The attached draft guidelines on good pharmacy practice: standards for quality of pharmacy services have been prepared jointly by FIP and WHO. Please address comments on this proposal, by 31 May 2010, to Dr Xuanhao Chan, Manager, Professional and Scientific Affairs, The International Pharmaceutical Federation (FIP), with a copy to Ms Marie Gaspard, Quality Assurance & Safety: Medicines, Essential Medicines and Pharmaceutical Policies, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: gaspardm@who.int.

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### SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/10.352:

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>First meeting of the FIP WG Good Pharmacy Practice</td>
<td>15 October 2007</td>
</tr>
<tr>
<td>Second meeting of the WG Good Pharmacy Practice</td>
<td>31 March 2008</td>
</tr>
<tr>
<td>First FIP Expert Consultation on the revision of the FIP/WHO Guidelines on Good Pharmacy Practice – Standards for Quality of Pharmacy Services in the community and hospital settings</td>
<td>September 2008</td>
</tr>
<tr>
<td>Presentation of the proposal by FIP Representative to the forty-third WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
<td>13 October 2008</td>
</tr>
<tr>
<td>First draft of the GPP reference document(^1)</td>
<td>December 2008</td>
</tr>
<tr>
<td>Review of the GPP reference document by the 120 FIP Member Organizations and FIP Bureau</td>
<td>January 2009</td>
</tr>
<tr>
<td>First World Wide Consultation of the GPP reference document</td>
<td>March to June 2009</td>
</tr>
<tr>
<td>Final drafting of the GPP reference document</td>
<td>June to September 2009</td>
</tr>
<tr>
<td>Approval of the final GPP reference document by FIP Council</td>
<td>3 September 2009</td>
</tr>
<tr>
<td>First meeting of the WG GPP policy drafting committee</td>
<td>6 September 2009</td>
</tr>
<tr>
<td>Update of process to the forty-fourth WHO Expert Committee on Specifications for Pharmaceutical Preparations</td>
<td>12-16 October 2009</td>
</tr>
<tr>
<td>Second meeting of the WG GPP policy drafting committee</td>
<td>29 October 2009</td>
</tr>
<tr>
<td>First draft of the revised FIP/WHO GPP policy guidelines</td>
<td>November 2009</td>
</tr>
<tr>
<td>Review of the revised FIP/WHO GPP policy guidelines by the FIP Bureau</td>
<td>February 2010</td>
</tr>
<tr>
<td>Review of the revised FIP/WHO GPP policy guidelines by the 120 FIP Member Organizations and WHO Expert Committee</td>
<td>March-June 2010</td>
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<tr>
<td>Final drafting of the revised FIP/WHO GPP policy guidelines</td>
<td>June-September 2010</td>
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\(^1\) The reference paper serves as a background document to the revision of the 1991 FIP/WHO GPP policy guidelines. It is an extensive compilation of information relating to GPP development since 1991, including a review of the literature, expert opinion, experiences from key GPP activities/projects and relevant elements from existing national GPP guidelines across 37 countries.
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<th>Event</th>
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<tbody>
<tr>
<td>Second round World Wide Consultation of the revised FIP/WHO GPP policy guidelines</td>
<td>July-August 2010</td>
</tr>
<tr>
<td>Approval of revised FIP/WHO GPP policy guidelines by FIP Council</td>
<td>September 2010</td>
</tr>
<tr>
<td>Presentation to the forty-fifth WHO Expert Committee on Specifications for Pharmaceutical Preparations for possible adoption</td>
<td>18-22 October 2010</td>
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</tbody>
</table>
Background

Under 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 of the World Health Assembly resolution WHA47.12 in May 1994 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 the thirtieth-fifth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, in the WHO Technical Report Series, No.885 in 1999.

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 presents a step-by-step approach to pharmaceutical care.

With the overall aim to improve standards and practice of drug distribution and drug utilization, using the FIP/WHO Guidelines for Good Pharmacy Practice (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 sets 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 WHO 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).

Additionally 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 need 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 Eastern Mediterranean Regional Office, 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 timeline that would allow sufficient consultation with all of FIP's 120 national Member Associations, relevant experts and WHO. A proposal of this initiative was presented to the forty-third WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2008 and an updated report was provided to the forty-fourth meeting of this WHO Expert Committee 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, poor access to trained health professionals and care, inadequate health workforce, unaffordable cost of care and poor standards of health care professionals education.

Medicines are an essential and critical part of health-care services in all cultures and societies. When accessed, medicines are often used as 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 drug selection and dosages, improper administration of medicines and lack of adherence by patients to prescribed treatment, drug-drug and drug food interactions, and adverse drug events. Besides clinical problems associated with drug-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 counterfeit medicines are a growing problem that compromises health. There is a need for a system of assuring the integrity of the drug supply chain to assure the value of medicines used for the prevention of disease and the treatment of patients.

Pharmacists are specifically educated and trained health professionals who are charged by their national or 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 an 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 medicines-use outcomes and evolving their practices to provide patients with enhanced medicines-use services.

As health care professionals, pharmacists thereby 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’ role 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 appropriate governing bodies and other health care professional associations, in order to support pharmacists in their countries through providing continuing professional development activities including distance-learning programmes and establishing national standards of pharmacy services and practice objectives.

This document is intended to provide a description of how pharmacists can improve access to health care, health promotion and the use of medicines on behalf of the patients that they serve. The role of FIP is to provide leadership for national pharmacy professional

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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.
organizations which in turn provide the impetus for setting national standards. 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
- Making responsible use of limited health care resources

In the community setting, pharmacists should be acknowledged as a health care professional who 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.

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3 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.
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 drug supply chain, including detecting counterfeit medicines, 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 are appropriate, instructions for use are clear, drug-drug and drug-food interactions are prevented, known and predictable adverse drug reactions including allergies and other contra-indications are avoided, unnecessary treatments minimized, and that 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, such as the correct timing of doses, foods or other drugs to avoid when taking a dose and what to expect after taking the medicine. Monitoring treatment to verify effectiveness and adverse drug events is also an important part of the process of medicines use.

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. Multi-disciplinary collaboration among health care professionals is the key success factor for 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 get feedback about adverse events, drug-related problems, medication errors, misuse or drug abuse, defects in product quality or detection of counterfeit products. This reporting may include information about drug use supplied by patients or health professionals, either directly or through pharmacists;

- the ongoing 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 as colleagues seeking to improve pharmacy service, rather than 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 medicines waste disposal;

• 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 to the profession should appropriately address both current and foreseeable future changes in pharmacy practice;

• 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:
  o defines who can practice pharmacy;
  o defines the scope of pharmacy practice;
  o ensures the integrity of the supply chain and the quality of medicines.

• A workforce framework that:
  o ensures the competence of pharmacy staff through continuing professional development (CPD or CE) programmes
  o defines the personnel resources needed to provide GPP

• An economic framework that:
  o 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 provided 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 on a set of activities supporting each respective function and role.

The minimum national standards for each activity are based on processes that need to be relevant and defined appropriately 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 also be further defined and measured by setting indicators of good practice within a national context and 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 and dispose medical products

- Function A: Prepare extemporaneous drug preparations and medical products

  Minimum national standards should be established for these activities.

  I. Pharmacists should ensure that drug preparation areas are appropriately designed to permit ease of extemporaneous preparation and are maintained in a manner that minimizes the potential for medication errors and assures the cleanliness and safety of medical products.

  II. Pharmacists should ensure that compounded medicines are consistently prepared to comply with written formulae and quality standards for raw materials, equipment and preparation processes, including sterility where appropriate.

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

  Minimum national standards should be established for these activities.

  I. 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.

  II. Pharmacists who are responsible for procurement should ensure that procurement is supported by strong quality assurance principles to assure that substandard, adulterated, unlicensed and counterfeit medicines are not procured or allowed into the system.

  III. Pharmacists who are responsible for procurement should ensure that procurement is supported by a reliable information system which provides accurate, timely and accessible information.

  IV. Pharmacists should establish contingency plans for medicines shortages and purchases in emergencies.

  V. 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 drug preparations and medical products

Minimum national standards should be established for these activities.

I. Pharmacists should ensure that all medical products, including medicine samples, are handled and distributed in a manner that assures reliability and safety of the drug supply.

II. 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 counterfeit, with a designated person(s) responsible for recalls.

III. 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.

IV. As part of a disaster or pandemic preparedness strategy, drug regulatory agencies may introduce new drugs which are authorised for marketing with limited safety data and that pharmacists have a responsibility to be aware of the safety issues and 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.

I. 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.

II. Pharmacists should have an educator, facilitator, and immunizer role, thus contributing for the prevention of diseases though participation in vaccination programs, by ensuring vaccination coverage, and by ensuring vaccine safety.

III. 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: Dispose of drug preparations and medical products
Minimum national standards should be established for these activities.

I. Pharmacists should ensure that regular drug inventory monitoring is conducted, and should always include medicines samples in the process of periodic inspection for expiration dates and removal of outdated stock.

II. Pharmacists should ensure that recalled medical products, including medicines samples, are immediately stored separately for subsequent disposal and prevented from further dispensing or distribution.

III. Pharmacists should establish a safe way of drug 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 management

• Function A: Assess patient health status and needs

Minimum national standards should be established for these activities.

I. Pharmacists should ensure that health management, disease prevention, and healthy lifestyle behaviour are incorporated into the patient assessment and care process.

II. 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.

I. Pharmacists should maintain access to an appropriate evidence base relating to the safe, rational and cost-effective use of medicines such as drug information reference books and journals, national essential medicines lists and standard treatment guidelines.

4 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.
II. 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.

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

IV. 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.

V. Pharmacists should establish a standard operating procedure for referrals to physicians, specialists or other health care providers, where appropriate.

VI. Pharmacists should provide continuity of care by transferring patient medicines information as patients move between sectors of care.

- Function C: Monitor patient progress and outcomes

  Minimum national standards should be established for these activities.

  I. Pharmacists should consider patient diagnosis and patient-specific needs when assessing patient response to drug therapy and intervene if necessary.

  II. Pharmacists should document necessary clinical and patient data to assess and monitor medication therapy and to track patients’ therapeutic outcomes.

  III. 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.

  I. Pharmacists should ensure that in every pharmacy there is a suitable place for discussing confidential information with the customers and patients.
II. Pharmacists should provide sufficient health, disease and drug-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.

III. 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 development strategies to improve current and future performance

Minimum national standards should be established for these activities.

I. Pharmacists should perceive continuing education as lifelong and be able to demonstrate evidence of continuing education or continuing professional development to improve clinical knowledge, skills and performance.

II. 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.

III. Pharmacists should take steps to update their knowledge and be engaged in implementation of new technology and automation in pharmacy practice, where feasible.

IV. Pharmacists should take steps to be informed and update their knowledge on changes to medical products information.

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.

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5 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.”
I. 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.

II. 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.

III. 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 information they find, particularly if obtained from the Internet.

IV. 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.
  I. 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.

  II. 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.
  I. 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.
I. Pharmacists should contribute to public and professional groups to promote, evaluate and improve health in the community

II. Pharmacists should collaborate with other health-care professionals in their efforts to improve health outcomes.

6. CONCLUSION

To summarise, 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 and dispose of medical products.
2. Provide effective medication therapy management.
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 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.

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