

Standards for Quality of Pharmacy Services

Good Pharmacy Practice



INTERNATIONAL PHARMACEUTICAL FEDERATION





Standards are an important part in the measurement of quality of service to the consumer.

The International Pharmaceutical Federation (FIP) in adopting international guidelines for Good Pharmacy Practice at its Council Meeting in Tokyo on September 5, 1993 believes that standards based on these guidelines should be used by national pharmaceutical organisations, governments, and international pharmaceutical organizations for nationally accepted standards of Good Pharmacy Practice.

This revised version of the statement was endorsed at the thirty-fifth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations in April 1997 and approved by the FIP Congress in September 1997.

The Good Pharmacy Practice guidelines are based on the pharmaceutical care given by pharmacists. The guidelines recommend that national standards are set for: the promotion of health, the supply of medicines, medical devices, patient self care, and improving prescribing and medicine use by pharmacists' activities. FIP urges pharmaceutical organisations and governments to work together to introduce appropriate standards or, where national standards already exist, to review these standards in the light of the guidelines set out in the Good Pharmacy Practice document.

INTRODUCTION

All practicing pharmacists are obliged to ensure that the service they provide to every patient is of appropriate quality. Good pharmacy practice 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 standards¹. The vital element is the commitment of the pharmacy profession throughout the world to promoting excellence in practice for the benefit of those served. The public and other professions will judge the profession on how its members translate that commitment into practice in community and hospital pharmacy settings.

1 *The role of the pharmacist in the health care system. Report of a WHO consultative group, New Delhi, India, 13-16 December 1988 and Report of a WHO Meeting, Tokyo, Japan, 31 August-3 September 1993.* Geneva, World Health Organization, 1994 (unpublished document WHO/PHARM/94.569; available on request from Division of Drug Management and Polices, World Health Organization, 1211 Geneva 27, Switzerland).

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. The conditions of practice vary widely from country to country and each national pharmaceutical organisation 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-university and post-university qualification, is designed to equip pharmacists for the roles 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.

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. Affluent countries usually have effective drug regulatory systems that are based on legislation. These monitor and assure the quality of industrially produced pharmaceutical products by several means: the issuance of product licenses or marketing authorizations; the licensing and inspection of pharmaceutical manufacturers, wholesale and other distributors, community and hospital pharmacies and other drug outlets; and occasional quality control in a government laboratory. Many developing countries lack an effective drug regulatory system, which puts the main responsibility for the quality of pharmaceutical products on the pharmacists. These then have to rely on their own, or their pharmacists' association's, quality assessment and must make sure that they procure medicines only from reliable sources. FIP has developed special guidelines for drug procurement².

2 *FIP Guidelines for drug procurement.* The Hague, International Pharmaceutical Federation, 1992

There are 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 products, and which threaten to erode confidence in the health care system. It was for this reason that in May 1994 the Forty-seventh World Health Assembly, 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.

UNDERLYING PHILOSOPHY

The mission of pharmacy practice is to provide medications and other health care products and services and to help people and society to make the best use of them.

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. This presupposes the acceptance by pharmacists of shared responsibility with other professionals and with patients for the outcome of therapy.

In recent years the term “pharmaceutical care” 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 good pharmacy practice are largely identical, it can be said that good pharmacy practice is the way to implement pharmaceutical care.

THE REQUIREMENTS OF GOOD PHARMACY PRACTICE

- Good pharmacy practice requires that a pharmacist's first concern in all settings is the welfare of patients.
- Good pharmacy practice 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.
- Good pharmacy practice requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and of appropriate use of medicines.
- Good Pharmacy Practice 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:

- Professionalism should be the main philosophy underlying practice, although 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, organisations, 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 programs for entry to the profession should appropriately address both current and foreseeable future changes in pharmacy practice.
- National standards of good pharmacy practice should be specified and should be adhered to by practitioners.

APPLYING GOOD PHARMACY PRACTICE

Good pharmacy practice involves four main groups of activities, namely:

- activities associated with the promotion of good health, the avoidance of ill-health and the achievement of health objectives;
- activities associated with the supply and use of medicines and of items for the administration of medicines or for other aspects of treatment (these activities may be undertaken in the pharmacy, in an institution or in a home-care setting);

- activities associated with self-care, including advice about and, where appropriate, the supply of a medicine or other treatment for symptoms of ailments that lend themselves to self-treatment;
- activities associated with influencing the prescribing and use of medicines.

In addition to these groups of activities good pharmacy practice also encompasses:

- establishment of arrangements with other health professional communities for health promotion activities at population level, including minimization of the abuse and misuse of medicines;
- professional assessment of promotional materials for medicines and other products associated with health care;
- dissemination of evaluated information about medicines and various aspects of health care;
- involvement in all stages of clinical trials.

SETTING STANDARDS FOR GOOD PHARMACY PRACTICE

For each of the four main elements of good pharmacy practice, national standards³ should be established in relation to processes and facilities. These standards should be promoted among members of the profession.

³ 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 organisations of pharmacy.

Promotion of health and prevention of ill-health

National standards³ are needed for:

- facilities for confidential conversation that cannot be overheard by others;
- provision of general advice on health matters;
- involvement of personnel in briefings for specific campaigns to ensure coordination of effort and consistency of advice;
- quality assurance of equipment used and advice given in diagnostic testing.

Supply and use of prescribed medicines and other health care products

Activity: Reception of the prescription and confirmation of the integrity of the communication

National standards³ are needed for:

- facilities;
- procedure;
- personnel.

Activity: Assessment of the prescription by the pharmacist

This activity involves therapeutic aspects (pharmaceutical and pharmacological), consideration of appropriateness for the individual, and social, legal and economic aspects.

National standards³ are needed for:

- information sources;
- competence of personnel;
- medication records.

Activity: Assembly of the prescribed items

National standards³ are needed for:

- sources of supply of medicines and other items;
- manufacture of medicines;
- storage;
- condition at time of supply to the patient;
- personnel involved;
- equipment required;
- facilities and workplace required;
- preparation and quality assurance of extemporaneous preparations;
- disposal of unused pharmaceutical products and pharmaceutical waste.

Activity: Advice to ensure that the patient or carer receives and understands sufficient written and oral information to derive maximum benefit from the treatment

National standards³ are needed for:

- facilities for confidential conversation that cannot be overheard by others;
- information sources;
- procedures to be followed and the appropriate documentation of these procedures;
- competence of personnel involved.

Activity: Following up the effect of prescribed treatments

National standards³ are needed for:

- procedure to be followed in regular, systematic evaluation of progress or outcomes of treatment for individual patients or for groups of patients;
- access to necessary monitoring equipment and facilities;
- quality assurance of monitoring facilities.

Activity: Documentation of professional activities

National standards³ are needed for:

- recording professional activities and pertinent data in a manner that allows access to comprehensive information;
- procedures for self-assessment of professional activities and quality assurance.

Self-care

National standards³ are needed for:

- facilities for confidential conversation that cannot be overheard by others;
- qualifications of personnel to be involved;

- the ways of correctly assessing need, (e.g. finding out who has the problem, what the symptoms are, how long the condition has existed, what action has already been taken, which medicines are already being taken);
- efficacy and safety of products recommended;
- timing of referral to the medical practitioner and methods of follow-up.

Influencing prescribing and medicine use

National standards³ are needed for:

- quality of prescribing data provided to the pharmacist;
- the preparation of formularies on medicines;
- contacts with physicians on individual prescribing;
- evaluation of data on the use of medicines in medical and pharmaceutical practices;
- assessment of promotional materials;
- dissemination of evaluated information within a formal network;
- educational programs for health professionals;
- reference sources available to the pharmacist;
- confidentiality of data relating to individual patients;
- reporting of adverse events, medication errors, defects in product quality and detection of counterfeit products.

DOCUMENTATION AND RESEARCH

Pharmacists have a professional responsibility to document practice experience and activities and to conduct and/or participate in pharmacy practice research and therapy research.

ACHIEVING GOOD PHARMACY PRACTICE

Specific standards of good pharmacy practice can be developed only within the framework of a national organisation.

These guidelines are recommended as a set of professional goals in the interest of the patients or customers in the pharmacy. Responsibility for moving the project forward will rest with each national pharmaceutical organisation. Achieving specific standards of good pharmacy practice for each nation within these guidelines may require considerable time and effort. As health professionals, pharmacists have a duty to begin the process without delay.



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