Standards for quality of pharmacy services

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 September 5, 1993 believes that standards based on these guidelines should be used by national pharmaceutical organisations, governments and international pharmaceutical organisations for nationally accepted standards of Good Pharmacy Practice.

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 practising 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 organisations which, in turn, will each provide the impetus for the setting of national standards. The vital element is the commitment of the profession, throughout the world, to promote excellence in practice for the benefit of those we serve. The public and other professions will judge our profession on how we translate that commitment into the practice they observe in the community and hospital settings.

This document is intended to encourage national pharmaceutical organisations to focus the attention of pharmacists in the community and hospital pharmacy sector on developing the elements of the service they provide to meet changing circumstances. It would be inappropriate for FIP to set standards and list the minimum requirements which must be achieved in all member countries. The conditions of practice vary widely from country to country and the national pharmaceutical organisations in individual countries are best able to decide what can be achieved and within what time scale.

National pharmaceutical organisations should also take action to ensure that pharmaceutical education, both pre- and post-initial qualification, is designed to equip pharmacists for the roles they have to undertake in hospital and community practice. This means that 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-initial qualification course to the relevant elements of the social and behavioural sciences and, at all stages, the development and improvement of communication skills should be given due emphasis.

This document provides a framework within which each country will decide reasonable aspirations and proceed to set its own standards under the headings relevant in that country.

In developing these standards, important differences amongst countries have to be recognised. Affluent countries usually have effective legally based drug regulatory systems which assure and monitor the quality of industrially produced pharmaceutical products through the insurance of product licences or marketing authorisations for pharmaceutical products; through licensing and inspection of pharmaceutical manufacturers, wholesalers and other distributors, community and hospital pharmacies and other drug outlets, and occasional quality control in a governmental quality control laboratory. Many developing countries lack an

effective drug regulatory system, which puts the main responsibility for the quality of pharmaceutical products on the pharmacists. They then have to rely on their own, or the pharmacists association's quality assessment and make sure that they only procure medicines from reliable sources. The FIP has developed special FIP Guidelines for Drug Procurement [1]. There are numerous reports about 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 very reason that resolution WHA 47.12 on the role of the pharmacist in support of the WHO revised drug strategy [2] adopted by the World Health Assembly in May 1994, when calling on the collaboration of pharmacists, starts with the pharmacists responsibilities in assuring the quality of the products they dispense.

The 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 encompasses involvement in activities to secure good health and the avoidance of ill health in the population. When the treatment of ill health is necessary, the quality of each person's medicine use process should be assured to achieve maximum therapeutic benefit and to 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 relevant to all patients taking medicines but becomes particularly relevant to special groups of the population such as the elderly, mothers and children, and chronically ill patients, and to the community as a whole, e.g. in terms of cost entertainment. It could be said that Good Pharmacy Practice is mainly based on the concept Pharmaceutical Care".

Good Pharmacy Practice Requirements

A. ***Good Pharmacy Practice*** requires that a pharmacist's **first concern** must be the welfare of the patient in all settings.

B. ***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 to the patient, and monitoring the effects of their use.

C. ***Good Pharmacy Practice*** requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and appropriate medicine use.

D. ***Good Pharmacy Practice*** requires that the objective of each element of pharmacy service is relevant to the individual, is clearly defined and is effectively communicated to all those involved.

In satisfying these requirements:

- professional factors should be the main philosophy underlying practice, although it is accepted that economic factors are important
- there must be pharmacist input to decisions on medicine use
- the ongoing relationship with other health professionals, particularly physicians, should be seen as a therapeutic partnership involving mutual trust and confidence in all matters relating to pharmacotherapeutics
- the relationship with other pharmacists should be as colleagues, each seeking to improve pharmacy services, rather than as competitors
- in practice organisations and group practices, pharmacy managers should accept a share of responsibility for the definition, evaluation, and improvement of quality
- the pharmacist should be aware of the essential medical and pharmaceutical information about each patient. Obtaining such information is simplified if the patient chooses to use only one pharmacy or if the patients' medication profile is available
- the pharmacist needs independent, comprehensive, objective and current information about therapeutics and medicines in use
- pharmacists in each field of practice should accept personal responsibility for maintenance and assessment of competence throughout their professional working lives
- educational programs for entry to the profession should appropriately address contemporary and foreseeable future changes in the practice of pharmacy

- it is necessary to specify national standards of good pharmacy practice that should be adhered to by practitioners.

The Requirements in Practice

There are four main elements of ***Good Pharmacy Practice*** to be addressed:

1. Activities associated with promotion of good health, avoidance of ill-health and the achievement of health objectives.

2. Activities associated with the supply and use of medicines and items for the administration of medicines or otherwise related to treatment. These activities may be undertaken in the pharmacy or in an institution or home care setting.

3. Activities associated with self-care, including advice about and, where appropriate, the supply of a medicine or other treatment for the symptoms of ailments that can properly be self-treated.

4. Activities associated with influencing prescribing and medicine use.

In addition to the four main elements ***Good Pharmacy Practice*** also encompasses:

- establishment of arrangements with other health professional communities for health promotion activities at a population level, including the minimisation of the abuse and misuse of medicines.

- professional assessment of promotional materials for medicines and other products associated with health.

- dissemination of evaluated information about medicines and aspects of health care.

- involvement in all stages of clinical trials.

Main Elements of *Good Pharmacy Practice*

For each of the four main elements of GPP, national standards covering processes and necessary facilities should be established and promoted to the profession.

1. Health Promotion and Ill-Health Prevention

National standards are needed for

(i) Facilities for confidential conversation that cannot be overheard by others.
(ii) Provision of general advice on health matters.
(iii) Involvement of personnel in briefings for specific campaigns to ensure co-ordination of effort and consistency of advice.
(iv) Quality assurance of equipment used and advice given in diagnostic testing.

2. Supply and the Use of Prescribed Medicines and Other Health Care Products

(a) Reception of the prescription and confirmation of the integrity of the communication

National standards are needed for

(i) Facilities
(ii) Procedure
(iii) Personnel

(b) Assessment of the prescription by the pharmacist

(1) Therapeutic aspects (Pharmaceutical and Pharmacological)
(2) Appropriateness for the individual
(3) Social; legal; economic aspects.

National standards are needed for

(i) Information sources
(ii) Competence of pharmacist
(iii) Medication records

(c) Assembly of the prescribed items

National standards are needed for

(i) Sources of supply of medicines and other items; *manufacture of medicines*
(ii) Storage
(iii) Condition at time of supply to

the patient

(iv) Personnel involved

(v) Equipment required

(vi) Facilities and workplace required

(vii) Preparation and quality assurance of extemporaneous preparations

(viii) *Disposal of unused pharmaceutical products and pharmaceutical waste*

(d) Advice to ensure that the patient or carer receives and understands sufficient written and oral information to provide maximum benefit from the treatment

National standards are needed for

(i) Facilities for confidential conversation that cannot be overheard by others

(ii) Information sources

(iii) Procedure to be followed and the appropriate documentation of these procedures

(iv) Competence of personnel involved.

(e) Following-up the effect of prescribed treatments

National standards are needed for

(i) Procedure to be followed in regular, systematic evaluation of progress or outcomes of treatment for individual patients or groups of patients.

(ii) Access to necessary monitoring equipment and facilities.

(iii) Quality assurance of monitoring facilities.

(f) Documentation of professional activities

National standards are needed for

(i) Recording professional activities and pertinent data in a manner that allows access to comprehensive information

(ii) Procedures for self-assessment of professional activities and quality assurance.

3. Self-Care

National standards are needed for

(i) Facilities for confidential conversation that cannot be overheard by others
(ii) Qualifications of personnel to be involved
(iii) How proper assessment of need is to be made, e.g.
  (a) who has the problem
  (b) what are the symptoms
  (c) how long has the condition existed
  (d) action already taken
  (e) medicines already being taken
(iv) Efficacy and safety of products recommended
(v) When reference to medical practitioner is appropriate and how to follow-up.

4. Influencing Prescribing and Medicine Use

a. General rational prescribing policies

National standards are needed for

(i) Quality of prescribing data provided to the pharmacist
(ii) The preparation of formularies on medicines
(iii) Contacts with physicians on individual prescribing
(iv) Evaluation of data on the use of medicines in medical and pharmaceutical practices
(v) Assessment of promotional materials
(vi) Dissemination of evaluated information within a formal network

(vii) Educational programs for health professionals
(viii) Reference sources available to the pharmacist.
(ix) Confidentiality of data relating to individual patients.

5. Research and Practice Documentation

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

Achieving GPP in Practice

Specific standards of ***Good Pharmacy Practice*** can be developed only within a national organisational framework.

FIP is recommended to adopt these guidelines 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 upon 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, we have a duty to begin the process without delay.

References

(1) FIP Guidelines for Drug Procurement

(2) 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 (WHO/PHARM/94.569). Resolution WHA47.12: Role of the pharmacist in support of the WHO revised drug strategy (WHA47/1994/REC/1)

Note

In August 1991 a group of 26 distinguished pharmacists representing 10 different countries participated in a workshop near Stockholm to discuss Good Pharmacy Practice (GPP). This resulted in a document, “The Stockholm Letter on GPP” addressed to the Bureau of FIP. After discussion in the Bureau, the document was sent to the member associations for their comment. A working group was also appointed to draft guidelines of members of FIP.GPP based on the original document and the comments from the member organisations and from individuals.

The members of the working group are:

John Ferguson, Great Britain **Charles Hepler, USA** **J. Lars G. Nilsson, Sweden, chairman**
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