

Annex 8

Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services

Background

1. Introduction
2. Underlying philosophy
3. Definition of good pharmacy practice
4. Requirements of good pharmacy practice
5. Setting standards for good pharmacy practice
6. Conclusions

Background

Under the World Health Organization (WHO)'s Revised Drug Strategy adopted by the World Health Assembly in 1986, WHO organized two meetings on the role of the pharmacist, in Delhi, India in 1988 and in Tokyo, Japan in 1993. This was followed by the adoption, in May 1994, of the World Health Assembly Resolution WHA47.12 on the role of the pharmacist, in support of the WHO Revised Drug Strategy.

In 1992 the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading "Good pharmacy practice in community and hospital pharmacy settings". The text on good pharmacy practice was also submitted to the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 1994. Following the recommendations of the WHO Expert Committee and the endorsement of the FIP Council in 1997, the FIP/WHO joint document on good pharmacy practice (GPP) was published in 1999 in the thirty-fifth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 885).

Subsequently WHO organized two more meetings on the role of the pharmacist, in Vancouver, Canada in 1997 and in the Hague, the Netherlands in 1998. These meetings reinforced the need for pharmacy curricular reform and the added value of the pharmacist in self-care and self-medication.

In collaboration with WHO, the first edition of a practical handbook *Developing pharmacy practice — a focus on patient care* was launched in 2006. This handbook is designed to meet the changing needs of pharmacists, setting out a new paradigm for pharmacy practice and presenting a step-by-step approach to pharmaceutical care.

With the overall aim of improving standards and practice of distribution and use of medicines, using the FIP/WHO guidelines for GPP as the framework, FIP took the initiative to explore the possibilities for providing technical assistance to its Member Organizations in Cambodia, Moldova, Mongolia, Paraguay, Thailand, Uruguay and Viet Nam, in developing national standards for GPP in a pilot study from 2005 to 2007. In 2007 the "Bangkok declaration on good pharmacy practice in the community pharmacy settings" in the South-East Asia Region was adopted by the FIP South-East Asia Pharmaceutical Forum and set out the commitment of its Member Associations towards raising standards of pharmacy services and professional practice.

Since the adoption of the GPP guidelines in community and hospital settings, significant changes in practice, applied science and technology and pharmaceutical policy have occurred, including the relevance of more recent World Health Assembly resolutions: WHA54.11 (WHO Medicines

Strategy), WHA54.13 (Strengthening health systems in developing countries), WHA55.14 (Ensuring accessibility of essential medicines), WHA55.18 (Quality of care: patient safety), WHA57.16 (Health promotion) and WHA60.16 (Rational use of medicines).

Furthermore, in 2007 FIP established an initiative to investigate the need to update the guidelines on GPP to reflect contemporary standards of practice and thinking. An FIP working group on GPP first met on 15 October 2007 to identify key issues that needed to be considered in the revision of the guidelines.

In 2008 FIP organized an expert consultation in Basel, Switzerland during its 68th World Congress. Fifty participants attended the meeting, including the FIP Working Group (WG) on GPP, WHO staff from headquarters, representatives from the WHO Regional Office for the Eastern Mediterranean, country medicines advisers from Ghana, Nigeria and the United Republic of Tanzania, Presidents and Secretaries of the six FIP Regional Pharmaceutical Forums, FIP Member Organizations and several invited experts.

Following this consultation, the FIP WG on GPP undertook an extensive review of the existing national standards on GPP in at least 37 countries and established a time frame that would allow sufficient consultation with all of FIP's 120 national Member Associations, relevant experts and WHO. A proposal for this initiative was presented to the forty-third meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2008 and an updated report was provided to the Expert Committee at its forty-fourth meeting in October 2009.

1. **Introduction**

The health of the public is fundamental to the happiness and welfare of all people. Barriers to good health include poor access to quality medical products, lack of access to trained health professionals and care, an inadequate health workforce, unaffordable cost of care and poor standards of education of health-care professionals.

Medicines are an essential and critical part of health-care services in all cultures and societies. When accessed, medicines are often an essential component of many disease prevention programmes and virtually all disease treatment plans. The potential benefit of medicines is often not realized — there is a gap between the proven efficacy of medicines demonstrated in clinical trials and their actual effectiveness in practice. The reasons for this gap include problems with medicine selection and dosages, improper administration of medicines and lack of adherence by patients to prescribed treatment, medicine–medicine and medicine–food interactions, and adverse medicine events. Besides clinical problems associated with medicine-related problems, there are cost

implications. It has been estimated that the cost of problems with the use of medicines is equal to or greater than the cost of the medicines themselves.

Medicines are also increasingly expensive and their cost is compromising the affordability of health care. Managing the costs of medicines is critical to making the best use of limited resources to maximize health care for as many people as possible.

Substandard, adulterated, unlicensed and spurious/false-labelled/falsified/counterfeit medicines are a growing problem that compromise health. There is a need for a system of assuring the integrity of the medicine supply chain to assure the value of medicines used for the prevention of disease and the treatment of patients.

Pharmacists¹ are specifically educated and trained health professionals who are charged by their national or other appropriate (e.g. state or provincial) authorities with the management of the distribution of medicines to consumers and to engage in appropriate efforts to assure their safe and efficacious use. There is also increasing recognition that providing consumers with medicines alone is not sufficient to achieve the treatment goals. To address these medication-related needs, pharmacists are accepting greater responsibility for the outcomes of medicines use and are evolving their practices to provide patients with enhanced medicines-use services.

As health-care professionals, pharmacists play an important role in improving access to health care and in closing the gap between the potential benefit of medicines and the actual value realized and should be part of any comprehensive health system. In addition, the increasingly complex and diverse nature of pharmacists' roles in the health-care system and public health demands a continuous maintenance of the competence of pharmacists as health-care professionals who have up-to-date skills and expertise.

National pharmacy professional associations need to work together with their governing bodies and other health-care professional associations to support pharmacists in their countries through provision of continuing professional development activities, including distance-learning programmes, and establishing national standards of pharmacy services and practice objectives.

These guidelines are intended to provide a description of ways in which pharmacists can improve access to health care, health promotion and the use of medicines on behalf of the patients they serve. The role of FIP is to provide leadership for national pharmacy professional organizations,

² Pharmacists are health-care professionals whose professional responsibilities and accountabilities include seeking to ensure that people derive maximum therapeutic benefit from their treatments with medicines. This requires them to keep abreast of developments in pharmacy practice and the pharmaceutical sciences, professional standards and requirements, the laws governing pharmacy and medicines and advances in knowledge and technology relating to use of medicines.

which in turn provide the impetus for setting national standards.² The vital element is the commitment of the pharmacy profession worldwide to promoting excellence in practice for the benefit of those served. The public and other professions will judge the pharmacy profession on how its members translate that commitment into practice in all settings, especially community and hospital pharmacy settings.

It is the policy of FIP and WHO to provide guidance to national pharmacy professional organizations regarding the development of their national GPP guidelines. The conditions of practice vary widely from country to country and each national pharmacy professional organization is best able to decide what can be achieved and within what time-scale.

2. **Underlying philosophy**

The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines.

There are six components to this mission:

- being readily available to patients with or without an appointment;
- identifying and managing or triaging health-related problems;
- health promotion;
- assuring effectiveness of medicines;
- preventing harm from medicines; and
- making responsible use of limited health-care resources.

In the community setting, pharmacists should be acknowledged as health-care professionals whom patients can consult for health-related problems. Because health-care products and services are available from the pharmacist, some problems can be managed at this point of care. Problems that require additional diagnostic skill or treatments not available from a pharmacist can be referred to an appropriate health-care professional or site of care, such as a hospital. This should be done in good collaboration between the health-care providers.

To improve the use of medicines, pharmacists have responsibilities for many aspects of the process of medicines use, each of which is important to achieve good outcomes from treatment. This begins with assuring the integrity of the medicine supply chain, including detecting spurious/false-labelled/falsified/counterfeit medicines, ensuring proper storage of medicines and quality preparation of medicines when needed. It also includes assuring the proper prescribing of medicines so that dose regimens and dosage forms

² Throughout this document, the term “national standards” includes laws, regulations, standards, ordinances or other requirements enacted or promulgated by an official body at any level of government, as well as guidelines, recommendations or other pronouncements of professional organizations of pharmacy.

are appropriate; instructions for use are clear; medicine–medicine and medicine–food interactions are prevented; known and predictable adverse medicine reactions, including allergies and other contraindications, are avoided; unnecessary treatments are minimized and the cost of medicines is considered.

Another important component of this mission is assisting patients and those administering medicines to understand the importance of taking medicines properly, including the correct timing of doses, foods or other medicines to avoid when taking a dose and what to expect after taking the medicine. Monitoring treatment to verify effectiveness and adverse medicine events is also an important part of the process of use of medicines.

3. **Definition of good pharmacy practice**

GPP is the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines.

4. **Requirements of good pharmacy practice**

- GPP requires that a pharmacist's first concern in all settings is the welfare of patients.
- GPP requires that the core of the pharmacy activity is to help patients make the best use of medicines. Fundamental functions include the supply of medication and other health-care products of assured quality, the provision of appropriate information and advice to the patient, administration of medication, when required, and the monitoring of the effects of medication use.
- GPP requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing, as well as dispensing.
- GPP requires that the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved. Multidisciplinary collaboration among health-care professionals is the key factor for successfully improving patient safety.

In satisfying these requirements, the following conditions are necessary:

- the well-being of patients should be the main philosophy underlying practice, even though it is accepted that ethical and economic factors are also important;
- pharmacists should have input into decisions about the use of medicines. A system should exist that enables pharmacists to report and to obtain feedback about adverse events, medicine-related problems, medication errors, misuse or medicine abuse, defects in product quality or detection

of counterfeit products. This reporting may include information about medicine use supplied by patients or health professionals, either directly or through pharmacists;

- the relationship with other health professionals, particularly physicians, should be established as a therapeutic collaborative partnership that involves mutual trust and confidence in all matters relating to pharmacotherapy;
- the relationship between pharmacists should be one of colleagues seeking to improve pharmacy service, rather than acting as competitors;
- in reality, organizations, group practices and pharmacy managers should accept a share of responsibility for the definition, evaluation and improvement of quality;
- the pharmacist should be aware of essential medical and pharmaceutical information (i.e. diagnosis, laboratory test results and medical history) about each patient. Obtaining such information is made easier if the patient chooses to use only one pharmacy or if the patient's medication profile is available;
- the pharmacist needs evidence-based, unbiased, comprehensive, objective and current information about therapeutics, medicines and other health-care products in use, including potential environmental hazard caused by disposal of medicines' waste;
- pharmacists in each practice setting should accept personal responsibility for maintaining and assessing their own competence throughout their professional working lives. While self-monitoring is important, an element of assessment and monitoring by the national pharmacy professional organizations would also be relevant in ensuring that pharmacists maintain standards and comply with requirements for continuous professional development;
- educational programmes for entry into the profession should appropriately address both current and foreseeable changes in pharmacy practice; and
- national standards of GPP should be specified and should be adhered to by practitioners.

At the national or appropriate (e.g. state or provincial) level, it is necessary to establish:

- A legal framework that:
 - defines who can practice pharmacy;
 - defines the scope of pharmacy practice;
 - ensures the integrity of the supply chain and the quality of medicines.
- A workforce framework that:
 - ensures the competence of pharmacy staff through continuing professional development (CPD or continuing education (CE)) programmes;
 - defines the personnel resources needed to provide GPP.

- An economic framework that:
 - provides sufficient resources and incentives that are effectively used to ensure the activities undertaken in GPP.

5. **Setting standards for good pharmacy practice**

GPP includes standards that often exceed those laid down by national legislation. Furthermore, legislation seldom gives precise instructions about how the services should be produced to meet the requirements. Therefore, national pharmacy professional associations have a role in setting standards required for GPP, which includes a quality management framework and a strategic plan for developing services. It is also recognized that in developing national standards for GPP, attention must be paid to both the needs of the users of health-care services and the capacity of national health-care systems to support these services.

Just as pharmacy practice will vary among nations, it will also vary among practice locations. Therefore, standards should recognize the uniqueness of different pharmacy practice settings (e.g. community and hospital pharmacy). In addition, as medicines and needs change, the standards should acknowledge evolving practice settings and provide these developing services with guidance without negatively affecting the evolutionary nature of practice. At the same time, a baseline should be established for practice below which the activity cannot be considered “pharmacy practice” at all and, therefore, should not be condoned.

When establishing minimum standards on GPP, FIP emphasizes the importance of first defining the roles played by pharmacists, as expected by patients and society. Secondly, relevant functions for which pharmacists have direct responsibility and accountability need to be determined within each role. Thirdly, minimum national standards should then be established, based upon the need to demonstrate competency in a set of activities supporting each function and role.

The minimum national standards for each activity are based on processes that need to be relevant and defined appropriately according to the local needs of the pharmacy practice environment and national profession aspirations. All national pharmacy professional associations should also adapt these roles and functions in accordance to their own requirements. The activities listed below can be further defined and measured by setting indicators of good practice within a national context and can be weighted by actual practice-setting priorities.

It is recommended that national pharmacy professional associations consider the following roles, functions and activities for pharmacists, *where appropriate*:

Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products

- Function A: Prepare extemporaneous medicine preparations and medical products

Minimum national standards should be established for these activities.

- Pharmacists should ensure that medicine preparation areas are appropriately designed to permit ease of extemporaneous preparations and are maintained in a manner that minimizes the potential for medication errors and assures the cleanliness and safety of medical products.
- Pharmacists should ensure that compounded medicines are consistently prepared to comply with written formulas and quality standards for raw materials, equipment and preparation processes, including sterility where appropriate.

- Function B: Obtain, store and secure medicine preparations and medical products

Minimum national standards should be established for these activities.

- Pharmacists who are responsible for procurement should ensure that the procurement process is transparent, professional and ethical so as to promote equity and access and to ensure accountability to relevant governing and legal entities.
- Pharmacists who are responsible for procurement should ensure that procurement is supported by strong quality assurance principles to assure that substandard, adulterated, unlicensed and spurious/false-labelled/falsified/counterfeit medicines are not procured or allowed into the system.
- Pharmacists who are responsible for procurement should ensure that procurement is supported by a reliable information system which provides accurate, timely and accessible information.
- Pharmacists should establish contingency plans for shortages of medicines and for purchases in emergencies.
- Pharmacists should assure that proper storage conditions are provided for all medicines, especially for controlled substances, used in the pharmacy or health-care facility.

- Function C: Distribute medicine preparations and medical products

Minimum national standards should be established for these activities.

- Pharmacists should ensure that all medical products, including medicine samples, are handled and distributed in a manner that assures reliability and safety of the medicine supply.
- Pharmacists should establish an effective distribution system which includes a written procedure, to recall promptly and effectively

medical products known or suspected to be defective or spurious/falsely-labelled/falsified/counterfeit, with a designated person(s) responsible for recalls.

- Pharmacists should develop with manufacturers, wholesalers and government agencies (where appropriate) an access plan for uninterrupted supply of essential medicines as part of a disaster or pandemic preparedness strategy.
 - As part of a disaster or pandemic preparedness strategy, national medicines regulatory agencies may introduce new medicines which are authorized for marketing with limited safety data; pharmacists have a responsibility to be aware of the safety issues and to institute necessary mechanisms for monitoring occurrence of adverse events.
- Function D: Administration of medicines, vaccines and other injectable medications

Minimum national standards should be established for these activities.

- Pharmacists should have a role in the preparation and administration of medicines, in establishing procedures in their work settings with respect to the administration, and in monitoring the outcomes of medication administration.
 - Pharmacists should have an educator, facilitator and immunizer role, thus contributing to the prevention of diseases through participation in vaccination programmes, by ensuring vaccination coverage and by also ensuring vaccine safety.
 - Pharmacists should participate in directly observed therapy (DOT) programmes in areas such as the management of drug addiction, HIV/AIDS, tuberculosis and sexually transmitted diseases, where applicable.
- Function E: Dispensing of medical products

Minimum national standards should be established for these activities.

- Pharmacists should ensure that appropriate facilities, trained personnel, standard dispensing practices and documentation procedures are in place in the pharmacy for the supply and dispensing of prescribed medicines and other health-care products.
- Pharmacists should assess and evaluate all paper or electronic prescriptions received, considering the therapeutic, social, economic and legal aspects of the prescribed indication(s) before supplying medical products to the patient. Where possible, generic substitution is recommended.
- Pharmacists should ensure patient confidentiality at the point of dispensing medical products and should provide advice to ensure that the patient receives and understands sufficient written and oral information to derive maximum benefit for the treatment.

- Function F: Dispose of medicine preparations and medical products

Minimum national standards should be established for these activities.

- Pharmacists should ensure that regular monitoring of the medicines inventory is conducted and should always include medicines samples in the process of periodic inspection for expiration dates and removal of outdated stock.
- Pharmacists should ensure that recalled medical products, including medicines samples, are immediately stored separately for subsequent disposal and prevented from being available for further dispensing or distribution.
- Pharmacists should establish a safe way of medicines waste disposal at the hospital and/or community pharmacy so that patients and the public can be encouraged to return their expired or unwanted medicines and medical devices. Alternatively, pharmacists should provide appropriate information to patients on how to safely dispose of expired or unwanted medicines.

Role 2: Provide effective medication therapy management³

- Function A: Assess patient health status and needs

Minimum national standards should be established for these activities.

- Pharmacists should ensure that health management, disease prevention and healthy lifestyle behaviour are incorporated into the patient assessment and care process.
- Pharmacists should acknowledge unique patient considerations such as education level, cultural beliefs, literacy, native language and physical and mental capacity in all individual patient assessments.

- Function B: Manage patient medication therapy

Minimum national standards should be established for these activities.

- Pharmacists should maintain access to an appropriate evidence base relating to the safe, rational and cost-effective use of medicines such as reference books on medicines, journals, national essential medicines lists and standard treatment guidelines.
- Pharmacists should ensure that medicine formulary system(s) (local, regional and/or national) are linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence.
- Pharmacists should have a key role in educating prescribers on the access to and evidence for optimal and appropriate use of medicines including the required monitoring parameters and prescribing adjustments. Where appropriate, pharmacists should provide advice

³ Medication therapy management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services are independent of, but can occur in conjunction with, the provision of a medication product.

or recommendations to the prescriber on medicine therapy, including the selection of the appropriate medication or dosage.

- Pharmacists should have access to, contribute to and use all necessary clinical and patient data to coordinate effective medication therapy management, especially when multiple health-care practitioners are involved in the patient's medication therapy, and intervene if necessary.
- Pharmacists should establish a standard operating procedure for referrals to physicians, specialists or other health-care providers, where appropriate.
- Pharmacists should provide continuity of care by transferring information on patients' medicines as patients move between sectors of care.

- Function C: Monitor patient progress and outcomes

Minimum national standards should be established for these activities.

- Pharmacists should consider patient diagnosis and patient-specific needs when assessing patient response to medicine therapy and intervene if necessary.
- Pharmacists should document necessary clinical and patient data to assess and monitor medication therapy and to track patients' therapeutic outcomes.
- Pharmacists should perform point-of-care testing for patients in order to monitor and adjust therapy, when needed.

- Function D: Provide information about medicines and health-related issues

Minimum national standards should be established for these activities.

- Pharmacists should ensure that in every pharmacy there is a suitable place for discussing confidential information with the customers and patients.
- Pharmacists should provide sufficient health, disease and medicine-specific information to patients for their participation in their decision-making process regarding a comprehensive care management plan. This information should aim at supporting adherence to treatment and empowerment of the patient.
- Pharmacists should be proactive in reducing antimicrobial resistance by providing information about the appropriate use of antimicrobials to consumers and prescribers.

Role 3: Maintain and improve professional performance

- Function A: Plan and implement continuing professional development⁴ strategies to improve current and future performance

⁴ The concept of continuing professional development (CPD) can be defined as "the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional, throughout their careers."

Minimum national standards should be established for these activities.

- Pharmacists should perceive continuing education as being lifelong and be able to demonstrate evidence of continuing education or continuing professional development to improve clinical knowledge, skills and performance.
- Pharmacists should take steps to update their knowledge and skills about complementary and alternative therapies such as traditional Chinese medicines, health supplements, acupuncture, homeopathy and naturopathy.
- Pharmacists should take steps to update their knowledge and be engaged in implementation of new technology and automation in pharmacy practice, where feasible.
- Pharmacists should take steps to become informed and update their knowledge on changes to information on medical products.

Role 4: Contribute to improve effectiveness of the health-care system and public health

- Function A: Disseminate evaluated information about medicines and various aspects of self-care

Minimum national standards should be established for these activities.

- Pharmacists should ensure that the information provided to patients, other health-care professionals and the public is evidence-based, objective, understandable, non-promotional, accurate and appropriate.
- Pharmacists should develop and/or use educational materials for health management, health promotion and disease prevention programmes that are applicable to a wide range of patient populations, age groups and health literacy levels.
- Pharmacists should educate patients on how to evaluate and use web-based or other forms of health-care information (including medicines information) and strongly encourage them to be advised by a pharmacist regarding the information they find, particularly if obtained from the Internet.
- Pharmacists should assist patients and their care providers to obtain and critically analyse information to meet their individual needs.

- Function B: Engage in preventive care activities and services

Minimum national standards should be established for these activities.

- Pharmacists should engage in preventive care activities that promote public health and prevent disease, i.e. in areas such as smoking cessation, infectious and sexually transmitted diseases.

- Pharmacists should provide point-of-care testing, where applicable, and other health screening activities for patients at higher risk of disease.
- Function C: Comply with national professional obligations, guidelines and legislations
 - Minimum national standards should be established for these activities.*
 - Pharmacists should take steps to ensure that they comply with the provisions of a national code of ethics for pharmacists.
- Function D: Advocate and support national policies that promote improved health outcomes
 - Minimum national standards should be established for these activities.*
 - Pharmacists should contribute to public and professional groups to promote, evaluate and improve health in the community
 - Pharmacists should collaborate with other health-care professionals in their efforts to improve health outcomes.

6. Conclusions

There are four main roles where pharmacists' involvement or supervision is expected by society and the individuals they serve:

1. Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products.
2. Provide effective medication therapy management.
3. Maintain and improve professional performance.
4. Contribute to improve effectiveness of the health-care system and public health.

These roles may vary for each individual pharmacist depending on their practice responsibilities.

Specific standards of GPP can be developed only within a national pharmacy professional organization framework.

This guidance is recommended as a set of professional goals to be met in the interest of the patients and other key stakeholders in the pharmaceutical sector. Responsibility for moving the project forward will rest with each national pharmacy professional association. Achieving specific standards of GPP for each nation within these recommendations may require considerable time and effort. As health professionals, pharmacists have a duty to begin the process without delay.