmacoeconomics, medicines information, and pharmacovigilance pharmacists — provide complementary expertise to support evidence-based, patient-centred, and system-wide decision-making.

Since the adoption of FIP's 2018 Statement of Policy on the authority of the pharmacist in the selection of pharmaceutical products, the global healthcare environment has undergone profound transformation. Advances in regulatory science, growing experience with generic and biosimilar medicines, expansion of digital health technologies, persistent medicine shortages, increasing economic and environmental pressures, and evolving models of patient-centred care have reshaped how medicines are selected, supplied and used.

This updated statement of policy reflects these developments and reaffirms the pharmacist's leadership role in pharmaceutical product selection. It positions substitution and therapeutic interchange as routine, evidence-based and people-centred clinical practices that support universal health coverage, equitable access to medicines, health system resilience and sustainability.

These practices vary across jurisdictions and should not be assumed where legal or regulatory provisions do not allow them. The statement provides globally applicable policy guidance for pharmacists, policymakers and stakeholders, adaptable to diverse regulatory, economic and practice contexts.

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Introduction

Pharmaceutical product selection, including substitution and therapeutic interchange, is foundational in optimising medicines and core to the professional responsibility of pharmacists. Since the adoption of the 2018 FIP statement of policy on the pharmacist's authority in pharmaceutical product selection, the global healthcare environment has undergone profound and sustained change. These developments have altered how medicines are developed, regulated, supplied and prescribed, how patients engage with treatment decisions, and how health systems pursue resilience, sustainability and equity.

Health systems worldwide are experiencing increasing pressure from demographic change, the rising burden of chronic and complex conditions, constrained financial and workforce resources, and growing expectations for timely and equitable access to effective therapies.1 At the same time, recurrent medicine shortages, supply chain disruptions and geopolitical instability have exposed vulnerabilities in global medicines systems.2 These challenges have underscored the importance of flexible, professionally led mechanisms supported by clear legal frameworks, governance mechanisms and professional standards, for pharmaceutical product selection that ensure continuity of care, patient safety and efficient use of available resources.

Scientific and regulatory advances have significantly reshaped the landscape of pharmaceutical product selection. Generic medicines are now well established globally as safe, effective and high-quality therapeutic options when approved by competent regulatory authorities. Similarly, biosimilar medicines have transitioned from potential emerging alternatives to integral components of treatment pathways in many therapeutic areas.

Growing real-world experience across jurisdictions supports the safe and effective use of biosimilars for their approved indications. Consequently, policy discussions have increasingly focused on implementation, governance, professional competence, and patient-centred communication.3-7 Pharmacists should be actively involved in the generation, interpretation and use of real-world evidence related to substitution and biosimilar use, contributing to improved patient outcomes, informed regulatory decisions and continuous improvement in implementation, governance, professional competence and patient-centred communication.

Healthcare systems have increasingly adopted people-centred care and shared decision-making as guiding principles. Pharmaceutical product selection is now widely recognised as clinical decision making with direct implications for patient experience, adherence and trust. Pharmacists are expected not only to apply regulatory and clinical evidence, but also to engage patients in informed discussions, address concerns and misconceptions, and support continuity of care across care settings and transitions.

Digital transformation has expanded the scope and complexity of medicines management. Electronic prescribing, electronic health records, clinical decision support systems, and data analytics increasingly inform pharmaceutical product selection, offering opportunities to enhance safety, documentation, traceability, and pharmacovigilance, particularly for biological medicines.

In particular, artificial intelligence (AI) and advanced data analytics are increasingly influencing prescribing and pharmaceutical product selection decisions. Pharmacists must be prepared to critically appraise algorithm-generated recommendations and ensure that digital tools complement, rather than replace, professional clinical judgement. Governance frameworks should ensure transparency, accountability, data integrity, and mitigation of bias in AI-enabled decision-making.

Economic sustainability and environmental responsibility have gained prominence in medicines policy. Value-based healthcare approaches emphasise achieving optimal health outcomes while ensuring efficient and responsible use of limited resources. Substitution and therapeutic interchange are increasingly recognised as mechanisms to improve affordability, support universal health coverage (UHC), reduce unwarranted variation in care and strengthen supply security. Consideration of environmental impact and responsible production has become an integral component of sustainable medicines stewardship. Policies promoting substitution and procurement efficiency should also ensure robust safeguards against substandard and falsified medicines, particularly in vulnerable supply chains.8

In parallel, the scope of pharmacy practice has expanded in many jurisdictions, with pharmacists assuming greater clinical authority through prescribing, minor ailments schemes, chronic disease management and collaborative care models. With expanded authority comes increased professional accountability, reinforcing the need for clear legal frameworks, robust professional standards, appropriate education and ethical safeguards.

The WHO-FIP Joint Guidelines on Good Pharmacy Practice (2011) affirm the central role of pharmacists in medicines optimisation and call on governments, in collaboration with national professional organisations, to make full use of pharmacists' expertise across health systems.6 These guidelines recognise generic substitution as part of responsible pharmacy practice. This statement builds upon that foundation while reflecting contemporary regulatory, scientific and health system developments.

Pharmaceutical product selection is not solely a matter of roles, but of professional responsibility. In line with the principles of pharmaceutical care, it represents the pharmacist's contribution to optimising medicines use and improving health outcomes for individuals and populations.9

Taken together, these developments necessitate an updated statement of policy that reflects contemporary healthcare realities, reaffirms the pharmacist's leadership role in pharmaceutical product selection, and positions substitution and therapeutic interchange as routine, evidence-based, people-centred and future-ready practices aligned with broader health system goals.

The purpose of this policy statement is to provide globally applicable guidance and make policy recommendations and calls to action to relevant stakeholders on pharmacist-led pharmaceutical product selection, including generic substitution, biosimilar substitution where permitted and defined by regulators, therapeutic interchange, and switching decisions led by authorised prescribers, in accordance with national legislation, regulatory determinations and professional standards.

Specifically, this statement aims to:

- Modernise the pharmacist's authority, responsibility and accountability in pharmaceutical product selection across diverse health systems;
- Position therapeutic interchange and substitution as essential clinical practices that support universal health coverage (UHC), equitable access to medicines, health system resilience and people-centred care;
- Provide globally applicable guidance that can be adapted to different regulatory, economic and resource contexts, including low- and middle-income countries; and
- Align pharmacist-led pharmaceutical product selection with value-based health care, sustainability and the responsible use of medicines.

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This statement seeks to move beyond justification of substitution and therapeutic interchange toward a clear articulation of pharmacist leadership, accountability, and integration within health systems. For clarity, it distinguishes between
(1) generic substitution;
(2) biosimilar substitution;
(3) therapeutic interchange conducted under agreed protocols or in consultation with prescribers; and
(4) switching, which in many jurisdictions remains a prescriber-led clinical decision.

These practices vary across jurisdictions and should not be assumed where legal or regulatory provisions do not allow them.

This statement of policy applies to pharmaceutical product selection involving generic medicines and biological medicines, including biosimilars. It covers substitution and therapeutic interchange in routine clinical practice, emergency situations and medicine shortages, across community, hospital, primary care and integrated care settings. It also encompasses decision-making supported by digital tools, electronic prescribing systems and real-world data, and applies to collaborative practice models involving pharmacists, and other healthcare professionals, including those with prescribing authority among both groups.

This statement should be interpreted and implemented in accordance with national legal and regulatory frameworks, recognising variability in scope of practice and authority across jurisdictions.

Core policy principles

Pharmacists as leaders in medicines optimisation

Pharmaceutical product selection is a clinical decision requiring specialised knowledge of medicines, understanding of patient needs, professional judgement and health system priorities. Pharmacists are uniquely qualified as medicines experts and should be formally recognised as leaders in medicines optimisation, including substitution and therapeutic interchange, across all practice settings. This leadership role includes assessing therapeutic equivalence, managing risks, supporting adherence, monitoring outcomes and contributing to continuous quality improvement.

People-centred substitution and therapeutic interchange

Substitution and therapeutic interchange should respect individual patient needs, preferences, values, and health literacy. Pharmacists should engage patients in informed discussions, explain the rationale for changes, address concerns or misconceptions, and support shared decision-making. Clear, compassionate, and culturally appropriate communication is essential to build trust, promote adherence, and ensure positive outcomes. Particular attention should be given to vulnerable populations, including older adults, patients with limited health literacy, refugees, and those receiving multiple medicines, where changes in product appearance or packaging may significantly affect adherence and safety. Additional caution, monitoring, and patient counselling may be required for narrow therapeutic index medicines, biologics, complex drug-device combinations, and medicines with significant adherence sensitivity.

Collaboration and shared accountability

Therapeutic interchange should occur within collaborative, interprofessional frameworks that promote shared responsibility for patient outcomes. Effective collaboration between pharmacists and other healthcare professionals, including those with prescribing authority among both groups, reduces fragmentation of care and supports safe, appropriate, and transparent product selection.10 Protocol-driven

approaches and collaborative practice agreements should be promoted where available. Prescriber notification requirements should be defined by national law and local protocols; where not defined, health systems should adopt standardised approaches (e.g., protocol-based standing agreements or timely post-dispensation notification) to support continuity of care.

Regulatory trust and transparency

Safe substitution and therapeutic interchange depend on trust in regulatory systems and transparency in decision-making. Substitution decisions must be based on rigorous regulatory evaluation of quality, safety, efficacy, bioequivalence or biosimilarity by competent authorities. Pharmacists should have access to clear, reliable and up-to-date regulatory information and practise in accordance with applicable legal requirements, including data on active substances, excipients and clinically relevant formulation characteristics to support patient-specific pharmaceutical product selection. Pharmacists should refer to the most current regulatory resources and guidelines on excipients in the labelling and package leaflet of medicinal products for human use, for comprehensive lists of excipients with recognised actions or effects that must be considered during substitution or therapeutic interchange. Transparency in these elements strengthens patient safety, supports informed professional judgement and reinforces trust in substitution and therapeutic interchange practices.

Health system resilience

Substitution and therapeutic interchange are essential tools for strengthening health system resilience by enabling continuity of care during medicine shortages, supply disruptions, public health emergencies and humanitarian crises. Embedding these practices into routine care and preparedness planning enhances system flexibility and responsiveness.

Legal and professional protection

Clear legal and regulatory frameworks are required to protect patients and healthcare professionals when substitution or therapeutic interchange is undertaken in accordance with professional standards and regulatory guidance. Legal clarity supports professional accountability and enables pharmacists to exercise their authority confidently in the best interests of patients. Liability frameworks should clearly delineate responsibilities among pharmacists, prescribers, and health system institutions to prevent defensive practice and ensure patient safety. Pharmacists should have access at the point of care to comprehensive, up-to-date information on pharmaceutical products and digital systems that support safe, transparent, and traceable decision-making. At minimum, substitution and therapeutic interchange events should be documented with product name, strength, dosage form, and manufacturer; for biological medicines, include trade name and batch/lot where feasible or required.

Value, sustainability and responsible use of medicines

Pharmaceutical product selection should contribute to value-based health care by promoting affordability, value-based use of medicines, and responsible stewardship of resources without compromising quality or outcomes. Consideration of environmental sustainability, supply security and responsible production is increasingly important and should be integrated into professional decision-making.

System-level policy integration domains

The following sections outline key system-level domains through which pharmacist-led pharmaceutical product selection, including substitution and therapeutic interchange, is operationalised, governed and integrated within health systems. These domains expand upon the Core Policy Principles and provide strategic direction for policy coherence, implementation and professional leadership.

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[redacted]

Health technology assessment and pharmaceutical product selection

HTA plays an increasingly influential role in determining which medicines are reimbursed, prioritised or preferred within health systems. Pharmacists are central to translating HTA-informed decisions into real-world practice and should be meaningfully involved in the development, interpretation and implementation of HTA decisions to ensure they are applied safely, ethically and in a patient-centred manner.

The value of substitution and therapeutic interchange

Substitution and therapeutic interchange are evidence-based clinical strategies that support medicines optimisation, continuity of care and health system sustainability. Clinical decision-making should also consider regimen complexity and its potential impact on adherence and therapeutic outcomes. While products may be pharmaceutically equivalent or interchangeable, differences in formulation, dosing schedules or fixed-dose combinations can influence real-world effectiveness and patient experience. When regimen consolidation occurs (e.g., multiple tablets to a single tablet formulation), pharmacists should ensure equivalence of therapeutic intent, provide appropriate patient counselling, and maintain continuity of care, consistent with prescriber and local practice standards.

Access to medicines, equity and global health considerations

Ensuring equitable access to safe, effective and quality-assured medicines is a core health system objective and professional responsibility. Substitution and therapeutic interchange can improve access, reduce unwarranted variation in care and mitigate supply constraints, particularly in resource-limited settings, humanitarian contexts and fragile health systems.

Integration with clinical guidelines, digital systems and real-world evidence

Effective pharmaceutical product selection requires alignment between regulatory decisions, HTA outcomes, clinical guidelines, digital medicines management systems and logistic supply chains. Pharmacists should be supported in using electronic prescribing, decision-support tools and real-world data to enhance safety, traceability, documentation and pharmacovigilance. Pharmacists, initiating prescribers and other stakeholders are co-responsible for health-system sustainability and co-accountable for protocol adherence and implementation, ensuring proportionality and fairness in accountability mechanisms. Punitive measures should not fall exclusively on pharmacists by payers where prescribers have failed to follow agreed protocols.

Pharmaceutical care and patient outcomes

Pharmaceutical product selection is an integral component of pharmaceutical care and should be embedded within comprehensive care processes that assess patient needs, resolve drug-related problems, support adherence and monitor outcomes. Substitution and therapeutic interchange are part of an ongoing therapeutic relationship requiring communication, follow-up and shared decision-making. Differences in packaging, labelling, device design and presentation should be considered where they may affect patient understanding, adherence, safe administration or risk of medication error, including risks from look-alike/sound-alike products. Pharmaceutical product selection should therefore take into account not only therapeutic equivalence but also practical factors influencing real-world use and patient outcomes.

Communication with patients

Effective communication with patients is essential to safe and appropriate pharmaceutical product selection. Pharmacists should ensure that patients are informed clearly and in a timely manner about any change in their medicine, including reasons, expected benefits and potential risks, while respecting individual health literacy, cultural context and preferences.

Medicines regulatory engagement and regulatory science
Pharmacists play a critical role at the interface between regulatory decision-making and real-world medicines use. Through pharmacovigilance, medication error reporting and real-world data generation, pharmacists contribute to regulatory science and continuous improvement of substitution and therapeutic interchange practices.

Integration of regulations, reimbursement and clinical decision-making
Effective pharmaceutical product selection requires coherence between regulatory approvals, reimbursement decisions, clinical guidelines and practice. Pharmacists are uniquely positioned to be involved in the decision making and to operationalise these interconnected processes and ensure that policy decisions translate into safe, effective and people-centred care. Liability and accountability frameworks should clearly delineate responsibilities among pharmacists, prescribers, and health system institutions to support safe pharmacist-led decision-making, continuity of care, and patient safety.

Medicines system stewardship and supply chain resilience
Pharmacists have a growing responsibility for stewardship of medicines systems, including procurement, formulary management and shortage mitigation. Through informed product selection and proactive substitution strategies, pharmacists contribute to resilient medicines systems and continuity of care.

Ethical and transparent engagement with the pharmaceutical industry
Engagement between pharmacists and the pharmaceutical industry should be transparent, ethical and governed by clear professional standards. Such engagement can support responsible innovation, medicine quality and sustainable access while safeguarding professional independence and managing conflicts of interest.

Pharmacist prescribing and expanded clinical authority
Where pharmacists are authorised to prescribe, substitution and therapeutic interchange are integral to responsible prescribing and medicines optimisation. Expanded authority must be supported by education, governance frameworks, accountability and collaborative practice models.

Contribution to innovation, sustainability and future health systems
Pharmacists contribute to innovation through digital integration, sustainability initiatives and evaluation of emerging therapies. Their role in informed product selection and evidence generation supports future-oriented, resilient and sustainable health systems.

Policy positions

1. Policy on substitution

Where substitution is permitted by legislation and/or regulation, or where the prescriber indicates acceptability, responsibility for selection of the pharmaceutical product rests with the pharmacist unless otherwise specified. Selection should be based on regulatory approval, interchangeability guidance and patient-specific considerations. For medicines with a narrow therapeutic index (NTI), where small differences in dose or plasma concentration may lead to clinically significant consequences, pharmacists should exercise particular caution. Regulatory authorities should provide specific guidance on NTI medicines in the context of substitution, and national pharmacy associations should be involved in the development of such guidance. Substitution practices should include appropriate patient-centred communication and documentation of the dispensed product in the health record. Patients should be clearly informed about the substituted product and their options. Substitution practices should support informed patient choice and shared decision-making. For biological

medicines, documentation should support traceability (e.g., trade name and batch/lot where feasible), consistent with national requirements.

In jurisdictions where substitution is not yet permitted, governments are encouraged to progressively expand pharmacist authority based on evidence of safety, system, performance and professional competency frameworks.

2. Policy on therapeutic interchange

Therapeutic interchange, understood as a collaborative, evidence-based clinical practice undertaken to achieve optimal therapeutic outcomes and efficient use of medicines, should occur in accordance with agreed protocols, formularies or consultation with prescribers and be promoted where it benefits patients and health systems.

Therapeutic interchange should be guided by formal governance structures, including formularies or medicines management committees, defined criteria, documentation requirements, and audit and feedback processes to ensure accountability and continuity of care. Where permitted within national regulations and supported by professional standards, pharmacists may also participate in initiating, adjusting, or discontinuing therapies to optimise patient outcomes, particularly for patients with multiple chronic conditions and multiple prescribers.

National health authorities are encouraged to establish standardised, publicly accessible and regularly updated lists of interchangeable medicines and guidance to support structured therapeutic interchange strategies, including mitigation of medicine shortages.

During medicine shortages, therapeutic interchange should follow predefined escalation pathways, with timely communication to prescribers and patients, and appropriate documentation in health records where applicable, to ensure continuity of care and patient safety.

Enabling conditions for safe and effective practice

1. Access to information and digital tools

Pharmacists should have access, at the point of care, to comprehensive, up-to-date information on pharmaceutical products and digital systems, as well as to the patient's electronic health record (EHR), ensuring that clinical decision-making is supported by the most complete therapeutic data available. This access enhances patient safety, supports safe, transparent and traceable decision-making, and improves overall quality of care.

2. Pharmacovigilance and real-world evidence (RWE)

Robust pharmacovigilance systems are essential. Pharmacists should document decisions and contribute to post-marketing surveillance and real-world evidence generation.

Appropriate traceability measures should be supported, particularly for biological medicines, including documentation of brand name and batch number where required by national regulations. Such measures strengthen pharmacovigilance systems, enable timely identification of product-specific safety concerns and contribute to robust post-marketing surveillance.

3. Education, training and competence

Education and continuing professional development should equip pharmacists with

knowledge, skills and competencies in substitution, biosimilars, HTA, digital health, communication and shared decision-making.

4. Ethics and conflicts of interest

Pharmaceutical product selection must be guided by ethical principles, transparency, and professional integrity, with conflicts of interest identified and managed appropriately. Health systems and professional bodies should implement conflict-of-interest policies that address incentives, procurement-linked pressures, and promotional influences, including disclosure requirements and separation of clinical decision-making from commercial inducements.

Emerging trends and future directions

FIP recognises emerging trends influencing pharmaceutical product selection, including advanced digital tools and AI, workforce evolution, biosimilar knowledge gaps, reimbursement dynamics, future-focused education, global regulatory variability, increasing cross-border procurement models, regional pooled purchasing initiatives, advanced therapy medicinal products, and personalised medicines, all of which may influence future substitution and interchange policies.

AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT AND CALLS FOR ACTION BY STAKEHOLDERS TO:

Governments and policymakers:

1. Establish clear legal frameworks enabling pharmacist-led substitution and therapeutic interchange.
2. Publish national or regional interchangeability guidance, including for generics and biosimilars where appropriate.
3. Avoid rigid classification of medicines through regulatory frameworks solely based on dispensing setting. The appropriate setting for dispensing should be determined by the individual's clinical condition and care needs, within a clinical team that includes the pharmacist, allowing treatment to be initiated in one setting (e.g. hospital) and continued in another (e.g. community) where appropriate.
4. Integrate substitution and interchange policies into medicines policy, universal health coverage (UHC) strategies, and shortage mitigation plans.
5. Support alignment of regulatory approvals, HTA outcomes, and clinical guidelines to enable safe and evidence-based product selection.
6. Lead initiatives to build public trust in generics and biosimilars.
7. Promote INN-based prescribing as a structural enabling condition for pharmacist-led generic substitution, supported by publicly accessible, regularly updated equivalence lists managed by the competent regulatory authority.
8. Ensure transparent and accessible product information, including excipients, supply risks, and pharmacovigilance data.
9. Encourage policies that promote sustainability, responsible production, and secure supply chains, and
10. Facilitate accessible communication and documentation between pharmacists, healthcare professionals, and patients.

Professional pharmacy organisations:

1. Develop and disseminate standards, protocols, and tools for substitution and therapeutic interchange.
2. Advocate for pharmacists' authority, leadership, and accountability in medicines optimisation at national and regional levels.
3. Lead initiatives to build public confidence in substitution and interchange practices;

4. Promote sustainability initiatives and responsible medicine use across practice settings, and
5. Support continuing professional development (CPD) and education on HTA, digital tools, patient-centred care, interprofessional collaboration, and competencies in substitution, therapeutic interchange and switching, including biosimilars, documentation, traceability, pharmacovigilance, and patient communication.

Pharmacy academic institutions and education providers:

1. Ensure undergraduate curricula includes biosimilars, interchangeability science, health economics, HTA, digital medicines management, sustainability, patient-centred communication, and shared decision-making.
2. Prepare students for collaborative, evidence-based, patient-centred, and sustainable pharmacy practice, and
3. Incorporate practical training on substitution, therapeutic interchange, and pharmacovigilance.

Pharmacists:

1. Ensure substitution and therapeutic interchange is underpinned with clinical judgement, patient-specific considerations, and evidence-based protocols.
2. Engage patients in informed discussions, addressing misconceptions, health literacy, and adherence issues.
3. Document details of all medicines supplied, including brand names, in local dispensing software and the centralised electronic health record (if available) to ensure continuity of care.
4. Document all decisions and contribute to pharmacovigilance and real-world evidence (RWE) generation.
5. Integrate digital tools, electronic prescribing, and clinical decision-support systems in practice.
6. Collaborate with prescribers, healthcare teams, and other stakeholders to ensure continuity of care.
7. Contribute real-world outcome data to inform future HTA reassessments, particularly in rapidly evolving therapeutic areas such as oncology, immunology, and rare diseases, and
8. Be actively involved in procurement design to ensure that tender criteria align with therapeutic interchange policies, continuity of care, patient safety, and long-term system sustainability. Pharmaceutical product selection should support sustainable and responsible medicines use, taking into account environmental and resource impacts.

Prescribers: (*see definition in annex*)

1. Participate in collaborative practice models.
2. Support protocol-driven therapeutic interchange.
3. Prescribe using international non-proprietary names (INN) where appropriate, and
4. Engage in patient education and shared decision-making initiatives.

Patients and patient organisations:

1. Take an active interest in educational and awareness initiatives on generics, biosimilars, and therapeutic interchange.
2. Participate as active partners in shared decision-making regarding pharmaceutical product selection, and
3. Engage in advocacy for equitable access to safe, effective, and sustainable medicines.

Payers and health system funders:

1. Collaborate with pharmacists, regulators, and professional bodies to implement evidence-based reimbursement and formulary decisions.
2. Support value-based healthcare strategies that integrate substitution and therapeutic interchange as mechanisms to improve access, sustainability, and responsible resource use, consistent with clinical guidelines and patient needs.
3. Ensure transparency and alignment between HTA outcomes, clinical guidelines, and reimbursement policies.
4. Acknowledge the contribution of pharmacists to the collection of real-world data to inform future HTA reassessments, particularly in rapidly evolving therapeutic areas such as oncology, immunology, and rare diseases, and
5. Recognise the value of pharmacist expertise and interventions in increasing efficacy and safety for individual patient outcomes but also healthcare systems in their entirety through the implementation of sustainable and equitable remuneration models.

Pharmaceutical manufacturers:

1. Collaborate with regulators, professional bodies, and pharmacists on responsible medicine production, supply security, and sustainability initiatives.
2. Provide timely, accurate, and transparent product information, including safety, bioequivalence, and pharmacovigilance data, and
3. Support educational and public trust-building initiatives related to generics, biosimilars, and substitution practices.

Digital health and information system developers:

1. Develop systems that support safe, transparent, and traceable substitution and therapeutic interchange decisions.
2. Enable integration of pharmacovigilance data, clinical decision support, and real-world evidence into daily practice, and
3. Facilitate accessible communication and documentation between pharmacists, prescribers, and patients.

AGAINST THIS BACKGROUND, FIP COMMITS TO:

1. Support capacity-building, regulatory harmonisation, and knowledge exchange, particularly in low- and middle-income countries.
2. Promote equitable access, sustainability, and adoption of best practices globally.
3. Facilitate collaboration between national authorities, professional organisations, and academic institutions, and
4. Provide reports on the health impact of these services in FIP Member Organisations countries.

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ANNEX: Definitions

For the purpose of this statement of policy, the following terms are used as defined below.

Active pharmaceutical ingredient (API): The active ingredient that alone or in combination with one or more other active ingredients is considered to fulfil the intended activity of a pharmaceutical. [11]

Bioequivalence: Two pharmaceutical products are said to be bioequivalent if they are pharmaceutically equivalent and their bioavailability (rate and extent of availability) after administration in the same molar dose is similar to such a degree that their efficacy and safety profiles can be expected to be essentially the same. [8] Regulators set parameters for bioequivalence designation. Regulator-approved bioequivalence to an original reference product is a necessary criterion for a pharmaceutical product to be classified as a generic brand in the regulator's country. [12-14] While generics are by definition bioequivalent, biosimilars are not.

Biological medicine: A medicine whose active ingredient is, wholly or in part, produced by or extracted from a biological source and requiring a combination of physical-chemical-biological testing together with the production process and its control in order to characterise the medicine and determine its quality. It may also be called the "biotherapeutic product", "biologic medicine" or "biopharmaceutical". [15]

Biosimilar product: A biological product that is highly similar in terms of quality, safety and efficacy to an already licensed reference biological product in quality, non-clinical and clinical evaluation. A biosimilar product and its reference biological product are expected to have similar safety and efficacy profile and once approved are used to treat the same indications. [15] A biosimilar is also highly similar to the reference biological medicine in terms of immunogenicity profile, which is the intrinsic ability of proteins and other biological medicines to cause an immune response. [16] Due to their nature, biosimilars are not automatically bioequivalent to their reference biological medicine and are not automatically regarded as a generic of a biological medicine. However, they are expected to produce the same clinical result as their reference biological product.

Biosimilar substitution: Dispensing a biosimilar in place of the prescribed reference biological medicine (or another biosimilar) when permitted by national law and consistent with regulator determinations (including, where applicable, interchangeability), supported by documentation and communication requirements. [3, 4, 17]

Generic medicines: These are pharmaceutical products containing the same amount of the same active pharmaceutical ingredients, formulated for administration by the same route and the same dosage form, meeting the required regulatory and pharmacopoeial standards and the same satisfactory standards of quality, safety and efficacy.[18] Generic medicines are bioequivalent to an originator medicine.[18] Generic medicines can only be marketed after the originator's patent(s) protection and marketing exclusivity (if relevant) have/has expired.

Generic substitution: is the mutual substitution of medicinal products having the same active ingredient, the same dose, and the same pharmaceutical form. This usually involves replacing the proprietary brand or reference medicinal product with a generic or parallel-imported product.[19]

Interchangeability: refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect.[20] Replacement can be done

by:[21]

- **Switching**, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent.
- **Substitution**: The practice of replacing a prescribed medicinal product with another product that contains the same active ingredient(s), dosage form, and strength, or that is considered to be therapeutically equivalent, often to improve access, affordability, or continuity of care.

International non-proprietary name (INN): The unique name of a pharmaceutical substance or active pharmaceutical ingredient that is globally recognised and is public property. A non-proprietary name is also known as a generic name. In many countries, it will be the same as the name of the active pharmaceutical ingredient.[22] The INN facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients.

Medicines optimisation: is a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines.[23]

Originator medicine: The first version of a medicine that has been developed and is patented by a pharmaceutical company. This company will have exclusive rights to market the pharmaceutical product for the life of the patent. An originator medicine has a unique trade (or brand) name for marketing purposes. It may also be called "first-in-class product" or "innovator product".[15,24] Once the patent(s) and marketing exclusivity (if relevant) have/has expired, and other products containing the same active pharmaceutical ingredient(s) are entering the market, the originator brand serves as the reference pharmaceutical product.

Prescriber: A prescriber is a licensed healthcare professional who is legally authorised to diagnose conditions and prescribe medications or other treatments to patients. Prescribing authority and medicines classification may be regulated differently across jurisdictions and different healthcare professionals.

Prescribing: The iterative process involving information gathering, clinical decision-making, communication and evaluation, which results in the initiation, continuation or cessation of a medicine.

Protocol: A formally agreed set of criteria and procedures governing therapeutic interchange within a health system or practice setting.

Substitution: See Interchangeability

Switching: See Interchangeability

Therapeutic equivalence: Medicinal products that are pharmaceutical equivalents with demonstrated bioequivalence and expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labelling.[25]

Therapeutic interchange: The act of dispensing a pharmaceutical product containing different active ingredient(s) which are of the same pharmacological class, and which have similar therapeutic effects as the prescribed pharmaceutical product.[26]

Therapeutic substitution: is the practice of replacing a prescribed medicine with a different medicine that has a different active substance, but is expected to provide a similar therapeutic effect and safety profile for the same condition, based on clinical judgement, agreed protocols, or formulary guidance, and typically within a

collaborative framework involving prescribers and pharmacists.

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This Statement replaces the following previous FIP Statements	:	International Pharmaceutical Federation. FIP statement of policy on Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution. The Hague: FIP, 2018.
This Statement can be quoted by stating:	:	International Pharmaceutical Federation (FIP). FIP Statement of Policy on pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution. The Hague: FIP, 2026. Available at: www.fip.org/statements.
This Statement references the following FIP Statements and documents:	:	World Health Organization (WHO). Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. Annex 8, WHO Technical Report Series No. 961. 10 Oct 2011. Available at: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex8-fipwhoguidelinesgoodpharmacypractice.pdf International Pharmaceutical Federation (FIP). FIP Statement of policy on medicines shortages. The Hague: FIP, 2020. Available at: https://www.fip.org/file/4786. International Pharmaceutical Federation (FIP). FIP Statement of policy on Improving access to safe and quality essential medicines and medical devices: The role of pharmacists. The Hague: FIP, 2024. Available at: https://www.fip.org/file/6036 International Pharmaceutical Federation (FIP). FIP Statement of Policy on Interprofessional collaboration. The Hague: FIP, 2024. Available at: https://www.fip.org/file/6041