

International Pharmaceutical Federation

FIP STATEMENT OF POLICY Strategic development of medicines information for the benefit of patients and users of medicines

INTRODUCTION

Medicines information comprises and encompasses a wide range of areas about medicinal products, such as identification, composition, uses, dosage, administration, adverse effects and contraindications, communicated to healthcare practitioners, patients and the general public by many and various means, including product labelling, package inserts, drug databases and electronic health records. Medicines information is usually supported by information about the body, health or diseases in order to better utilise that medicines information.

The quality of medicines information and ways of communicating it are important to patients and their caregivers; stakeholders such as healthcare practitioners, health regulatory authorities; and the pharmaceutical and health industry.

Challenges in ensuring the quality of medicines information often relate to the decentralised and unsupervised ways of creating health and well-being information online which can increasingly result in misinformation, with potential detrimental effects on the health of populations as demonstrated in the recent COVID-19 pandemic, especially with regard to vaccine hesitancy. Providing and communicating well-articulated, readable, accessible, actionable, evidence-based, unbiased and effective medicines information to patients, caregivers and users of medicines is a priority for pharmacists and underpins all the health services they deliver.

It is acknowledged that there are differences between countries in terms of legislation, regulations and guidelines on medicines information and how it is shared. However, for the purposes of this statement of policy, no individual country or national organisation will be named. Such details can be found in the <u>FIP report</u> entitled "Medicines information: Strategic development".

The purpose of medicines information

Enhancing public health literacy through medicines information can empower and help patients, healthcare practitioners and caregivers to promote safe, effective, and appropriate use of medicines.

Medicines information underpins and informs healthcare practitioners' clinical decisionmaking and supports their efforts to promote safe and optimal use of medicines by patients and other users. Fédération Internationale Pharmaceutique

Users of medicines need accurate, comprehensible, appropriate, objective, independent, up-to-date, unambiguous and relevant information which can adequately inform and assist them in safe, effective and better health decisions to ultimately achieve better health outcomes.

Sources of medicines information for patients, caregivers and users of medicines

There is a range of sources of medicines information available to the public, including:

- Verbal information (from healthcare practitioners);
- Written information directly supplied with individual medicines by pharmaceutical companies, pharmacists and other healthcare practitioners, and patient associations (e.g., medicines labelling and patient information leaflets and package inserts);
- Written information available from patient or healthcare practitioner organisations, governmental and non-governmental health organisations, pharmaceutical companies and other organisations that communicate with patients; and
- Websites and social media platforms (i.e., providing information on medicines or health conditions).

Supporting the development of high-quality medicines information

In addition to quality and appropriate content, the application of good information design and writing will ensure comprehensible printed and electronic medicines information. This is particularly important because suboptimal health literacy is a widespread issue. Health literacy ("the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions") varies both within and between countries.

There is a correlation between enhanced health literacy and positive health outcomes, such as lower hospitalisation rates, improved compliance with medication and better management of chronic illnesses. It is crucial to consider the target audience and utilise different communication methods and customised formats to ensure patients and users of medicines have the opportunity to participate in the early stages of development of medicines information.

The availability of artificial intelligence (AI) has presented new and emerging challenges and opportunities for medicines information. Users of medicines can find information through AI platforms such as ChatGPT by posing their questions and receiving responses, but the information may be incorrect. While ChatGPT, for example, can simplify complex medicines information, the correctness of this information is limited by the unknown sources it uses. Furthermore, simplification, while welcome and needed by patients, without the necessary checks increases the risks of confusion and misconceptions. Hence, raising awareness about the intersectionality of medicines information and AI is crucial to ensure that healthcare practitioners and the general public are well-informed and equipped to safely leverage the benefits of these technologies.

The Pharmacist's role

Demographic change, digital development and the growing expectations of individuals as well as governments and healthcare practitioners demand new ways of communicating.



Pharmacists will continue to play a pivotal role in the provision of reliable, objective, understandable, non-promotional, accurate, up-to-date and appropriate written and spoken medicines information to the public, patients and healthcare practitioners. This should happen within the context of a therapeutic interprofessional team, the patient and caregiver(s), where applicable. As people increasingly access information through the internet and via digital devices (e.g., smartphones) pharmacists can act as guides and interpreters, to help address common misconceptions regarding health and medicines-related information, and to help identify reliable sources of medicines information for use by patients, caregivers, users of medicines and other healthcare practitioners (physicians, nurses, etc.). To facilitate this, pharmacists need to be adequately trained in accessing and disseminating unbiased medicines information.

The strategic development of medicines information

Although medicines information is an integral part of health care, only a few countries have national medicines information strategies. Strategic development of medicines information is often included as part of national medicines policies, action plans or pharmacovigilance work. Pharmacists' expertise within a collaborative, interprofessional, interdisciplinary team is essential to guide the development and implementation of medicines information strategies within national medicines and health policies.

A medicines information strategy should be nationally embedded and allow for the development of new legislation and guidelines to advance the availability and quality of medicines information. The strategy should be guided by the evidence as well as highlight gaps that require further research.

Potential outcomes of strategic development of medicines information

Strategic development of medicines information is expected to bring about numerous advantages for different stakeholders and produce diverse outcomes in the short-, medium- and long-term, including but not limited to supporting remote health care, enabling more targeted care, facilitating shared decision-making, enhancing the visibility of pharmacists as medication specialists, assisting with consultations, reducing the workload of pharmacy teams and boosting job satisfaction among pharmacy staff.

Short-term outcomes include:

- Improved communication between patients, caregivers, pharmacists, and other healthcare practitioners;
- Better informed patients and caregivers before, during and after medicines use, regarding their medicine(s), associated harm, benefits and actions required for appropriate and optimal use;
- Improved trust in and adherence to treatment;
- Increased cooperation and teamwork among all parties involved in developing and disseminating high-quality medicines information; and
- Broader awareness of medicines information activities and their importance for digital health care.

Medium-term outcomes include:

- Improved and supported safe and appropriate self-care and medicines taking;
- Improved experience and satisfaction for patients and caregivers actively engaged in managing their health and medication;
- Improved patient motivation to take a more active role in his or her treatment;



- Improved communication between patients and healthcare practitioners, and increased patients' ability to manage their own health;
- Improved communication between pharmacists, physicians and other healthcare practitioners;
- Development of information tools to ensure effective sharing of information;
- Equitable access to medicines information and information sharing to empower patients to make informed decisions regarding their health and medication management;
- Better access to reliable, unbiased and high-quality information for stakeholders seeking medicines information;
- Improved pharmacovigilance and promotion of safe and appropriate use of medicines along the continuum of healthcare provision and treatment; and
- For the healthcare system as a whole, increased public confidence, improved cost-effectiveness via the development of high quality, consistent information nationally, as well as strengthened partnerships between statutory and independent sector information and service practitioners.

Long-term outcomes include:

- Improved patient adherence and health status;
- Improved self-management and self-care;
- Improved public health literacy, focused on disease prevention and reduced inappropriate medicines use, improved patient and public health outcomes and lower healthcare costs;
- Improved patient outcomes, including better health, reduced hospitalisation rates and more effective management of chronic conditions;
- Reduced risk of medication errors and adverse drug events, leading to improved patient safety in the long term;
- Recognised visibility and reputation for pharmacists among patients, healthcare practitioners and the wider community, ultimately leading to improved patient care and better health outcomes; and
- A patient-centred approach to care, with greater emphasis on shared decisionmaking and patient empowerment.

This FIP Statement of Policy is intended to:

- 1. Advocate to governments, the pharmaceutical and health industries, FIP member organisations, educational institutions and pharmacists to develop approaches to advance medicines information according to local needs.
- 2. Highlight and expand upon issues relevant to medicines information and the role of pharmacists and key stakeholders.
- 3. Encourage the development and adoption of national or organisational strategic approaches to the development and communication of medicines information to ensure its quality and effectiveness, including the identification and dissemination of best practices, as well as the provision of clear guidelines and recommendations for reliable information searching and distribution to all relevant parties, such as healthcare practitioners and patients.

AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT:

Governments should:

1. Commit to promoting data transparency from medical and pharmaceutical research related to drug adverse effects, risks, contraindications and

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precautions to enable the development of evidence-based medicines information.

- 2. Monitor and appropriately regulate against medicine misinformation practices.
- 3. Improve the quality of medicines information resources through global coordination and the identification of best practices, which can lead to more effective and optimal medicines management policies, by learning from the experiences of countries with well-established medicines information policies and strategies.
- 4. Compile a national medicines policy which includes strategic development and tools and involves patients, pharmacists and other healthcare practitioners to aid appropriate sharing of medicines information.
- 5. Compile a national medicines information strategy to illustrate challenges and needs related to medicines information more explicitly.
- 6. Oversee the implementation of an accepted medicines information strategy and relevant guidelines.
- 7. Promote medication literacy skills as well as other vital literacy skills, such as economics or informatics, in connection with medicines information to enhance patients' ability to make informed decisions regarding their medication management and improve overall health literacy.
- 8. Support pharmacists and other healthcare practitioners to adapt their practices and embrace new digital tools in order to ensure patients receive accurate, reliable and unbiased medicines information.
- 9. Develop policies where pharmacists act as key players in informing patients about medicines and encourage patients and users of medicines to seek advice from pharmacists regarding medicines and their use.
- 10. Offer economic incentives to pharmacists that acknowledge and provide suitable reimbursement models for the services related to medicines information that can be performed by pharmacy and other healthcare professions.
- 11. Provide or encourage the development of medicines information guidelines that ensure high-quality information that is consistent among all healthcare practitioners and establish clear lines of separation between medicines advertising and medicines information.
- 12. Integrate usability as a core outcome measure in policies and guidelines relevant to the development and evaluation of written medicines information to ensure fitness for purpose.
- 13. Provide resources and support to integrate the usability of medicines information including promoting and acknowledging the importance of medicines information.
- 14. Foster the establishment of specialised medicines information centres operated by pharmacists specialising in the provision of medicines information.
- 15. Develop and implement the requirements and criteria for certifying or accrediting medicines information centres and medicines information resources in collaboration with professional and educational bodies.
- 16. Prohibit or carefully regulate direct-to-consumer advertising of prescription medicines.
- 17. Promote the adoption of new communication and information technologies to facilitate access to reliable and pharmacy-based medicines information.
- 18. Highlight the need for accurate and up-to-date medicines information, not only about the medicines themselves but also about their availability. Drug shortages is a prevalent issue in many countries and can impede access to medicines.



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The pharmaceutical and health industries should:

- Provide reliable and easily accessible information on their medicinal products for healthcare practitioners. This information should be updated regularly and based on up-to-date evidence gained from clinical trials or use of the products.
- 2. Provide reliable and easily accessible information on their medicinal products for users of medicines (e.g., patient information leaflets).
- 3. Comply with local and national laws and regulations related to direct-toconsumer advertising of prescription medicines and, where this may be allowed, to follow standards of balance and accuracy.
- 4. Aim to provide evidence-based, unbiased risk information on treatment benefits and harms (in particular, side effect risks) to enable users of medicines and healthcare practitioners to make informed treatment decisions.
- 5. Include users of medicines as key stakeholders when developing medicines information.
- 6. Develop multimedia materials such as videos and infographics, interactive tools such as online questionnaires and chatbots, and written medicines information such as leaflets that are understandable by users of medicines of all health literacy levels. Any information that is developed should also be evaluated with expected end-users in mind to ensure that it is fit for purpose.
- 7. Follow local regulations on the marketing of medicinal products and acknowledge the difference between medicines information and promotional materials or advertising.
- 8. Use innovative ways and formats to distribute medicines information that is effective and accessible for users of medicines including people who require special consideration such as people with disabilities.

FIP member organisations should:

- 1. Initiate strategic development of medicines information nationally.
- 2. Promote the adoption of standardised terminology and classification systems across the health system to promote the effective and safe sharing of health and medicines information.
- 3. Be actively involved when strategic development of medicines information is being undertaken.
- 4. Work with allied health organisations to develop guidelines for development and use of medicines information materials.
- 5. Demonstrate the importance of accurate medicines information to increase rational medicines use, medication safety and adherence.
- 6. Develop strategies that encourage pharmacists and other healthcare practitioners to provide high-quality medicines information as well as take an active role in assisting patients to facilitate patient decision-making.
- 7. Promote the development of tools and easy-to-access databases for medicines information and pharmaceutical services.
- 8. Encourage the development of effective and user-friendly software systems that offer access to precise, current and customised medicines information for individual patients' treatment needs. This can be achieved not only by emphasising the importance of promoting and spreading best practices related to medicines information but also with governmental support in terms of providing funding and creating policies that promote the development and use of such systems.
- Promote the importance of accurate medicines information by organising campaigns and influencing the digital transformation of the healthcare system. With their medication management expertise and regular interactions with patients and healthcare practitioners, pharmacists can lead awareness



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campaigns and collaborate with software developers to improve the quality and safety of medicines use.

- 10. Promote pharmacies and pharmacist teams as first contact points for medicines information and digital communication for added value pharmaceutical services.
- 11. Advocate transparency with regard to sources of information.

Educational institutions involved in training healthcare practitioners should:

- 1. Include interprofessional courses in their curricula on medicines information and critical analysis of medical and scientific literature with a special focus on the information available on the internet.
- 2. Include skills on how to access, use and disseminate evidence-based, unbiased medicines information databases and clinical decision-making tools in daily practice in their curricula.
- 3. Include effective use of reliable medicines information sources in their curricula.
- 4. Promote development of exemplary medication counselling skills, supported by effective communication skills and provision of reliable medicines information.

Pharmacists should:

- 1. Practise excellent oral and written communication skills and be able to appropriately communicate and apply pertinent information to the patient care situation.
- Help patients, caregivers and users of medicines to obtain and critically analyse reliable health and medicines information to meet their individual needs. Special attention should be given to:
 - Educating patients on how to use web-based healthcare information (including medicines information) and strongly encouraging them to speak to a pharmacist about questions regarding information that they find online or via other digital channels;
 - Advising patients and caregivers about reliable information sources;
 - Implementing mechanisms to inform patients and caregivers living in remote areas of the benefits of medicines information counselling and assisting patients in educating themselves on their medical conditions and treatments;
 - Ensuring patient privacy and confidentiality are maintained; and
 - Facilitating patient empowerment and patient responsibility for their health.
- 3. Provide information on both the risks and benefits of medicines through effective patient counselling.
- 4. Use printed or electronic information to reinforce spoken information provided to patients, caregivers or users of medicines.
- Tailor medicines information to specific situations (e.g., first-time use of medicines by patients, repeated use, poor integration of medication regimens into individual daily lifestyles and routines, incorrect use or application of medicines, and combination of prescription and over-the-counter medicines).
- 6. Discuss medicines information with patients, caregivers and users of medicines, keeping two-way communication in mind.
- 7. Employ universal health literacy precautions to ensure that all patients or caregivers, regardless of their literacy levels, receive understandable and accessible information. This includes avoiding medical terminology, simplifying

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complex information, breaking down instructions into discrete steps, and using the teach-back method to assess comprehension.

- 8. Engage in efforts to produce and disseminate appropriate medicines information.
- 9. Provide information in formats (e.g., pictograms, easy language, etc) accessible to people who require special consideration such as people with disabilities.
- 10. Adapt medicines information formats to different groups of patients considering their age, cultural background and level of knowledge.
- 11. Facilitate the provision of unbiased medicines information that is tailored to patient needs.
- 12. Provide support to other healthcare practitioners, in all healthcare settings, to enhance medicines reconciliation activities (at every transition of care), improve patient medication adherence, improve medication-related outcomes and participate in interprofessional collaborative initiatives.
- 13. Recognise the role of medicines information in relation to rational use of medicines by other healthcare practitioners, particularly in complex patient care settings such as hospitals.
- 14. View the advancement of technology as an opportunity for supporting personalised medicines information.
- 15. Utilise their expertise to lead the creation and execution of effective medicines information strategies, while establishing their role as a trusted partner and knowledge base for other healthcare practitioners, and the primary resource for obtaining accurate and unbiased medicines information.
- 16. Leverage their expertise to develop effective medicines information strategies and engage with all relevant parties to ensure accurate medicines information via digital channels, and counteract in a joint effort the proliferation of inaccurate medicines information circulating on social media and other digital platforms, proposing solutions that prioritise patient safety and well-being.
- 17. Commit to continuing education activities and professional development in medicines information.

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