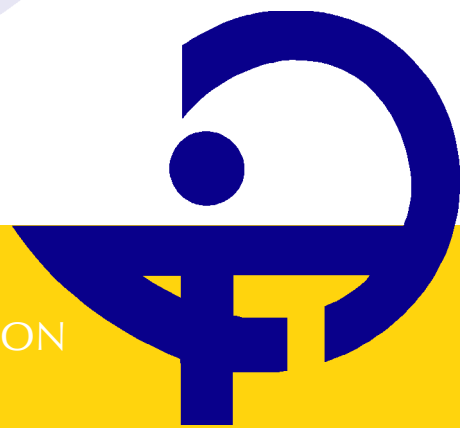


Good Pharmacy Practice (GPP) in developing countries

**Recommendations
for step-wise implementation**



INTERNATIONAL PHARMACEUTICAL FEDERATION





Conscious of the need to help developing countries achieve Good Pharmacy Practice (GPP), 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 (Royal Pharmaceutical Society of Great Britain) 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 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

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 Organization (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 effect 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)^{6,7}; WHO Certification Scheme for Manufacturers; WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce; FIP Guidelines for Drug Procurement.)

⁶ Good Practice in Donations of Medicines, FIP 1997

⁷ WHO Guidelines for Drug Donations, 1996

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

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 recognised 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.

MEMBERSHIP OF WORKING GROUP

Over the years, this group has included:

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Representing pharmacists and pharmaceutical scientists worldwide



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