भारतीय भेषजी परिषद्

(भेषजी अधिनियम, 1948 के अंतर्गत स्थापित)

PHARMACY COUNCIL OF INDIA

(CONSTITUTED UNDER THE PHARMACY ACT, 1948)

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Regd.

All diploma, degree & Pharm.D institutions approved 9 JUN 2011

- **u/s 12 of the Pharmacy Act, 1948**
- **for conduct of course**

To all universities / Examining Authorities

Sub: Guidelines for pharmacy practice for hospital & community pharmacists.

Sir/Madam

With reference to the subject cited above, it is informed that subject cited issue was considered by 87/C in its meeting held in february, 2011 & it was resolve to adopt the WHO Good Pharmacy Practice (GPP) in community & hospital pharmacy. Kindly include the features of Good Pharmacy Practice (GPP) as a part of the curriculum at all levels.

The said guidelines on Good Pharmacy Practice (GPP) in community & hospital pharmacy setting are enclosed as **Appendix-I** for ready reference.

This is for necessary action at your end.

Yours faithfully

(ARCHNA MUDGAL)
Registrar-cum-Secretary

Appendix - I 51 54

WHO/PHJARM/DAP/96.1
DISTR.: GENERAL
Original: english

GOOD PHARMACY PRACTICE (GPP)

IN COMMUNITY AND HOSPITAL PHARMACY SETTINGS

World Health Organization
1996

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WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

WHO/PHARM/DAP 96.1
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GOOD PHARMACY PRACTICE (GPP)

IN COMMUNITY AND HOSPITAL PHARMACY SETTINGS

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 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 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. 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.

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 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)

GOOD PHARMACY PRACTICE (GPP)

IN DEVELOPING COUNTRIES

Recommendations for step-wise implementation

FOREWORD

Conscious of the need to help developing countries achieve good pharmacy practice, the FIP Community Pharmacy Section Executive Committee established a working group to produce guidelines in this area in 1992. This was chaired by Mike Rouse who, as the Committee's Developing Country Observer, first encouraged the establishment of the group. Work commenced with a survey of 67 developing countries, to establish a baseline of existing community pharmacy practice. The results of this survey provided detailed information about the standards prevailing in the selected countries, and reflected a high degree of variation, including countries where community practice as it is normally defined does not exist. The group then devised a simple set of recommendations, with the intention of helping pharmacists in developing countries to achieve GPP.

The ensuing report was presented at the FIP Congress in The Hague (September 1998) when the recommendations were accepted, having been endorsed by the Executive Committee of the Community Pharmacy Section. This completed the task of the working group.

These guidelines are intended for pharmacists and others in developing countries. It is hoped that the recommendations can be used where necessary to form the basis of negotiations with governments, regulatory bodies and health care systems to ensure the optimum use of available pharmacists, to the benefit of the general population of the country concerned. More extensive guidelines may be found in the FIP document "Good Pharmacy Practice in Community and Hospital Settings" and other references.

Thanks are due to Mike Rouse for initiating the work, Elaine Harden (RPSGB) for producing the final report and all the members of the working group for their patience and perseverance.

I am delighted to commend this report and its recommendations to you all in the hope that it will be found a useful tool for those wishing to achieve good pharmacy practice.

Linda Stone
Chairman of the Working Group on GPP in Developing Countries from 1997

BACKGROUND AND OBJECTIVES

1. The Alma-Ata Declaration on Primary Health Care (1978)[1] states that "...health is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal". In addressing the main health problems in the community, Primary Health Care (PHC) must "provide promotive, preventive, curative and rehabilitative services". The Declaration states that PHC includes at least " ... prevention and control of locally endemic diseases, appropriate treatment of common diseases and injuries and the provision of essential drugs". It recognises the role played by all health workers and the need for suitable training to enable these people to work as a health team to respond to the expressed needs of the community.

2. Clearly, an adequate pharmaceutical service, ideally provided by pharmacists, is a vital component of Primary Health Care. This is recognised by the World Health Organisation (WHO), and several subsequent publications of the WHO [2,3,4] emphasise the role of the pharmacist in the Health Care System. Standards are an important part in the measurement of quality of service and at the International Pharmaceutical Federation (FIP) Congress in Japan in 1993 the Tokyo Declaration on Good Pharmacy Practice (GPP) was adopted. FIP has drawn up guidelines which can be used as the basis for the setting of national standards for pharmacy practice. The GPP document has been subsequently reviewed by the WHO (primarily the Expert Committee on Specifications for Pharmaceutical Preparations) and it is anticipated that an agreed text on GPP could be included in the WHO Technical Report Series which would give the guidelines more formal status and ensure wider distribution.[5]

3. It is recognised and accepted that conditions of pharmacy practice vary widely from country to country, but it is also possible that conditions of practice may vary between different sectors/areas within a country. For example, in developing countries there is likely to be a significant difference between the health services available in urban and rural areas. In many cases this difference is due to the fact that the number of pharmacists is less than desirable. The benefits that accrue from the direct supervision of the pharmacist in ensuring the quality of pharmaceutical products and services throughout the distribution chain cannot be realised in areas where there are insufficient numbers of pharmacists, or at least persons with formal pharmaceutical training. It has to be accepted that, for the foreseeable future, pharmacists will continue to be in short supply in developing countries. For this reason, there is a real need and role for trained support personnel, such as pharmacy technicians. In developed countries such personnel would probably work only under the direct supervision of pharmacists. In developing countries, in most cases they will work alone, without any meaningful supervision. They may have duties and responsibilities which are inappropriate to their level of training.

4. Both FIP and WHO believe that national pharmaceutical associations in individual countries are best able to decide what can be achieved in terms of GPP and within what timescale. However, based on the results of a survey conducted by a Working Group established by the Executive Committee of the Community Pharmacy section of FIP, it is concluded that, in many developing countries, national associations are either non-existent or else too small to be in a position to carry out such an exercise. For this reason, the working group has decided to put forward some simple recommendations designed to be of assistance primarily to developing countries.

DESIGN AND METHODOLOGY

1. Recognising the differences in levels of practice, it is the feeling of the Working Group that its recommendations should follow a *step-wise* approach. Each person can identify the "step" (level) on which they are currently operating and work towards reaching the next step (level of practice), thereby continually improving the quality of pharmaceutical service offered to their community. This step-wise approach can be applied to a number of different components of pharmaceutical services. Particularly in developing countries, it was recognised that some of the areas of focus of the GPP Guidelines may not yet be relevant. It was, therefore, agreed that these recommendations would concentrate on those aspects perceived to be most applicable and relevant to developing countries at this point in time. Having gained some experience in implementing the principles of GPP, it is believed that countries would be able to progress into the other areas on their own.

2. By proposing a step-wise approach, it is also believed that more countries are likely to take-up the challenge, perceiving each step to be achievable. If an exercise is seen to be too difficult it is possible that it may not even be attempted. It must be accepted that implementing and achieving GPP is not an overnight process. To the contrary, it must be seen as an ongoing process.

3. ***The fundamental objective at all times must be the striving towards ever higher standards of practice, for the benefit of the patients and community being served, by achieving better outcomes as well as the development of the profession.***

4. At the same time, there needs to be an effort to educate the public, government and all health professionals about the services that can be offered by pharmacists and the benefits that can accrue from full use of their expertise and knowledge. This increased awareness should also serve to raise public expectations, resulting in a parallel driving force to raise standards of practice.

5. Every effort should be made to encourage the development of a formal National Drug Policy. A national drug policy helps countries meet the objectives of universal good health by ensuring equitable access to, and rational use of, safe and effective medicines of good quality.

6. However, the main driving force will have to come from pharmacists themselves. This may be difficult where their numbers are small. It will be pharmacists who will have to decide what is the highest level of service that can be provided, and achieving it will, and must be, a professional decision. The pharmacists will need to be committed to change and to using their influence to convince the authorities of the need for change. In many cases the government machinery within which they will have to work will be weak and there may need to be a major upheaval of the existing system.

7. In developing countries, it is recognised that pharmaceutically trained personnel will be involved largely in a distributive role. As the number of pharmaceutically trained personnel increases, more time should be available for other functions, notably the dissemination of information aimed at improving the whole medicine use process. For this reason no attempt has been made, in this document, to include "activities associated with influencing prescribing and medicine use", one of the 4 main elements of GPP.

RECOMMENDATIONS

The 3 major areas on which this paper will focus are:

1. PERSONNEL
2. TRAINING
3. STANDARDS
4. LEGISLATION & NATIONAL DRUG POLICY

1. PERSONNEL

Aim: all people have access to a qualified pharmacist

Access to pharmaceutical personnel

1.1. In developing countries it is accepted that at present, and for some time to come in most cases, due to insufficient numbers of pharmacists, it is not possible for people in all areas to have direct access to a pharmacist. The level of pharmaceutical service that can be offered will, therefore, largely be determined by location.

1.2. However, the underlying principle that has to be adopted is that all people should have access to an adequate pharmaceutical service.

1.3. In many cases it is perceived that the level of responsibility placed on health workers is disproportionate to the training that they have received. The working group recommends that all community health care workers are given at least a basic training appropriate to the level of pharmaceutical service they are required to render. It is assumed that at the primary health care level, the medicines will be relatively simple and few in number. The community health care workers need to be given basic training in how these medicines must be used to ensure that patients are given medicines which are appropriate for the condition/problem being treated, along with accurate instructions.

1.4. As one progresses upwards to the next higher level of health institution, it would be assumed and recommended that a worker with a greater level of training/specialisation would be available. In the step-wise approach, this would be represented as follows:

1.5. All people should have:

STEP 1	Access to a community health care worker with appropriate pharmaceutical training
STEP 2	Access to a person trained to a higher level than a community health care worker
STEP 3	Access to a qualified pharmacy technician with appropriate training
STEP 4	Access to a qualified pharmacy technician working under the direct supervision of a pharmacist
STEP 5	Direct access to a pharmacist

1.6. In the first instance this may represent simply a move up through the levels within the health delivery service, but the recommendation is that each location offering a particular level of service should attempt to progress to the next higher level of service.

1.7. Governments need to be convinced of the need for, and value of, a quality pharmaceutical service before they will make a commitment to allocating resources to the training of more pharmaceutical personnel, and doing so at a higher level. It has to be borne in mind that health authorities in many developing countries may be training and deploying community health care workers trained in a number of health disciplines, namely nursing, "pharmacy", laboratory technology, public health, etc. It is essential that, if this category of health care worker is perceived to be the solution where resources and/or manpower are limited, they receive training appropriate to the level of pharmaceutical service they are expected to deliver.

2. TRAINING

Aim: for the country to be self-sufficient in training pharmacy personnel

2.1. The requirement is to increase the number of pharmaceutically trained personnel, ultimately pharmacists, as well as to continuously extend and improve the level of training, knowledge and expertise of all pharmaceutical personnel. At each level the training must be appropriate to the level of service provided and medicines used. For the community health care worker, this should include a basic knowledge of the use and safe dosage of the medicine supplied within a limited specified range.

2.2. It is recognised that in many smaller countries, it may not be cost effective to train pharmacists within the country. In such cases, resources must be made available to enable pharmacists to be trained elsewhere. Depending on the availability of suitably qualified/experienced personnel to carry out the training, training of technicians and CHC workers may or may not be possible "in country". In cases where this is not possible, it should be feasible to bring in outside trainers, possibly under inter-government aid programmes.

2.3. Standards and curricula must be established for each level of training to ensure consistency and appropriateness. In time, these standards can be raised to improve the competency and knowledge base of all levels of pharmaceutical workers.

2.4. Protocols should be drawn up for the different services performed as well as medicine use protocols, e.g. Zimbabwe's EDLIZ (Essential Drug List) Treatment Guidelines developed with the assistance of WHO under the Essential Drug Action Programme.

2.5.

STEP 1 Train local community health care workers with appropriate pharmaceutical input

STEP 2 Train workers to a higher level with appropriate pharmaceutical input

STEP 3 Train pharmacy technicians

STEP 4 Educate pharmacists to graduate level or provide access to education elsewhere

STEP 5 Provide access to continuing education and continuing professional development for pharmacists and pharmacy technicians

Note: Step 1 workers deal with a very limited range of conditions and medicines.
Step 2 workers deal with a broader range of conditions in greater depth.

3. STANDARDS

It is recognised that in most developing countries, pharmaceutical services are virtually exclusively carried out from the institutions or premises at which the worker is based. No attempt has, therefore, been made to include domiciliary services.

3.1. Premises

Aim: that there should be adequate premises from which to provide services

Pharmaceutical services and products should be provided from an area which is separate from other activities/services and products. The aim is to guarantee the integrity and quality of the product and minimise the risk of dispensing errors. The requisites here (not ranked in order) are:

- Clean, tidy and hygienic conditions
- Adequate space
- Appropriate conditions for storage, re-packing, dispensing and distribution of medicines, including security
- Adequate light
- Protection from exposure to excessive light and heat – refrigeration if required
- Availability of equipment appropriate to the tasks carried out (dispensing/compounding/manufacturing)
- Access to basic reference texts
- Direct access to the public for instruction, counselling, etc

If a clearly defined, separate area for the provision of pharmaceutical services is not available, this should be the first objective. Thereafter, the premises can be upgraded allowing for clearer separation of different activities e.g. dispensing, manufacturing, storage.

STEP 1	Secure, insulated container or area for storage
STEP 2	Secure area within a health facility specifically designed for medicines
STEP 3	Area or room with facilities for storage and supply
STEP 4	Clearly defined, self-contained area or facility i.e. community pharmacy or pharmacy department in hospital

Premises must improve commensurate with the level of service provided and personnel involved, e.g. need for running water, benches, light, refrigeration etc. The level of training of personnel will vary at each step, e.g. service may be provided by an itinerant pharmacist or a community health care worker may be based in a self-contained facility.

3.2. Dispensing

Aim: to ensure that the right patient receives the appropriate medicine in the correct dose and form

The requisites here (not ranked in order) are:

- The right patient gets the right medicine
- Possible interactions are avoided
- The quality and integrity of the medicine are maintained throughout the indicated shelf life
- Correct and clear instructions are given to the patient to ensure correct and safe use of the medicine, to the optimal benefit of the patient in line with the objective of the treatment

- The patient is given, at the least, basic information regarding special instructions for use, warnings if applicable, possible adverse/side effects and action to take in the event of certain events occurring:

3.3. Containers

Aim: to preserve the integrity of the product

Tablets/capsules are dispensed in:

STEP 1	An air-tight plastic wallet (this is considered to be the minimum requirement)
STEP 2	An airtight, rigid container
STEP 3	An airtight, rigid container with a child resistant closure
STEP 4	The manufacturer's original pack

Liquid preparations should be dispensed in "pharmaceutical" bottles so as to distinguish them from non-pharmaceutical preparations - such as drinks/foods/consumer products

Poisonous products/products intended for external use should be packed in distinguishable bottles.

Recycled containers may be used if adequately cleaned internally and externally.

3.4. Labelling

The minimum requirements for a label (not ranked in order) are:

- Generic name & strength of medicine
- Dose, frequency & duration of course, if applicable
- Date of dispensing
- Name of patient
- Name/address of supplier
- Child safety warning

Every package should be marked in such a way that the potential danger to children is noted.

3.5. Instructions to the patient

Aim: to ensure that the patient knows how and when to take/use the product

STEP 1	Instructions are verbal
STEP 2	Instructions are verbal + hand-written and affixed to the container
STEP 3	Instructions are verbal + printed/typed and affixed to the container
STEP 4	In addition to step 3, verbal counselling is given to the patient
STEP 5	In addition to step 4, supplementary written information is given
STEP 6	GPP is observed

3.6. Records

Aim: to facilitate patient care and provide an audit trail

STEP 1 A record of all medicines supplied should be kept detailing name of patient, name & strength of medicine, dosage, quantity supplied, date of dispensing

STEP 2 Individual patient medicine records should be maintained in a system, manual or computerised, which allows for easy retrieval of patient information

3.7. Health information, patient counselling & pharmaceutical care

Aim: to promote good health and prevent ill health

All personnel should be trained and equipped in terms of literature and support material to give advice on general health matters as well as more specific information and services relating to medicines supplied by them.

In terms of the provision of this service the steps would be as follows:

STEP 1 Provide health promotion literature and support materials on general health

STEP 2 Provide or identify an area suitable for the delivery of basic information, counselling and pharmaceutical care

STEP 3 Provide a separate, confidential room or facility for the above activities

3.8. Self-medication

Where pharmacists or other pharmaceutically qualified personnel are involved in self medication and response to symptoms, protocols should be devised to ensure that the advice is accurate and appropriate.

3.9. Products

Legal mechanisms must be in place to ensure quality, safety and efficacy of medicines. The Working Group feels that there is a role for the WHO and FIP here in terms of guidelines which could be drawn up for countries who do not yet have adequate regulatory mechanisms in place. *(e.g. WHO Guidelines for Drug Donations (May 1996); WHO Certification Scheme for Manufacturers; WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce; FIP Guidelines for Drug Procurement.)*

4. LEGISLATION & NATIONAL DRUG POLICY

4.1. Legislation

Aim: to establish a national GPP policy that can be adequately enforced.

This is regarded as a fundamental prerequisite for GPP. Not only must it be in place, but it must be adequately enforced.

STEP 1 Enact legislation to control:

- requirements for premises from which medicines are dispensed, distributed or manufactured
- categories for distribution/supply
- labelling of medicines

- control & ownership of pharmacies
- registration & control of pharmacists and pharmacy personnel
- import and export of medicines

This legislation must be practical and enforceable.
(WHO has draft legislation designed to assist countries without adequate legislation in this area.)

STEP 2 Establish an autonomous body/bodies to control all aspects of medicine registration, distribution, personnel, etc.

STEP 3 Access to facilities for quality assurance of medicines must be available.

4.2. National Drug Policy

Aim: to ensure equitable access to safe and effective drugs of good quality by establishing a National Drug Policy

The distribution of all medicines must come under the control and supervision of pharmaceutically trained persons, ideally pharmacists. Wherever possible, this supervision should be direct. However, indirect supervision will be required in areas where there are no pharmacists. As the number of pharmacists increases, the degree and quality of supervision will improve and become more meaningful/beneficial.

Pharmacists must be involved in all policy decisions that affect the distribution and use of medicines and related products.

STEP 1 Establish a National Drug Policy based upon WHO guidelines

STEP 2 Create a suitable Essential Drugs List

References:

1 Primary Health Care - Report of the International Conference on Primary Health Care, Alma-Ata, USSR 1978

2 The Role of the Pharmacist in the Health Care System - Report of a WHO Consultative Group, New Delhi, India 1993

3 Role of the Pharmacist in Support of the WHO Revised Drug Strategy, 47th World Health Assembly, 1994

4 Revised Drug Strategy, 49th World Health Assembly, 1996

5 Good Pharmacy Practice in Community and Hospital Settings, WHO 1997

6 Good Practice in Donations of Medicines, FIP 1997

7 WHO Guidelines for Drug Donations, 1996

Appendices:

1 Definitions

2 FIP GPP Document

3 RPSGB document on standards

4 Membership of Working Group

APPENDIX I

Definitions

Community Pharmacy - *The area of pharmacy practice in which medicines and other related products are sold or provided directly to the public from a retail (or other commercial) outlet designed primarily for the purpose of providing medicines. The sale or provision of the medicine may be either on the order or prescription of a doctor (or other health care worker), or "over the counter" (OTC).*

Pharmacist - *A person with a formal higher qualification such as a three-year (minimum) university degree or diploma in pharmacy.*

Qualified Pharmacy Technician/Dispensary Assistant - *A person with formal dispensing training (at a lower level than a pharmacist) involved in the dispensing of medicines. (The training, or at least a part of it, would have taken place at a recognized training institution and a certificate or licence would have been issued.)*

Unqualified Pharmacy Technician/Dispensary Assistant - *A person who is involved in the dispensing of medicine, but who has only received "on the job" or "in house" training*

Community Health Care Worker - *A person who is trained to provide simple, low level health care commensurate with the level of training.*

APPENDIX 4

Membership of Working Group

Over the years, this group has included:

Ross Holland	Australia	
John Ware	Australia	
Lu Li-Zhu	China	
Mohamed Abd El Gawaad	Egypt	
Yahra Fiagome	Ghana	
Jimi Agbaje	Lagos	
Jimi Adesanya	Nigeria	
Barbro Hammarström	Sweden	
Sue Putter	South Africa	
Linda Stone	UK	*Chairman from 1997*
Mike Rouse	Zimbabwe	*Chairman until 1997*

International Pharmaceutical Federation
Fédération internationale pharmaceutique

PO Box 84200, 2508 AE The Hague, The Netherlands

STATEMENT OF POLICY
GOOD PHARMACY EDUCATION PRACTICE

Background

The role of the pharmacist is developing rapidly to meet the needs of modern health care systems. Ensuring accurate dispensing of prescribed medicines against prescriptions and providing sound advice on responsible self-medication remain vitally important parts of the service provided by pharmacists. Pharmacists have, however, recognised for some years that equally important roles are to advise other healthcare professionals on safe and rational use of medicines and to accept responsibility for seeking to ensure that medicines are used safely and effectively by those to whom they are supplied so that maximum therapeutic benefit is derived from treatment. This activity contributes both to the welfare of the individual and the overall improvement of public health.

These developments have established an important focus of activity for the practising pharmacist. This involves not only contributing to discussions leading to appropriate prescribing but also advising people on how to use medicines effectively.

These developments also impose important ethical demands on the profession. They must be underpinned both by legislation and by changes in the basic and continuing education of pharmacists. The basic (first degree) course of education is designed to ensure that the newly qualified pharmacist has the necessary knowledge and skills to commence practising competently in a variety of settings including community and hospital pharmacy and the pharmaceutical industry. Continuing professional development must then be a lifelong commitment for every practising pharmacist.

The implementation of Pharmaceutical Care, while recognising the responsibility of the patient as end user of a medicine, requires the pharmacist to use a range of processes to facilitate the responsible provision of medicinal treatment until tangible results are achieved, improving the patient's quality of life.

Pharmacists provide their services in a variety of settings in response to a dynamic and evolving set of primarily local health care priorities and needs. There are also regional, national and international policies and factors, which dictate the need for developments in pharmacy practice. Within this context, pharmacists are medication experts in the treatment of disease and in health promotion. This expertise, in its broadest sense, encompasses the preparation, supply and control of medicinal products and assurance of desired outcomes of treatment by medication. It thus begins with the medicine development process and continues through to medication's ultimate benefit to the individual and to society generally. This expertise has its foundations in the pharmaceutical sciences and related research, and has its focus on the individual and populations.

Recommendations•

1. Basic (first degree) education programmes should provide pharmacy students and graduates with a sound and balanced grounding in the natural, pharmaceutical and healthcare sciences that provide the essential foundation for pharmacy practice in a multi-professional healthcare delivery environment.

   The following are relevant areas of study :-

   - biological systems, the chemistry of drugs and other constituents of medicines, patho-physiology and disease states and the interaction between medicines and biological systems,
   - dosage form design and development,
   - the actions and uses of medicines and other relevant products,
   - the laws governing the practice of pharmacy and the sale and supply of medicines,
   - the principles governing ethical conduct as set out in FIP's Code of Ethics for Pharmacists (1997) and the relevant national Code,
   - safety and risk management,
   - pharmaco-epidemiology and pharmaco / health-economics,
   - an introduction to the practice of pharmacy in community and hospital pharmacies, industrial, academic, and where appropriate, clinical biology settings including an introduction to the relevant aspects of the social and behavioural sciences, leading to competency in delivering patient care,
   - an introduction to the effective management of resources (human, physical, fiscal and time),
   - an introduction to guidelines governing good practices in manufacturing, distribution and laboratories.

   The programme must maintain the university character of the education, while balancing scientific knowledge with practical training. This will provide the pharmacy graduate with a unique body of knowledge, equipping the pharmacist to apply the wide range of traditional and emerging technologies to help patients to achieve the desired health outcomes from use of medicines.

2. Educational programmes should ensure that patient-focused pharmaceutical care as outlined in the FIP Statement "Pharmaceutical Care" (The Hague 1998) is a mandatory part of the curriculum.

3. Future developments in pharmacy and medicine should lead to continuous evolution of the educational programme as has been seen to be necessary with the introduction of new subjects such as molecular biology, biotechnology and gene-therapy and developments in information technology in recent years. This is essential if pharmacists are to be equipped properly by their course of education, to practise in various fields.

4. Educational programmes should reflect the fact that current and future pharmacists must have sufficient knowledge and professional, social and communication skills, and exhibit specific attitudes and behaviour, to enable them effectively to discharge their professional roles, within the requirements governing Good Pharmacy Practice including assisting an individual to evaluate and interpret information they have obtained from other sources.

5. Educational programmes should be based in a research active environment at a university or institute of equal standing and thus derive the benefit of multidisciplinary support for teaching, research, patient care and service to the public.

6. A final examination should lead to the granting of a diploma or degree signifying either achievement of the academic requirement for recognition as a pharmacist or, if in-service training has also been successfully completed and competency established, the right to commence practising as a pharmacist.

7. Educational outcomes should reflect the needs of society and the contemporary and developing practice of pharmacy in the nation and region concerned.

8. Educational programmes and curricula should be designed to be consistent with and reflective of their respective required educational outcomes. Assessment and quality assurance should be employed to guarantee that intended educational outcomes have been achieved and the required competencies gained.

9. Teaching and learning should be student-centred. Educational philosophy, structures, outcomes, methods and context should be considered of equal importance to content of syllabus, and should be subject to evaluation.

10. Practising pharmacists should recognise their responsibility to contribute to the training of future pharmacists.

11. National pharmaceutical associations should share responsibility for the education of pharmacy students by :
    - being involved in the design, implementation and evaluation of the educational programmes of the schools and faculties of pharmacy in their countries,
    - establishing a co-operative working relationship with the schools and faculties of pharmacy,
    - promoting the appointment of practitioners as teachers in schools and faculties of pharmacy,
    - seeking to ensure that practising pharmacists and pharmacy students are involved in discussions on changes to curricula,
    - ensuring that pharmacist tutors of pre-registration graduates have adequate training for that responsibility,
    - organising practical training possibilities and promoting post-graduate residencies and training programmes.

12. Schools and faculties of pharmacy should share knowledge and educational resources with their colleagues world-wide.

13. Schools and faculties of pharmacy should develop close alliances with educators of other health professionals involved with any aspect of human or animal health.

Conclusion

There is no single, best model for the education and training of pharmacists on a world-wide basis but there are common concepts, principles and practices that should be employed by pharmacy education policy-makers to meet the needs of society locally, regionally and world-wide.

The recommendations in this document on *Good Pharmacy Education Practice* provide a conceptual framework for the design, implementation and assessment of contemporary educational programmes for pharmacists throughout the world.

It is anticipated that pharmaceutical education policy-makers, working together, will jointly explore strategies and methods to ensure the successful implementation of good pharmacy education practice.

Annex

WHO Consultative Group on "Preparing the Future Pharmacist" (Vancouver 1997)

Caregiver: the pharmacy graduate calls upon his/her expertise as a medication expert to provide high quality caring services in primarily two areas. First, pharmacy graduates, in partnership with patients and other health care providers, use their knowledge and skills to directly (e.g. clinical, dispensing) or indirectly (e.g. analytical, technological, logistical, regulatory) meet patient's drug-related needs, with the objective of achieving optimal patient outcomes and maintaining or improving the patient's quality of life. Second, pharmacy graduates provide education, information and recommendations to the individual and populations concerning medications and medication use to ensure optimum and cost-effective patient care and to promote health.

Knowledge, Decision Making and Thinking Abilities: the pharmacy graduate shall possess knowledge and understanding of the core information associated with the profession of pharmacy, including the biomedical sciences; pharmaceutical sciences; social, behavioural and administrative pharmacy sciences; clinical pharmacy science and pharmacy practice. Pharmacy graduates will be able to utilise the principles of scientific inquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice and while conducting practice-related research. Graduates will also be able to systematically find, analyse, evaluate and apply information and shall make informed, defensible decisions.

Communication Abilities: the pharmacy graduate will be able to effectively use and respond to written, verbal and non-verbal communications from diverse audiences and for varied purposes. To do so, pharmacy graduates must be able to use information, media and technology.

Leadership Abilities: the pharmacy graduate is obligated to assume a leadership position in the overall welfare of the community.

Manager/Entrepreneur: the pharmacy graduate effectively and creatively manages resources (human, physical, fiscal, time) and information with the goal of assuring access and availability of pharmaceuticals and pharmaceutical care services, thus optimising patient care. Pharmacy graduates must also be comfortable with delegating duties and being managed by others, whether employers or the manager/leader of the health care team.

Lifelong Learning Abilities: the pharmacy graduate must possess the concepts and principles of and a commitment to lifelong learning as a means of fulfilling and advancing their practice and professional role in society.

Teacher: the pharmacy graduate has a responsibility to assist with the education and training of future generations of pharmacists. Participating as a teacher not only imparts knowledge to others, it offers an opportunity for the pharmacist to gain new knowledge and to fine-tune existing skills.

Additionally, the pharmacy graduate will possess a sense of unity with his/her colleagues, and a professional identity and pride consistent with high values and ethical principles.

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List of banned FDCs w.e.f. 01.01.2002
List of formulations containing PPA
List of FDCs of Rifampicin + Isoniazid
List of Indian CROs
List of CROs (International)
US FDA: Warnings
US FDA: Approved NMEs upto November 2005
US FDA: New Approvals
US approved Labs with

▸ Events

53rd IPC to announce India specific Good Pharmacy Practices guidelines on December 23
Friday, June 15, 2001 08:00 IST
Joe C Mathew, Hyderabad

The 53rd Indian Pharmaceutical Congress (IPC), to be organized at New Delhi on the December 21, 22 and 23 2001, will be remembered for its attempt to bring about a sea change in the professional standards of retail pharmacies in India. The last day of the congress will see IPC coming out with a set of India specific guidelines Good Pharmacy Practices (GPP) for the first time in the country, says Brijesh Regal, organizing secretary, 53rd IPC.

According to him, a committee has already been formed for the purpose in Delhi and has started looking into the matter. A draft document should be ready by this September. It will be circulated amongst various experts for approval and the announcement of the GPP guidelines should be expected on December 23. It will be the most important event of the coming IPC.

"The committee has representatives from other states also and will be documenting what is practically possible to be followed in India. We want to take community pharmacy in India on par with international standards. The biggest achievement of the IPC will be that we will be able to prescribe international standards which are practical for the retail pharmacists of our country," he added.

The secretary informed that the campus of Indian Agricultural Research Institute has been chosen as the venue of the Congress.

"It is a massive campus, and we have allocated 10,000 sq ft area for exhibition alone. The event is definitely going to be a special one, very scientific, productive and absolutely international class, with no frills attached to it. We will be utilizing all latest technologies during the congress," he said.

It is known that the Federation of Indian Chambers of Commerce and Industry (FICCI) will be organizing the exhibition.

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Prof. Dr. B.T. Chidananda Murthy, Director, Central Council for Research in Yoga & Naturopathy.
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"We are going to have a couple of pre-symbosia, satellite symbosia in addition to the regular programmes of IPC. The community pharmacy division of Indian Pharmaceutical Association (IPA) will be organizing a meeting specifically for the retail pharmacists. All India Organisation of Chemists and Druggists will also be involved and we have invited the president of AIOCD, Dilip Mehta to be present there," he informed.

About 4,000 delegates are expected to attend the congress. The organizing committee will launch a website, www.indianpharmaceuticalcongress.com , in July for the purpose. The website will continue to be there for all future IPCs and will have links to all the constituent associations of Indian Pharmaceutical Congress Association (IPCA).

IPCA is a confederation of Indian Pharmaceutical Association (IPA), Indian Hospital Pharmaceutical Association (IHPA), Indian Pharmacy Graduates Association (IPGA), Association of Pharmacy Teachers of India (APTI) and All India Drug Control Officers Confederation (AIDCOC). It represents the different facets of the profession of pharmacy that include industry, R&D, quality assurance, clinical & hospital pharmacy, marketing and distribution, academia and regulators. However, the GPP document will be prepared after taking inspiration from FIP and WHO Guidelines, he added.

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