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JOINT FIP/WHO GUIDELINES ON GOOD PHARMACY PRACTICE: STANDARDS FOR QUALITY OF PHARMACY SERVICES

The attached draft guidelines on good pharmacy practice: standards for quality of pharmacy services have been prepared jointly be 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:
Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services

First meeting of the FIP WG Good Pharmacy Practice	15 October 2007
Second meeting of the WG Good Pharmacy Practice	31 March 2008
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	September 2008
Presentation of the proposal by FIP Representative to the forty-third WHO Expert Committee on Specifications for Pharmaceutical Preparations	13 October 2008
First draft of the GPP reference document[1]	December 2008
Review of the GPP reference document by the 120 FIP Member Organizations and FIP Bureau	January 2009
First World Wide Consultation of the GPP reference document	March to June 2009
Final drafting of the GPP reference document	June to September 2009
Approval of the final GPP reference document by FIP Council	3 September 2009
First meeting of the WG GPP policy drafting committee	6 September 2009
Update of process to the forty-fourth WHO Expert Committee on Specifications for Pharmaceutical Preparations	12-16 October 2009
Second meeting of the WG GPP policy drafting committee	29 October 2009
First draft of the revised FIP/WHO GPP policy guidelines	November 2009
Review of the revised FIP/WHO GPP policy guidelines by the FIP Bureau	February 2010
Review of the revised FIP/WHO GPP policy guidelines by the 120 FIP Member Organizations and WHO Expert Committee	March-April 2010
Second round World Wide Consultation of the revised FIP/WHO GPP policy guidelines	April-June 2010

[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.

Final drafting of the revised FIP/WHO GPP policy guidelines	June-September 2010
Approval of revised FIP/WHO GPP policy guidelines by FIP Council	September 2010
Presentation to the forty-fifth WHO Expert Committee on Specifications for Pharmaceutical Preparations for possible adoption	18-22 October 2010

Draft for comment

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.

Contents

1. INTRODUCTION

Major issues challenging governments and health-care leaders include convenient and timely access to care, patient safety and health outcomes, quality of medicines, financial sustainability and scopes of practice of health professionals.

Complications resulting from the use of medicines are common and often preventable. The costs of these events are thought to be equal to or more than the costs of the medicines themselves.

Pharmacists[2] play an important role in the debate and resolution of these issues.
GPP is at the very heart of the profession of pharmacy and is indeed the very essence of the profession. Moreover, it expresses FIP's covenant with the patient not only to "do no harm" but also to improve the economic, clinical and humanistic outcomes from the use of medicines.

[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 requirements, the laws governing pharmacy and medicines and advances in knowledge and technology relating to use of medicines.

All practicing pharmacists are obliged to ensure that the service they provide to every patient is of appropriate quality in the health care system. GPP is a means of clarifying and meeting that obligation.

The role of FIP is to provide leadership for national pharmaceutical organizations which in turn provide the impetus for setting national standards.[3] 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.

This document is intended to encourage national pharmaceutical organizations to focus the attention of pharmacists working in community and hospital pharmacies on developing the elements of the service they provide to meet changing circumstances. It would be inappropriate for WHO or FIP to set standards or list the minimum requirements which must be achieved in all member countries. It is, however, the policy of FIP and WHO to provide guidance to professional organizations regarding the development of their national GPP guidelines. The conditions of practice vary widely from country to country and each national pharmaceutical organization is best able to decide what can be achieved and within what time-scale.

National pharmaceutical organizations should also take action to ensure that pharmaceutical education, both pre- and post-university qualification, is designed to equip pharmacists for the roles and competencies they have to undertake in community and hospital practice. Thus within the necessary base of pharmaceutical sciences there must be adequate emphasis on the action and uses of medicines; there should be a reasonable introduction in the pre-university qualification course to the relevant elements of the social and behavioural sciences; and at all stages of pharmaceutical education the development and improvement of communication skills should be given due emphasis.

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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.

This document provides a framework within which each country can develop aspirations and standards that suit its situation and meet its needs.

In developing these standards important differences between countries have to be recognized. All countries are or should work towards establishing a long-term vision for pharmacy practice. The first steps in such strategic planning usually involve determining the functions of pharmacists that are desired by patients, physicians, policy makers, insurers, payers and other health-care practitioners and then to determine who should have accountability for these functions. It is also considered important to describe key competencies that the pharmacy profession brings to the continuum of health-care delivery in the country, in all settings and health care environments.

There are also numerous reports of an unacceptable prevalence of substandard and counterfeit pharmaceutical products in international trade. Developing countries are the ones most frequently exposed to such products which may be inefficacious or toxic and which threaten to erode confidence in the health-care system. The Forty-seventh World Health Assembly in 1994, in adopting resolution WHA47.12 on the role of the pharmacist in support of the WHO Revised Drug Strategy, drew attention to pharmacists' responsibilities in assuring the quality of the products they dispense. The resolution also recognized that the pharmacist can play a key role in public health and particularly in the field of medicines, and that the rational use of drugs is contingent upon the availability to the whole population at all times of essential drugs of good quality at affordable prices.

2. UNDERLYING PHILOSOPHY

The mission of pharmacy practice is to provide medicines, other health-care products and consistent professional services to help the individual and society to improve health. Comprehensive pharmacy service involves activities both to secure good health and to avoid ill health in the population. When ill health is treated it is necessary to assure quality in the process of using medicines in order to achieve maximum therapeutic benefit and avoid untoward side effects.

Pharmacy practice is or should be about managing patient care, including assuring appropriate drug therapy outcomes and patient safety. Health promotion and health maintenance are key components of pharmacy practice and effective drug therapy

management. The pharmacist, as the trained medication management specialist, has a leadership role to play in the collaborative effort to help patients better manage their health care and to help other health-care practitioners address the complexities of drug therapy. In recent years the term "pharmaceutical care"[4] has established itself as a philosophy of practice, with the patient and the community as the primary beneficiaries of the pharmacist's actions. The concept is particularly relevant to special groups such as the elderly, mothers and children, and chronically ill patients, as well as to the community as a whole in terms of, for example, cost containment. While the basic concepts of pharmaceutical care and GPP are largely identical, it can be said that GPP is the way to implement pharmaceutical care.

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 by providing 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 the supply of medication and other health-care products of assured quality, appropriate information and advice for the patient, and monitoring of the effects of use.

- GPP requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and of rational use of medicines.

- 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.

In satisfying these requirements, the following conditions are necessary:

[4] Pharmaceutical care is a patient-centered practice in which the practitioner assumes accountability for a patient's drug-related needs and is held accountable for this commitment.

- professionalism should be the main philosophy underlying practice, even though it is accepted that 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 adverse events, medication errors, 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 seen as a therapeutic partnership that involves mutual trust and confidence in all matters relating to pharmacotherapeutics;

- 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 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 independent, comprehensive, objective and current information about therapeutics and medicines in use;

- pharmacists in each practice setting should accept personal responsibility for maintaining and assessing their own competence throughout their professional working lives;

- educational programmes for entry to the profession should appropriately address both current and foreseeable future changes in pharmacy practice; and

- national standards of GPP should be specified and should be adhered to by practitioners.

At the national level it is necessary to establish:

- A legal framework that:
  - defines who can practice pharmacy;
  - defines the scope of pharmacy practice; and
  - ensures the integrity of the supply chain and the quality of medicines.

- A workforce framework that:
  - ensures the competence of pharmacy staff;and
  - defines the personnel resources needed to provide GPP.

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

5. APPLYING GOOD PHARMACY PRACTICE

Medicines are an essential and critical part of health-care services in all cultures and societies. Pharmacists are specifically trained health professionals who are charged by their national authorities with the management of the distribution of medicines to consumers and to engage in appropriate efforts to assure their safe and efficacious use.

The pharmacy profession also recognizes that providing consumers with medicines alone is not sufficient to achieve the treatment goals. Therefore, pharmacists are accepting greater responsibility for medicines-use outcomes and evolving their practices to provide patients with enhanced medicines-use services.

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 in order to support pharmacists in their countries through providing continuing

professional development activities and establishing national standards of pharmacy services and practice objectives.

6. 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 pharmaceutical 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, distribute 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 and store 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 must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system.

  III. Pharmacists who are responsible for procurement should ensure that procurement must be 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 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 accountability 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 and wholesalers an access plan for uninterrupted supply of essential medicines as part of a disaster or pandemic preparedness strategy.

- Function D: Dispose of drug preparations and medical products

Minimum national standards should be established for these activities.

I. Pharmacist should ensure that drug inventory monitoring includes 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 removed from all inventory sources.

III. Pharmacists should establish a safe way of drug waste disposal at the pharmacy so that patients and the public can be encouraged to return their expired or unwanted medicines and medical devices.

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.

II. Pharmacists should utilize a medicine formulary system (local, regional and/or national) 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.

IV. 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 have access to and use all necessary clinical and patient data to coordinate effective drug therapy management, especially when multiple health care practitioners are involved in the patient's drug therapy and intervene if necessary.

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

- Function D: Provide patient education

Minimum national standards should be established for these activities.

I. Pharmacists should ensure that patient education takes place in an environment conducive to patient involvement, learning and confidentiality.

II. Pharmacists should provide sufficient health and disease and drug-specific information to patients for their participation in the decision-making process regarding a comprehensive care management plan.

Role 3: Maintain and improve professional performance

- Function A: Plan and implement continuing professional development[5] 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 herbal therapy, homeopathy, naturopathy, and other non-traditional health management options.

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

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

- Function A: 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.

[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."

- Function B: 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

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

  Minimum national standards should be established for these activities.

  I. Pharmacists should ensure that the information provided to patients and the public is evidence-based, objective, understandable, non-promotional, accurate and appropriate.

  II. Pharmacists should develop 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 literary levels.

  III. Pharmacists should educate patients on how to evaluate and use web-based health-care information (including medicines information) and to strongly encourage them to be advised by a pharmacist regarding information they find online.

  IV. Pharmacists should assist patients and their care providers to obtain and critically analyse information to meet their individual needs.

7. ACHIEVING GOOD PHARMACY PRACTICE

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

1. Prepare, obtain, store, distribute 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.

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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