



## **2019 Joint Statement of Policy by the International Pharmaceutical Federation (FIP) and the Global Self-Care Federation (GSCF) on Responsible and Effective Self-care**

### **Objective**

The objective of this statement is to describe the united role and intention of the pharmacy profession and industry in delivering solutions to people to facilitate self-care and in engaging with stakeholders including governments to further develop self-care as a core pillar of sustainable healthcare systems. This statement considers regulated or evidence-based self-care products designed to promote good health, or to prevent and/or to treat ill health through self-care, and to achieve positive outcomes for people's health. In this context, pharmacists play a key role when assisting individuals as they can provide unbiased, evidence-based advice and information about regulated or evidence-based self-care products and services available.

### **Definition**

The World Health Organization defines self-care as the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a healthcare provider. Self-care encompasses several issues including hygiene, nutrition, lifestyle, environmental and socio-economic factors.<sup>1</sup> Promotion of self-care is a means to empower individuals, families and communities for informed health decision-making. It has the potential to improve the efficiency of health systems and to contribute towards health equity.<sup>1</sup>

### **Background**

Self-care has been an integral part of healthcare for many years.

Today, many people accept greater personal responsibility for their health status and obtain as much quality information as possible from expert sources to help them make appropriate decisions about their health. Health literacy is a foundational pre-requisite to responsible self-care which makes two-way communication between the individual and their healthcare professional an essential element of effective self-care.

Governments and health insurers are increasingly recognizing the value of self-care for its accessibility, empowerment of individuals to take greater responsibility for their health and its value in preventing disease and promoting positive health outcomes. Given this value

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<sup>1</sup> World Health Organization, Regional Office for South-East Asia. (2014). Self-care for health. WHO Regional Office for South-East Asia. <http://www.who.int/iris/handle/10665/205887>

proposition, these entities should include self-care as an important element of the care continuum and include its coverage as part of their health benefit offerings.

Pharmacists can play an important role in facilitating effective self-care. Pharmacists are often ranked as the most accessible and most trusted healthcare professionals. Their education and training enable them to translate quality, evidence-based information into sound, unbiased advice on self-care products and strategies to the public. Pharmacists are key healthcare professionals in rational selection, administration and responsible use of self-care products. This is augmented by a pharmacist's individual counselling, support and follow up for safety and efficacy.

Pharmacists and manufacturers share the common goals of providing quality products and services to the public and encouraging responsible and effective self-care. These goals are best achieved by adequate product labelling with factual and evidence-based information and by ensuring that all healthcare professionals involved in the continuum of care give evidence-based and unbiased guidance and advice.

Products and services provided by GSCF member companies are regulated by governments in each country where they are sold. Compliance with regulations ensures their quality, safety and efficacy when used as intended. The quality, safety and efficacy of these self-care products can be assured through such authorizations. Regulators have an important role in assuring product safety and efficacy for people while ensuring timely access to new innovations and encouraging regulatory convergence across the regions.

Responsible advertising [is one vehicle that] enables individuals to make properly informed decisions. Advertising is either regulated by regulatory authorities or self-regulated by industry. This varies across countries. Such advertising enables people to make an informed decision in managing their own health and reflects industry's commitment to provide the most appropriate information. In those jurisdictions, where allowed, advertising is helpful in informing people about self-care products and conditions that can be self-managed by those products. FIP and GSCF support responsible advertising and encourage individuals to read and follow the product label and package insert, if any, including seeking advice from a pharmacist or other healthcare professionals for more information.

## **THE RESPONSIBILITY OF THE PHARMACIST**

Pharmacists have a professional responsibility to:

1. Support the person with evidence-based, unbiased and sound advice about self-care, the range of available treatment options, and the accurate self-identification of many self-treatable conditions. Pharmacists should provide each patient with holistic advice, which may include, but is not limited to: diet, exercise and other lifestyle changes;
2. Adapt communication to the individual's level of health literacy. Provide information leaflets or reliable information on self-treatable conditions and self-care products from available digital and other sources;
3. Encourage the individual to provide the pharmacist with information required to best assess a condition (e.g. coexisting medical conditions, use of other medicines, and the

- patient's lifestyle or unique needs for dosing forms, etc.);
4. Verify whether self-care products can safely be used (e.g. in the case of pregnancy, breastfeeding or driving a motorised vehicle and/or when using medication for a chronic disease);
  5. Encourage the person to always use self-care products appropriately, safely, efficaciously and judiciously. Guide the person to only use the product as instructed and for its intended purposes;
  6. Invite the person to speak to the pharmacist if he/she experiences unexpected/unwanted effects from the use of a self-care product;
  7. Assess and triage the patient to serve as a gateway to care based on information provided. Appropriately refer patients to other healthcare providers when self-care is not appropriate.
  8. Apply pharmacovigilance principles in day-to-day practice. Report to the regulatory authorities, and inform the manufacturer, of any adverse event encountered by an individual that may be associated with the use of a self-care product. In some jurisdictions, the individual can report an adverse event to a national website and the pharmacist can draw the attention of the person to this, if available;
  9. Encourage the person to proactively manage his/her own health and lifestyle and establish a strong relationship with their pharmacist;
  10. Encourage the person to use health system resources responsibly and to engage in self-care where needed and appropriate;
  11. Establish a relationship to gather and document patient's self-care condition and self-care products used in an appropriate patient record, along with their records of prescription medicines and diagnosis;
  12. Advise the public on the benefits of consulting the pharmacist as an expert healthcare professional when looking to self-care;
  13. Encourage the person to advise family and friends to consult a pharmacist or other appropriate healthcare professionals in case of health complaints.
  14. Help improve the awareness of the public and healthcare professionals to utilise self-care to address public health issues of current importance - for example antibiotic resistance.

## **THE RESPONSIBILITY OF THE MANUFACTURER OF SELF-CARE PRODUCTS**

The entity responsible for the product, who will normally be the manufacturer, but may also be the primary distributor, is herewith referred to as "the manufacturer".

The manufacturer has the responsibility to:

1. Provide self-care products and services that meet all applicable requirements for safety, quality and efficacy as well as packaging and labelling;
2. Ensure that all interactions with healthcare professionals are conducted in compliance with regulations and best practices;
3. Encourage collaboration with all healthcare professionals involved in the continuum of care to improve individual's comprehension of information on product labels and package inserts;
4. Engage with regulatory authorities to work towards appropriate regulation and international convergence;

5. Provide healthcare professionals, including pharmacists, with the available information and scientific evidence that will allow them to provide evidence-based guidance to the individual;
6. Ensure that health claims made in product advertising do not exceed those approved under the authority of national regulations, that they follow industry guidelines and internal company controls and are not misleading and encourage responsible use;
7. Ensure that marketing methods encourage individuals to use self-care products responsibly as directed by the product labelling, discourage inappropriate use and purchasing of more than the required quantities for responsible use;
8. Encourage the individual to make proactive healthy living decisions and exercise responsible self-care for self-treatable conditions, and support effective engagement and utilization of healthcare system resources, including pharmacist's services;
9. Encourage individuals to report any unwanted/unexpected events from self-care products to the appropriate agency and/or the manufacturer. Manufacturers should monitor and address reported adverse effects.
10. Promote and contribute to improve health literacy by providing appropriate information about self-care products and services.

## CONCLUSION

The public interest will be best served when pharmacists and the self-care products industry work together to ensure that self-care is responsible and effective, is only undertaken when it is appropriate to do so, and advice is always given to seek a healthcare professional's support when that is necessary.

FIP and GSCF commit to work together to ensure that pharmacists and manufacturers appropriately work towards fulfilling these responsibilities.

Date of Adoption	:	21 September 2019
Proposed by	:	FIP Bureau
This Statement replaces the following previous FIP Statements	:	Joint FIP-WSMI Statement on Responsible Self-medication 1998
This Statement can be quoted by stating:	:	Joint FIP/GSCF Statement of Policy on Responsible and Effective Self-care
This Statement references the following FIP Statements and documents:	:	International Pharmaceutical Federation (FIP). Pharmacists as a gateway to care: Helping people towards better health. The Hague: International Pharmaceutical Federation, 2017. Available at: <a href="https://www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf">https://www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf</a>