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GOOD PHARMACY PRACTICE (GPP)

IN COMMUNITY AND HOSPITAL PHARMACY SETTINGS

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BACKGROUND

Under WHO's Revised Drug Strategy adopted by the World Health Assembly in 1986, WHO has organized two meetings on the role of the pharmacist in Delhi in 1988 and in Tokyo in 1993 (WHO/PHARM/94.569). This was followed by the adoption of resolution WHA 47.12 on The role of the pharmacist in support of the WHO revised drug strategy in May 1994.

In 1992, the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading Good Pharmacy Practice in Community and Hospital Pharmacy Settings which were circulated in March 1993 to WHO Information Officers for comments.

The FIP Congress held in Tokyo in 1993 adopted the FIP/GPP text under the Tokyo declaration on standards for quality of pharmacy services, which reads as follows:

"Standards are an important part in the measurement of quality of service to the consumer. The International Pharmaceutical Federation (FIP) in adopdng international guidelines for Good Pharmacy Practice at its Council Meeting in Tokyo on 5 September 1993 believes that standards based on these guidelines should be used by national pharmaceutical organizations, governments and international pharmaceutical organizations 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 organizations 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".

The FIP/GPP text was also submitted to the Thirty-fourth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations held in Geneva from 29 November to 3 December 1994. In its report, the Expert Committee thanked the FIP for drawing its attention to the text on GPP as adopted by the FIP Congress in 1993. The Committee welcomed the FIP initiative in so far as it provided a basis for implementation of some of the principles embodied in the resolution WHA47.12. However, if the text were to be endorsed by the Committee, it would need to be expanded so as to reflect current emphasis on the pharmacist's specific responsibility for assuring the quality of pharmaceutical products throughout the distribution chain. Particular attention would have to be paid to the current inadmissible prevalence of substandard and counterfeit products in some national markets.

The recommendations made by the Thirty-fourth Expert Committee coincide with comments received from governments when the FIP text was first circulated by WHO in 1993 and have been accommodated in the text given below. This revised text has already been provisionally approved by the FIP, subject to any further modifications that might be introduced at the Thirty-fifth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, which is expected to meet in Spring 1997 and to which this text will be submitted for inclusion as an annex to the Committee's report. This inclusion in the WHO Technical Report Series will provide the Good Pharmacy Practice recommendations with a more formal status and ensure wide distribution in at least English, French and Spanish.

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 organizations 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 served. The public and other professions will judge the profession on how its members translate that commitment into the practice they observe in the community and hospital settings.

This document is intended to encourage national pharmaceutical organizations 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 WHO/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 organizations in individual countries are best able to decide what can be achieved and within what timescale.

National pharmaceutical organizations 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 ads 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 behav sciences and, at all stages, the development and improvement of communication 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 ha' recognized. Affluent countries usually have effective legally based drug regulatory systems which assure and monitor the quality of industrially produced pharmaceutical products through the issuance of product licenses or marketing authorizations for pharmaceutical products; through licensing and inspection of pharmaceutical manufacturers, wholesale and other distributors, community and hospital pharmacies and other drug outlets, and occasional quality control in a governmental quality contra laboratory. Many developing countries lack an effective drug regulatory system, 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 asse and make sure that they only procure medicines from reliable sources. The FIP 1 developed special FIP Guidelines for Drug Procurement (1). There are numerous reports about an unacceptable prevalence of substandard and counterfeit pharmaceutical 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 healthcare system. It was for this very reason that resolution V 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, started with the pharmacists's responsibilities in assuring the quality of 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 beneficiary of the pharmacist's actions. The concept becomes particularly relevant to special groups of populations such as the elderly, mothers and children, and chronically ill patients, and to

the community as a whole, e.g. in terms of cost containment. While the basic concepts of *Pharmaceutical Care* and *Good Pharmacy Practice* are largely identical, it could be said that Good Pharmacy Practice is the way to implement Pharmaceutical Care.

GOOD PHARMACY PRACTICE REQUIREMENTS

A. *Good Pharmacy Practice* requires that a pharmacist's first concern must be the welfare of the patients 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 for 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 service, rather than as competitors
- in practice organizations 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 patient's 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 programmes 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.
5. 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 minimization 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 cace
- 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 coordination of effort and consistency of advice.

(iv) (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 derive 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.

2. <u>Self-care</u>

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.

3. Influencing prescribing and medicine use

(h) 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 programmes for health professionals

(viii) Reference sources available to the pharmacist

(ix) Confidentiality of data relating to individual patients.

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 organization framework.

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 upon each national pharmaceutical organization. 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.

REFERENCES

(1) FIP Guidelines for Drug Procurement

(2) The role of the pharmacist in the health cure 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)