

# FIP STATEMENT OF POLICY

# Strategic development of medicines information for the benefit of patients and users of medicines

#### Introduction

Medicines information is essential to empower patients, caregivers and users of medicines to engage effectively in appropriate, quality and safe use of medicines. There is a wide range of information sources and formats that medicine users may access. The effectiveness of information and its communication is of importance to patients and their caregivers, as well as to a range of stakeholders such as physicians, pharmacists and other health care professionals, health regulatory authorities, and the pharmaceutical and health industry.

Providing and communicating 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. More attention should be paid to coordinating and improving the quality of medicines information resources. There is potential to learn from the experiences of other countries, especially from those with well established medicines information policies and strategies. By assisting one another, a global approach to developing medicines information may be achieved and linked with medicines management policies.

It is acknowledged that there are differences between countries in terms of legislation, regulations and guidelines on medicines information. 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 FIP report entitled "Medicines information: Strategic development".

# Statement of Policy aims

The aims of this Statement are to:

- 1. Expand on issues relevant to medicines information and the role of pharmacists and key stakeholders;
- 2. Emphasise the need for a strategic approach to the development of medicines information to ensure high quality medicines information.

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# **Background**

## The purpose of medicines information

The primary purpose of medicines information is to improve public health literacy and to empower and assist citizens, patients, caregivers, users of medicines and health care professionals in achieving safe, effective and appropriate use of medicines. This includes providing information that allows users of medicines to make informed decisions about the appropriate selection and use of medicines. Users of medicines value accurate, comprehensible, appropriate, objective, independent, up-to-date and relevant information which can adequately inform and assist them in safe, effective and appropriate self-management.

# Sources of health and 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 health care professionals).
- Written information directly supplied with individual medicines by pharmaceutical companies, pharmacists, and other health care professionals (e.g., medicines labelling and information leaflets or package inserts).
- Written information available from patient or health care professional organisations, governmental and non-governmental health organisations, pharmaceutical companies and other organisations that communicate with patients.
- Websites (i.e., providing information on medicines or health conditions).
- Digital resources such as mobile health (m-health) apps and social media (e.g., Twitter, Facebook and YouTube).

Supporting the development of high quality written medicines information

In addition to relevant, accurate, comprehensible, appropriate, objective, independent and up-to-date content, the application of good information design and writing will ensure comprehensible printed and electronic medicines information. Suboptimal health literacy is a widespread issue within an international context, where 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. These differences should be considered when developing medicines information tools, with particular attention given to alternative methods of communication and special/tailored formats, such as the

<sup>1</sup> Nielsen-Bohlman L, Panzer AM, and Kindig DA (Editors): Prescription to End Confusion (2004). Available at: <a href="http://www.nap.edu/read/10883/chapter/4">http://www.nap.edu/read/10883/chapter/4</a>

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use of large font size, pictograms, audio versions and Braille, as well as mixed approaches (e.g., written and audio-visual).

# The role of pharmacists

Demographic change, digital development and the growing expectations of individuals as well as governments and health care professionals, demand new ways of communicating. Pharmacists must be innovative in the way they communicate with people in order to ensure the efficiency and effectiveness of their informative, educational and digital initiatives. Pharmacists will continue to play a pivotal role in the provision of reliable, objective, understandable, nonpromotional, accurate, up-to-date and appropriate written and spoken medicines information to the public, patients and health care professionals. This should happen within the context of a therapeutic interprofessional team, where applicable. As people increasingly access information through the Internet and via digital devices (e.g., mobile phones) pharmacists can act as guides and interpreters, in order to help address common misconceptions regarding health and medicine-related information, and to help identify reliable sources of medicines information for use by patients, caregivers, users of medicines and other health care providers (physicians, nurses, etc.). In order to facilitate this, pharmacists need to be adequately trained and provided with access to unbiased medicines information.

#### 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 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.

<u>Potential outcomes of strategic development of medicines information</u>

The strategic development of medicines information is likely to benefit many parties and lead to many short-, medium- and long-term outcomes.

# Short-term outcomes include:

 Improved communication between patients, caregivers, pharmacists, and other health care professionals; Fédération Internationale Pharmaceutique

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- Better informed patients and/or caregivers before, during, and after medicines use, regarding their medicine(s), associated risks, benefits, and actions required;
- Improved adherence to treatment;
- Increased cooperation and teamwork among all parties involved in developing high quality medicines information;
- 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 selfmedication;
- Improved experience and satisfaction for patients and/or caregivers actively involved in health management;
- Improved patient motivation to take a more active role in his or her treatment;
- Improved communication between patients and health care professionals, and increased patients' ability to manage their own health;
- Improved communication between pharmacists, physicians and other health care professionals;
- Development of information tools to ensure effective sharing of information:
- Better access to reliable, unbiased and high-quality information;
- Improved pharmacovigilance and promotion of safe and appropriate use of medicines along the continuum of health care provision and treatment;
- For the health care 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 providers.

# Long-term outcomes include:

- Improved patient adherence and health status;
- Improved self management and self care;
- Improved public health literacy, focused on prevention and reduced inappropriate medicines use, improved patient health outcomes, and lower health care costs.

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### AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT:

#### **Governments:**

- 1. Compile a national medicines policy which includes strategic development of medicines information;
- 2. Compile a national medicines information strategy to illustrate challenges and needs related to medicines information more explicitly;
- 3. Oversee the implementation of an accepted medicines information strategy and relevant guidelines;
- 4. 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;
- 5. Give pharmacists economic incentives that recognise pharmacists' value in providing medicines information;
- Provide or encourage the development of medicines information guidelines that assure high-quality information, which is consistent among all health care professionals;
- 7. 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;
- 8. Provide resources and support to allow such work to be undertaken (including promoting and acknowledging the importance of medicines information);
- 9. Foster the establishment of specialised medicines information centres;
- 10. Develop and implement criteria for certifying or accrediting medicines information centres and medicines information resources in collaboration with professional and educational bodies;
- 11. Prohibit direct-to-consumer advertising of prescription medicines;
- 12. Promote the adoption of new communication and information technologies to facilitate access to reliable and pharmacy-based medicines information.

### Pharmaceutical and health industry:

- Provide reliable information on their medicinal products for health care professionals and users of medicines (e.g., leaflets developed specifically for users of medicines based on the relevant medicinal product information intended for health care professionals). This information should be updated regularly and based on up-to-date evidence gained from clinical trials;
- 2. Refrain from DTC advertisement for prescription-only medicines;
- 3. Aim to provide risk information on treatment benefits and harms , (in particular, side effect risk information) to enable users of medicines and health care professionals to make informed treatment decisions;

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- 4. Include users of medicines as key stakeholders when developing medicines information;
- 5. Develop written medicines information (e.g., leaflets) that is understandable by patients of all health literacy levels. Any information that is developed should also be evaluated with anticipated end-users to ensure that it is fit for purpose;
- 6. Follow the local regulations on the marketing of medicinal products and acknowledge the difference between medicines information and promotional material(s)/advertising;
- 7. Use innovative ways and formats to distribute medicines information that is effective for users of medicines, as well as accessible to people who require special attention.

# Member organisations:

- 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 throughout the health care continuum;
- 3. Take action and be actively involved when strategic development of medicines information is undertaken;
- 4. Work with allied health organisations to develop guidelines for development and use of medicines information materials;
- 5. Demonstrate the importance of medicines information to increase rational medicine use, medication safety and adherence;
- 6. Develop strategies that encourage pharmacists and other health care professionals to provide high-quality medicines information as well as take an active role in assisting patients to manage their medicines;
- 7. Promote the development of tools and databases for medicines information and pharmaceutical services;
- Motivate computer software developers to provide systems that give access to accurate, up-to-date, user-friendly medicines information which can be tailored to meet the needs of individual patients with regards to their treatment;
- 9. Organise and promote campaigns on medicines information to highlight its role and importance;
- 10. Influence and shape the digital transformation for all actors in the health care system;
- 11. Promote pharmacies and the pharmacist teams as first contact point for medicines information and digital communication for added value pharmaceutical services;
- 12. Advocate for transparency with regards to the source of information.

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### **Educational institutions involved in training health care professionals:**

- Include interprofessional courses in the curriculum on medicines information and critical analysis of medical and scientific literature with special focus on the information available on the Internet and m-health technology;
- 2. Include skills on how to use unbiased medicines information databases and clinical decision-making tools in daily practice in the curriculum;
- 3. Include the effective use of reliable medicines information sources in the curriculum;
- 4. Promote the development of exemplary medication counselling skills.

#### **Pharmacists:**

- 1. 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 topics, such as:
  - a. Educating patients on how to use web-based health care information (including medicines information) and strongly encouraging them to speak to a pharmacist about questions regarding information that they find online;
  - b. Advising patients and/or caregivers about reliable information sources;
  - c. Informing patients and caregivers who do not come into the pharmacy to receive their medicines;
  - d. Encouraging and assisting patients in educating themselves on their medical condition(s) and treatment(s);
  - e. Ensuring that a private area is available in every pharmacy for use in patient care (for instance when sensitive information is being conveyed);
  - f. Facilitating patient empowerment and patient responsibility for their own personal health.
- 2. Provide information on both the harms and benefits of medicines;
- 3. Use printed or electronic information to reinforce spoken information provided to a patient, caregiver and/or user of medicine;
- 4. Tailor medicines information to specific situations (e.g., first time use of medicine(s) by patients, repeated use, poor integration of medication regimen(s) into individual daily lifestyles and routines, incorrect use or application of medicines, and combination of prescription and over-the-counter medicines).
- 5. Discuss medicines information with patients, caregivers and users of medicines, keeping two-way communication in mind;
- 6. Engage in efforts to produce and disseminate appropriate medicines information;

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- 7. Provide information in formats accessible to people who require special attention;
- 8. Adapt medicines information formats to different populations of patients considering their age, cultural background and level of knowledge;
- 9. Facilitate the provision of unbiased and tailored information to other health care professionals, particularly in complex patient care settings such as hospitals;
- 10. Provide support to other pharmacists and health care professionals, in all health care settings, in order to ensure quality use of medicines, enhance medicines reconciliation activities, engage in improving patient medication adherence and improve medication-related outcomes;
- 11. Provide support to other health care professionals and participate in interprofessional collaborative initiatives;
- 12. Recognise the role of medicines information in relation to rational medicine use, medication safety and increased adherence;
- 13. Use reliable medicines information sources appropriately;
- 14. Consider the evolution of technology in supporting individualised medicines information;
- 15. Use expertise to guide the development and implementation of medicines information strategies.

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Proposed by: Board of Pharmaceutical Practice / Health and Medicines Information

This Statement replaces the following

previous FIP Statements

International Pharmaceutical Federation. FIP Statement of Policy on

Medicines Information for Patients. The Hague: FIP, 2008.

This Statement can be quoted as: International Pharmaceutical Federation, FIP Statement of Policy -Strategic development of medicines information for the benefit of

patients and users of medicines. The Hague: FIP, 2017. Available at: www.fip.org/statements

This Statement references the following FIP

Statements and documents:

International Pharmaceutical Federation. Medicines information: Strategic development The Hague: FIP, 2017. Available at:

http://www.fip.org/publications