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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

BOARD NOTICE RAADSKENNISGEWING

NOTICE 2 OF 2004

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends, in terms of section 35A(b)(ii) of the Pharmacy Act, 1974, (Act 53 of 1974), as amended, to make the rules in the Schedule.

Interested persons are invited to submit, within two months after the date of publication of this notice, substantiated comments on or representations regarding the rules and Annexure A (good pharmacy practice guidelines) to the Registrar, The South African Pharmacy Council, PO Box 40040, Arcadia, 0007, or Fax (012) 326 1496 or email: h1one@pharmcouncil.co.za or registrar@pharmcouncil.co.za

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act, 1974 (Act 53 of 1974), as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.
2. The good pharmacy practice guidelines published herewith as Annexure A shall constitute good pharmacy practice in accordance with section 35A(b)(ii) of the Act.

JS DU TOIT
REGISTRAR
December 2003

ANNEXURE A



**THE SOUTH AFRICAN PHARMACY
COUNCIL**

**GOOD PHARMACY PRACTICE
IN
SOUTH AFRICA**

December 2003

INDEX
THE SOUTH AFRICAN PHARMACY COUNCIL

GOOD PHARMACY PRACTICE IN SOUTH AFRICA

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THE SOUTH AFRICAN PHARMACY COUNCIL

GOOD PHARMACY PRACTICE IN SOUTH AFRICA

1. INTRODUCTION

The vision of the South African Pharmacy Council ("the Council"), in serving the public interest and in terms of its statutory obligation, is to ensure that pharmaceutical services are the best to meet the health care needs of the people.

The vital element in this vision is the commitment of the pharmacy profession to promote excellence in practice for the benefit of those they serve. The public and other professions will judge the pharmacy profession on how that commitment is translated into the practice they observe.

The education and training of pharmacists in South Africa must equip them for the roles they have to undertake in practice and be in line with the unit standards for entry-level pharmacists accepted by Council. Within the necessary base of pharmaceutical sciences there must thus be adequate emphasis on the action and uses of medicines, a reasonable introduction in disease states and the relevant elements of the social and behavioral sciences. At all stages, the development and improvement of communication skills should be given due emphasis.

All practising pharmacists are obliged to ensure that the service they provide is of high quality. This document (good pharmacy practice guidelines) demonstrates how that obligation can be met.

1.1 THE UNDERLYING PHILOSOPHY

Pharmacy as a dynamic, information-driven, patient-orientated profession, through its infrastructure, competence and skills, is committed to fulfill the health care needs of South Africa and its people by being the:

- (a) Custodian of medicine;
- (b) Formulator, manufacturer, distributor and controller of safe, effective and quality medicine;
- (c) Adviser on the safe, rational and appropriate use of medicine;
- (d) Provider of accessible, essential clinical services including screening and referral services;
- (e) Accessible provider of health care information;
- (f) Provider of pharmaceutical care by taking responsibility for the therapeutic outcome of therapy and by being actively involved in the design, implementation and monitoring of an effective pharmaceutical service;
- (g) Profession committed to competency and professionalism;

- (h) Profession committed to co-operation with members of the health care team in the interest of the patient; and
- (i) Profession committed to cost-effective pharmaceutical services.

1.2 THE SCOPE OF PRACTICE OF PHARMACISTS

In order to fulfill the needs of South Africa and its people relating to pharmaceutical care, the scope of practice of the pharmacy profession has been prescribed in terms of Section 35A of the Pharmacy Act 53 of 1974, as amended, ("the Pharmacy Act") and in the *Regulations relating to the practice of pharmacy*.

The following services or acts are regarded as being services or acts pertaining to the scope of practice of a pharmacist –

- (a) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:
 - (i) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;
 - (ii) dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine;
 - (iii) furnishing of information and advice to any person with regard to the use of medicine;
 - (iv) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met; and
 - (v) the provision of pharmacist initiated therapy;
- (b) the compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof;
- (c) the manufacturing of any medicine or scheduled substance or the supervision thereof;
- (d) the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, repackaging, supplying or selling of any medicine or scheduled substance or the supervision thereof;
- (e) the application for the registration of a medicine in accordance with the Medicines and Related Substances Act, 101 of 1965, as amended ("the Medicines Act");
- (f) the formulation of any medicine for the purposes of registration as a medicine;
- (g) the distribution of any medicine or scheduled substance;
- (h) the repackaging of medicines;
- (i) the initiation and conducting of pharmaceutical research and development; and
- (j) the promotion of public health.

1.3 GOOD PHARMACY PRACTICE REQUIREMENTS

- (a) A pharmacist's first concern must be the welfare of the patient and of the public in general.
- (b) The core of pharmacy activity is the supply and distribution of medicines and other health care products, the provision of appropriate information and advice to the patient, ensuring the correct use of medicine and monitoring the effects of the use of medicines (pharmaceutical care).
- (c) Pharmacists must adhere to Good Manufacturing Practice as determined by the Medicine Control Council to ensure the safety, quality and efficacy of medicine.
- (d) An integral part of the pharmacist's contribution to health care is the promotion of rational and economic prescribing and optimal use of medicines.
- (e) The objective of each element of the care provided by pharmacists is clearly defined, relevant to the individual and effectively communicated to and accepted by all those involved.
- (f) In satisfying these requirements:
 - (i) the ongoing relationship with other health professionals should be seen as a therapeutic alliance involving mutual trust and confidence in all matters relating to pharmacotherapeutics;
 - (ii) the relationship with other pharmacists should be as colleagues, each seeking to improve pharmaceutical services, rather than as competitors;
 - (iii) there must be input by the pharmacist to decisions on medicine use policy at all levels;
 - (iv) the relationship with those involved in paying for pharmaceutical services should also be one of mutual trust, involving appropriate professional discretion for the pharmacist;
 - (v) the pharmacist should be aware of essential medical and pharmaceutical information about each person to whom a pharmaceutical service is provided. Obtaining such information is simplified if the patient chooses to use only one pharmacy;
 - (vi) the pharmacist needs independent, comprehensive, objective and current information about therapeutics and medicines in use;
 - (vii) the philosophy underlying practice should be professionally rather than commercially orientated;
 - (viii) pharmacists in each field of practice should accept personal responsibility for the self-assessment and maintenance of competence throughout their professional working lives;
 - (ix) good pharmacy practice guidelines as published in rules by the Council must be adhered to by all pharmacists practising in South Africa; and
 - (x) educational programs for entry to the profession and continuing professional development programmes should address contemporary practice appropriately as well as foreseeable changes in the practice of pharmacy in the future.

1.4 GOOD PHARMACY PRACTICE REQUIREMENTS ADDRESSED

The following main elements of Good Pharmacy Practice (GPP) will be addressed in this document:

- (a) Ethics in pharmacy.
- (b) Guidelines for pharmacy premises, facilities and equipment.
- (c) Guidelines for services provided in a pharmacy (including record keeping).
- (d) Human resources in pharmacy.
- (e) Management of the pharmacy/pharmaceutical services.
- (f) Guidelines for inspections.

The order in which chapters are presented does not reflect their relative importance in pharmacy practice. An extensive table of contents enables quick access to any aspect covered in this manual and it is recommended that these guidelines be kept at hand for easy reference in all situations.

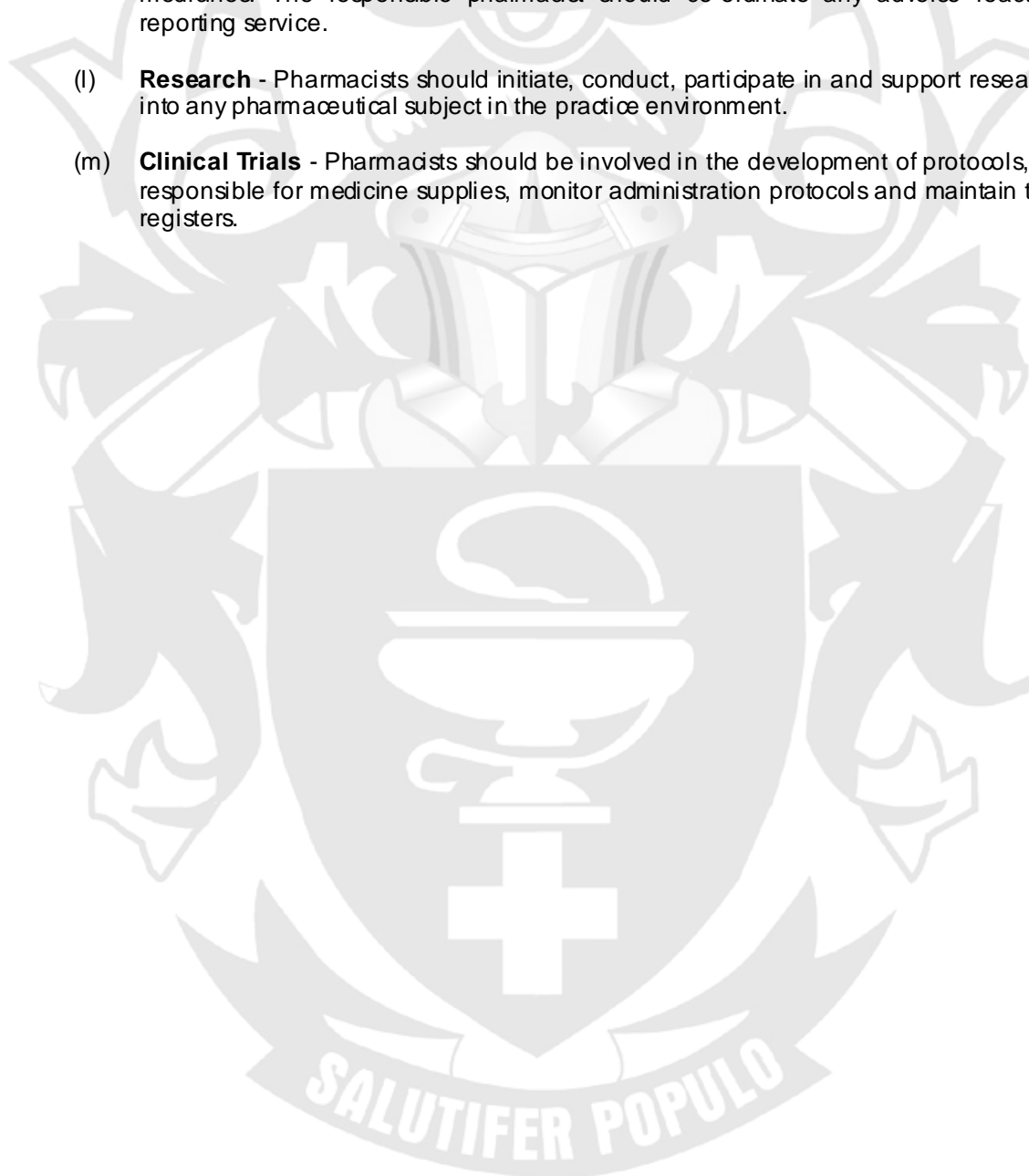
1.5 GENERAL OBJECTIVES OF PHARMACEUTICAL SERVICES

The following broad objectives are common to pharmaceutical services.

- (a) **Management** - A sound management structure must be established to ensure efficient working. The structure should reflect the requirements of various patient groups, the organisational needs and the range and level of activity within the pharmaceutical service. Lines of professional and managerial accountability should be established.
- (b) **Available and appropriate services** - A pharmaceutical service should be readily available for both advisory and logistical purposes. The service should reflect the level of use of medicines for patient care groups.
- (c) **Quality assurance** of pharmaceutical practice.
- (d) **Facilities** must comply with statutory requirements, be of sufficient size with adequate equipment to provide the range of activities required of the pharmaceutical service. They must be secure and situated so as to be convenient to both patients and staff.
- (e) **Safe systems of work** must be established and maintained to eliminate, as far as possible, errors in any component of the pharmaceutical service. This requirement is particularly important in the interpretation and dispensing of prescriptions and the distribution of medicines. Such systems should take account of the need to protect staff from hazardous processes or materials and the safe disposal of all waste.
- (f) The professional pharmaceutical function of medicine logistics and medicine control - effective systems of **drug supply management** must be provided to ensure efficiency and economy.
- (g) A **prescription monitoring service** must be provided to ensure that both prescribing and administration of medicines are monitored regularly and to ensure compliance with accepted practice and safe systems of work and encourage effective prescribing.
- (h) The **counselling of patients** should be undertaken to promote the correct and safe use of medicines. The responsible pharmacist should ensure that patients are

counselled before they receive medicines that they are to self-administer, when they are discharged, transferred or treated as outpatients.

- (i) A **medicine information service** should be provided to promote the safe, effective and economic use of medicines by active and passive provision of accurate information and advice to all members of the health care professions.
- (j) **Health education** - Pharmacists should be available to contribute actively to health education programmes in schools, community clinics, patient support groups and any patient area where compliance is particularly important.
- (k) An **adverse drug reaction reporting system** must be established to facilitate the detection of previously unknown or unpublished adverse effects, to permit the evaluation of factors that influence the safety and toxicity of medicines and promote the generation of statistics on the incidence of various adverse reactions to medicines. The responsible pharmacist should co-ordinate any adverse reaction reporting service.
- (l) **Research** - Pharmacists should initiate, conduct, participate in and support research into any pharmaceutical subject in the practice environment.
- (m) **Clinical Trials** - Pharmacists should be involved in the development of protocols, be responsible for medicine supplies, monitor administration protocols and maintain trial registers.



CHAPTER 1

ETHICS IN PHARMACY

1. INTRODUCTION

The South African Pharmacy Council ("the Council") holds the view that a person registered with the Council should at all times endeavour to act in the interest of promoting public health. A pharmacist should maintain and enhance the honour and dignity of the pharmacy profession and refrain from any activity, which may discredit his/her profession. Adherence to a Code of Ethics will assist in achieving the aforementioned goal.

A breach of the Code of Ethics as published in these guidelines could form the basis of a complaint, subject to disciplinary steps by the Council, provided that the Council, in considering whether or not action should follow, takes into consideration the circumstances of an individual case and does not regard itself as being limited to those matters which are mentioned in the Code of Ethics.

The Code of Ethics is supplemented by more detailed information. Together these set out the fundamental duties, which apply, to all pharmacists and pharmacist's assistants. The information provided cannot, however, cover every situation and when in doubt the advice of Council should be sought.

The Code of Ethics is intended to set the standard of professional conduct for all pharmacists and registered pharmacy support personnel within the scope of the Pharmacy Act. It is also regarded as governing the conduct of all pharmacists both within and outside the practice of pharmacy.

2. CODE OF ETHICS

- (a) A pharmacist's prime concern in the performance of his/her professional duties must be for the welfare of both the patient and other members of the public.
- (b) A pharmacist must uphold the honour and dignity of the profession and not engage in any activity, which may bring the profession into disrepute.
- (c) A pharmacist must at all times have regard for the laws, regulations and rules applicable to pharmacy practice and maintain a high standard of professional conduct. A pharmacist must avoid any act or omission, which would impair confidence in the pharmacy profession. When a pharmaceutical service is provided a pharmacist must ensure that it is efficient.
- (d) A pharmacist must respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family. Such information must not be disclosed to anyone without the consent of the patient or appropriate guardian (caregiver), unless the interest of the patient or the public requires such disclosure.
- (e) A pharmacist must keep abreast of the progress of professional knowledge in order to maintain a high standard of competence relative to his/her sphere of activity.

- (f) A pharmacist must neither agree to practise under any conditions, which compromise professional independence or judgment nor impose such conditions on other pharmacists.
- (g) A pharmacist should, in the public interest, provide information about the availability of relevant services. Such publicity must not claim or imply any superiority over the professional service provided by other pharmacists or pharmacies must be dignified and must not bring the profession into disrepute.
- (h) A pharmacist offering services directly to the public must do so in premises, which reflect the professional character of pharmacy.
- (i) A pharmacist must at all times endeavor to co-operate with professional colleagues and members of other health professions so that patients and the public may benefit.

2.1 WELFARE OF THE PATIENT

Principle: *A pharmacist's prime concern in the performance of his/her professional duties must be for the welfare of both the patient and other members of the public.*

In adhering to this principle the following should be taken into consideration:

The pharmacist's goal in the provision of medicine therapy should be to achieve definite therapeutic outcomes toward patient health and quality of life. The attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist should therefore be focused on primarily benefiting the patient and the public as a whole.

2.2 HONOUR AND DIGNITY OF THE PROFESSION

Principle: *A pharmacist must uphold the honour and dignity of the profession and not engage in any activity, which may bring the profession into disrepute.*

In adhering to this principle the following should be taken into consideration:

- (a) A pharmacist must have due regard for the reasonably accepted standards of behaviour both within and outside his professional practice.
- (b) Any breach of the law, whether or not directly related to a pharmacist's professional practice, may bring the profession into disrepute and be considered to be misconduct.
- (c) A pharmacist must not use or permit the use of his/her qualifications or his/her position as a pharmacist to mislead or defraud.
- (d) While a pharmacist is encouraged to make reference to a doctorate that he/she holds as an additional qualification, care should be taken to ensure that it is not used in such a way as to lead the public to believe that the pharmacist is a medical practitioner.

2.3 STANDARD OF PROFESSIONAL CONDUCT

Principle: *A pharmacist must at all times have regard for the laws and regulations applicable to pharmacy practice and maintain a high standard of professional conduct. A pharmacist must avoid any act or omission, which would impair confidence in the pharmacy profession. When a pharmaceutical service is provided a pharmacist must ensure that it is efficient.*

In adhering to this principle certain fundamental issues in professional conduct should be considered.

Eight main concepts constitute the core of the professional conduct of the pharmacist. All professional acts of omission or commission are related in one way or another to these eight concepts. At all times, the pharmacist must:

- (a) be a law-abiding citizen;
- (b) refrain from purporting to be a medical practitioner or any category of health service professional unless so registered;
- (c) co-operate to ensure safety and order in the provision of health care in his/her work situation;
- (d) within the range of his/her professional ability, safeguard the physical and mental well-being, the personal rights and the dignity of the person receiving care;
- (e) protect the good name of the pharmacy profession;
- (f) observe the rules of professional confidentiality;
- (g) remain professionally competent and abreast of the latest developments in the health area in which he/she functions in accordance with his/her scope of practice;
- (h) observe the provisions of the Pharmacy Act, the Medicines Act, all other Acts which impinge on the practice of pharmacy and the regulations published in terms of these Acts.

2.4 CONFIDENTIALITY

Principle: *A pharmacist must respect the confidentiality of information acquired in the course of professional practice relating to a patient and the patient's family. Such information must not be disclosed to anyone without the consent of the patient or appropriate guardian (caregiver), unless the interest of the patient or the public requires such disclosure.*

In adhering to this principle the following should be taken into consideration:

- (a) A pharmacist must restrict access to information relating to a patient and the patient's family to those who, in the pharmacist's judgment, need that information in the interests of the patient or in the public interest.
- (b) A pharmacist must ensure that anyone who has access to information relating to a patient and the patient's family;
 - (i) is aware of the need to respect its confidential nature;
 - (ii) does not disclose such information without reference to and only with the written consent of the patient.
- (c) If a pharmacist judges it necessary to disclose information relating to a patient and the patient's family the content should be limited to the minimum necessary for the specific purpose involved. The following are guidelines regarding circumstances when information might need to be disclosed:
 - (i) Where the information is to be shared with others who participate in, or assume responsibility for, the care or treatment of the patient, and would be

unable to provide that care or treatment without that information (the need-to-know concept).

- (ii) Where disclosure of the information is to a person or body, which is empowered by statute to require such a disclosure; for example in connection with a scheduled medicine or a notifiable disease.
 - (iii) Where disclosure is directed by the presiding officer of a court. It should be noted that such a direction relates to disclosure only to the person presiding or to a person named by the court.
 - (iv) Where necessary for the purpose of a medical research project, which has been approved by a recognised ethics committee.
 - (v) Rarely, where disclosure is justifiable on grounds of public interest; for example, to assist in the prevention, detection of or prosecution for serious crime or where disclosure could prevent a serious risk to public health.
 - (vi) Where necessary to prevent serious injury or damage to the health of a third party.
 - (vii) If a pharmacist is of the opinion that disclosure of the information requested might cause serious harm to the patient's physical or mental health or well-being, he/she may allow access to this information if the requester can prove to his/her satisfaction that adequate provision is made for counselling or arrangements as are reasonable before, or during or after the disclosure of such information to alleviate or avoid such harm to the patient.
- (d) In the last three exceptions listed above, it will be necessary to assess the risk and seriousness of the potential consequence of failure to disclose as against the rights of the patient to confidentiality.
- (e) If the condition of the patient precludes the seeking of his/her consent, for example, through unconsciousness, mental handicap, psychiatric illness, dementia or brain injury, the assessment of the best interests of the patient should take into account any known wishes of the patient, the patient's next of kin, any other relative and anyone with powers of attorney.
- (f) Where the patient is a child, the pharmacist may have to decide whether to release information to a parent or guardian without the consent of the child but in the child's best interests. Much will depend on the maturity of the child concerned and his/her relationship with his/her parent or guardian.
- (g) When undertaking contraceptive advice, or pregnancy testing, efforts should be made to establish whether the girl is under 16 years of age. If this is the case, the pharmacist should strongly urge her to seek advice from her general practitioner, parent or similar responsible adult. In deciding whether to provide contraceptive advice, regard should be paid to the maturity of the girl and the consequences of unprotected intercourse taking place. Information concerning a positive pregnancy test result should not normally be referred without the girl's consent.
- Rarely, if the pharmacist believes that there may be risk to the life of the girl or her pregnancy following the receipt of this information, it may be judged necessary to inform a responsible person without the girl's consent.
- (h) Where necessary, any disclosure and its extent should be recorded on the patient's record.

- (i) None of the above precludes the collation of data from patient records, on condition that it is presented anonymously, for the purpose of research or as information to an interested commercial source.

2.5 CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

Principle: *A pharmacist must keep abreast of the progress of professional knowledge in order to maintain a high standard of competence relative to his/her sphere of activity.*

In line with the national education policy of life long learning, it is the responsibility of all pharmacists to:

- (a) keep abreast of changes in pharmacy practice;
- (b) remain up-to-date in the law relating to pharmacy and the control of medicine and the knowledge and technology applicable to pharmacy; and
- (c) maintain competence and effectiveness as a practitioner.

Pharmacists must commit themselves to the concept of Continuing Professional Development, which is defined as the process by which pharmacists continuously enhance their knowledge, skills and personal qualities throughout their professional careers.

It encompasses a range of activities including:

- (a) continuing education - which is the on-going learning that professionals need to undertake throughout their careers as a contribution towards the maintenance and enhancement of their professional development and professional competence;
- (b) professional audit - which is the study of the structure, process or outcome of pharmacy practice carried out by individual pharmacists, groups of pharmacists or groups of health care practitioners, to measure the degree of attainment of agreed objectives;
- (c) participation in non-pharmacy related but relevant formal post-graduate education;
- (d) performance appraisal, self-assessment, identification and documentation of personal development targets;
- (e) research, including practice research and the achievement of higher degrees by research;
- (f) active involvement in professional organisations; and
- (g) provision of training, coaching or mentoring.

2.6 PROFESSIONAL INDEPENDENCE

Principle: *A pharmacist must neither agree to practise under any conditions, which compromise professional independence or judgment nor impose such conditions on other pharmacists.*

In adhering to this principle the following should be taken into consideration:

- (a) Pharmacists should not agree to practise under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause

deterioration of the quality of professional services, or that require consent to unethical conduct.

- (b) Pharmacists may not collude with any person not authorised to own a pharmacy or have a beneficial interest in a pharmacy in terms of the *Regulations relating to the ownership and licensing of pharmacies*, to perform acts specifically pertaining to the profession of a pharmacist.

2.7 INFORMATION REGARDING SERVICES

Principle: *A pharmacist should, in the public interest, provide information about available services in or from a pharmacy complying with good pharmacy practice guidelines and duly recorded in terms of the Pharmacy Act. Publicity must not claim or imply any superiority over the service provided by other pharmacists or pharmacies, must be dignified and must not bring the profession into disrepute.*

In adhering to this principle the following should be taken into consideration:

2.7.1 General guidelines

- (a) A pharmacist may make information about himself/herself or his/her practice available, which is intended or may reasonably be regarded as being necessary for the public to be informed about.
- (b) The distribution and content of publicity for professional services should be dignified and restrained. This approach will impress upon the public that medicines are not normal commodities of trade and that a pharmacist, in addition to supplying medicines, provides skilled and informed advice on pharmaceutical matters and health care.
- (c) Publicity covers all forms of announcements or information addressed to the general public or health care professionals concerning the goods and services offered by pharmacists or pharmacies.
- (d) All forms of communication are embraced and include, for example: newspapers, leaflets, notices, signs, packaging material, labels, public address systems, websites, and radio and television announcements.
- (e) It is advisable to separate publicity for professional services from all other publicity.
- (f) Pharmacists may make known to the general public and erect remote direction signs indicating:
 - (i) the location of the pharmacy;
 - (ii) the trading title;
 - (iii) the address of the pharmacy;
 - (iv) telephone numbers;
 - (v) emergency services provided; and
 - (vi) the business hours of the pharmacy.
- (g) Pharmacists may not advertise outside the pharmacy by way of flashing lights and/or moving signs.
- (h) Medicines may only be advertised in or outside a pharmacy in accordance with regulation 45 of the general regulations published in terms of the Medicines Act (GNR. 7636 of 10 April 2003).

- (i) Paragraph (h) must not be so construed as to prohibit a pharmacist from informing the public of the prices, names, pack sizes and strengths of medicines, which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6.
- (j) A pharmacist may make known the names of medical schemes with which he/she has contracted and/or to whose members he/she is prepared to provide pharmaceutical services.
- (k) Publicity must not abuse the trust, or exploit lack of knowledge, of a consumer/patient.

2.7.2 Publicity for services

- (a) Medicine and services in or from the various categories of pharmacies should be advertised in a way that is not misleading, does not harm the dignity or honour of the profession and is factually correct.
- (b) The advertising of medicines should not disparage any other product, medicine or substance and should not promote the misuse, abuse, detrimental, injudicious or unsafe use of medicine.
- (c) Advertising of service(s) should not disparage the service(s) of other pharmacists or pharmacies, nor make claims of superiority, either expressed or implied, in this respect.
- (d) Publicity for services should not involve any unsolicited approach directly to a member of the public by way of a telephone call or a visit made without prior appointment.
- (e) Publicity for services may not offer any inducement by way of a gift, reward, rebate or participation in a competition in relation to professional services.
- (f) It should not contain matters other than:
 - (i) the name, address, telephone number and trading hours of the pharmacy and other branches;
 - (ii) arrangements made for emergency services;
 - (iii) the titles "chemist" and "pharmacy" used in relation to the provision of professional services. Unnecessary repetition of these words, and personal titles, such as pharmacist and chemist, should be avoided;
 - (iv) a pharmacist's name and qualifications;
 - (v) the location of the pharmacy with a map together with transport details and parking facilities.
- (g) The services which may be provided in the various categories of pharmacies in terms of Chapter VI of the *Regulations relating to the practice of pharmacy* (GNR. 1158 of 20 November 2000), may be made known.
- (h) A specialised service should only be referred to in any publicity, if a comprehensive service in that specialisation is provided.
- (i) Information provided on services should be presented so as to allow the recipient to decide which services are to be used, without being subject to pressure. No attempt should be made to solicit custom or to seek to influence choice, save by

the provision of information, which conforms to the guidelines above.

In particular, a pharmacist should ensure that no inducements are offered in connection with the supply of medicine or items on prescription.

- (j) Discreet information relating to services may be supplied to, and displayed in a doctor's surgery, health care centre or local health care clinic. A pharmacist should not seek or agree to an arrangement giving exclusive rights for the display of such advertisements.

2.7.3 Newspaper features

Newspaper features are advertisements and particular care should be taken with them. Features usually comprise editorial comment together with a collection of individual advertisements by interested parties, particularly contractors involved in the refit of a pharmacy or suppliers of goods to a pharmacy. In such features, restraint should be exercised.

2.7.4 Directories

When advertising in telephone and other local directories, bold type or super bold type is acceptable, as are display and semi-display advertisements, which do not conflict with other principles.

2.8 PROFESSIONAL APPEARANCE AND NATURE OF PHARMACY

Principle: *A pharmacist offering services directly to the public must do so in or from pharmacy premises that comply with good pharmacy practice guidelines, which reflect the professional character of pharmacy, and which is duly recorded in terms of the Pharmacy Act.*

In adhering to this principle the following should be taken into consideration:

2.8.1 Control over medicines

2.8.1.1 General guidelines

- (a) A pharmacist has a professional responsibility to exercise control over all medicinal and related products, which are purchased or supplied.
- (b) All pharmacists should keep abreast of current thinking, including legislation on safety and use of medicines. A pharmacist involved in the supply of other products associated with maintenance of health should keep abreast of the current thinking on safety and use of such products. Action must be taken promptly on such matters as product recall.
- (c) A pharmacist must not purchase, sell or supply any medicinal product where the pharmacist has any reason to doubt its safety, quality or efficacy.
- (d) A pharmacist must be satisfied that both the supplier and the source of any medicine purchased are recorded with Council and are reputable. Due regard must be paid to the storage conditions before purchase and to the labels, leaflets, appearance, origin and subsequent chain of supply of the medicine concerned.
- (e) A pharmacist must not purchase, sell or supply any product associated with maintenance of health or a food supplement where there is any reason to doubt its safety or quality.

- (f) To avoid confusion and in the interest of the patient, a pharmacist must ensure that when any medicinal product is sold or dispensed to the patient, all the information on the package or container which is necessary for the safe and effective use of the medicine as stipulated in the Medicines Act, is written in at least one official language and that a patient information leaflet is made available at the point of dispensing as required in terms the general regulations to the Medicines Act.
- (g) When appropriate, a pharmacist should ensure that the proposed user or purchaser of a medicinal product receives advice on its safe use. Special needs may arise where the user is vulnerable (e.g. blind, disabled, illiterate).
- (h) A pharmacist must not give an impression to a potential purchaser that any product associated with maintenance of health or a food supplement is efficacious when there is no evidence of efficacy.
- (i) The keeping, compounding, dispensing or supply of any medicine or scheduled substance by a pharmacist, pharmacist intern or pharmacist's intern or services provided in a pharmacy may only take place in or from such pharmacy if the pharmacy complies with good pharmacy practice guidelines relating to premises, equipment, reference sources and safety and is duly recorded in terms of the Pharmacy Act.

2.8.1.2 Counterfeit and stolen medicines

- (a) Counterfeiting in relation to medicine includes the deliberate and fraudulent mislabelling with respect to the identity and/or source of the medicine. A pharmacist must report to the Medicines Control Council or other competent authority any instance where he/she suspects that he/she has been offered or has been supplied with counterfeit medicines. He/she must isolate and withhold from sale or supply any such medicinal products.
- (b) A medicine registered with the Medicines Control Council must have the registration number on each pack. A pharmacist must not accept medicinal products from a supplier that are not so labelled.
- (c) The purchase, possession, sale, supply or dispensing of an unregistered medicinal product, except where specifically permitted by legislation, is considered by the Council to be unprofessional conduct, and subject to disciplinary action by the Council in terms of Chapter V of the Pharmacy Act.

2.8.1.3 Foil or blister packs

Medicinal products should not be accepted other than in their original outer packaging and should not be removed from a manufacturer's blister or foil pack in order to create a bulk dispensing pack. They may, however, be removed at the time of dispensing for an individual patient at the pharmacist's discretion to assist patient compliance.

2.8.1.4 Re-use of medicines

A pharmacist should not dispense for any patient a medicine previously dispensed for another patient and subsequently returned to a pharmacy from the patient's home.

2.8.1.5 Medicine misuse

- (a) A pharmacist must exercise professional judgment to prevent the supply of unnecessary and excessive quantities of medicines and other products, particularly those that are liable to be misused, or which are claimed to depress appetite, prevent absorption of food or reduce body fluid.

- (b) Many scheduled medicines have a potential for misuse or dependency. Care should be taken with their supply even when it is legally authorised by prescription or signed order. A pharmacist should be alert to the possibility of medicine dependency in health care professionals and patients and should be prepared to make inquiries to ensure that such medicines are to be used responsibly.
- (c) Some over-the-counter medicines and non-medicinal products are liable to be misused, which in this context usually means:
 - (i) consumption over a lengthy period; and/or
 - (ii) consumption of doses substantially higher than recommended.

Requests for such products should be dealt with personally by the pharmacist and sale should be refused if it is apparent that the purchase is not for a genuine medicinal purpose or if the frequency of purchase suggests overuse. A pharmacist should not attempt on his own to control a misuser's habit, unless he/she has appropriate training, and should liaise with bodies such as drug abuse clinics in any local initiative to assist misusers.

- (d) The products, which are abused, are subject to change and pharmacists should keep abreast of local and national trends.

2.8.1.6 Medicines used to reduce intoxication

A pharmacist must not purchase, supply or advise a person to buy any preparation, whether classified as a medicine or not, which is claimed, to mask the signs of intoxication which indicate unfitness to drive a vehicle by accelerating the removal of alcohol from the body or otherwise.

2.8.1.7 Products/services, which may not be sold/provided in a pharmacy

The following products/services may not be sold/provided in a pharmacy:

- (a) Arms and ammunition;
- (b) Fireworks;
- (c) Tobacco, snuff, cigarettes and tobacco related products;
- (d) Liquor, except when meant for medicinal purposes; and
- (e) Lotto machines

The above-mentioned products/services should, however, not be regarded as an exhaustive list and the selling/provision of any product/service that could harm the honour and dignity of pharmacy or could be regarded as not in the public interest, could be subject to disciplinary action by the Council.

2.8.1.8 Tobacco products

Certain products marketed as medicines contain purified extract of tobacco or nicotine. No objection is made to the sale of such products when intended to help the purchaser to stop smoking.

2.8.1.9 Chemicals

A pharmacist must take steps to ensure that all chemicals supplied will be used for a proper purpose and in appropriate circumstances.

- (a) The following chemicals may be used for the preparation of explosives or fireworks: chlorates, nitrates, magnesium, potassium permanganate (especially with glycerine/glycerol), sulphur, powdered aluminium, phosphorus and any oxidising or reducing agent.
- (b) Reasonable steps should be taken by the pharmacist to ensure that such chemicals are not used for these purposes. Such chemicals including solvents should not be sold to a person under 14 years of age.
- (c) Pharmacists should take reasonable steps to ensure that chemicals bought for use in a child's chemistry set will be used under the supervision of an adult. A pharmacist should take reasonable steps to be satisfied that the purchaser of chemicals, including solvents, for industrial purposes or for a hobby, has sufficient knowledge to handle the chemicals safely and will use the chemicals for a proper purpose. A pharmacist should be aware of the requirements of all relevant legislation relating to occupational health and safety, hazardous substances and the abuse of dependence producing substances.

2.8.1.10 Keeping, compounding, dispensing and supply of medicines and scheduled substances

- (a) The keeping, compounding, dispensing or supply of any medicine or scheduled substance by a pharmacist, pharmacist intern or pharmacist's intern may only take place in or from a pharmacy that complies with relevant good pharmacy practice guidelines relating to premises, equipment, reference sources and safety and is duly recorded in terms of the Pharmacy Act.
- (b) Pharmacists must ensure that all medicines and scheduled substances are procured, kept, compounded, dispensed or supplied in or from a pharmacy in accordance with section 22A of the Medicines Act, and good pharmacy practice.

2.8.1.11 Indirect supply of medicine (mail order/courier pharmaceutical service)

- (a) A pharmacist must not normally distribute or encourage the distribution of any medicine or scheduled substance by mail order/courier.
- (b) When a pharmacist needs to sell, supply or deliver medicine or scheduled substances by or through the mail/courier to a patient or members of the public or a person who receives medicine on behalf of the patient, the pharmacist must ensure that:
 - (i) the medicine is packaged in such a manner that it will guarantee the safety, quality and efficacy of medicines in accordance with the registration requirements for such medicine in terms of the Medicines Act, throughout the delivery process;
 - (ii) a control system is implemented that will enable the pharmacist to detect and correct a delay in the delivery process;
 - (iii) a report back system is introduced to ensure that problems with medicine distribution and delivery are detected timeously;
 - (iv) a patient information leaflet is made available as required in terms of regulation 10 of the general regulations to the Medicines Act;
 - (v) medicines which are prescribed for acute ailments or conditions (immediate need, not repeatable and non-chronic conditions) shall not be delivered to patients by mail/courier; and

- (vi) medicines that are registered to be stored in conditions under 8°C shall not be delivered to patients by mail/courier.

2.8.1.12 Emergency supply of medicine or scheduled substances

- (a) A pharmacist must do everything reasonably possible to assist a person in need of emergency medical treatment or emergency supplies of medicines.
- (b) Section 22A of the Medicines Act allows for the following circumstances in which a pharmacist may sell (supply) medicine or scheduled substances in an emergency, namely a pharmacist may-
 - (i) on the verbal instruction of a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, and who is known to such pharmacist sell any Schedule 5 or Schedule 6 substances in a quantity not greater than that required for continuous use for a period of 48 hours. Provided that the prescriber who has given such verbal instruction must within 72 hours after giving such instruction furnish the pharmacist concerned with a written prescription confirming his/her instructions;
 - (ii) sell a Schedule 2, Schedule 3, or Schedule 4 substance on a non-recurring basis for a period not exceeding 30 days in accordance with the original prescription to ensure that treatment is not disrupted. Provided that the pharmacist must be sure that an authorised prescriber has initiated the treatment concerned and that the intention was that the treatment must be continued, as well as that proper record keeping of such sale is kept.

2.9 CO-OPERATION WITH HEALTH CARE PROFESSIONALS

Principle: *A pharmacist must at all times endeavour to co-operate with professional colleagues and members of other health professions so that patients and the public may benefit.*

In adhering to this principle the following should be taken into consideration:

2.9.1 Association with medical practitioners or other health professionals

- (a) A pharmacist must not enter into any association with a medical practitioner or other health professional, which may compromise the pharmacist's professional independence.
- (b) While the closest professional co-operation between pharmacist and medical practitioner or other health professional is to be welcomed, the pharmacist-
 - (i) must ensure that patients have the freedom to choose where they obtain their pharmaceutical services; and
 - (ii) must, whenever possible, ensure that patients have given their consent to their prescription being directed to a specific pharmacy.
- (c) Close professional co-operation between other health personnel and the pharmacist is to be encouraged in the interests of all concerned, particularly the patient.

2.9.2 Multi-professional (group) practice(s)

- (a) In any multi-professional (group) practice the following principles should be adhered to:
- (i) professional accountability - health and allied professionals are personally accountable for compliance with all ethical rules, policies, standards, codes of conduct and legislation which regulate their respective professional activities;
 - (ii) professional independence - professional independence must be ensured so as to support the principle of professional accountability;
 - (iii) professional responsibility - professional practitioners must only assume responsibility within their scope of professional competence and accountability, utilising the expertise of the most appropriately trained practitioner;
 - (iv) peer review and practice parameters must be encouraged within the multi-professional (group) practice to promote efficient, effective and safe practice;
 - (v) equal norms and requirements - policies, ethical rules and codes of conduct must be applied consistently in all health care delivery systems, including solo practices;
 - (vi) client/patient/community interest - all multi-professional (group) practice activities must be for the benefit of the patient who must be protected from exploitation;
 - (vii) freedom of referral - appropriate and necessary referrals are unrestricted;
 - (viii) arrangements of sharing - health and allied professionals may share facilities, equipment, clinical records and support staff, subject to the principles of professional and ethical accountability, independence and responsibility;
 - (ix) any place wherein or from which acts specially pertaining to the scope of practice of a pharmacist are performed is defined as a pharmacy in terms of the Pharmacy Act;
 - (x) all pharmacies in multi-professional (group) practices must be properly licensed with the Department of Health and recorded with the Council;
 - (xi) all premises must conform with good pharmacy practice guidelines as determined by the Council;
 - (xii) all pharmacies must be under the control of a responsible pharmacist in terms of applicable legislation; and
 - (xiii) the pharmacy within a multi-professional practice must be clearly demarcated.
- (b) A patient may be issued with prescriptions intended for dispensing at a specified pharmacy but must have the right to present it for dispensing at any pharmacy of his choice. A pharmacist must not approach a medical practitioner or medical practice staff to secure direction of prescriptions to a particular pharmacy. A prescription should only be sent directly from a medical practice to a pharmacy when:

- (i) the patient has requested the direction; or
 - (ii) the patient is in residential care and has indicated his/her wish that the person providing that care may collect or receive prescriptions on his/her behalf; or
 - (iii) the patient has an addiction problem and receives medication by instalments.
- (c) A pharmacist shall not offer or give inducements to any person in consideration of his supplying to the pharmacist, either:
 - (i) prescriptions for medicines or appliances for patients; or
 - (ii) orders for medicines other than those for use by a practitioner in his practice;
- (d) A pharmacist must not recommend a medical practitioner, medical practice or any other health care professional unless so requested by a member of the public seeking medical advice or health care services and then only if the pharmacist concerned is sure that the medical practitioner or other health care professional is properly registered with the relevant statutory health council.
- (e) In order to prevent perverse incentives or moral hazards, the following is not permissible nor is it ethical for a pharmacist, pharmacist intern or pharmacist's assistant to:
 - (i) engage in any activity or action that could be regarded as over servicing.
 - (ii) advertise or endorse or encourage the use of any health establishment or medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health related product or health related service in a manner that unfairly promotes the practice of a particular health care professional or a health care facility for the purpose of improper financial gain or other valuable consideration.
 - (iii) engage in or advocate the preferential usage of any health establishment or medical device or health related service or sell any medicine, complementary medicine, veterinary medicine or scheduled substance, if any improper financial gain or other valuable consideration is derived from such preferential usage or prescription or the advocacy of preferential usage by the health care professional, unless entitled by law.
 - (iv) referral of clients or patients to any health establishment or to other health care professionals if such referral would constitute over servicing.
 - (v) accept commission or any financial gain or other valuable consideration from any person(s) or body or service in return for the purchase, sale or supply of any goods, substances or materials used by the health care professional in his or her practice.
 - (vi) pay commission or render any financial gain or other valuable consideration from any person(s) or body or service in return for the purchase, sale or supply of any goods, substances or materials used by the health care professional in his or her practice.
 - (vii) charge or receive a fee for services not personally rendered.

2.10 DUAL REGISTRATION

Principle: *The registration with more than one statutory health council would be permissible provided that at all times the pharmacist should comply with the ethical rules of each of the registered professions under the respective Council.*

In adhering to this principle the pharmacist who holds registration with more than one statutory health council shall at all times ensure that –

- (a) no conflict of interest arises from such dual registration in the rendering of health services to patients;
- (b) patients are clearly informed at the start of the consultation of the status of the pharmacist, i.e. in which capacity the pharmacist will be acting and the informed consent of the patient thereto is obtained in writing;
- (c) patients are not consulted in a dual capacity or charged fees based on such dual consultation;
- (d) the ethical rules applicable at a given moment to the profession in which he or she is acting, are strictly adhered to.

CHAPTER 2

GUIDELINES FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

1. INTRODUCTION

The keeping, compounding, dispensing or supply of any medicine or scheduled substance by a pharmacist, pharmacist intern or pharmacist's intern or services provided in a pharmacy may only take place in or from such pharmacy if the pharmacy complies with good pharmacy practice guidelines relating to premises, facilities and equipment and is duly recorded in terms of the Pharmacy Act.

In adhering to good pharmacy practice guidelines it should also be taken into consideration that pharmacists are obliged to exercise proper and/or reasonable care in respect of and control over-

- (a) the acquisition, storage, manufacture, dispensing, sale, supply or disposal of medicines, or of raw materials for the manufacture of medicines, for human or veterinary use;
- (b) chemical and hazardous substances;
- (c) access of the public to scheduled substances;
- (d) the hygiene, cleanliness and neatness of a pharmacy;
- (e) the appearance of a pharmacy, which failure may result in the dignity of the profession being harmed or potentially harmed.

Each section sets out minimum standards for pharmaceutical facilities, which must be met. Failure to meet the standards could form the basis of a complaint of misconduct. General guidelines with which all pharmacies must comply are provided, followed by general guidelines for premises, facilities and equipment in community and institutional pharmacies.

The above-mentioned general guidelines are then supplemented with specific guidelines which are applicable to the various categories of pharmacy namely community pharmacy, institutional pharmacy, wholesale pharmacy and mobile pharmacy. Manufacturing pharmacies must comply with standards of Good Manufacturing Practice as prescribed by the Medicines Control Council.

2. GENERAL GUIDELINES FOR PREMISES AND SECURITY

2.1 APPEARANCE OF PHARMACY PREMISES

- (a) The design and layout of the pharmacy must permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimise the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of the products.
- (b) All parts of the premises must be maintained in an orderly and tidy condition.

- (c) The name of the responsible pharmacist must be conspicuously displayed over the main entrance of a pharmacy.
- (d) The name of the pharmacist(s) on duty must be displayed conspicuously in the pharmacy for purposes of identification of such person(s) by the public.
- (e) The external appearance of pharmacies must inspire confidence in the nature of the health care service that is provided and portray a professional image.
- (f) Entrances and doorways should be wide enough to allow wheelchairs and pushchairs to enter should it be necessary.

2.2 SAFETY OF PREMISES

Working conditions must be so arranged as to protect the safety of the public and people working on the premises.

2.3 CONDITION OF PHARMACY PREMISES

- (a) The walls, floors, windows, ceiling, woodwork and all other parts of the premises must:
 - (i) be kept clean; and
 - (ii) be kept in such good order, repair and condition as to enable them to be effectively cleaned and to prevent, as far as is reasonably practicable, any risk of infestation.
- (b) Walls must be finished in a smooth, impervious, washable material.

2.4 CONSTRUCTION OF PREMISES

Construction of the premises should ensure that the entry of insects, animals (especially rodents) or birds is prevented and that the premises can be easily cleaned and disinfected.

2.5 ENVIRONMENT

- (a) Storage of thermolabile medicines must be in accordance with the storage instructions of the manufacturer in a refrigerator that is regularly calibrated.
- (b) Products must be protected from the adverse effects of light, freezing or other temperature extremes and dampness.
- (c) Levels of heat, light, noise, ventilation, etc., must exert no adverse effects on personnel.
- (d) All parts of the premises must have suitable and effective means of heating, lighting and ventilation. If windows are capable of being opened, they must be securely locked when the pharmacy is closed.
- (e) Background music or other broadcasts in the pharmacy must not be played at such a volume so as to cause distraction.

2.6 HYGIENE

- (a) There must be an area where equipment and other utensils can be washed which has a source of hot and cold tap water, a suitable, clean washbasin made of impervious material and a closed drainage system.

- (b) Adequate toilet facilities must be available and must be kept clean and in good order. Toilets must not open directly into the dispensary or be able to contaminate the place where medicines are kept and prepared in any way.
- (c) Hand-washing facilities must be provided in the toilet area or the lobby together with a conspicuous notice requesting users to wash their hands. Facilities must include readily available hot water, soap, nailbrush and clean towels or other satisfactory means of drying the hands.
- (d) Toilet areas must not be used for storage, or as a source of water for dispensing.

2.7 STORAGE AREAS

- (a) Storage areas should have sufficient shelving constructed from an impervious, washable material for the keeping of medicines above floor level.
- (b) Storage areas for pharmaceuticals must be self-contained and secure.
- (c) Storage areas should be large enough to allow orderly arrangement of stock and proper stock rotation.

2.8 SECURITY

- (a) Careful consideration needs to be given to the overall security of the pharmacy. It must be lockable and as far as possible exclude any unauthorised entry.
- (b) Pharmacists must ensure that unauthorised persons cannot by lawful means obtain access to the pharmacy outside of normal working hour.
- (c) A security policy must be implemented which is designed to ensure as far as is reasonably practicable the safety of both staff and medicines, and should take account of local crime prevention advice.
- (d) A health and safety procedure must be read and signed by all staff.
- (e) Fire extinguishers must be checked regularly and all staff must know the fire procedure.
- (f) Electrical equipment must be regularly maintained.

2.9 CONTROL OF ACCESS TO PHARMACY PREMISES

- (a) The responsible pharmacist of a pharmacy must ensure that every key, keycard or other device, or the combination of any device, which allows access to a pharmacy when it is locked, is kept only on his/her person or the person of another pharmacist at all times.
- (b) Schedule 1 to 6 substances shall be inaccessible to the public and shall not be supplied during the absence of the pharmacist.
- (c) Control of access to pharmacy premises must be of such a nature that only pharmacists or pharmacist interns and pharmacist's assistants under the direct personal supervision of a pharmacist, may handle medicine or scheduled substances in a pharmacy.
- (d) Every pharmacy must, except in such circumstances and subject to such conditions as described in section 2 of Chapter 4 of these Good Pharmacy

Practice guidelines, be conducted under the direct personal supervision of a responsible pharmacist.

2.10 ANOTHER BUSINESS OR PRACTICE IN A PHARMACY

- (a) Without first having obtained the approval of Council, a responsible pharmacist may not allow a person who is not registered with the Council to conduct a separate practice or business in a community-, institutional-, wholesale- or consultant pharmacy.
- (b) The pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice.
- (c) Only pharmacists or pharmacist interns and pharmacist's assistants under the direct personal supervision of a pharmacist, may handle and/or have access to medicine or scheduled substances in the pharmacy premises during normal trading hours as well as outside normal trading hours.

3. GENERAL GUIDELINES FOR PREMISES, FACILITIES AND EQUIPMENT IN COMMUNITY AND INSTITUTIONAL PHARMACIES

3.1 DISPENSARY

3.1.1 Size of dispensary

- (a) The size of the dispensary must reflect the volume of prescriptions dispensed and allow a safe and efficient flow of work and effective communication and supervision for the number of persons working in the dispensary.
- (b) The minimum area for the dispensary necessary to allow a safe and efficient flow of work and effective communication and supervision, will depend on a number of factors, which include the number of prescriptions dispensed, the daily pattern of prescription peaks, the configuration of available space and the space available elsewhere in the premises for storage of stock.
- (c) Dispensaries in new pharmacies should be designed to accommodate the forecast workload and the maximum available space should be allocated. In existing pharmacies the opportunity should be taken to monitor space requirements on a continuing basis.
- (d) A clear working area of approximately 90 cm to 1 m must be provided for each pharmacist working in the dispensary.

3.1.2 Suitability of dispensary

- (a) The dispensary, its fittings and equipment must be adequate and suitable for the purpose of dispensing.
- (b) The dispensary surface area should be sufficient for the volume of prescriptions dispensed.
- (c) The temperature in the dispensing area should be below 25°C.

3.1.3 Water supply

- (a) The dispensary must be provided with a source of potable water. If the main hand-washing facilities for the pharmacy staff are located in the dispensary, there must be one additional to the sink used for dispensing purposes.

- (b) A sink, of durable material (e.g. stainless steel) must be provided in the dispensary, with readily available hot and cold water. The sink must have a plumbed-in waste pipe.

3.1.4 Waste disposal

Waste disposal includes all the waste generated by health care establishments, research facilities and laboratories.

- (a) A suitable and adequate means of waste disposal must be available and in use.
- (b) Waste material must not be allowed to accumulate and should be collected in suitable, covered receptacles for removal to collection points.
- (c) Written sanitation procedures should be available detailing schedules, methods, materials and equipment available. Responsibility should be assigned in writing.
- (d) Incineration is the preferred disposal route for small amounts of solid medicines and injectables, except where manufacturers' advice differs, e.g. chlorates.
- (e) Under no circumstances should substances be disposed of, down surface water drains, i.e. storm water drains, as these may discharge directly into the nearest water source.
- (f) In all situations, a pharmacist should use his pharmaceutical knowledge and skill, together with any necessary expert advice from a Local Authority / Provincial Department of Health, to segregate and dispose of materials safely.
- (g) A medicine or scheduled substance may only be destroyed as prescribed in regulation 27 of the general regulations to the Medicines Act.

3.1.5 Dispensing equipment

There must be adequate, suitable dispensing equipment in the dispensary. Each item must be clean, in good repair and of suitable material. The list below provides a guideline and may be adapted depending on the services provided in the pharmacy.

- (a) A suitable means of counting tablets and capsules. This equipment must be cleaned regularly so that cross contamination between products is avoided.
- (b) An accurate dispensing balance with proof of annual maintenance.
- (c) A range of graduated, stamped glass measures.
- (d) A refrigerator equipped with a maximum/minimum thermometer and capable of storing products at temperatures between 2°C and 8°C. The refrigerator must be cleaned, defrosted and checked periodically to ensure efficient running. Unless there are adequate arrangements for separating various items to avoid cross contamination, this refrigerator must be used only for pharmaceutical products.
- (e) A suitable range of dispensing containers for medicinal products. The use of child resistant closures is to be encouraged.
- (f) Dispensing labels. Additional warning labels must be available, unless those warnings are printed on the dispensing labels. Where computer software is relied on for warnings/interactions, this should be the latest version available. A service contract will often include the provision of software upgrades when available.

- (g) An ointment tile and spatula, stirring rods, pestles, mortars and other appropriate equipment.
- (h) Suitable means for sterilisation of medicinal products if prepared on the premises.
- (i) Suitable refuse receptacles with closable lids.

3.1.6 Reference sources

The following reference material in the current editions must be available for consultation in all pharmacies:

- (a) One of the last three (3) editions of Martindale;
- (b) the latest edition of MIMS;
- (c) the latest edition of Daily Drug Use (Tincture Press Publications) or other Drug Interactions reference source;
- (d) the latest edition of either MDR or SAMF;
- (e) a recent and comprehensive textbook on Pharmacology;
- (f) a medical dictionary;
- (g) Compendium of Laws and Regulations (PSSA), which must be regularly updated; and
- (h) A Good Pharmacy Practice manual.

A wider range of reference material should be available in institutional pharmacies and in premises approved for pre-registration training. Electronic access to the required references is also acceptable.

A responsible pharmacist may apply to Council for a relaxation of the minimum requirements relating to reference books, in exceptional circumstances.

3.1.7 Safety in the dispensary

With the proliferation of electrical equipment such as computers and tablet counters in pharmacies, proper provision for connection should be made with an adequate number of electrical sockets. Care should be taken to avoid trailing wires across floors, work surfaces or sinks.

3.2 WAITING, CONSULTATION AND SALES AREAS

- (a) The minimum space necessary for the sales and waiting areas will depend upon a number of factors, including customer flow, the volume of dispensing and sales, the need to provide seats in the waiting area and the size of the counselling area. Journals, books and equipment can be used in this area to establish a medicine information point.
- (b) Space required for storage and display of stock should be additional to that allocated to the sales and waiting area. Where diagnostic testing facilities are provided an appropriate area should be available for the carrying out of the tests and a private, quiet consultation area available for discussion of the results.
- (c) There should be a separate area or room available where staff may take meal breaks or refreshments.

3.3 COUNSELLING AREA

A minimum requirement for pharmacies where medicines are supplied directly to the public is a suitable counselling area for the furnishing of advice to patients in a reasonably private environment. To assist the pharmacy profession in creating the appropriate area the following guidelines apply:

- (a) The counselling area must be easily accessible and, where possible, be close to the dispensary.
- (b) Clear directions should be provided indicating the counselling area.
- (c) The counselling area must be constructed in such a manner as to ensure reasonable privacy to the patient at all times and eliminate background noise as far as possible.
- (d) The counselling area must have a professional appearance, which can be kept clean and tidy with ease.
- (e) The counselling area must have sufficient space to promote appropriate counselling and possible demonstration of the correct and safe use of specific medicines.

4. SPECIFIC GUIDELINES FOR PREMISES, FACILITIES AND EQUIPMENT IN COMMUNITY PHARMACIES

General guidelines for premises, facilities and equipment in community pharmacies are specified in Section 3 of this Chapter. More specific guidelines for community pharmacies are describe below.

4.1 WAITING AREA

- (a) Waiting areas should preferably be situated near to the dispensing area and areas for the furnishing of information or advice and consultation areas.
- (b) Comfortable chairs should be provided.
- (c) The number of chairs available in the waiting area will depend on the physical space available as well as the number of patients expected to arrive in the pharmacy at any one time.
- (d) Appropriate health related literature should be provided. Where possible, a further educational aid, which can be installed, is a video machine and monitor. Information regarding health and health related matters can be given to patients in this manner while they wait, for example for their prescriptions to be dispensed.

4.2 AREA FOR THE FURNISHING OF ADVICE

Research has shown that better patient compliance in the correct and responsible use of medicine can be obtained in cases where pharmacists give adequate advice to patients. Not only does adequate advice lead to adherence/compliance, but it also affects the eventual outcome of the patient's illness/condition.

When advice is provided to patients, communication is both verbal and non-verbal. As a health professional the pharmacist must show empathy, listening skills, courtesy and professional competence in counselling and advising the patient on his/her medicine and healthcare needs.

It has been established that a lack of privacy leads to a breakdown in effective communication between pharmacist and patient. A private area must therefore be part of the layout of the pharmacy. The following guidelines apply:

- (a) The area must be easily accessible and, where possible, be close to the dispensary.
- (b) Clear directions should be provided indicating the area.
- (c) The area should be constructed in such a manner as to ensure reasonable privacy to the patient at all times and eliminate background noise as far as possible.
- (d) The area should have a professional appearance that can be kept clean and tidy with ease.

4.2.1 Types of areas for the furnishing of information and advice

Two models of areas for the furnishing of information and advice should be considered for the pharmacy, depending on the services offered by the pharmacy and the degree of privacy required. These models are:

- (a) A semi-private area; and/or
- (b) A private area.

Every pharmacy must have at least one type of area for the furnishing of information and advice.

4.2.1.1 Semi-private area

This area is for the provision of information and/or advice that occurs in an area visible to other patients.

- (a) The area could be of a modular “bank teller” type, where a counter is utilised, offering the patient reasonably private access to the pharmacist. Figure 1 is a schematic representation of such a semi-private area.
- (b) In such an area, patient counselling may take place in a professional manner regarding medicine use and other relevant information, but does not provide the privacy required to advise patients on sensitive issues.

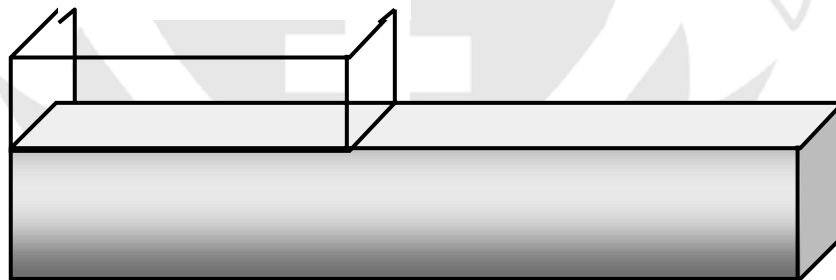


FIGURE 1: SEMI-PRIVATE COUNSELLING AREA

4.2.1.2 Separate private area

The area envisaged in this model is a small private room within the pharmacy, which is in close proximity to the dispensary.

- (a) The area should be professionally planned, tastefully and professionally furnished and equipped, so as to allow the pharmacist to consult and counsel patients who may have sensitive emotional or health care problems and advise patients on their medicines, and other related issues.
- (b) The area should be such that the pharmacist has easy access from the dispensary, and the patient easy access from the waiting area.
- (c) The size of the area should be at least 10 square meters. It should have a table, comfortable chairs and shelves for reference books. The pharmacist's qualifications could also be displayed. Informative wall posters and charts could be used. Figure 2 is a representation of a private area for the furnishing of advice.

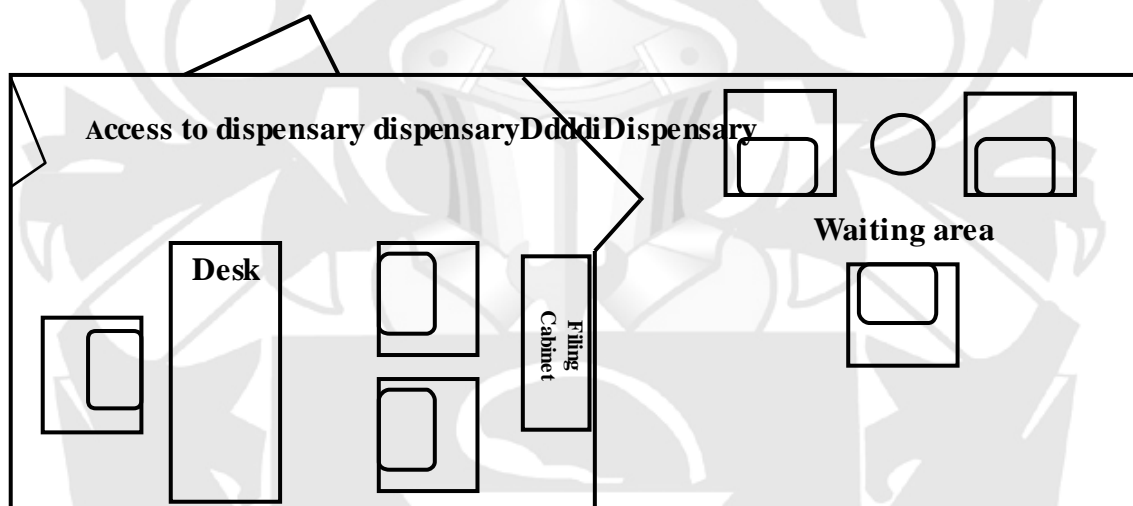


FIGURE 2: PRIVATE COUNSELLING AREA

4.3 CONSULTATION AREA FOR THE PROVISION OF SCREENING AND MONITORING SERVICES

A consultation area for the provision of screening and monitoring services is an isolated area within which the pharmacist can consult in private with a patient and/or perform certain screening and monitoring pharmaceutical services, e.g. cholesterol tests or blood pressure monitoring.

4.3.1 LOCATION AND APPEARANCE OF THE CONSULTATION AREA

- (a) The consultation area must have a professional appearance and be able to be kept clean and tidy with ease. Figure 3 is a schematic representation of such a consultation area.

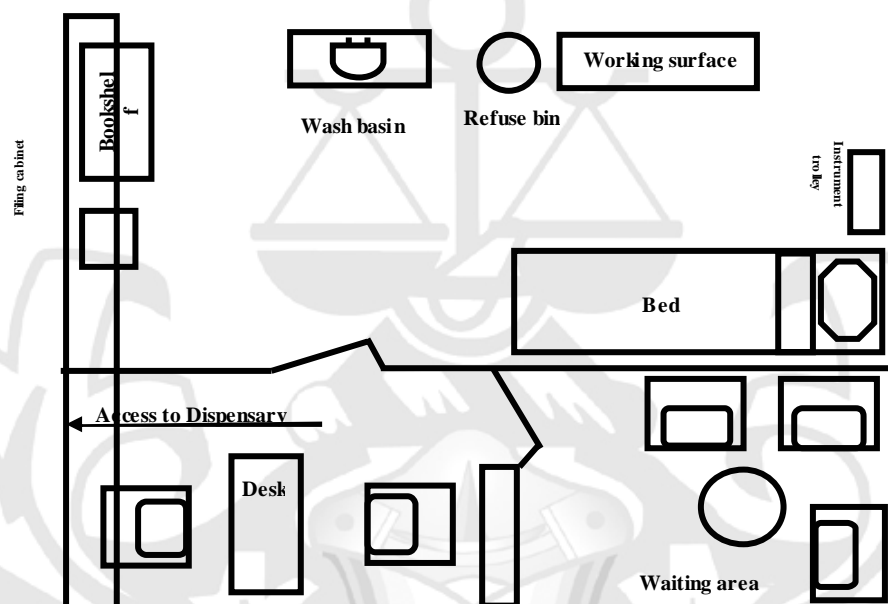


FIGURE 3: CONSULTATION AREA

- (b) The consultation area should have sufficient space (at least 15 square meters) to enable appropriate consultation on the correct and safe use of specific medicines/appliances and the performance of screening/monitoring tests.
- (c) The working surface in the area must be of impermeable washable material.
- (d) The area must at least have the following:
- an examination couch with spare clean sheets;
 - a suitable trolley and/or cabinet for the necessary equipment;
 - an emergency tray;
 - applicable facilities for the taking and analysis of urine and/or blood samples where necessary;
 - a wash basin with hot and cold running water;
 - a closable rubbish bin with a lid and disposable plastic liners;
 - effective equipment for record keeping; and
 - a biohazardous materials bin and sharps container.
- (e) It is advisable to have a refrigerator with a freezing compartment in the consulting area, especially when immunisation services are provided.
- (f) A toilet in the vicinity of the consultation area is strongly recommended.
- (g) A comfortable waiting area for patients situated, if possible, near the consultation area is a necessity.
- (h) Procedures must be in place to ensure that medicines and working areas are not contaminated by infected materials and/or instruments.

4.3.2 Equipment

The services rendered would determine the minimum equipment needed. The following list may be used as a guideline:

- (a) A sphygmomanometer (Mercury type) and stethoscope;
- (b) An otoscope;
- (c) A tuning fork;
- (d) A snellen chart (E-type);
- (e) A blood glucose meter;
- (f) A peak flow meter;
- (g) A "Road to Health Card" and additional copies for supply to patients;
- (h) Tongue depressors;
- (i) Equipment used for first aid e.g. plaster, gauze, cotton wool, sterile wound dressings, scissors;
- (j) Disposable rubber gloves;
- (k) Oxygen with a flow meter;
- (l) A clinical thermometer;
- (m) Alcohol swabs of 70% alcohol solution or surgical spirits;
- (n) A magnifying glass;
- (o) Tissues;
- (p) Towels or paper towels;
- (q) Disinfectants (especially disinfectants recommended for control of the AIDS virus e.g. 2% glutaraldehyde, 1% halocid, sodium hydrochloride, biodecyl 1%) for equipment and clothing/fabric, ready prepared; and
- (r) Applicable equipment for approved screening tests, should these services be rendered;
- (s) A mirror;
- (t) A scale plus baby scale, and
- (u) A height chart and tape measure.

5. SPECIFIC GUIDELINES FOR PREMISES, FACILITIES AND EQUIPMENT IN INSTITUTIONAL PHARMACIES

The institutional pharmacist is an important link in the chain which has been designed to ensure the quality, safety, and efficacy of all medicines supplied to the patient in or from health institutions. It is therefore important that facilities are so designed, equipped and

organised to permit pharmacists to perform their essential role in the maintenance and protection of public health.

General guidelines for pharmacy facilities are stipulated in Section 3 of this Chapter. The following guidelines relate more specifically to institutional pharmacies:

- (a) The pharmacy must be located in an area easily accessible to patients and staff.
- (b) The communication and transportation system of the hospital/institution must include the pharmacy.
- (c) The location of the pharmacy, its equipment and supplies and the space allocated must be adequate to cater for the professional and administrative activities and actions of the pharmacy personnel. The size of rooms and the number and position of work stations should allow proper workflow and segregation of activities.
- (d) The range of activities carried out in an institutional pharmacy will vary according to the size of the hospital/institution or other facilities serviced and the range and level of patient cases treated.
- (e) There must be sufficient and suitable space and facilities for the normal dispensing activities and requirements for ward and clinical services as well as, where necessary, compounding, pre-packing, parenteral admixture preparation, other aseptic compounding and cytotoxic preparation in accordance with the Medicines Act.
- (f) A suitable area and facilities (space, equipment, journals, books) for providing a medicine information service should be provided.
- (g) Offices should be appropriate for the size of the pharmacy and personnel structure.
- (h) Separate service areas for outpatients and staff should be provided that are large enough to allow effective communication. In addition, separate facilities for the provision of information or advice should be provided to ensure confidentiality of discussion.
- (i) An adequate waiting area which is under cover should be provided for outpatients and their companions.
- (j) A reception area should be provided for pharmaceutical representatives and visitors from other departments.
- (k) Where manufacturing, compounding and pre-packing are to be carried out in accordance with the Medicines Act, suitable separate facilities should be provided to ensure that errors do not occur.
- (l) Where sterile or aseptic dispensing is to be carried out in accordance with the Medicines Act, suitable facilities should be installed.
- (m) Where cytotoxic or other hazardous substance preparation is to be carried out in accordance with the Medicines Act, a special cabinet should be provided. The cabinet must be designed to protect both the product and the operator.
- (n) Where radioactive pharmaceuticals are to be prepared in accordance with the Medicines Act, the premises must comply with the requirements for aseptic preparation. The premises should also meet the requirements for radioactive

products and a special cabinet to protect both the product and the operator should be provided.

- (o) There must be a clearly defined goods receiving area.

5.1 DISPENSARY

Guidelines relating to the dispensing area can be found in Section 3 of this Chapter.

5.2 OUT-PATIENT WAITING AREA

- (a) Waiting areas should preferably be situated near to the dispensing area and areas for the furnishing of information or advice.
- (b) If the waiting area is in an open area it must be assured that patients are protected from rain and that comfortable temperature is assured.
- (c) Comfortable chairs should be provided.
- (d) The number of chairs available in the waiting area will depend on the physical space available as well as the number of patients expected to arrive in the pharmacy at any one time.
- (e) Health related literature should also be provided. A further educational aid which, can be installed, is a video machine and monitor. Information regarding health and health related matters can be given to patients in this manner while they wait for their prescriptions to be dispensed.

5.3 AREA FOR THE FURNISHING OF ADVICE

Guidelines relating to the various types of areas for the furnishing of information and advice can be found in Section 4 of this Chapter.

6. SPECIFIC GUIDELINES FOR PREMISES, FACILITIES AND EQUIPMENT IN WHOLESALE PHARMACIES

General guidelines relating to premises, facilities and equipment are provided in Section 3 of this Chapter. Licences to act as a pharmaceutical wholesaler or distributor will in future be issued by the Medicines Control Council. The same body would also be responsible for monitoring and ensuring compliance with good pharmaceutical wholesaling practice as part of the licensing process. More specific guidelines for wholesale pharmacies and distributors could thus be found in Chapter 18 of the Guidance Document: Good Manufacturing Practice for medicines in South Africa (GNR.7659 of 2 May 2003) published by the Medicines Control Council.

7. SPECIFIC GUIDELINES FOR MOBILE PHARMACIES

A mobile pharmacy is a non-static pharmacy, duly licensed and recorded in terms of the Pharmacy Act.

7.1 PREREQUISITES FOR CONDUCTING A MOBILE PHARMACY

- (a) The mobile pharmacy must have a permanent address as the *domicillium citandi* of the mobile pharmacy for purposes of licensing and recording in terms of the Pharmacy Act.

- (b) The mobile pharmacy may provide a pharmaceutical service at the place or places as approved by Council only. This information must be stated in the application form for the licensing and recording of the mobile pharmacy concerned.
- (c) A mobile pharmacy may not operate within a radius of five kilometres from any other community pharmacy taken from the shortest road route: Provided that written permission may be obtained by the applicant from the pharmacies concerned to allow the applicant to operate a mobile pharmacy within a radius of five kilometres.
- (d) Only medicine, medicinal and relevant products and/or approved supplementary services may be sold/provided from a mobile pharmacy.
- (a) The functioning of the mobile pharmacy will in all aspects be subject to the same legal requirements as in the case of a community pharmacy.
- (f) The mobile pharmacy must, except in such circumstances and subject to such conditions as may be prescribed by Council, be conducted under the continuous personal supervision of a pharmacist.

7.2 MINIMUM STANDARDS FOR A MOBILE PHARMACY

- (a) The mobile unit must be -
 - (i) insulated with double-sided side panels and ceiling; and
 - (ii) must be cross-ventilated.
- (b) Working surfaces, cupboards, shelves and equipment in the mobile unit must comply with the same requirements as community and institutional pharmacies.
- (c) Light conditions, temperature and humidity within the mobile unit must comply with the requirements for the storage of medicine, other pharmaceutical products, raw materials and packaging materials.
- (d) Separate facilities for the washing of hands and the cleaning of equipment must be provided.
- (e) A private area/facility for the collection of samples for screening tests, where appropriate, must be available.
- (f) The working surfaces/space within the mobile unit should be large enough to allow at least two persons to perform dispensing functions or the provision of supplementary services under safe conditions.
- (g) If supplementary services such as approved screening tests are provided, suitable facilities should be available. Privacy should also be ensured as necessary.

7.3 STORAGE AND CONTROL OF MEDICINE AND SCHEDULED SUBSTANCES IN A MOBILE PHARMACY

- (a) Storage of medicine and scheduled substances must be in original packaging or could be pre-packed in accordance with the Medicines Act. If, in specific cases, certain products have to be transferred to appropriate new containers, contamination must be avoided and the new containers correctly labelled.

- (b) Proper facilities (e.g. a refrigerator with a temperature of 2° - 8°C) for the storage of thermolabile medicines and substances must be provided or installed and the temperature monitored regularly.
- (c) Medicines must not be stored on the floor or outside the mobile unit.



**GUIDELINES FOR SERVICES PROVIDED IN A
PHARMACY (INCLUDING RECORD KEEPING)**

1. INTRODUCTION

The Pharmacy Act 53 of 1974 as amended makes provision for different categories of pharmacy to be prescribed. The regulations published in terms of the Act make provision for five different categories of pharmacy, namely manufacturing pharmacy, wholesale pharmacy, consultant pharmacy, community pharmacy and institutional pharmacy, which may be situated in a public or a private health facility. The services, which may be provided in the different categories of pharmacy, have also been prescribed. The relevant extracts of the Regulations relating to the practice of pharmacy are provided below.

2. SERVICES WHICH MAY BE PROVIDED IN THE DIFFERENT CATEGORIES OF PHARMACY

2.1 MANUFACTURING PHARMACY

Except as provided for in the Medicines Act, only the following services pertaining to the scope of practice of a pharmacist, may be provided in a manufacturing pharmacy -

- (a) the manufacturing of any medicine or scheduled substance;
- (b) the manufacturing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;
- (c) the furnishing of information and advice to any person with regard to medicine manufactured by him, her or it;
- (d) the application for the registration of a medicine or medical device;
- (e) the formulation of medicine for the purposes of registration as a medicine;
- (f) the distribution of medicine or scheduled substances;
- (g) the repackaging of medicine in accordance with the Medicines Act;
- (h) the initiation and conducting of pharmaceutical research and development; and
- (i) any other health service as may be approved by council from time to time.

2.2 WHOLESALE PHARMACY

Except as provided for in the Medicines Act, only the following services pertaining to the scope of practice of a pharmacist, may be provided in a wholesale pharmacy -

- (a) the wholesale distribution of any medicine or scheduled substance through the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;
- (b) the furnishing of information and advice to any person with regard to medicine distributed by him, her or it;
- (c) the application for the registration of a medicine or medical device;

- (d) the initiation and conducting of pharmaceutical research and development; and
- (e) any other health service as may be approved by council from time to time,

Provided that the above provisions shall not prohibit the repackaging of medicine in wholesale pharmacies owned or controlled by an organ of the State in accordance with the Medicines Act.

2.3 COMMUNITY AND INSTITUTIONAL PHARMACY

Except as provided for in the Medicines Act, only the following services pertaining to the scope of practice of a pharmacist may be provided in a community or institutional pharmacy –

- (a) the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:
 - (i) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;
 - (ii) dispensing of any medicine or scheduled substance on the prescription of an authorised prescriber;
 - (iii) furnishing of information and advice to any person with regard to medicine; determining patient compliance with the therapy and follow up to ensure that the patient's needs are being met; and provision of pharmacist initiated therapy;
- (b) the compounding, manipulation or preparation of any medicine or scheduled substance;
- (c) the purchasing, acquiring, keeping, possessing, using, supplying or selling of any medicine or scheduled substance;
- (d) the application for the registration of a medicine or medical device;
- (e) the re-packaging of medicine in accordance with the Medicines Act;
- (f) the promotion of public health in accordance with guidelines and standards as determined by a competent authority which includes but shall not be limited to:
 - (i) the provision of information and education regarding the promotion of human health;
 - (ii) the provision of immunisation, mother and childcare, blood pressure monitoring; health education; blood-glucose monitoring; screening tests for pregnancy; family planning; cholesterol screening tests; HIV screening tests; urine analysis; and visiometric and audiometric screening tests;
- (g) the provision of animal health care services which includes:
 - (i) the compounding and dispensing of prescriptions written by veterinarians and ensuring the optimal use of veterinary medicines;
 - (ii) the immunisation of animals;

- (iii) the handling of minor and/or self-limiting ailments in animals; and
- (iv) the provision of information and education regarding the promotion of animal health.
- (h) the initiation and conducting of pharmaceutical research and development;
- (i) the provision of primary care drug therapy with prior authorisation from council; and
- (j) any other health service as may be approved by council from time to time.

2.4 CONSULTANT PHARMACY

Only the following services pertaining to the scope of practice of a pharmacist may be provided in a consultant pharmacy –

- (a) the provision of pharmaceutical care with the goal of improving compliance with medicine therapy and which shall be limited to the following functions:
 - (i) evaluation of a patient's medicine regimen with respect to the indications, safety and effectiveness of therapy;
 - (ii) the provision of information and advice to any person with regard to the use of medicine; and
 - (iii) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met;
- (b) the initiation and conducting of pharmaceutical research and development;
- (c) the application for the registration of a medicine or medical device;
- (d) the promotion of public health; and
- (e) any other health service as may be approved by the council from time to time.

3. GENERAL GUIDELINES FOR MANUFACTURING OF ANY MEDICINE OR SCHEDULED SUBSTANCE

Manufacturing has been defined in the general regulations published in terms of the Medicines Act as *all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls.*

Manufacturing must be performed in terms of Good Manufacturing Practice (GMP) as determined by the Medicines Control Council (MCC). Further reading in this regard would be the Guidance Document: Good Manufacturing Practice for medicine in South Africa (GNR. 7659 of 2 May 2003), published by the MCC.

4. GENERAL GUIDELINES FOR PROCUREMENT, STORAGE AND DISTRIBUTION

Definition: Materials means raw materials, containers and closures, prescription ingredients, finished products, proprietary preparations and any other medicinal substances purchased for the purpose of a pharmaceutical use.

4.1 RESPONSIBILITY FOR PROCUREMENT

The pharmaceutical aspects of the purchase of all medicinal products and related materials must be the responsibility of a pharmacist.

4.2 SOURCES OF SUPPLY

- (a) A pharmacist has a professional responsibility to exercise control over all medicinal and related products, which are purchased or supplied.
- (b) A purchasing policy should be in place that ensures the safety of medicine.
- (c) A pharmacist should not purchase, sell or supply any medicinal product where the pharmacist has any reason to doubt its safety, quality or efficacy.
- (d) The pharmacist should know and select suppliers by applying various quality parameters, in accordance with the Medicines Control Council's standards of Good Manufacturing Practice.
- (e) A pharmacist should be satisfied that both the supplier and the source of any medicine purchased is reputable and recorded with Council. Due regard must be paid to the storage conditions before purchase and to the labels, leaflets, appearance, origin and subsequent chain of supply of the medicine concerned.
- (f) A Medicine Control Council registration number must be on the container of every medicine.
- (g) Stock rotation must always be done on the "FIRST IN - FIRST OUT" (FIFO) or "FIRST EXPIRED – FIRST OUT" (FEFO) basis. Stock that expires first or is received first (where expiry dates are not available) must therefore be used first. This principle should ensure that well-dated stock is always available and no wastage occurs due to old stock that expires.
- (h) Patients must receive stock that has been stored suitably and has an appropriate expiry date.

4.3 SAFE SYSTEMS OF WORK

A pharmacist should take all reasonable steps to ensure that working conditions are so arranged as to protect the safety of the public and people working in the pharmacy. In adhering to this principle the following should be taken into consideration:

- (a) Safe systems of work should be established and maintained by a pharmacist, to eliminate, as far as possible, errors in any component of the pharmaceutical service.
- (b) Procedures must be established and followed to ensure secure receipt of medicinal products and their onward passage to the pharmacy where delivery is not direct. Delivery of scheduled medicines must be made directly to the pharmacy.
- (c) Secure storage for medicines should be provided in all premises and approved store-keeping procedures and adequate stock control systems should be maintained.
- (d) A medicines policy for the storage and administration of medicines in hospitals should be defined and regularly updated. A pharmacist should establish systems, and be responsible, for the professional element of the procurement of all medicinal products purchased through the hospital pharmaceutical service.

- (e) Within a multidisciplinary system a pharmacist should be responsible for providing advice on the pharmaceutical element of the procurement of surgical dressings.

4.4 MEDICAL GASES

- (a) All equipment supplied for use shall be fit for its purpose and must be maintained in a safe and proper manner.
- (b) Cylinders of medical gases should be stored in accordance with the current guidelines issued by the manufacturers.
- (c) The supply of medical gases to a patient must be in association with treatment of a medical condition.
- (d) Each patient, and appropriate members of the patient's family or carers, must receive full and proper instruction from a pharmacist or suitably trained person in the safe care and handling of the cylinders and associated equipment.
- (e) To facilitate recalls of faulty oxygen giving sets, the name, type, serial number and location of each regulator should be recorded and held in the pharmacy.

Further reading in this regard would be the Guidance Document: Good Manufacturing Practice for medicine in South Africa (GNR. 7659 of 2 May 2003), published by the MCC.

5. SPECIFIC GUIDELINES FOR THE PROCUREMENT, STORAGE AND DISTRIBUTION OF MEDICINES IN COMMUNITY PHARMACIES

5.1 GENERAL

General guidelines for the procurement, storage and distribution of pharmaceutical products and related materials are provided in Section 4 of this Chapter.

A written procurement policy should be available in the pharmacy. This will assist in ensuring:

- (a) Product availability when required;
- (b) That the procurement and distribution process is fully documented;
- (c) Effective batch recall of medicines when necessary;
- (d) That optimal storage conditions are monitored (including during transport);
- (e) The safety of medicines;
- (f) That patients receive stock that has been suitably stored and has an expiry date that allows sufficient time for usage by the patient before the expiry date; and
- (g) That all medicines are sourced from approved suppliers only (and are therefore traceable to legitimate sources of supply).

5.2. COLD STORAGE OF PHARMACEUTICALS

- (a) Thermo labile medicines must be kept in a refrigerator.
- (b) The refrigerator must be inside the dispensary or clinic and should be readily accessible to the pharmacist.

- (c) The refrigerator must be used for pharmaceuticals only.
- (d) The size of the refrigerator must enable the pharmacist to keep the necessary stock in an organised manner. The size must therefore prevent overloading of the refrigerator at any time.

5.2.1 Maintenance of the refrigerator

- (a) The temperature of the refrigerator must be maintained between 2°C and 8°C.
- (b) The temperature of the refrigerator should be controlled by a bi-metal thermometer. This thermometer must be placed in the middle of the refrigerator.
- (c) If the power is off for any length of time, the refrigerator should not be opened until the power supply is restored.
- (d) The refrigerator should be cleaned and defrosted at least once a month.
- (e) The cold chain must be maintained when the refrigerator is cleaned. Cooler boxes should be used to maintain the cold chain.
- (f) The following procedures should be followed when the refrigerator is cleaned:
 - (i) The inside of the refrigerator should be cleaned with an appropriate antiseptic solution and wiped dry.
 - (ii) The door gasket should be cleaned, especially along the bottom edge on upright units;
 - (iii) It should be determined whether the freezing compartment needs defrosting (more than 10mm of ice on the evaporator) and be defrosted if necessary;
 - (iv) The condensor coil on the back of the refrigerator should be cleaned and dust removed from the compressor; and
 - (v) Ensure that the door closes correctly.

Shake Test:

The Shake Test will confirm whether DPT, DT, TT, Hepatitis B or Hib vaccines have been frozen. If a vaccine has never been frozen, the liquid will be smooth and cloudy immediately after shaking, and will have no or very little sediment 30 minutes after standing. When the vial is tilted the sediment will move. If the vaccine has been frozen, granular particles (flocculation) will be seen on close inspection, and heavy sediment will be visible after standing for 30 minutes. This sediment will be less likely to move when the vial is tipped. Hepatitis B has very small flocculates when it has been frozen and the sedimentation test is the most reliable for judging if it has been frozen. If a comparison is made between a vial known to be unfrozen and a suspect vial it is imperative that the two vials are from the same manufacturer and the same batch.

5.2.2 Storage principles for vaccines:

- (a) All vaccines and diluents must be stored in the refrigerator between 2°C and 8°C in a pharmacy that issues to the end-user or clinics.

- (b) During distribution all vaccines must be transported in insulated containers at a temperature between 2°C and 8°C. Vaccines which are naturally stored frozen (Polio), may be refrozen after transportation.
- (c) Various aids can be used to monitor the temperature of vials, eg. cold chain monitors (CCM's) and vaccine vial monitors (VVM's).
- (d) Correct packing of vaccines and diluents in the refrigerator is vital if they are to be kept at safe temperatures. Figure 6 indicates how a refrigerator should be packed.

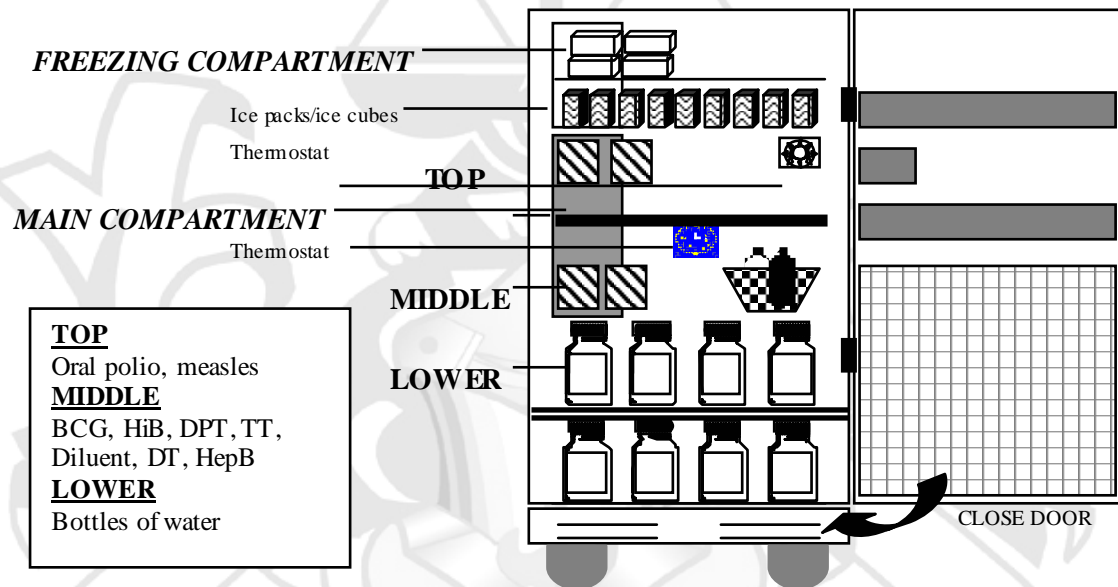


FIGURE 6: CORRECTLY PACKED REFRIGERATOR

- (e) Vaccines must not be kept:
 - (i) In the door compartments of domestic refrigerators;
 - (ii) In such a way that they can come into contact with the evaporator plate i.e. not close to the back or top of the compartments.
- (f) Vaccines should not be stored for longer than the specified storage period.
- (g) Vaccines must be stored in such a way that they cannot be confused with other thermo labile drugs.
- (h) Diluents should be at the same temperature as the vaccine at the point of use.
- (i) Only the designated diluents should be used for specific vaccines.
- (j) All vaccines should be protected by insulated packing during distribution. The containers must be filled with sufficient ice packs to give the container twice the length of cold life anticipated for a particular journey. For example: if a courier service guarantees to deliver a package within 24 hours that package must have a cold life of a minimum of 48 hours.

6. SPECIFIC GUIDELINES FOR PROCUREMENT, STORAGE AND DISTRIBUTION OF MEDICINES IN INSTITUTIONAL PHARMACIES.

6.1. GENERAL

General standards for procurement, storage and distribution of pharmaceutical products and materials are provided in section 4 of this Chapter.

A written procurement policy must be available in the pharmacy. This will assist in ensuring the following:

- (a) Product availability when required;
- (b) That the procurement and distribution process is fully documented;
- (c) Effective batch recall of medicines when necessary;
- (d) That optimal storage conditions are monitored (including during transport);
- (e) The safety of medicines; and
- (f) That patients receive stock that has been suitably stored and has an expiry date that allows sufficient time for usage by the patient before the expiry date.

6.2. SELECTION OF PHARMACEUTICALS

- (a) The pharmaceutical coding and a formulary / the Essential Drug List should be used as the basis for medicine therapy and the promotion of the rational use of medicine. This system includes a formulary of approved pharmaceutical substances and motivation procedures as well as a policy and procedures for the approval and provision of medicine not included in the formulary if required.
- (b) The Pharmacy and Therapeutics Committee should be responsible for the formulary.
- (c) Pharmaceutical usage review programmes should be developed to ensure maximum patient benefit on the most economical basis.
- (d) Medicine used in approved clinical trials should be channelled through and controlled from the pharmacy. A nominated pharmacist should be a member of the trial team.
- (e) Samples of medicine(s) must be left in the pharmacy only and may be used only when motivated for and approved by the Pharmacy and Therapeutics Committee.

6.3. PROCUREMENT AND STORAGE

- (a) The pharmaceutical storage area must be under control of the pharmacy.
- (b) The pharmaceutical storage area must be under control of the pharmacy.
- (c) Delivery of Schedules 5 and 6 medicine or scheduled substances must be made directly to the pharmacy.

- (d) Procurement and stock control of medicinal products and all other items dealt with by the pharmacy must be the responsibility of a pharmacist. There must be written procedures covering all activities, which should be regularly updated.
- (e) The responsible pharmacist must establish and maintain adequate records of purchases for inventory control and satisfaction of legal and audit requirements
- (f) The responsible pharmacist should be accountable for:
 - (i) the selection of medicinal products with due regard to quality and registration status, in co-operation with the Pharmacy and Therapeutics Committee;
 - (ii) the maintenance of up-to-date price records to ensure that the most favourable prices are obtained when applicable;
 - (iii) adherence to central contract or purchasing agreements;
 - (iv) the responsible pharmacist must establish and maintain adequate records of purchases for inventory control and satisfaction of legal and audit requirements;
 - (v) the establishment and maintenance of a system for reporting accidents and withdrawing defective products.
- (g) All orders must be on official documents carrying an order number. There should be only a small number of authorised signatories. Telephonic orders should be confirmed in writing immediately.
- (h) The responsible pharmacist must ensure that all areas where medicines are stored are of acceptable standard.
- (i) The responsible pharmacist should ensure that all medicine storage areas are inspected regularly (at least three-monthly) to ensure that:
 - (i) medicines and scheduled substances are stored in accordance with the pharmaceutical manufacturer's requirements;
 - (ii) no out-dated or obsolete medicines are stocked;
 - (iii) medicines requiring special environmental conditions are properly stored;
 - (iv) stock levels are appropriate;
 - (v) inflammable substances are stored separately and in an appropriate manner; and
 - (vi) disinfectants and preparations for external use are stored separately from medicines for internal use.
- (j) Adequate inventory control systems for bulk pharmaceutical stock as well as for ward and clinic pharmaceutical stock should be maintained by:
 - (i) establishing minimum and maximum stock/re-order levels;
 - (ii) stock control accounting for pharmaceutical products, received into and removed from stock;

- (iii) identification and proper disposal of outdated, deteriorated, recalled or obsolete pharmaceutical products and the timely return of items for credit;
- (iv) recording of orders, usage as well as financial data for analysis, interpretation and planning by pharmacists, the Pharmacy and Therapeutics Committee and pharmaceutical services.

6.4. COLD STORAGE OF PHARMACEUTICALS

Guidelines relating to the cold storage of pharmaceuticals can be found in Section 5.2 of this Chapter.

6.5 DISTRIBUTION OF PHARMACEUTICALS TO WARDS, DEPARTMENTS, THEATRES AND CLINICS (WDTC)

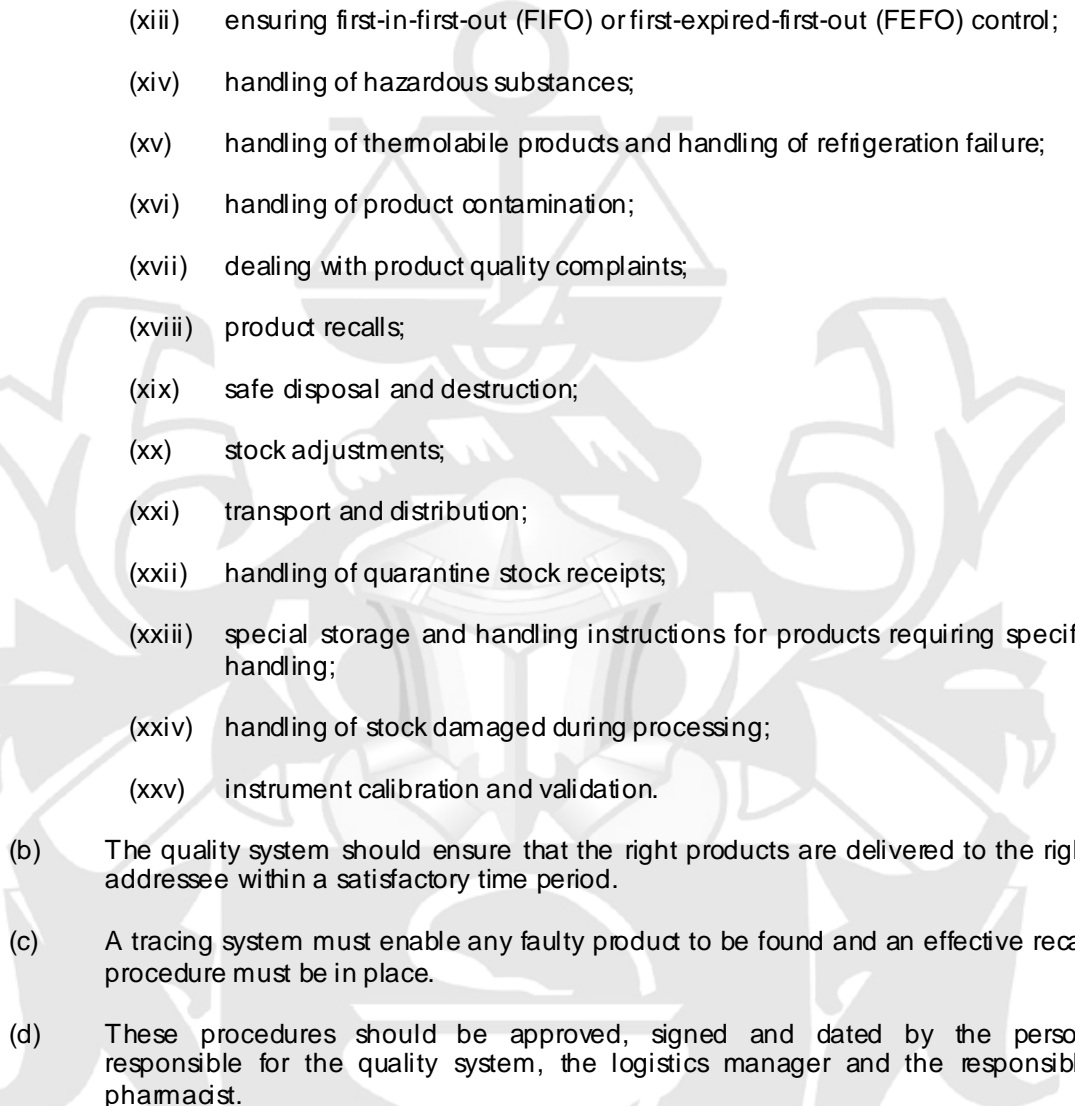
- (a) Distribution of medicines within a hospital/institution must take place under the direction and control of a pharmacist.
- (b) For each WDTC agreement should be reached with nurses and clinicians for those items, which are to be held as stock. Stock levels should be determined from analysis of previous issues and agreed with nursing staff.
- (c) A WDTC stock list should be prepared.
- (d) A copy of the WDTC stock list should be made available to nursing staff who will be responsible for obtaining stock supplies, and to prescribers servicing the ward.
- (e) Written guidelines should be provided on how stock supplies of medicines are to be obtained from the pharmacy together with an indication of nurses' responsibilities for signing approved requisition documents i.e.:
 - (i) an order in writing on approved documents signed by a registered nurse; or other professionally qualified person in charge of WDTC;
 - (ii) in accordance with a standing order signed by such a person, requiring the stock of medicines to be maintained at a stated level by regular planned replenishment;
 - (iii) separate procedures should be provided for Schedule 5 – 6 medicines;
 - (iv) when stock is issued without a written order in an emergency, the written order should be furnished within 24 hours of the issue of the product; and
 - (v) the order in writing, signed by any of the above persons, will be interpreted as a requisition for stock and not as a prescription for an individual patient.
- (f) Procedures should define normal action to be taken by pharmaceutical staff for routine stock replacement and action to be taken in the case of incomplete documentation or other queries.
- (g) A record must be kept for a minimum period of 5 years of the quantity supplied of each item and the requisition must be dated and signed. Any item temporarily out-of-stock should be supplied as soon as possible.
- (h) Procedures should be agreed upon for the return of empty stock packs to deter potential misuses.

- (i) Procedures should be established to ensure that adequate control of issues is maintained and that regular review of stock ranges are carried out to minimise wastage and overstocking.
- (j) Regular stock checking by pharmacy personnel should be undertaken at least two-monthly to ensure that stock rotation is maintained in all the hospital medicine storage areas.
- (k) Procedures should be agreed with nursing staff to allow pharmacist's assistants access to medicine storage facilities with the prior agreement of the nurse-in-charge or other responsible person.
- (l) Procedures should ensure that a thorough stock-check is carried out prior to topping-up to agreed stock levels.
- (m) After the drawing up of the topping-up list by pharmacist's assistants, the signature of the nurse-in-charge or other responsible person should be sought either before returning to the pharmacy or on receipt of the stock medicines on a computer printed requisition/packing note.
- (n) Stock should not be returned to the pharmacy without the agreement of the nurse-in-charge or other responsible person. A written record of its removal should be made on the topping-up list.
- (o) If pharmacy personnel fill-up medicines to the WDTC, stock rotation should be practised. If this remains a nursing responsibility, failure to rotate stock should be referred to the nurse-in-charge of the ward for further action.

7. SPECIFIC GUIDELINES FOR PROCUREMENT, STORAGE AND DISTRIBUTION OF MEDICINE IN A WHOLESALE PHARMACY/DISTRIBUTOR.

7.1 GENERAL

- (a) Written procedures should describe the different operations, which may affect the quality of products or of the distribution activity. These include written procedures for:
 - (i) receipt and checking of deliveries;
 - (ii) storage, cleaning and maintenance of the premises (including pest control);
 - (iii) recording of the storage conditions;
 - (iv) security of stock on site and of consignments in transit;
 - (v) withdrawal from saleable stock;
 - (vi) records, including records of client orders, returned products, recall plans, etc.;
 - (vii) appointment of deputies;
 - (viii) personnel training;
 - (ix) the opening of accounts;
 - (x) stock control of controlled substances;

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- (xi) goods returned procedures;
 - (xii) handling of expired stock;
 - (xiii) ensuring first-in-first-out (FIFO) or first-expired-first-out (FEFO) control;
 - (xiv) handling of hazardous substances;
 - (xv) handling of thermolabile products and handling of refrigeration failure;
 - (xvi) handling of product contamination;
 - (xvii) dealing with product quality complaints;
 - (xviii) product recalls;
 - (xix) safe disposal and destruction;
 - (xx) stock adjustments;
 - (xxi) transport and distribution;
 - (xxii) handling of quarantine stock receipts;
 - (xxiii) special storage and handling instructions for products requiring specific handling;
 - (xxiv) handling of stock damaged during processing;
 - (xxv) instrument calibration and validation.
- (b) The quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period.
- (c) A tracing system must enable any faulty product to be found and an effective recall procedure must be in place.
- (d) These procedures should be approved, signed and dated by the person responsible for the quality system, the logistics manager and the responsible pharmacist.

Further reading in this regard would be the Guidance Document: Good Manufacturing Practice for medicine in South Africa (GNR. 7659 of 2 May 2003), published by the MCC.

7.2. DOCUMENTATION AND RECORDKEEPING

Good documentation constitutes an essential part of the Quality Assurance (QA) system. Clearly written documentation prevents errors from spoken communication and permits tracing of procedures for various purposes.

- (a) Records should be made at the time of each operation in such a way that all significant activities or events are traceable.
- (b) Records should be clear and readily available.
- (c) All records must be retained for the legislative period applicable for the product concerned.

- (d) It is useful to employ a batch-tracking system which enables the tracking of specific batches of medicines.
- (e) There should be a written SOP for the handling of spillage of harmful products (e.g. cytotoxics, hormones, penicillins).
- (f) There should be a written SOP for the handling of product complaints.
- (g) Guidelines on electronic data processing published by the Medicines Control Council should be adhered to at all times.

7.2.1 Purchases and sales

- (a) Records should be kept of each purchase and sale, showing the following:
 - (i) date of purchase or supply;
 - (ii) name of the medicine or scheduled substance;
 - (iii) quantity received or supplied;
 - (iv) name and address of the supplier or consignee;
 - (v) batch number and expiry date.
- (b) A valid written order must be obtained prior to any sale and/or dispatch of specified schedule 5, Schedule 5 and 6 items. This order, as well as record keeping of all sales of specified schedule 5, schedules 5 or medicines must comply with legislative requirements (refer regulation 30 of the general regulations in terms of the Medicines Act).
- (c) For transactions between manufacturing pharmacies and wholesale pharmacies, records should ensure the traceability of the origin and destination of products, for example by use of batch numbers, so that all the suppliers of, or those supplied with a medicine or scheduled substance can be identified.
- (d) The sale of medicine or scheduled substances shall only take place to persons legally entitled thereto. In this regard, proof of registration of the purchaser with his/her relevant statutory body must be in the possession of the wholesale pharmacy or distributor before medicines are sold.

7.3 RECEIPT OF STOCK

- (a) Stock must be received in a separate receiving area and examined for damaged containers.
- (b) All relevant documentation must be recorded and all stock must be checked for quantity, quality, type, condition and expiry dates.
- (c) There must be a system for the recognition of and the prompt and correct handling by the pharmacist of Schedule 5, 6 and 7 substances and for those products requiring storage at specific temperature ranges.
- (d) All applicable documentation and receipts for medicines and scheduled substances must be retained for a period of five years after the date of the last entry made therein. In the case where a register is kept by computer, a computer print out must be made monthly, dated, signed and filed.

- (e) Medicines and scheduled substances may only be purchased from a manufacturing pharmacy, wholesale pharmacy or distributor licensed by the Department of Health and recorded as such with the Council.
- (f) The wholesale pharmacy or distributor must be able to trace the distribution chain for medicines purchased back to the manufacturer of such medicine.

7.4. STOCK ROTATION AND CONTROL

- (a) There must be an effective system to ensure effective stock rotation.
- (b) Periodic stock counts should be performed to check if medicines have expired.
- (c) Products approaching their expiry dates must be removed from saleable stock and neither be sold nor supplied. All stock which has expired and cannot be returned to the manufacturer, must be destroyed -
 - (i) to prevent accidental usage or such medicine coming into the possession of unauthorised persons,
 - (ii) in such a manner as not to cause harm or potential harm to the environment.
- (d) Sterile products with broken seals and/or damaged packaging, and stock suspected of possible contamination, must neither be sold nor supplied.
- (e) Stock which is contaminated or withheld from supply and which is not destroyed immediately must be kept separately from saleable stock so that it cannot be sold in error and that leakage from damaged packaging cannot contaminate other medicines.
- (f) All product recalls must be carried out on the instructions of the appropriate manufacturing pharmacy.
- (g) Goods which have been rejected or recalled or which are to be returned must be stored in a separate storage area and not be placed with other products in order to avoid possible redistribution, until instructions have been issued with regard to their eventual disposal.
- (h) Expired or damaged stock designated for disposal as well as the applicable disposal procedure must be open to inspection by representatives of the respective manufacturing pharmacy.

7.5. MEDICINES AND SCHEDULED SUBSTANCES RETURNED

- (a) Non-scheduled medicine and scheduled substances which have been returned should be kept apart from saleable stock to prevent redistribution until a decision has been reached regarding the disposal or use thereof.
- (b) Medicines and scheduled substances which have left the care of the wholesale pharmacy may only be returned to saleable stock if -
 - (i) the goods are in their original containers, in good condition and bear valid registration numbers;
 - (ii) the containers are unopened;
 - (iii) the medicines have not been subjected to adverse conditions nor is it suspected that the medicines have been subjected to such conditions;

- (iv) the remaining shelf life is acceptable;
 - (v) the medicines and scheduled substances have been examined and assessed by a person authorised and experienced to do so, whose assessment must take into account the nature of the product, special storage conditions required, and the time which has elapsed since the supply thereof.
- (c) If necessary, advice must be sought from persons responsible for the quality control of the manufactured product.
 - (d) Records of returns should be kept.
 - (e) Products returned to saleable stock should be placed such that the 'first in first out' or 'first expired first out' system operates effectively.

7.6. SUPPLY OF MEDICINE

- (a) The onus is on the wholesale pharmacy or distributor to ensure that all legal requirements are met, when medicines or scheduled substances are supplied.
- (b) Wholesale pharmacies and distributors should ensure that accounts are only opened or agreements entered for purposes of the sale of medicines and scheduled substances in the name of the legal entity (company, close corporation, partnership or sole proprietor), which is appropriately authorised to purchase such medicine.
- (c) The recording numbers with the South African Pharmacy Council, the practice numbers with the Board of Health Care Funders and licence numbers with the Department of Health must be recorded.
- (d) When medicines and/or scheduled substances are supplied to pharmacies, confirmation of the recording of the pharmacy with the Council must be obtained.
- (e) Medicines and scheduled substances may be sold to medical practitioners, dentists and veterinarians or persons who are authorised to dispense medicines in terms of Act 101 of 1965 as amended when the medicines and scheduled substances are to be used within the scope of practice of the health care professional and in terms of the conditions of the dispensing licence issued. Registration with the relevant councils and/or the holding of a dispensing licence must be confirmed before such supply takes place.
- (f) Medicines may also be supplied to persons who are in possession of section 22C license in terms of the Medicines Act. Proof of the existence of a permit must be obtained by a wholesale pharmacy or distributor before medicine or scheduled substances are supplied. The wholesale pharmacy or distributor may only supply those medicines or scheduled substances specified in the permit.

7.7. TRANSPORT AND DELIVERIES

- (a) Products must only be dispatched on valid sale orders.
- (b) Supplies must include a document stating the date, the name(s) and pharmaceutical form(s) of the medicine(s) or scheduled substance(s), the quantity supplied and the name and address of the supplier and addressee, batch number and expiry date.
- (c) Suitable packaging materials must be used to protect the integrity of products dispatched.

- (d) Medicine and scheduled products should be transported in such a way that:
 - (i) their identification is not lost;
 - (ii) they do not contaminate, and are not contaminated by, other products or materials;
 - (iii) adequate precautions are taken against spillage, breakage or theft;
 - (iv) they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, nor to attack by micro-organisms or pests;
 - (v) the cold chain, if necessary, is preserved.
- (e) Thermolabile products must be stored and dispatched under suitable conditions and in suitable containers to preserve the integrity of the product and maintain the cold chain.
- (f) If third party distributors are utilised, the distributor must ensure that the third party distributor is informed of standard operating procedures and trained to handle delivery of pharmaceutical products. The distributor must ensure adherence to the procedures and the suitability of the third party distributor to handle pharmaceutical products.

7.8. TEMPERATURE CONTROL

More information regarding the general management of the cold chain can be obtained in section 6 of this Chapter.

- (a) Adequate facilities for the effective storage of thermolabile medicines must be provided.
- (b) Temperature-controlled storage areas must be equipped with temperature recorders that indicate when the specified temperature ranges have been exceeded.
- (c) Written procedures must be available detailing the actions to be taken in the event of a temperature violation.
- (d) All thermolabile products must be distributed under temperature-controlled conditions to maintain the cold chain.

7.9. CLEANLINESS

- (a) All areas within the distribution facility must be kept neat and clean.
- (b) All waste material must be removed on a regular basis.
- (c) Regular cleaning programmes must be drawn up and followed.
- (d) Any breakage and/or spillage must be cleaned up promptly, and
 - (i) any cross-contamination of other products in these circumstances must be prevented;
 - (ii) if any cross-contamination occurs, those products must be removed for disposal and must not be sold or supplied;
 - (iii) written procedures must exist for the handling of potentially dangerous spills.
- (e) Written insect and rodent elimination programmes must be drawn up and adhered to.

- (f) Pest control agents may be used provided there is no risk of contamination.

7.10. EMERGENCY PLAN AND RECALLS

In case of recall, the wholesale pharmacy may decide to inform all their customers of the recall or only those having received the batch to be recalled. The decision to recall should remain that of the manufacturer or medicine regulatory authority.

7.11. COUNTERFEIT MEDICINAL PRODUCTS

Counterfeit medicinal products found in the distribution network should be kept apart from other medicinal products to avoid any confusion. They should be clearly labelled as not for sale and competent authorities and the holder of marketing authorisation of the original product should be informed immediately.

7.12 THEFT OF PRODUCTS

It is incumbent upon the responsible pharmacist to inform the police and relevant authorities where instances of theft of pharmaceutical products are discovered.

8. GENERAL GUIDELINES FOR THE DISPENSING OF MEDICINE OR SCHEDULED SUBSTANCES ON THE PRESCRIPTION OF AN AUTHORISED PRESCRIBER

Definition: The following phases are performed during the “dispensing” process: evaluation of the prescription, the preparation and labelling of the medicine prescribed and the advising of the patient, to ensure the optimal use of medicine.

- (a) The dispensing procedure must ensure that the prescriber's intentions are accurately interpreted, that the medicine is correctly dispensed with reasonable promptness and that an appropriate container and correct label are used. If, on occasion, a prescription cannot be dispensed, the patient must be advised of an alternative dispensing source or be referred back to the prescriber.
- (b) Within this procedure, physical and human resources should be allocated to ensure that prescriptions are dispensed safely and efficiently, with effective, interruption-free personal communication with the patient when that is considered necessary.

8.1 DISPENSING PROCEDURES

This section applies to pharmacists, pharmacist interns, pharmacist's assistants (post-basic) and other healthcare professional who are licensed to dispense in terms of section 22C of the Medicines Act. This section must be read and applied in context of its relevance and pertinence to the respective health care professional.

The dispensing process is divided into 3 phases, namely:

- Phase 1: Evaluation of the prescription.
- Phase 2: Preparation and labelling of the prescribed medicine.
- Phase 3: Advising the patient to ensure the optimal use of medicine.

Phases 1 and 3 are performed by the pharmacist or pharmacist intern under the supervision of the pharmacist to ensure the quality use of medicine.

Phase 2, which involves the logistical and manipulative functions, may be performed by a

pharmacist's assistant (post-basic) under the supervision of a pharmacist.

8.1.1 Phase 1: Evaluation of the prescription

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

Adequate procedures should exist for:

- (i) Identifying the patient, the prescriber and the entity responsible for payment.
- (ii) Ensuring the legality/authenticity of the prescription. A permanent copy of the faxed, e-mailed, telephoned or other
- (iii) Electronically transmitted prescription or order must be made for record purposes. The faxed, e-mailed, telephoned or other electronically transmitted prescription or order should be followed by the original prescription or order within 7 working days.
- (iii) Helping the patient to resolve the problem when the prescription cannot be dispensed.
- (iv) Interpreting the type of treatment and the prescriber's intentions.
- (v) Identifying the medicine, and checking the pharmaceutical form, strength, posology (appropriate dosage), presentation, method of administration and duration of treatment.
- (vi) Informing the patient of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine.

- (b) Assessment of the prescription to ensure the optimal use of medicine. Each prescription should be professionally assessed by a pharmacist on:

- (i) Therapeutic aspects (Pharmaceutical and Pharmacological) i.e.
 - the safety of the medicine;
 - possible contra-indications;
 - drug/drug interactions;
 - drug/disease interactions;
 - treatment duplications;
- (ii) Appropriateness for the individual; and
- (iii) Social, legal and economic aspects.

- (c) Pharmacist interventions

Whenever necessary the pharmacist should communicate with the prescriber regarding any identified problems and work out a plan of action with the prescriber and/or the patient.

- (d) For the assessment of a prescription the following information sources can be used:

- (i) Questions put to the patient or caregiver;

- (iii) Questions put to the prescriber where doubts arise or further information is required;
- (iv) Pharmacopoeias, formularies, technical books, electronic sources, professional journals, compendia of pharmaceutical legislation and medicine supply agreements with the health services; and
- iv) Outside information from drug information centres, competent authorities and pharmaceutical manufacturers.

8.1.2 Phase 2: Preparation and labelling of the prescribed medicine

Selecting or preparing the medicine includes the following activities:

- (a) Patient-ready-packs/pre-packed medicines are correctly selected.
- (b) Preparation of extemporaneous preparations. Every pharmacy should have adequate facilities for dispensing individual prescriptions extemporaneously. When medicines are prepared in a pharmacy:
 - (i) The method of preparation should be adequately documented;
 - (ii) All procedures should comply with good practices;
 - (iii) A shelf life for each product should be established; and
 - (iv) Clean and assized measures and/or scales and clean mortars and pestles must be used.
- (c) Counting must be done on a dean counting tray and the final dosage form placed in a suitable container.
- (d) The container of the medicine must be clearly labelled with the correct directions along with any other information for the safe, proper and effective use of the medicine. Cautionary/advisory labels and instructions must always be used.
- (e) All dispensing procedures must be carefully checked for accuracy and completeness.
- (f) Signing the prescription. Accountability must be accepted by the pharmacist who signs the prescription or copy of the prescription accepting liability for the correctness of the dispensing of the medicine and confirming that the medicine was supplied.

8.1.3 Phase 3: Advising of the patient to ensure the safe and efficacious use of medicine

8.1.3.1 Supply to the patient

- (a) Advising a patient or the patient's agent/caregiver (physical presence is preferred) should be carried out by a pharmacist.
- (b) A patient information leaflet, containing the information as prescribed in the general regulations to the Medicines Act must be made available at the point of dispensing.
- (c) Where a pharmacist is not handing out the prescription, additional advice in writing should accompany the medicine.
- (d) Information should be structured to meet the needs of individual patients.

8.1.3.2 Monitoring patient outcomes

Monitoring patient outcomes includes the ongoing evaluation of the patient and the therapeutic plan with regard to progress towards the therapeutic goal.

- (a) The pharmacist should assess the patient for signs of compliance, effectiveness and safety of the therapy.
- (b) The pharmacist should identify areas for modification, implementation of modifications (taking into account legal requirements), revise the patient record and record the action taken.

8.2 SUPERVISION OF DISPENSING AND SALES

- (a) Dispensing must be done under the supervision of a pharmacist.
- (b) In a pharmacy with only one pharmacist present, this pharmacist must be able to supervise activities in the medicines sales area at the same time as supervising dispensing.
- (c) A pharmacist responsible for supervising the dispensing, sale or supply of any medicine in a pharmacy bears the associated legal and professional responsibility.
- (d) Every prescription for a medicine must be seen by a pharmacist and a judgement made by him/her as to what action is necessary.
- (e) The pharmacist must exercise judgement to ensure fulfilment of professional duties to the patients in the best possible way. The pharmacist must thus be able to delegate to pharmacist's assistants (post-basic) "phase 2" tasks that he/she is confident can be undertaken by them. The pharmacist must be available in the pharmacy to intervene, to advise and to check the dispensing of any prescription under his/her supervision.
- (f) Systems must be developed to ensure that the distribution of medicines is reliable and secure to the point of delivery.
- (g) Although collection and delivery is sometimes necessary, the best pharmaceutical service is provided where the opportunity exists for direct face-to-face contact between patient and pharmacist.

8.3 SAFETY IN DISPENSING PROCEDURES

8.3.1 Interpretation of prescription

- (a) In cases of uncertainty, the pharmacist must make every effort to contact the prescriber. If it is impossible to contact the prescriber, the pharmacist should use his/her professional judgement and decide, in all the circumstances, what course of action would be in the best interest of the patient.
- (b) Where the problem cannot be resolved and if there appears to be a potential risk to the patient, the pharmacist may decide not to dispense the prescription even if the prescriber confirms that the product should be dispensed. In taking this decision, however, the pharmacist should assess the relative harm, which may result from this refusal and use his/her professional judgement to decide what course of action would be in the best interest of the patient.

- (c) The prescription should be endorsed according to any action taken e.g. telephonic confirmation of an unusual dosage, etc.

8.3.2 Forged prescriptions

A pharmacist must be aware of the probable methods of prescription forgery and exercise due care to satisfy himself/herself that prescriptions are genuine.

8.3.3 Dispensing containers

- (a) The container must be appropriate for the product dispensed, bearing in mind the need to protect the product from moisture and sunlight as well as from mechanical stresses imparted by transport and use of the product.
- (b) All containers intended for medicinal products must be protected and kept free from contamination.
- (c) All solid dose oral preparations should be dispensed in a redosable container or in unit packaging of strip or blister type unless:
 - (i) The original pack is such as to make this inadvisable;
 - (ii) The patient is elderly or handicapped and will have difficulty in opening the redosable container; or
 - (iii) A specific request is made that the product shall not be dispensed in a reclosable container.
- (d) Advice must be given to keep all medicines out of the reach of children.

8.3.4 Reuse of containers

- (a) Plastic containers and caps for solid or liquid dose preparations must not be reused as satisfactory cleaning cannot be ensured.
- (b) Under no circumstances may reclosable child resistant closures be used more than once, as continued use affects the child resistant properties of the closure.
- (c) Glass containers are capable of being reused only after satisfactory cleaning and drying. High standards must be maintained, which may make reuse uneconomical.

8.3.5 Reuse of medicines

A pharmacist must use his/her professional knowledge in relation to reuse of medicines as follows:

- (a) Medicines brought in by patients:
 - (i) All such medicines are the patients' own property.
 - (ii) Under no circumstances may they be considered for reuse by anyone else.
- (b) Medicines returned from a hospital ward:
 - (i) All expired medicines must be destroyed;

- (ii) Only blister packs may be considered for re-use provided that the pharmacist is confident that the correct storage conditions have been adhered to; and
- (iii) The continued use of patients' own medicines while in hospital may be necessary in special circumstances. Appropriate safeguards will be required and any system for handling such medicines must be in accordance with current Good Pharmacy Practice.

8.3.6 Labels

- (a) Labelling of dispensed products must be clear and legible and indelible; lettering must as far as possible be mechanically printed.
- (b) The following information should be indicated on the label in accordance with regulation 8(4) of the general regulations in terms of the Medicines Act:
 - (i) The proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
 - (ii) the name of the person for whose treatment such medicine is sold;
 - (iii) the directions in regard to the manner in which such medicine should be used;
 - (iv) the name and business address of the person authorised to sell such a medicine;
 - (v) date of dispensing; and
 - (vi) reference number.

8.3.7 Pricing

Pricing of the prescription or copy of the prescription (where applicable) should bear the following:

- (a) All information necessary to prevent a member of a medical-aid scheme from gaining any benefit to which he/she would not otherwise be entitled; and
- (b) The final price paid by the member or an indication of the total cost of the account rendered to the patient if payment is not effected. (Any discounts should be endorsed on the medical aid copy).
- (c) The professional fee charged must be indicated separately from other charges on the account.

8.3.8 Confidentiality

No information may be divulged about the affairs of any person obtained in the course of dispensing a prescription except to a person authorised to have access to such information and acting within his/her lawful jurisdiction. More information regarding this principle can be found in Chapter 1 of this manual.

8.3.9 Delivery of medicine

More information regarding the delivery of medicine can be found in Chapter 1 of this manual.

8.3.10 Storage

- (a) Medicines and chemicals must normally be stored in the manufacturer's original containers. If, in exceptional cases and with due consideration of the nature of the product concerned, the contents need to be transferred to other containers, care must be taken to avoid contamination and all relevant information must be marked clearly on the new container.
- (b) All materials must be stored under suitable conditions, appropriate to the nature and stability of the material concerned. Particular attention must be paid to protection from contamination, sunlight, atmospheric moisture and adverse temperatures.
- (c) A pharmacist must exercise his/her knowledge of stability of materials to segregate for disposal and destroy any substances which have deteriorated, or which have been in stock for unduly long periods, or which have reached their expiry dates.

8.3.11 Recalls

- (a) A pharmacist must comply immediately with any warning about or recall of defective medicines.
- (b) Every institutional pharmacy should have a recall policy to ensure that the defective medicine will be obtained from the wards and satellite pharmacies.
- (c) A pharmacist should actively participate in any arrangements made for warning the profession of problems associated with medicines, and should inform appropriate bodies of hazards which come to their attention.

8.3.12 Personal hygiene

- (a) High standards of personal cleanliness must be observed in dispensing.
- (b) Direct contact between the dispensed product and the operator's hands must be avoided.
- (c) Cuts or abrasions must be covered with a suitable occlusive dressing. A person with an open lesion or readily transmittable infection must report to the pharmacist who will decide whether they may be engaged in the dispensing process.
- (d) No personnel may smoke or prepare or consume food in any area where medicines are dispensed, sold or supplied.

8.3.13 Expiry dates

Particular care should be taken with prescriptions for several months treatment. Ideally prescriptions should be for a maximum of 28 days' treatment but, where a quantity covering a longer period is dispensed, the pharmacist must ensure that the product will still be in date at the end of that period.

8.3.14 Adverse drug reaction reporting

Adverse drug reaction must be reported to the patient's medical practitioner, as well as to the Medicines Control Council in accordance with guidelines published in this regard (GNR. 7659 of 2 May 2003).

9. SPECIFIC GUIDELINES FOR DISPENSING PROCEDURES IN INSTITUTIONAL PHARMACIES

Section 8 of this Chapter provides general guidelines for the dispensing of medicines on the prescription of an authorised prescriber. Specific guidelines for dispensing medicines in institutional pharmacies are provided below

9.1. INDIVIDUAL PATIENT DISPENSING (IPD)

- (a) If a unit dose dispensing system is in operation, the pharmacist must be responsible for ensuring that medicines are dispensed in individually labelled containers and are delivered to the ward in time for the next medicine round.
- (b) The pharmacist should ensure that a suitable trolley is provided which is lockable. Ideally it should contain sufficient drawers for each patient's medication and a large compartment to accommodate those items too large for the drawers.
- (c) Medicines dispensed but not used should be returned to the pharmacy. Procedures should be established to ensure that the inspection of returned medicines, their return to stock (if appropriate) and crediting are instituted in accordance with local policy.
- (d) The responsible pharmacist should ensure that supplies of medicines are made available either by use of an emergency medicine cupboard or via an on-call pharmacist to meet prescriptions written up outside normal pharmacy hours.
- (e) The responsible pharmacist should also ensure that an on-call pharmacist is available to provide other services as necessary.
- (f) The Pharmacy and Therapeutics Committee should determine the normal supply for individually dispensed items, except:
 - (i) where a specified course of administration is prescribed;
 - (ii) where the medication is available as a suitable pre-pack;
 - (iii) where the medication is presented in a calendar pack and is to be continued after discharge; and
 - (iv) where a unit dose dispensing system is in operation.
- (g) The pharmacist must be responsible for ensuring that unit doses are individually labelled to facilitate full identification of contents and that unit dose carts or medication trays are used as medicine storage facilities in the ward. Labelling should contain the following minimum detail:
 - (i) Name of ward;
 - (ii) Approved name, form, strength and schedule of medicine;
 - (iii) Number of dose units in container;
 - (iv) Name of patient and hospital number;
 - (v) Date of dispensing;
 - (vi) Expiry date and batch number where appropriate; and

- (vii) Additional labels, warnings and storage instructions according to local policy.
- (h) The pharmacist should be responsible for initiating and discontinuing the supply of individually dispensed medicines at ward level. The frequency of ward visits should be determined by the needs of patients in individual wards.

9.2 EMERGENCY MEDICINE TROLLEY

- (a) Emergency trolleys must be equipped with essential medicines and equipment so that medical and nursing personnel can respond immediately should an emergency situation develop in a ward or clinic e.g. cardiac arrest, anaphylactic shock.
- (b) The emergency trolley must be under control of the pharmacist.
- (c) Policies should be agreed, in conjunction with the Pharmacy and Therapeutics Committee, specifying those medicines to be included in emergency stocks.
- (d) Procedures should be instituted to review the contents and expiry dates of these trolleys/trays periodically.

9.3. DOCUMENTATION AND RECORD MAINTENANCE

A complete, readily retrievable patient-medication profile system should be implemented. Section 10 of this Chapter gives more information regarding standards for record keeping procedures.

9.3.1 Expired stock

- (a) It is important to keep an adequate record of expiry dates:
 - (i) in wards, clinics, and wherever medicines are stored;
 - (ii) in the pharmacy;
 - (iii) thermolabile substances in the refrigerator;
 - (iv) the emergency cupboard/trolley in the wards; and
 - (v) intravenous solutions.
- (b) Those items which have expired must be recorded and priced. The medicines can then be destroyed according to the controls as laid down in the general hospital regulations.
- (c) Ward pharmacists or registered nurses in charge of units must return excessive and short dated stock to the pharmacy timeously.
- (d) Expired schedule 5 and 6 medicine and scheduled substances may only be destroyed in the presence of an inspector, an officer of the South African Police Service or any other person authorised by the Director-General of the national Department of Health. Such inspector, person, or officer, as the case may be, must issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register.
- (e) In the case of Schedule 1,2,3 and 4 substance or medicine, a pharmacist or an authorised person in charge of a place where medicines or substances are kept

may destroy such medicines or substances. Such pharmacist or authorised person must certify such destruction.

- (f) No medicine may be disposed of into municipal sewerage systems.

9.4 CONFIDENTIALITY

Confidentiality on all aspects of medicine use must be preserved and applied throughout by all staff members. Chapter 1 of the core GPP Manual provides guidelines regarding confidentiality.

9.5 GUIDELINES FOR THE FURNISHING OF INFORMATION AND ADVICE

- (a) Section 11.1 of this Chapter deals with the furnishing of information and advice.
- (b) The responsible pharmacist must ensure that patients are counselled prior to discharge or transfer from hospital or when they are to be treated as outpatients.
- (c) The responsible pharmacist should ensure that only suitably experienced and trained staff carry out this task.
- (d) The pharmacist involved should assess each patient's ability to understand information imparted by question and answer and be able to modify their approach accordingly. Care should be taken with the advising of parents, relatives, the elderly or ethnic groups or where understanding is likely to be a problem.
- (e) The provision of advice should take place in a suitable environment and the patient should be put at ease, especially with regard to sensitive information.
- (f) Particular caution may be necessary when dealing with certain categories of patients, e.g. those attending addiction or venereal disease clinics.

10. GUIDELINES FOR RECORD KEEPING PROCEDURES

10.1 PATIENT MEDICATION RECORDS

- (a) Records for medicine purchased/sold should be kept on all premises for the prescribed period of 5 years from the date of sale.
- (b) Original prescriptions should be kept for a period of 5 years from the date of dispensing.
- (c) Patient medication records should be developed, preferably using computer technology.
- (d) Patient medication records kept must respect the patient's privacy.
- (e) The following information should be captured in a patient record:
 - (i) the full name of the patient;
 - (ii) the address and telephone number of the patient;
 - (iii) the patient's age or date of birth;
 - (iv) the patient's gender;
 - (v) mass of the patient;
 - (vi) medical aid details;

- (iv) the name of the prescriber and date of consultation;
 - (v) a list of all medicines obtained (prescription as well as non-prescription) by the patient at the point of supply during the twelve month period immediately preceding the date of dispensing;
 - (vi) the number allocated to each prescription dispensed by the pharmacy and the date thereof;
 - (vii) any known allergies of the patient;
 - (viii) any possible reactions of the patient towards medicine;
 - (ix) family history;
 - (x) idiosyncrasies or negative reactions of the patient towards medicine;
 - (xi) the presence of other factors e.g. smoking;
 - (xii) chronic conditions or disease states of the patient; and
 - (xiii) the identity of any other medicine or devices currently being used by the patient which may be relevant to the medicine review and evaluation process, and any related information indicated by a medical or other health care professional.
- (f) Records should:
- (i) be readily retrievable by manual or electronic means;
 - (ii) enable the pharmacist to identify previously dispensed medicine and known disease conditions; and
 - (iii) enable the pharmacist to determine the impact of previously dispensed medicine and known disease conditions upon the newly submitted prescription or other medicine sold or supplied to the patient.
- (g) The pharmacist should ensure a system is in place to guarantee the confidentiality of data relating to individual patients.

10.2 DOCUMENTATION OF PROFESSIONAL ACTIVITIES

Pharmacists should keep records of professional activities in a manner that allows access to information. Particular attention should be given to the following:

- (a) The pharmacist should record all professional actions that might require confirmation in the future.
- (b) Up-to-date records should be kept of prescriptions as already discussed as in (f) above.
- (c) The source of supply of a generic medicine to a pharmacy should be readily available.
- (d) Any warning or precaution issued by professional institutions or authorised officials regarding medicines or pharmaceutical legislation should be recorded and complied with immediately.

10.3 SCHEDULE 1 RECORD

The following information must be recorded with regard to the supply of Schedule 1 medicines without a prescription:

- (a) The name of the person to whom it was sold;
- (b) its name and quantity; and
- (e) The name of the pharmacist, pharmacist intern or pharmacist's assistant who sold it.

10.4 PRESCRIPTION BOOK

According to the general regulations in terms of the Medicines Act, a prescription book or other permanent record in respect of schedule 2,3,4,5 and 6 medicines or substances must be kept on all premises where prescribed medicines are dispensed or sold and must contain the following details:

- (a) the name of the medicine or scheduled substance;
- (b) the date on which the prescription was dispensed;
- (c) the dosage form and quantity of the medicine or scheduled substance;
- (d) the name and address of the patient, or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance was sold;
- (e) where applicable, the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription; and
- (f) prescription reference number.

A prescription record must be retained at the business address of the seller for a period of at least five years after the date of the last entry made therein.

11. GENERAL GUIDELINES REGARDING THE ROLE OF THE PHARMACIST IN THE PROVISION OF PHARMACEUTICAL CARE

- (a) Pharmacists should ensure that any information or services offered by a pharmacy to patients in the area of health promotion are safe, up-to-date and in accordance with the relevant local and national guidelines.
- (b) Pharmacists, with their unique knowledge of the therapeutic use of medicines, have a responsibility towards the utilisation of scientific knowledge in the proper use of medicines and the protection of the public against dangers that are inherent in the use of medicines.
- (c) Information provided to patients regarding their medicine use should always be done with professional judgement and the prescriber contacted when necessary.

11.1 GENERAL GUIDELINES ON PATIENT INFORMATION

Patient information is of vital importance in the correct use of medicines. Lack of information and misunderstanding contribute to the failure of the therapy, thus wasting resources and adding to the costs of care.

11.1.1 Purposes

Patient information should respect patient autonomy, improve health and enhance the outcome of medical treatment by:

- (a) Empowering consumers to make informed decisions about their medical treatments and take responsibility for their own health care;
- (b) Improving communication between patients and healthcare providers; and
- (c) Aiding and encouraging effective use of medicines.

11.1.2 General considerations

- (a) Pharmacists should give advice and information to patients on how to use medicines safely and effectively to maximise therapeutic outcomes.
- (b) Patients should have access to as much information as they require within the ethical and professional judgement of the pharmacist to meet individual needs.
- (c) Although specific presentation and language must be adapted to local communities and public comprehension, information presented to patients should as far as possible be nationally consistent.
- (d) Pharmacists should professionally assess and, where appropriate, comment upon promotional materials for medicines and other products associated with health.

11.1.3 Patient information in practice

- (a) Patient information should be simple, clear and easily understandable.
- (b) The simple transmission of information cannot be considered sufficient in itself, how the information is received and acted upon is a vital factor. For all patient information programs, the effectiveness of communication must be evaluated. Persistent efforts should be made to convince people of the importance of reading information about a medicine they are about to take or use and to ask all relevant questions. Pharmacists should be ready to help with advice on how to act on the information given.
- (c) Patient information programs and materials should be revised regularly, based on evaluation of treatment outcome and on patient and health care provider understanding.

12. SPECIFIC GUIDELINES FOR THE FURNISHING OF ADVICE IN COMMUNITY PHARMACIES

- (a) The furnishing of advice on the use of medicine is an act specially pertaining to the profession of a pharmacist. The pharmacist should be aware of his/her professional responsibility in this regard.
- (b) Upon receipt of a prescription, or a request for dispensing of medicine on own initiative, a pharmacist must offer to counsel each patient or patient's caregiver on matters which, in the pharmacist's professional judgement, will enhance or optimise the medicine therapy prescribed.
- (c) The patient should be put at ease before counselling takes place.

- (d) Counselling should be in a facility that allows for confidential conversation.
- (e) If the patient or patient's caregiver is not present, the pharmacist must furnish comprehensive written instructions that shall include the patient details and information regarding the correct use of the medicine together with the statement:
"If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free or other telephone number)";
and
- (f) Care should be taken to assess the wishes of the prescriber and the information and counselling needs of individual patients.
- (g) Written information should be used to supplement verbal communication as appropriate.
- (h) Counselling should be evaluated and a record of the counselling and any problems identified should be kept.
- (i) The pharmacist should assess each patient's ability to understand information imparted by question and answer and be able to modify his/her approach accordingly. Care should be taken with the counselling of ethnic groups or where understanding is likely to be a problem.
- (j) Confidentiality of the patient should be respected.

12.1 DELIVERY OF MEDICINES BY A COMMUNITY PHARMACY

- (a) All efforts should be made to enable face-to-face counselling of the patient by a pharmacist.
- (b) When a person other than a pharmacist delivers medicines, a note must be attached inviting telephone inquiries should more information be required.
- (c) All medicines should whenever possible be delivered to patients at an agreed time
- (d) In the absence of an adult to receive the medicine, it must be taken back to the pharmacy.

12.2. DOCUMENTATION AND RECORD MAINTENANCE

A complete, readily retrievable patient-medication profile system must be implemented. Section 10 of this Chapter gives more information regarding standards for record keeping procedures.

12.3 CONFIDENTIALITY

Confidentiality on all aspects of medicine use must be preserved and applied throughout by all staff members. Chapter 1 provides guidelines regarding confidentiality.

13. SPECIFIC GUIDELINES FOR CLINICAL PHARMACEUTICAL SERVICES IN INSTITUTIONAL PHARMACIES

13.1. INTRODUCTION

Clinical pharmacy is concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients.

The effective provision of clinical pharmacy services relies on the knowledge and skills of clinical pharmacists and the quality of various clinical support services provided by the pharmacy department.

The practice of clinical pharmacy can be separated into two components. The first is the overall management of medicines in the ward through advice on safe handling and formulary management. The second is the contribution to the care of the individual patient through the provision of drug information and assisting in problem solving.

13.2. WARD PHARMACY SERVICES

Ward pharmacy is a patient orientated, decentralised service where the pharmacist becomes an integral and indispensable part of the hospital professional health team.

- (a) Ward pharmacists should utilise their knowledge and skills of pharmaceutical sciences and product awareness to promote safety, efficiency and economy in the use of medicines.
- (b) Ward pharmacists should offer advice to clinicians and nurses on appropriate medication to ensure that medicines are used correctly and in the appropriate therapeutic context.
- (c) The responsible pharmacist should co-operate with clinicians in determining the minimum number of ward rounds to be attended to ensure that the ward or clinical pharmacist has a full appreciation of the clinical context in which advice on the use of medicines is given.
- (d) Ward pharmacists should participate in specialist care teams and perform a wide range of activities.
- (e) Close involvement with decisions on therapy will bring the pharmacist closer to the patient and provide opportunities for advising patients on self-administration of medicines.
- (f) In order to safeguard the patient and ensure that prescribing and administration documents remain at ward level, a prescription monitoring service should be provided. It should be tailored to the individual needs of patients on each type of ward.
- (g) Where a local formulary is in operation the ward pharmacist should be responsible for ensuring that all new treatment prescribed takes account of its recommendations. This should be done in close co-operation with other health care professionals.
- (h) Ward pharmacists should provide a patient counselling service where the need arises.

13.3. PRESCRIPTION MONITORING SERVICE

The purpose of prescription monitoring is to help ensure that patients receive drug treatment as intended by the prescriber and as required for optimal care. Prescription monitoring is a component of, and not a substitute for, the assessment of patients to identify patient and medication risk factors. Used skilfully such monitoring assists in a complete and continuous assessment of an individual's need for pharmaceutical care.

Through prescription monitoring the pharmacist must identify problems or opportunities for optimising treatment.

- (a) A multi-disciplinary approach should be followed regarding the monitoring of prescriptions.
- (b) The prime objective of this service is to safeguard the patient and ensure the optimal use of medicine. Potential problems should be communicated to the clinician and resolved preferably before the medicine is dispensed or the first dose is administered.
- (c) Use should be made of all information available including that contained within the patient's notes, obtained on ward rounds, by direct communication with the patient, the prescriber and/or other health care professionals.
- (d) Potential medicine-related problems should be discussed with the clinician and suitable advice relating to alternative treatment should be offered. The frequency of monitoring should be determined according to the patient's condition and the nature of medicines prescribed.
- (e) The occurrence of any problems relating to the use of medicines should be documented by a pharmacist, clinician or nurse and should become a permanent record in the patient's notes. Confidentiality should be respected at all times.
- (f) Prescriptions should be evaluated for the following:
 - (i) legality, legibility and completeness;
 - (ii) relative efficacy of the medicine for the clinical indication;
 - (iii) duplication of pharmacologically similar drugs;
 - (iv) potential adverse reactions to medicines, including allergies;
 - (v) possible drug/disease incompatibilities;
 - (vi) significant drug/drug interactions;
 - (vii) correct dosage, route, dosage interval and duration of treatment;
 - (viii) appropriate dosage form and route of administration; and
 - (ix) problems relating to intravenous administration, including potential incompatibilities, medicine stability, volume of intravenous fluid for medicine administration and rate of administration.
- (g) Patients and their medicine therapy should be monitored for the following:
 - (i) the manifestation of adverse reactions or drug toxicity. The pharmacist should attempt to detect those adverse effects at an early stage. Any recognised reaction or adverse effect whether possibly or definitely drug related, should be investigated and reported according to approved hospital policy;
 - (ii) possible altered kinetics of drug absorption, distribution, metabolism or excretion which may affect therapy. This may include the interpretation of pharmacokinetic laboratory data and utilisation of the data to establish an appropriate dose. If necessary, recommendations should be made regarding the need for blood concentration monitoring of certain drugs and the critical relationship between the time of administration and the collection of the blood samples;

- (iii) the appropriate duration of therapy;
 - (iv) administration errors and omissions;
 - (v) drug-laboratory test interference;
 - (vi) drug-food interactions;
 - (vii) drug-drug interactions;
 - (viii) additional medication which may be needed for optimum response or prevention of adverse effects; and
 - (ix) the patient's response to therapy to determine if it is adequate or excessive in relation to the desired therapeutic endpoint.
- (h) Patients with special problems likely to affect therapy with medicines, will require more intensive monitoring, according to the following criteria:
- (i) patients whose age, clinical state or condition may affect drug absorption or disposition, alter dosage requirements or predispose the patient to adverse reactions or drug toxicity;
 - (ii) patients taking medicines known to have a high risk of toxicity and a narrow therapeutic index;
 - (iii) patients taking medicines which may interact;
 - (iv) patients taking an investigational medicine;
 - (v) patients whose therapy is changed frequently; and
 - (vi) patients receiving intravenous therapy.
- (i) Monitoring schedules should be set at a frequency suitable for the patient mix and prescribing practice.
- (j) All pharmacists monitoring prescriptions should be able to provide appropriate information on request using local or other information sources.

13.4 PROVISION OF DRUG INFORMATION AND ADVICE

The purpose of this service is to ensure that appropriate advice is available timeously to meet the requirements of health care professionals. The advice could range from the rational choice of medicines within a particular class of drugs in order to support formulary review, to the selection of an appropriate dosage regimen of a new antibiotic for an elderly patient with deteriorating renal function.

If a drug information service is established within the hospital it must be maintained and developed in conjunction with other established drug information centres. This service must take cognisance of the specific needs of the hospital personnel and patients.

The service could include:

- (a) contributions to the Pharmacy and Therapeutics Committee;
- (b) participation in drug utilisation evaluations;

- (c) participation in development of investigational drug studies and clinical trials, if such programmes exist in the hospital.

13.4.1 Minimum requirements for a drug information service

- (a) Allocated space should be sufficient for reference collection and provision of service.
- (b) Minimum essential furniture and equipment including dedicated telephone, computer and lockable filing cabinets need to be available.
- (c) The unit should maintain a current collection of reference materials appropriate to the scope and nature of the service provided. This includes books, journals, drug profiles, relevant formularies and manufacturer's information.
- (d) The unit should have access to at least one secondary reviewed and referenced literature source.
- (e) A system for consultation with specialists in the various fields for problem cases is necessary.
- (f) Access to a medical library with an inter-library loan facility is necessary.
- (g) Access to other drug information centres, including specialised centres, is necessary for:
 - (i) handling of enquiries beyond the unit's scope;
 - (ii) providing access to appropriate computer-based information; and
 - (iii) providing access to a medical library with an inter-library loan facility.
- (h) Adequate personnel for the size of the hospital and the number of enquiries should be employed.
- (i) The personnel should develop and maintain a current standard operating procedure manual outlining procedures appropriate to the services provided.
- (j) The service should be available during normal pharmacy hours. If provided, a toxicology service must be available 24 hours a day.
- (k) Methods should be in place for:
 - (i) enquiry receiving, researching, answering, referencing, logging and storing;
 - (ii) a patient counselling service;
 - (iii) publication of a bulletin or newsletter directed at identified drug related problem areas of that specific hospital;
 - (iv) reporting adverse drug events;
 - (v) providing statistical analyses of enquiries;
 - (vi) research and retrieval of new data and previously researched and answered queries;
 - (vii) filing of collected material and product information;

- (viii) providing verbal and written responses to queries;
- (ix) continuing education of pharmacists and other hospital personnel; and
- (x) quality assurance.

14. GUIDELINES FOR PHARMACIST INITIATED THERAPY

14.1 SERVICES RELATING TO A SPECIFIC PATIENT

14.1.1 Response to symptoms

Pharmacists should be prepared and available at all times to give advice on general health matters. When called upon by a member of the public to advise on symptoms, the request should be dealt with by the pharmacist or other member of staff who is an appropriate health care professional. In the latter case, arrangements should ensure that an intervention by a pharmacist can be made at an appropriate stage, when necessary. The following steps should be taken:

- (a) Obtain sufficient information to enable a proper assessment of the situation to be made. This should include information about who has the problem, what are the symptoms, how long the condition has persisted, has any action already been taken, and which medicines the person concerned is already taking.
- (b) Decide whether the symptoms might be associated with a serious condition, and in such circumstances refer the patient for immediate medical advice.
- (c) In the case of a minor self-limiting health problem, appropriate advice should be given and a medicine recommended only when necessary.
- (d) The patient record should be updated, whether medicine has been supplied or not and the patient be advised to consult a doctor should the symptoms persist beyond a stated time.

14.1.2 Self Care Products

- (a) For each type of health problem that can be treated within the framework of self-care, protocols for the pharmacist's action should be established.
- (b) Suitably trained staff may be delegated to provide advice on self care at a certain level provided the protocol defines when referral to the pharmacist is necessary.

14.1.3 Supply of Scheduled 0, Schedule 1 and Schedule 2 medicines

- (a) The pharmacist should utilise experience to select medicines taking into account their quality, efficiency and safety, and the advantages of effective formulations.
- (b) If a medicine is supplied, the pharmacist should do his/her best to ensure that the patient or caregiver has no doubts as to:
 - (i) the name (generic/trade) and physical description of the medicine;
 - (ii) intended use of the medicine and expected action;
 - (iii) route, dosage form, dosage and timing of administration;
 - (iv) any special directions or precautions for the preparation or administration of doses;

- (v) duration of treatment;
 - (vi) any relevant drug/drug, drug/food, drug/alcohol interactions;
 - (vii) common severe side or adverse effects or interactions and therapeutic contra-indications that may be encountered, including their avoidance, and the action required if they occur;
 - (viii) techniques for self-monitoring of medicine therapy;
 - (ix) storage conditions; and
 - (x) action to be taken in the event of a dose not taken or in the event of an overdose;
- (c) The supply of all medicine should be indicated in the patient's profile.

14.1.4 Follow up

- (a) The pharmacist should assess the outcome of the therapy with the patient's co-operation.
- (b) The pharmacist should advise the patient to consult a doctor if the symptoms persist beyond a stated time.

14.2 THE PROMOTION OF PUBLIC HEALTH

Pharmacists should be aware of current health education activity, both local and national, and co-operate whenever possible in any campaigns. Pharmacists should have available comprehensive information on local and national health facilities, such as drug addiction centres and self-help groups.

15. SPECIFIC GUIDELINES ON ENSURING THE QUALITY USE OF MEDICINE

15.1 GENERAL RATIONAL PRESCRIBING POLICIES

15.1.1 Therapeutic committees and preparation of practice formularies

- (a) Therapeutic committees made up of pharmacists, medical practitioners and other appropriate health care professionals should, whenever possible, be set up at practice level to assess and define appropriate treatments.
- (b) Practice formularies should be drawn up taking into account quality, safety and efficacy as well as cost-effectiveness of the proposed medicines.

Further information regarding therapeutic committees and practice formularies may be found in the Section 3 of Chapter 5.

15.1.2 Evaluation of data on the use of medicines

On a local and national level pharmacists should participate in research into medicine use (e.g. response to treatment, compliance, etc.) and pharmacoepidemiological studies.

15.1.3 Dissemination of evaluated information within a formal network

The pharmacist should have access to sources of reference providing information on medicines, both at therapeutic level and in terms of pharmaceutical quality. On a local or

national level networks should be set up which permit safe and rapid access to the information required in the course of professional activities.

15.1.4 Educational programs for health professionals

The pharmacist should both be a source of independent information on rational prescribing and use of medicines and actively take part in educational programs for other health professionals.

15.1.5 Research and practice documentation

- (a) Pharmacists have a professional responsibility to conduct or take part in research relating to pharmacotherapy and to record professional practice experience and activities.
- (b) The pharmacist should collaborate, and take the initiative, in carrying out research into pharmacy practice, rational pharmacotherapy, pharmaco-epidemiology, pharmaco-economics, and health economics.

15.2 FOLLOWING UP THE EFFECT OF PRESCRIBED TREATMENTS

- (a) Certain procedures should be followed in evaluating regular progress of outcomes of treatment for individual patients or groups of patients.
- (b) In all cases it is essential that the patient adheres to the assessment method to be used.
- (c) It is essential that the prescriber is encouraged to analyse the results in co-operation with the pharmacist.
- (d) If in the course of monitoring treatment an adverse drug reaction is detected it should be reported by filling in a form to be sent to the Medicines Control Council in accordance with national procedures for pharmacovigilance.
- (e) Co-operation between the pharmacist and prescriber and other health professionals should be put into practice with the assistance of universities and other private or official institutions involved in research and healthcare provision.
- (f) Pharmacists should be involved in clinical trials.

15.3 MEDICINE INFORMATION SERVICE

Medicine information is a clinically orientated service providing a focus for the accumulation, organisation, evaluation and dissemination of information pertaining to all aspects of medicine use. The service should be provided to pharmacists and other health care professionals.

- (a) The ideal medicine information service should be:
 - (i) readily accessible;
 - (ii) able to provide up-to-date information quickly;
 - (iii) accurate and therefore reliable;
 - (iv) unbiased;
 - (v) able to cover all aspects of medicine information;

- (vi) able to provide clinically useful and practical information; and
 - (vii) affordable to users.
- (b) The active dissemination of information to health professionals in the form of newsletters, local bulletins, similar publications or by other appropriate means, should be part of the service.

16. SPECIFIC GUIDELINES FOR SCREENING AND MONITORING SERVICES IN PHARMACIES

SCREENING AND TESTING BIOCHEMICAL AND PHYSIOLOGICAL PARAMETERS

- (a) As a healthcare centre, the pharmacy can offer services relating to screening and testing a patient's biochemical and physiological parameters.
- (b) Protocols should be established which specify records to be kept of test results and allow objective validation of the quality of both methods and equipment used for screening. Testing should be carried out at regular intervals within the protocol.
- (c) There should be effective communication with the patient's doctor and other relevant health care professionals.
- (d) Pharmacists and members of staff involved should have sufficient training to enable them to give appropriate and sound advice.

More information regarding detailed guidelines for screening and monitoring facilities may be found in the Annexure dealing specifically with Community Pharmacy.

16.1 GENERAL GUIDELINES

Pharmacists who are competent to do so may provide certain screening and monitoring services.

16.1.1 Physical facilities

The taking of samples, the performance of screening tests and blood pressure monitoring must be done in a private consultation area in the pharmacy. The consultation area should comply with the requirements described in Chapter 2 of this manual.

16.1.2 Documentation and record keeping

- (a) The patient must give informed consent for the test to be performed. Consent may be either written or oral as appropriate.
- (b) Results should be provided to the patient in writing. Such written confirmation could also be used as a referral document, to be presented to the patient's medical practitioner or other health care practitioner.
- (c) Patients must be counselled regarding the test results and advice must be given concerning health risks and healthy lifestyles when appropriate.
- (d) All referral documents should be signed by the pharmacist as a confirmation that the test has been done by a professionally trained person.
- (e) The name of the pharmacy, as well as the name of the pharmacist who performed the test, should appear on all referral documents.

- (f) Should results be given telephonically, the pharmacist must ensure that the results are given to the appropriate person. This should, however, be avoided and results should be confirmed in writing.
- (g) Should it be requested by the patient that all patient records and test results are made available to other health care professionals caring for the patient, this should be complied with.
- (h) The following information should be kept for a period of at least three years:
 - (i) a complete record of patient information;
 - (ii) the kind of test used;
 - (iii) the batch number of the testing material;
 - (iv) the test results; and
 - (v) advice given to patients.

16.1.3. Professional and ethical aspects

- (e) Pharmacists must ensure that they have adequate training, knowledge and skills to perform screening tests and interpret and discuss the results thereof.
- (f) Confidentiality of patient information should be ensured throughout. More information regarding patient confidentiality may be found in Chapter 1 of this manual.
- (g) Patient information should only be disclosed with the consent of the patient or, in the case of a minor, with the consent of the parent or guardian, or where such information must be furnished to a person authorised by law to request it - unless such disclosure is in the interest of the patient.
- (h) The pharmacist must always act in the best interest of the patient.
- (i) Pharmacists should establish criteria for the referral of patients. It is preferable that these criteria are determined in consultation with local medical practitioners.

16.1.4 Advertising of service

The specific service should be introduced to local members of the health professions (such as doctors, private registered nurses, etc.) and local clinics. The purpose of the service, for example that it is a screening and/or monitoring service, should be clearly emphasised.

- (b) Pharmacists are entitled to inform the public of the availability of screening and monitoring tests.
- (c) According to the code of conduct of pharmacists, the advertisement should be factually correct, should not be misleading and should not bring the profession into disrepute.

16.1.5 Financial remuneration

Pharmacists may sell screening and monitoring tests to the public to perform at home. If the pharmacist performs the test, he/she is entitled to a professional fee based on an

hourly tariff and the disposable items used (refer services for which a pharmacist may charge a professional fee and guidelines for charging such a fee or fees).

16.2 GUIDELINES REGARDING TESTING

- (a) Patients should not be treated by a person suffering from an infectious disease.
- (b) Disposable units should be used for biohazardous substances.
- (c) Puncture-resistant containers should be used that are located as close as possible to the area of use.
- (d) Suitable procedures must be adopted for the disposal of waste material, bearing in mind the risks associated with materials contaminated with blood.
- (e) Needles or other sharp objects should not be recapped, bent or broken.
- (f) Factors such as exercise, pregnancy, recent illness, certain drugs etc. that may influence test results should be taken into consideration when interpreting the test results.

16.2.1 Guidelines regarding test materials and instruments

- (a) Reliable tests and instruments must be used at all times.
- (b) Pharmacists performing the tests should be familiar with the instructions and requirements of individual products on the market, and should be aware of the limitations of the tests and realise that no test is 100% accurate.
- (c) The storage requirements of the test material should be noted and the product stored according to the manufacturer's instructions.
- (d) All unused material should be stored in the original containers.
- (e) If applicable, the drying material should not be removed from the original container. Lids should be replaced immediately after use.
- (f) Contamination of material and samples must be prevented.
- (g) The testing areas of reagent strips should not be touched.
- (f) Any discoloration or darkening of material can be an indication of deterioration of the reagent strips.
- (g) Expiry dates of material should be checked before use.
- (h) Instruments should be kept clean and in good working order and be calibrated regularly.

16.2.2 Guideline regarding the taking of samples

- (a) Correct methods for sample collection should be followed.
- (b) Samples should be collected in clean, dry containers not contaminated with cleansers. If manufacturers supply containers, these should be used.
- (c) Gloves should be worn in the following instances:

- (i) when touching blood and body fluids, mucous membranes or non-intact skin of all patients; and
- (ii) when handling items or surfaces soiled with blood or body fluids when performing venipuncture or other vascular access procedures.
- (d) Gloves must be changed after contact with each patient and hands washed.
- (e) Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or body fluids.
- (f) Plastic aprons and gowns should be worn during procedures where blood or body fluid splashes are likely.
- (g) Hands and other skin surfaces should be washed immediately and thoroughly if they become contaminated with blood or body fluids.
- (h) All blood and body fluid specimens should be placed in sturdy containers with a secure lid and contamination of the outside of the container avoided.

16.3 GUIDELINES FOR BLOOD PRESSURE MONITORING SERVICES

Hypertension is a disease condition, which can initially be asymptomatic. A well-planned blood pressure determination service allows the pharmacist to play a role in the discovery of hypertensive patients and the control of blood pressure of hypertension sufferers. The following guidelines must be considered in the implementation of a blood pressure monitoring service in a community pharmacy.

16.3.1 Equipment

- (a) Equipment needed for the performance of blood pressure monitoring is blood pressure monitors and stethoscopes
- (b) Equipment should be accurate, reliable, simple to use, easily cleaned and easily maintained
- (c) To ensure ongoing accuracy and precision of determinations a suitable quality control system should be implemented and applied on a regular basis to apparatus that is used.

16.3.2 Procedure and interpretation of results

The following aspects should be considered in blood pressure monitoring:

- (a) The procedure should be explained to the patient, his/her permission obtained and the patient made to feel comfortable.
- (b) The person monitoring blood pressure should be thoroughly trained. When a monitor with a stethoscope is used instead of electronic equipment, eye, hand and ear co-ordination is essential to control the rate of inflation and deflation and to note the correct reading.
- (c) Blood pressure measurements of a specific patient should as far as possible be performed by the same person with the same instrument every time.
- (d) The patient should do no strenuous exercise, smoke, eat or drink coffee in the preceding 30 minutes. Blood pressure should not be taken immediately following defecation or urination.

- (e) The patient should be relaxed and sit in a comfortable chair in a pleasant and relaxing atmosphere for at least three minutes before the reading.
- (f) The patient's arm should rest on a soft surface. The arm from which the reading is to be taken should be on the same level as the heart in a horizontal position. This is especially important in the standing and seated positions.
- (g) The pulse rate should be determined at the same time as the blood pressure.
- (h) When the patient's blood pressure is being monitored at brief intervals, the same arm should be used.
- (i) Readings should be rounded off to the nearest whole number. This rounding off should be maintained consistently in order to prevent differences in interpretation.
- (j) Criteria for referral should be compiled in co-operation with local medical practitioners.
- (k) The diagnosis of hypertension is made on multiple sustained high blood pressure values taken on a few occasions (at least three occasions) preferably on different days or with intervals of 15 minutes. The patient must be calm and relaxed during the intervals.
- (l) The patient's age must be taken into account in the interpretation of blood pressure values.
- (m) The influence of certain drugs on the blood pressure of a patient should be taken into account.
- (n) When the blood pressure reading is noted, it should also be indicated whether the patient was seated, prone or standing up, as well as the extremity to which the apparatus was connected (left or right upper arm or thigh). Both systolic and diastolic pressure should be noted. Presence of arrhythmias and unusual circumstances such as anxiety should be noted.

16.3.3 Documentation and record keeping

For regular monitoring of a patient's blood pressure it is essential that a complete patient profile system be kept. Apart from information that should be kept as described earlier, the following information should also be available:

- (a) Height and body mass;
- (b) Medicines used and dosages for hypertension as well as other conditions;
- (c) Family history (chronic diseases and problems);
- (d) Presence of other risk factors such as smoking;
- (e) Results of blood pressure measurements including, the date on which the measurement was done, the position of the patient, the extremity to which the apparatus was connected and the pulse.

16.4 GUIDELINES FOR THE PERFORMANCE OF PEAK FLOW TESTS

The performance of peak flow tests in a pharmacy has a dual function. The first is to identify patients with reduced lung function scientifically, for referral to a medical practitioner, and secondly it provides an opportunity to advise asthma patients

receiving medication on a chronic basis, about the control of their condition with the help of peak flow tests. The following guidelines should be used in the implementation and provision of the services.

16.4.1 Equipment

- (a) Equipment needed for the rendering of the service are peak flow meters and standard charts with expected peak expiration flow values for men, women and children.
- (b) Equipment must be accurate, reliable, simple to use, easily cleaned and easily maintained.
- (c) Individual manuals of the various types of peak flow meters should be followed for the cleaning procedures. Instruments should be cleaned at least once a week. Peak flow meters should be checked regularly to ensure that they function correctly. A damaged instrument should never be used.
- (d) Pharmacists should implement a suitable quality assurance program and apply it regularly to instruments to ensure the reliability of the determinations.

16.4.2 Procedure and interpretation of results

The following aspects are of particular importance in the determination of peak expiration flow:

- (a) The procedure should be explained to the patient, his/her permission obtained and the patient made to feel comfortable.
- (b) The peak expiration flow rate gives an objective indication of lung function. It is not an absolute value, but varies with the age, sex, height and medical condition of a person. It is important to observe the patient's age, sex and height in the interpretation of results.
- (c) Peak expiration flow rate is totally dependant on the correct technique being used.
- (d) The patient should preferably be in a standing position, otherwise he/she must sit upright.
- (e) Determinations should always be done with the patient in the same position and with the same peak flow meter.
- (f) There is a natural variation in the peak expiration flow rate with values in the morning generally lower than those taken in the evening. Determination should be done two or three times a day. On each occasion three determinations have to be taken. The best value, date and time should be noted. The mean of the three determinations should not be noted.
- (g) Individual results of the patient should be compared to the expected average peak flow values (according to sex, age and height) on the nomograms that are supplied with the peak flow meter. Individual results can also be compared to the goal value determined by the patient's medical practitioner. The goal value of a patient should be re-evaluated annually to provide for the growth of children and possible changes in the disease of the patient.
- (h) On its own, peak flow determinations are not adequate to make a diagnosis. A diagnosis of asthma and other airway obstructions should be confirmed through the determination of lung function with the help of a spirometer by a medical practitioner.

- (i) Patients' doctors must be consulted in the case of reduced lung function, concerning the criteria for referral of the patient or adjustment of drug therapy.

16.4.3 Documentation and record keeping

For regular monitoring of a patient's peak expiration flow it is essential that a complete patient profile system be kept. Apart from general information that should be kept, the following information should also be available:

- (a) Medicines used for asthma and/or other respiratory diseases and the dosages as well as medicines used for other conditions;
- (b) Family history (Chronic diseases and problems);
- (c) Presence of other risk factors such as smoking;
- (d) Goal peak flow value (determined by the patient's doctor);
- (e) Results of peak flow measurements including the date, time and any abnormal symptoms experienced by the patient); and
- (f) Results of peak flow measurements must be kept for at least three years.

16.5 GUIDELINES FOR THE PERFORMANCE OF HIV TESTS

Tests to detect HIV1 or HIV2 antibodies are now widely used in order to identify patients and to screen blood products. HIV infection is usually not noticed in the first few years after infection. Later signs and symptoms may suggest HIV infection or AIDS. The HIV antibody test is often the first and only definite evidence of HIV infection.

16.5.1 Physical facilities and equipment

- (a) Private consultation area
 - (i) Taking of samples and the performance of HIV antibody tests should be done in a private allocated area in the pharmacy.
 - (ii) The consultation area must comply with the following requirements:
 - It should have a professional appearance;
 - It should provide adequate space;
 - Patient privacy must be ensured;
 - Background noise should be eliminated as far as possible;
 - It should be accessible and close to the dispensing area;
 - The area should be easy to keep clean and neat;
 - There should be a cloakroom or toilet as part of or close to the consultation room;
 - A comfortable waiting area should be available;
 - Furniture should be such that tests and determinations can be done easily.
 - (iii) The following minimum furnishing or facilities should be supplied in the consultation room:
 - A desk with seating;
 - A working surface of impermeable washable material;
 - A basin with hot and cold running water;
 - An instrument cabinet or trolley with an emergency tray;

- A filing cabinet for keeping records;
- A mirror;
- A scale;
- Facilities for the disposal of bio-hazardous materials.
- Access to a fridge (for storage of test materials)

Note: It is advisable that the fridge is situated in the consultation room, so that observers / by-standers cannot link the client with the removal of test material from the fridge.

If the pharmacy sends the samples to local pathology laboratories, the pathologists should be satisfied that the clinic facilities comply with the applicable standards and that the person performing the tests (pharmacist or nurse) is competent to collect samples and to counsel the patients.

(b) Test material

- (i) Reliable tests should be used. The most commonly used HIV antibody tests used by laboratories are the ELISA and the Western Blot tests. Some other rapid immunofiltration tests are currently used for the screening of HIV 1/2 antibodies (e.g. HIV-1/HIV-2 Rapid Assay, Sensy test). (NOTE: Review based on information obtained by HIV/AIDS task team).

(c) Requirements:

- a reliable HIV antibody test with its sample containers, diluents, etc; that is recommended by the Medicines Control Council (MCC) * and purchased from a reputable company;
- requirements for the collecting of samples (e.g. blood tubes, etc);
- disposable rubber gloves;
- alcohol swabs or 70% alcohol solutions;
- tissues;
- paper towels;
- disinfectants (especially disinfectants recommended for control of the AIDS virus e.g. 2% glutaraldehyde, 1% halocide, sodium hydrochloride, biodecyl 1%).

* Please note that at present the MCC does not register HIV tests, but recommends that these tests should be purchased from reputable companies and that it should be ascertained whether the test is registered in the country of its origin.

- (d) Pharmacists should be familiar with the instructions and requirements of individual products on the market. Instructions pertaining to one product will not necessarily be applicable to another.
- (e) Pharmacists should be aware of the limitations of tests used and realise that no test is 100% accurate.
- (f) Expiry dates of HIV antibody tests should be checked.
- (g) The manufacturer's storage requirements for the test material should be followed.

16.5.2 Collecting of samples

- (a) The correct method of collecting samples (serum, plasma, whole blood or saliva) has an important influence on the accuracy of the results. Personnel must be trained in the correct method of collecting samples.

- (b) A procedure to prevent interchange of blood samples should be implemented. Contamination of blood samples must be prevented. The samples should be clearly and correctly marked if they are sent to a laboratory.
- (c) Samples should be collected in clean, dry containers which are not contaminated. If manufacturers supply containers, these must be used.
- (d) Results are most accurate if samples are tested immediately.
- (e) Instructions for the execution of the different tests and the interpretation of results must be followed closely.
- (f) The person executing the test should be aware of his/her own physical limitations which could influence the interpretation of the results, for example colour blindness.
- (g) Pharmacists should be familiar with the WHO guidelines for the prevention of HIV and hepatitis. The WHO has recommended that "universal" precautions be taken with all patients, i.e. all patients be treated as if potentially infected and all body fluids and specimens from all patients be treated as potentially infectious. Infection control precautions existing in health care settings for Hepatitis B are sufficient to prevent transmission of HIV.

(h) **Recommendations for universal precautions are outlined as follows:**

Wear gloves in the following situations:

- when touching blood and body fluids, mucous membranes or non-intact skin of all patients;
- when handling items or surfaces soiled with blood or body fluids;
- when performing venipuncture or finger pricking procedures.

Change gloves or wash your gloved hands after contact with each patient.

Wear masks and protective eyewear or a face shield during procedures that are likely to generate droplets of blood or body fluids.

Wear plastic aprons and gowns during procedures where blood or body fluid splashes are likely.

Wash your hands and other skin surfaces immediately and thoroughly if they become contaminated with blood or body fluids.

Wash your hands immediately after removing gloves.

Do not recap, bend or break needles or other sharp objects.

Place used sharps in puncture-resistant containers located as close as possible to the area of use.

Place large-bore re-useable needles in a puncture-resistant container for transport to reprocessing areas.

Make mouthpiece, resuscitation bags and other ventilation devices available in areas where the need for resuscitation is likely.

Do not treat patients yourself or handle patient care equipment if you have exudative lesions or weeping dermatitis.

If a glove is torn, replace glove with a new one as soon as possible.

Place all blood and body fluid specimens in sturdy containers with a secure lid. Avoid contaminating the outside of the container.

Suitable procedures must be adopted for the disposal of waste material, bearing in mind, the risks associated with materials contaminated with blood or other body fluids.

Note: Circumstances which require Post Exposure Prophylaxis (PEP)

- (a) A pharmacist should seek counseling from another health care professional if he/she incurs a needle stick injury during the performance of his/her duties. The HIV test should be done by another health care professional.
- (b) In a case of rape the pharmacist should refer patients to a center where post-exposure prophylaxis is available. Pharmacists in community pharmacy who were able to recover their cost on medicines for HIV post-exposure prophylaxis (PEP) may provide these medicines according to the guidelines of the National Department of Health.

16.5.3 Informed consent

When a patient requests an HIV test, he/she must sign an informed consent form.

What is informed consent?

Informed consent is legal authorisation given to the pharmacist or other health care worker to proceed with the HIV testing.

Informed consent to HIV testing must be specific and explicit and means that the individual has been made aware of, and understands, the implications of the test.

Consent to HIV testing is not covered by the standard contractual agreement which is implied when a patient consults a doctor/pharmacist/nurse as the implications of a positive test may be extreme.

What does informed consent imply in the context of HIV testing?

Informed consent implies that the patient has received at least the essential amount of pre-test information and understands the following:

1. The reason or purpose for which the test is being performed.
2. The potential advantages and disadvantages of having his/her HIV status determined.
3. The influence the result of the HIV test may have on his/her treatment.
4. The possible psycho-social impact of a positive test result.
5. The patient is free to decide against HIV testing even after having received pre-test counselling.
6. The testing procedure.
7. When the patient is ready for such counselling, post-test counselling is done one week after pre-test counselling and the blood test. The principle of informed

consent implies that once the patient's test result is known (whether positive or negative), appropriate counselling must follow. Post-test counseling is an ongoing process.

8. Points 1-7 above must be conveyed clearly by a pharmacist to the patient in a manner that the patient will understand.

Proxy consent

Proxy consent is consent by a person legally entitled to grant consent on behalf of another individual. A parent or guardian of a child below the age of consent to medical treatment may give proxy consent to HIV testing of a child.

16.5.4. Counselling

- (a) HIV testing needs to be done with much care and consideration. Due to the implications of receiving a positive result a person should always be counselled before testing in order to prepare the person as far as possible for the impact of the results (a pre-test counsel or interview).
- (b) Careful counselling be provided to a person after the test (a post-test counsel or interview).
- (c) Counselling must be provided to persons whose results are negative to ensure that their results remain negative;
- (d) It is critical at the start, to establish a trusting relationship with the patient.
- (e) Total privacy must be assured during the consultation with the patient.

Pre-Test Counseling

Pre-test counselling is that counselling given to an individual before an HIV test, to make sure that the individual has sufficient information to make an informed decision about having an HIV test. Pre-test counselling should include discussions on:

- (a) Ensuring confidentiality;
- (b) The definition of HIV/AIDS;
- (c) Transmission of HIV infection;
- (d) What an HIV test is, the purpose of the test;
- (e) The procedure and when to expect a result;
- (f) The meaning of a negative HIV test;
- (g) The concept of the window period;
- (h) The meaning of a positive result, including the practical implications such as medical treatment and care, sexual relations, psycho-social implications, work etc;
- (i) The personal and practical implications of performing the test;
- (j) Assessment of personal risk of HIV infection;
- (k) Safer sex and strategies to reduce risk;
- (l) Possible reactions to negative and positive test;
- (m) Coping with a positive test result, including who to tell and identifying needs and support services; and
- (n) The social support available;
- (o) The return appointment;
- (p) The need to avoid blood/plasma/organ donation.
- (q) An opportunity for decision making about taking the HIV test.

Post-Test Counselling

Post-test counselling is the counselling provided when an individual receives his or her HIV test result. Post-test counselling involves one or more sessions (ideally at least two) and should include discussions on:

- (a) Feedback and understanding of results;
- (b) If the result is negative:
 - Strategies for risk reduction;
 - Possibility of infection in the 'window' period;
 - *Suggest retesting in three months time;*
- (c) If the result is positive:
 - Immediate emotional reaction and concerns;
 - Personal, family and social implications;
 - Difficulties a client may foresee and possible coping strategies;
 - Who the client wants to share the results with;
 - Immediate needs and social support identification;
 - Follow-up supportive counseling; and
 - Follow-up medical care;
 - Possible routes of transmission ;
 - Explain that the person is both infected and infectious;
 - The importance of notifying sexual partners;
 - The likely progression of infection;
 - The availability of care programme, such as Aid for AIDS.
- (d) The counsellor should therefore ensure that the HIV – positive patient is directed to an appropriate facility where he/she will receive ongoing counselling, support and care. If possible sexual partners and/or families should also undergo counselling.
- (e) It is, therefore, essential to establish referral systems in the area, such as social workers, clinical psychologists, ministers of churches and other care givers in the community. Meet with them to discuss this very important matter and establish whether they are knowledgeable about HIV/AIDS and whether they are prepared to collaborate with you.
- (f) Keep monthly statistics of all pre-test and ongoing counselling sessions as well as the number of tests completed during the month.

16.5.5 Interpretation of results

- (a) It usually takes up to 12 weeks for the pathology laboratory tests to be able to detect the presence of HIV antibodies. This means that an HIV antibody test may be negative very early after infection (before the 12 week period). This is called the "window" period.
- (b) If the HIV test is negative it usually means that the person has not been exposed or infected with the HIV virus (this is a "true" negative test). It may be a false negative test. This means that the person has been exposed and infected with the HIV virus, but the test may have been done too soon after infection (1 - 12 weeks) and he/she is still in the "window" period.
- (c) If the HIV test is positive it means that the person is infected with HIV and can spread the virus to another person during sex or through his/her blood or during pregnancy, childbirth or breast feeding. It does not mean that the person has AIDS or that the person will definitely develop AIDS. Many people who are HIV positive will, however, develop AIDS within 3 - 7 years after having been infected.

Tests performed in pharmacies

Note: A doctor's signature is not required for an HIV test to be carried out.

- (a) The wide availability of rapid tests enables pharmacists to contribute to the important measure of voluntary testing and counseling (VCT). Rapid tests have the advantage that the patient can receive the result virtually immediately and does not have to return to the pharmacy later. A major disadvantage is that the short time interval between the performance of the test and the receipt of the result poses challenges for counseling. Only rapid tests which use a blood sample should be performed in a pharmacy.

Bear the following precautions and procedures in mind.

- (i) Follow the test instructions to the letter
 - (ii) Screening tests alone cannot be used to diagnose AIDS.
 - (iii) If the test is positive the patient should be referred to a laboratory to confirm the result with an ELISA and/or Western Blot.
 - (iv) A negative test result at any time does not exclude the possibility of exposure to, or infection with HIV 1/2.
 - (v) If the test result is negative and you suspect that the test has been done too early after a possible infection, advise the person to undergo a test again. This repetition of the test should be done at least 12 weeks after any likely infection.
- (c) One way of deciding that the patient should be tested again or referred is by finding out whether the patient or his/her sexual partner has been at risk for acquiring HIV in the 12 weeks preceding the test. Ask if there has been any risky sexual activity in the 12 weeks before having been tested. Also make sure that you ask whether the patient's sexual partner has been at risk for the past 3 months.
- (d) Risky sexual activity may include having sex without a condom with a new partner, with more than one partner or with a sex worker (prostitute). Other risk factors that are important include sexually transmitted diseases in the past three months, sharing of needles or blood transfusions in the past three months.

16.5.6 Collecting and sending blood samples to a laboratory

- (a) If a pharmacist only collects the blood samples and sends them to a laboratory the following remarks are important:
 - (i) If a positive test is found with the ELISA, in low risk patients, the same test should be repeated on the same sample.
 - (ii) If it is positive a second time, the recommendation is to confirm the ELISA with a test that is more specific, i.e. the Western Blot.
 - (iii) Patients with repeatedly positive ELISA and confirming test (e.g. Western blot) results should be considered infected and contagious.

16.5.7 Documentation and record keeping

- (a) A patient must request in writing i.e. give informed consent that an HIV antibody test be performed.

- (b) Results should be provided to the patient in writing. Such written confirmation can also be used as a referral document, to be presented to the patient's doctor or local pathology clinic.
- (c) All referral documents should be signed by the pharmacist or other health care professional, as a confirmation that the test had been done by a professional person.
- (d) The name of the pharmacy, as well as the name of the pharmacist/health care professional who performed the test, should appear on all referral documents.
- (e) Results should not be given telephonically.
- (f) The following information should be kept for a period of at least one year:
 - (i) Name and address of patient, as well as ID number;
 - (ii) Date of birth of patient;
 - (iii) Brand of HIV antibody test used;
 - (iv) Lot number of the testing material;
 - (v) Result of tests;
 - (vi) Action taken by pharmacist/health care professional;
 - (vii) The name of the pharmacist/health care professional who performed the test.

16.5.8 Ethical aspects

- (a) It is advisable for the patient to make the final decision and choice whether to have the test or not.
- (b) Co-operation should be maintained with local pathology laboratories, local doctors and clinics.
- (c) A patient can only be tested with his/her informed consent.
- (d) Confidentiality of patient information should be ensured throughout. Patient information should only be disclosed with the consent of the patient, or in the case of a minor, with the consent of the parent or guardian, or where such information must be furnished to a person authorised by law to request it - unless such disclosure is in the interest of the patient.
- (e) In the provision of the service, the pharmacist must always act in the best interest of the patient.
- (f) Total privacy must be assured during the consultation with the patient.
- (g) All clients require and deserve the full attention of the person interviewing them. Rushed appointments, abbreviated counselling sessions and inadequate record keeping in no way serves the best interest of the patient.
- (h) Pharmacists should not sell HIV tests for patients to perform at home.
- (i) It is preferable that the infected person should tell his/her partners and family themselves. A counsellor can be present.

16.5.9 Training

- (a) According to "ethical rule" 22 pharmacists who want to perform HIV antibody testing have to ensure that they have adequate training, knowledge and skills to

perform HIV antibody tests, interpret the results and to counsel patients being tested.

- (b) Every pharmacist who wants to do HIV antibody testing must be a trained HIV counsellor. Such training is provided for example by AIDS training and information centres.
- (c) Pharmacists involved in this service should be aware of
 - (i) the importance of a professional appearance
 - (ii) the importance of pre- and post-test counselling
 - (iii) confidentiality of patient information
 - (iv) the instructions and requirements of individual HIV antibody tests
 - (v) correct interpretation of results
 - (vi) the necessity of record keeping and referral of patients.
- (d) Pharmacists have to ensure that they have adequate knowledge about -
 - (i) The immune system and the molecular biology of the virus
 - (ii) Signs and symptoms of HIV/AIDS
 - (iii) Opportunistic infections
 - (iv) Major diseases associated with AIDS
 - (v) Drug therapy
 - (vi) Transmission of the virus
 - (vii) Counselling
 - (viii) Ethical and legal aspects
 - (ix) Role of the pharmacist in the prevention of HIV/AIDS

16.5.10 Advertising the service

- (a) The specific service should be introduced to local members of the health professions (such as local pathology laboratories, doctors, local clinics, private registered nurses, etc.)
- (b) Co-operation with local pathology laboratories, local HIV/AIDS training centres, etc. should be maintained.
- (c) Pharmacists are entitled to inform the public about the availability of HIV antibody tests.
- (d) According to "ethical rule" 5, the advertisement should be factually correct, should not be misleading and should not harm the dignity of the profession.
- (e) The following methods can be used:
 - (i) Oral information given to people visiting the pharmacy
 - (ii) Endosures in accounts
 - (iii) Newsletters to regular clients
 - (iv) Posters in the pharmacy, etc.

16.5.11. Financial remuneration

Pharmacists may charge professional fees on an hourly tariff basis for the performance of HIV tests.

17. GUIDELINES FOR THE PROMOTION OF PUBLIC HEALTH IN COMMUNITY PHARMACIES

17.1 GENERAL

Community pharmacists are in a unique position to provide general health care services and education to the community. This section provides guidelines regarding some of the services that can be offered by community pharmacists.

These health care services may be advertised according to the guidelines stipulated in Chapter 1 of this manual.

17.2 GENERAL HEALTH PROMOTION

Community pharmacists should participate actively in health promotion. The following guidelines apply:

- (a) The pharmacy should display health promotion leaflets.
- (b) The pharmacist or other suitably trained staff should be available to give advice on general health matters.
- (c) Pharmacists should be aware of current local and national health promotion campaigns and participate in these campaigns.
- (d) Pharmacists should be informed of, or involve themselves in local health promotion facilities.

17.3 IMMUNISATION SERVICES IN COMMUNITY PHARMACIES

The purpose of immunisation programs has moved beyond mere control of infectious diseases to new goals of elimination and eradication. Community pharmacists have an opportunity and a responsibility to be at the forefront of this movement towards preventive medicine. Although the pharmacist's involvement with immunisation varies with each practice setting, the pharmacist can be actively involved in the following activities:

- (a) Educating the public and other health professionals about immunisation;
- (b) Advocating paediatric immunisation;
- (c) Providing immunisation for international travel;
- (d) Screening patients who are at risk of preventable infectious diseases by occupation, life-style or underlying disease state;
- (e) Administering immunisation agents;
- (f) Recording immunisation data; and
- (g) Using the immunisation database to generate reminder letters for booster doses.

17.3.1 Physical facilities and equipment

The following guidelines should be followed in the implementation of immunisation services.

- (a) Counselling and administration of immunisation agents should be done in a private allocated area in the pharmacy. The consultation area must comply with the requirements described.

- (b) The correct storage procedures for vaccines must be adhered to according to the guidelines for the cold storage of pharmaceuticals in Chapter 2 of this manual.
- (c) The following equipment should be available:
 - (i) syringes and administering devices; and
 - (ii) biohazardous materials and sharps disposal container.
- (d) Adequate emergency drugs such as adrenaline 1:1000 solution, antihistamine (e.g. chlorpheniramine) injection, hydrocortisone injection and equipment (e.g. plaster, gauze, cotton wool, sterile wound dressings, etc.) should be available.

17.3.2 Procedure

- (a) Pharmacists should be familiar with the instructions, requirements and guidelines of the National Expanded Programme on Immunisation (EPI) policy.
- (b) Pharmacists should be familiar with the instructions and requirements of individual vaccines and human immunoglobulins on the market. Instructions pertaining to one product will not necessarily be applicable to another.
- (c) The storage requirements of the different products should be noted and stored according to the manufacturer's instructions. Vaccines should be stored under refrigerated conditions. Vaccines should not be stored in the door of a refrigerator as fluctuations in temperature are more likely to occur there.
- (d) The cold chain (system of ensuring that a product is stored at the correct temperature during transport and storage right until the moment of immunisation) should be maintained as described in Chapter 2 of this manual.
- (e) Live virus vaccines may be used after they have been frozen, but repeated freezing and thawing should be avoided. The National open vial policy should be followed, namely:

Opened vials of DPT, DT, TT, HepB and Oral Polio which are used in a pharmacy, may be used at more than one immunisation session, providing that the cold chain is maintained. The same vaccines, taken on an outreach, must be destroyed at the end of the day. No reconstituted vaccines may be kept for re-use. Reconstituted measles and BCG must be discarded after six hours or the end of a session, whichever is the shorter.
- (f) Vaccines should never be used beyond the expiry date.
- (g) If required, reconstitution of vaccines should be done immediately prior to their use, and only with the diluent provided by the manufacturer. The diluent should be at the same temperature as the vaccine which is being reconstituted. If unused, reconstituted vaccines should be discarded at the end of the working day.
- (h) Prior to the administration of immunisation agents, patients should be questioned about:
 - (i) previous reactions to vaccines;
 - (ii) sensitivity to eggs, antibiotics and preservatives;
 - (iii) possibility of pregnancy;

- (iv) concurrent medication such as immuno-suppressive agents;
 - (v) presence of other diseases for example febrile conditions, active untreated tuberculoses, eczema, leukaemia, lymphoma, other malignancies, etc.; and
 - (vi) general health status of the patient, including the immune status of the patient (e.g. immuno-suppression).
- (i) Pharmacists performing immunisations must be familiar with the handling of syringes and administration devices.
- (j) Pharmacists performing immunisations must have the necessary skills to administer injections.
- (k) Pharmacists performing immunisations should be familiar with the National and Provincial schedules for immunisation of infants, children and travellers. Table 1 is a recommended schedule for infants and children.
- (l) Pharmacists performing immunisations should be familiar with the WHO guidelines for the prevention of HIV and Hepatitis virus. The WHO have recommended that "universal" precautions be taken with all patients, i.e. all patients be treated as if potentially infected and all body fluids and specimens from all patients be treated as potentially infectious. Infection control precautions existing in health care settings for Hepatitis B are sufficient to prevent transmission of HIV.
- (m) The following general injection procedures should be followed:
- (i) Ensure privacy.
 - (ii) Strict aseptic technique should be applied.
 - (iii) Locate the injection site anatomically.
 - (iv) Prepare medication. Determine the correct syringe capacity, needle gauge and needle length.
 - (v) Check the dosage.
 - (vi) Get the patient to relax.
 - (vii) Get assistance if the patient is very young or nervous.
- (n) Pharmacists must be familiar with:
- (i) The possible adverse reactions of vaccines.
 - (ii) The recommended time and route of administration of the different vaccines.
 - (iii) The contraindications for injections in general and for vaccines in particular.
 - (iv) The local effects of injections.
 - (v) The management of anaphylaxis including the prevention of anaphylaxis.

- (vi) The management of cardio-pulmonary resuscitation.
- (o) The pharmacist should carefully review package inserts before deciding to administer a vaccine as some contain preservatives (e.g. thiomerosal) or trace amounts of antibiotics (e.g. neomycin) to which patients may be hypersensitive.
- (p) After immunisation the pharmacist must complete the patient immunisation card.

Table 1 provides a summary of the recommended childhood immunisation schedule for South Africa:

TABLE 1: RECOMMENDED CHILDHOOD IMMUNISATION SCHEDULE

AGE	VACCINE
Birth	TOPV(0), BCG*
6 weeks	TOPV(1), DPT, HepBV(1)
10 weeks	TOPV(2), DPT, HepBV(2)
14 weeks	TOPV(3), DPT, HepBV(3)
9 months	MEASLES(1)
18 months	TOPV(4), DPT, MEASLES(2)
5 years	TOPV(5), DT

Reference: *Department of Health technical guidelines on immunisation in South Africa, September 1995*

* Repeat BCG once at next visit if no scar is visible

TOPV Trivalent Oral Polio Vaccine
DPT Diphtheria, Pertussis & Tetanus Vaccine
DT Diphtheria & Tetanus Vaccine
HepBV Hepatitis B Vaccine
BCG Bacillus Calmette Guérin (Tuberculosis Vaccine)

This schedule is recommended for general use in South Africa. It can be modified according to individual circumstances.

Rubella vaccine can also be given to girls at 13 years of age (note must be taken of local District Health Policies and Practices in this regard).

Table 2 provides guidelines regarding the route and dosage of vaccines and Table 3 provides guidelines regarding catch-up vaccinations in older children.

TABLE 2: ROUTE AND DOSE OF VACCINES

VACCINE	DOSE	PREFERRED ROUTE	AGE
BCG	One drop	Percutaneous	Birth
TOPV	Drops as per package insert	Oral	Birth 6, 10 & 14 weeks 18 months 5 years
HepBV	0.5 ml	Intramuscular	6, 10 & 14 weeks
DPT	0.5 ml	Intramuscular	6, 10 & 14 weeks 18 months
Measles	0.5 ml	Intramuscular	9 & 18 months
DT	0.5 ml	Intramuscular	5 years

TABLE 3: CATCH-UP VACCINATIONS IN OLDER UNIMMUNISED CHILDREN

AGE	VACCINE TO BE GIVEN
9 months	Give TOPV, Measles, DPT and HepBV at the same time. All outstanding doses are then given with normal time intervals.
2 years – 10 years	Give TOPV, Measles and DT at the same time. All outstanding doses are then given with normal time intervals.

17.3.3 Documentation and record keeping

- (a) Immunisation cards should be completed to keep a record of immunisations. This information should be kept for a period of at least five years. The record cards should contain the following details:
- (i) Patient name and address, including ID number;
 - (ii) Date of birth of patient;
 - (iii) Date of administration of vaccine;
 - (iv) Name of manufacturer;
 - (v) Batch number of vaccine;
 - (vi) Expiry date;
 - (vii) Route of administration;
 - (viii) Date of next injection;
 - (ix) Signature of pharmacist/nurse who administered vaccine; and
 - (x) Other important information e.g. previous reactions to vaccines and sensitivities to eggs, antibiotics and preservatives which may be contained in vaccines.
- (b) Immunisation of children should be noted on the growth chart supplied by the Department of Health ("Road to Health card").
- (c) Should it be requested that all patient records be made available to doctors, this should be complied with.

- (d) Co-operation with local clinics should be maintained.
- (e) The pharmacist should provide immunisation statistics to the local District Health Co-ordinator for epidemiological purposes and for proper stock control.

17.3.4 Ethical Aspects

- (a) Confidentiality of patient information should be ensured throughout. Patient information should only be disclosed with the consent of the patient or, in the case of a minor, with the consent of the parent or guardian, or where such information must be furnished to a person authorised by law to request it - unless such disclosure is in the interest of the patient.
- (b) In the provision of the service, the pharmacist should always act in the best interest of the patient.

17.3.5 Training

- (a) Pharmacists must ensure that they have adequate training, knowledge and skills to provide the service.
- (b) Pharmacists should be competent in cardio-pulmonary resuscitation techniques.
- (c) Pharmacists involved in this service should be aware of:
 - (i) The importance of a professional manner.
 - (ii) Confidentiality of patient information.
 - (iii) The benefits and risks associated with the use of immunisation agents.
 - (iv) The instructions and requirements of individual vaccines.
 - (v) The necessity of record keeping.

17.3.6 Remuneration

- (a) Pharmacists are entitled to supply vaccines, with proper instructions, and in accordance with the Medicines Act to the public.
- (b) If the pharmacist performs the immunization procedure, he/she is entitled to a professional fee based on an hourly tariff.

17.4. FAMILY PLANNING SERVICES IN COMMUNITY/INSTITUTIONAL PHARMACIES

The community/institutional pharmacist is in a position to render a comprehensive family planning service if he/she has obtained the necessary training.

The following guidelines should be used to ensure that a service is rendered according to the requirements of the National Family Planning Program and in the interest of the family planning client.

If a prescription is received, pharmacists can administer injectable contraceptives and hormone injections should the pharmacist be competent in injection techniques.

17.4.1 Physical facilities and equipment

Family planning counselling should be done in a private designated area in the pharmacy. The consultation area must comply with the requirements as described in Chapter 2 of this manual.

17.4.2 Procedure

- (a) Requirements of registration of the applicable supplementary training with Council must be finalised.
- (b) Co-operation must be maintained with local family planning clinics.
- (c) No oral contraceptive therapy must be initiated without the prescribed interview and completion of the client file.
- (d) Clients on pharmacist initiated oral contraceptives must be referred to a medical practitioner or an authorised family planning clinic at least once a year for a full physical evaluation.

17.4.3 Documentation and record keeping

Client records must be completed and updated in the prescribed manner.

17.4.4 Legal and ethical aspects

- (a) The authorisation for family planning services in community pharmacies is issued to a pharmacist with the required training only and not to a pharmacy. The particular pharmacist will therefore be held responsible for the family planning service which is rendered under the auspices of his/her registration as pharmacist with supplementary training in family planning.
- (b) Confidentiality of patient information should be ensured throughout. More guidelines regarding patient confidentiality may be found in Chapter 1 of this manual.
- (c) In the provision of the service, the pharmacist should always act in the best interest of the patient.
- (d) Reasonable privacy should be assured during the consultation with the patient.
- (e) All clients require and deserve the full attention of the person interviewing them. Rushed appointments, incomplete examinations, abbreviated counselling sessions and inadequate record keeping must not occur.
- (f) Clients should receive information (oral and written) about family planning.
- (g) According to the Medicines Act, the pharmacist who supplies oral contraceptives to a particular patient must make the required entry into the prescription book. Such records should be kept for a period of at least five years.

17.4.5 Training

- (a) Pharmacists must ensure that they have adequate training, knowledge and skills to provide the service.
- (b) No pharmacist may render a family planning service unless he/she has obtained specific training and such supplementary training is registered with Council.

- (c) Pharmacists involved in this service should be aware of:
 - (i) The importance of a professional manner.
 - (ii) Confidentiality of patient information.
 - (iii) The necessity of record keeping and referral of patients.
- (d) Pharmacists must ensure that they are knowledgeable about the latest developments in contraception through self-training, training by suppliers and continuing education courses.

17.4.6 Financial remuneration

- (a) Family planning services are deemed to be a professional supplementary service and pharmacists are therefore entitled to charge a professional fee for such a service based on an hourly tariff.
- (b) Pharmacists that obtain contraceptive supplies from the State may not sell such supplies.

17.5 OTHER HEALTH CARE SERVICES

17.5.1 Residential and nursing homes

Pharmacists are in a unique position to provide pharmaceutical care to residential and nursing homes. By providing pharmaceutical care pharmacists can use their knowledge to improve the quality of life of these patients and save money in cases where medicine is used inappropriately.

The following guidelines should be followed:

- (a) A comprehensive pharmaceutical service should be provided.
- (b) The pharmacist should visit the patient as regularly as required to provide optimum pharmaceutical care.
- (c) Whenever possible the visits should be made at the same time as the prescriber and the prescriber's approval must be obtained for any recommendations for change.
- (d) Medication review visits should always be made by appointment.
- (e) Medicines should be provided with all necessary supplementary information.
- (f) Medicine policies such as the administration of the medicine, storage of the medicine and medicine disposal should be reviewed on a regular basis.
- (g) The pharmacist should carry a form of identification.
- (h) A comprehensive record must be kept of every visit and of every patient to ensure resident safety, compliance and evaluation of the service.

17.5.2 Smoking cessation

The adverse effect of smoking on the health of the community is well known. Smoking further interacts with the action of certain medicine and causes certain diseases. Pharmacists should therefore advise patients to stop smoking and give patients information regarding pharmaceutical products that can assist them with this process.

The following guidelines should be followed:

- (a) The pharmacy should have written information on how to stop/reduce smoking.
- (b) The pharmacy should participate in:
 - (i) Local anti-smoking campaigns; and
 - (ii) National anti-smoking campaigns.
- (c) The pharmacist involved in assisting patients in smoking cessation should have an up-to-date knowledge base on the optimum ways of stopping smoking and should be able to advise on the products available to assist the patient in giving up smoking;
- (d) All anti-smoking products should be sold with an invitation to come back and report progress.
- (e) Supporting information should be readily available.
- (f) Counseling sessions to stop smoking should be available from the pharmacist by appointment or a suitable system should exist for referral.
- (g) Smoking must not be permitted in the pharmacy.

17.5.3 Nutrition advice

Because of the pressures of modern life people often do not eat in a healthy manner. Pharmacists are in a position to provide patients with up-to-date information regarding healthy nutrition and lifestyles.

The following guidelines should be followed:

- (a) Pharmacists should provide advice regarding vitamin and mineral supplementation for patients with nutritional deficiencies.
- (b) Pharmacists should explain to patients the benefits of high fibre diets.
- (c) Pharmacists must be informed on the signs and symptoms of anorexia.
- (d) Pharmacists should be informed on nutrition advice to be given during pregnancy i.e the supplementary fluoride intake.
- (e) Requests for weight reduction advice and products should be met in a structured manner.
- (f) A policy should exist to ensure that weight reduction advice is not given to those who do not require it.
- (g) A weight reduction guide should be available in the pharmacy for patients to take away with them.
- (h) Those who need to lose weight should be given advice on healthy eating and exercise.
- (i) Slimming mixtures and unhealthy slimming medicines/techniques should not be promoted by the pharmacy.

- (j) The following patients should not be advised to go on very low calorie diets:
 - (i) Patients who are underweight;
 - (ii) Patients who are pregnant;
 - (iii) Diabetic patients; and
 - (iv) Children.
- (k) Specialist groups for whom nutritional advice is of particular importance can be identified and counselled appropriately. Examples of such patient groups are:
 - (i) Patients with diabetes.
 - (ii) Hypertensive patients.
 - (iii) Patients requiring lipid advice.
 - (iv) Elderly patients.
 - (v) Stoma patients;
 - (vi) Terminally ill patients; and
 - (vii) Pregnant women.
- (l) All symptoms that show prolonged change of bowel habit in customers over 50 years must be referred to a medical practitioner.

17.5.4 Baby and child health

Pharmacists are often the first person contacted by mothers with babies and small children.

The following guidelines apply regarding this service:

- (a) Pharmacists and pharmacy support personnel must be informed regarding childhood problems and on the importance of early referral.
- (b) All symptoms in young babies under one year must be referred to the pharmacist for advice.
- (c) The pharmacist should keep up to-date regarding the latest guidelines on child safety.
- (d) The pharmacist must know the symptoms of common childhood illnesses.
- (e) The pharmacist should provide advice regarding sugar intake and dental caries.
- (f) All parasitic worm preparations should be sold with advice on hygiene and treating all family members.
- (g) Pharmacists should know the principles of vitamin supplementation for infants.
- (h) Pharmacists must actively promote immunization programmes.
- (i) Pharmacists should provide patient information and advice on the benefits of breast feeding and alternative milk products in line with WHO guidelines for substitute milk products.

- (i) The pharmacy should stock a range of accessories and equipment to facilitate breast feeding.
- (ii) The pharmacist and pharmacy support personnel should actively encourage mothers to continue breast feeding.
- (iii) The pharmacist should refer mothers experiencing difficulty with breast feeding for specialist professional help.
- (iv) The pharmacist must give advice on medicines in association with breast feeding.
- (v) Pharmacy support personnel should know the range of formula milk and its relative advantages and mixing and storage procedures.

18. GUIDELINES FOR SMALL SCALE MANUFACTURING, COMPOUNDING, MIXING AND PRE-PACKING

All small scale manufacturing, compounding, mixing and pre-packing may only take place in accordance with the provisions of the Medicines Act. Further reading in this regard would thus be the Guidance Document: Good Manufacturing Practice of medicine in South Africa (GNR. 7659 of 2 May 2003), published by the MCC.

18.1 ASEPTIC DISPENSING SERVICE

- (a) An aseptic dispensing service provides, in response to a clinician's prescription, a sterile product prepared by the admixture of sterile components without terminal heat sterilisation.
- (b) Aseptic dispensing must be carried out in a cabinet equipped with a high efficiency particulate air (HEPA) filter situated in a room with a clean air environment to prevent contamination with micro-organisms and particulate matter.
- (c) A safe system of work should apply throughout preparation and there should be safeguards to ensure that the final product is stable and safe throughout its labelled life.
- (d) Only staff trained in pharmaceutical aseptic technique should provide this service. All personnel should be trained in the proper procedures for aseptic technique.
- (e) Procedures should be introduced to ensure that dosage calculations are correct and that final containers are appropriate to the route of administration to be employed.
- (f) Procedures should be established to ensure that the application of the principles of Good Manufacturing Practice are applied to the aseptic dispensing service.
- (g) Particular attention should be paid to ensuring that validated procedures are used. Prescription details, work sheets, labels and ingredients should be checked prior to preparation. The final product, documentation and label details should be checked prior to release.
- (h) Accurate records should be kept for each product prepared including label details. These should include:

- (i) patient's name (hospital number) and ward;
- (ii) name, form and strength of medicine;
- (iii) recommendations for use;
- (iv) appropriate warnings; and
- (v) batch number, expiry date, date and time of preparation.
- (i) Quality control procedures should ensure that new formulations undergo stability testing, preferably prior to use. Microbiological and particulate monitoring should be carried out even though results may be retrospective.

18.2 INTRAVENOUS ADDITIVE SERVICE

- (a) Standard policies and procedures should be established for IV preparation and administration.
- (b) The minimum requirement must be the use of a cabinet equipped with a high efficiency particulate air (HEPA) filter, ideally situated in a room with clean air environment.
- (c) Only staff trained in the pharmaceutical aseptic technique should handle such solutions.
- (d) Procedures should be introduced to ensure that dosage calculations are correct and that the addition will not result in any chemical or physical incompatibility.
- (e) Procedures should be instituted to ensure that safe systems of work are applied throughout the admixture process and there should be safeguards to ensure that the solution is stable and safe throughout administration to the patient.
- (f) Policies and procedures should be established for the addition of medicines to intravenous fluids and their administration. The pharmacy should have access to adequate information sources concerning the intravenous administration of medicines and related compatibilities and stabilities.
- (g) Accurate records should be kept of each admixture including label details. The following information should be included on the label:
 - (i) patient's name, (hospital number) and ward;
 - (ii) name and amount of additive(s);
 - (iii) name, strength and quantity of the primary IV solution;
 - (iv) batch number, expiry date and date and time of preparation;
 - (v) method of IV administration - continuous or intermittent. If intermittent, the interval of administration should be stated; and
 - (vi) Rate of administration.
- (h) All admixtures must be inspected for particulate matter before they are supplied for administration.
- (i) All admixtures must be inspected for particulate matter before they are supplied for administration.

- (j) Quality control testing should be conducted to monitor IV additive procedures. The quality assurance programme should be designed to evaluate the performance of equipment, personnel and procedures and include testing of the final product and of remnants returned from the ward.
- (k) The pharmacy should provide an efficient system for distribution of ready-prepared admixture solutions.
- (l) The pharmacist should, where possible, ensure that intravenous additives are used appropriately, e.g. within the specified shelf life. Unwanted admixtures should be removed from the ward area.

18.3. TOTAL PARENTERAL NUTRITION (TPN) PREPARATION SERVICE

- (a) The preparation of TPN solutions must be performed in a cabinet equipped with a high efficiency particulate air (HEPA) filter ideally situated in a room with a clean air environment to prevent contamination with micro-organisms and particulate matter.
- (b) A safe system of work should apply throughout preparation and there should be safeguards to ensure that the solution is stable and safe throughout administration to the patient.
- (c) Accurate batch control records should be kept of all TPN solutions issued for administration to patients.
- (d) There should be a uniform standard for labelling TPN solutions. The following information should be included in the label:
 - (i) identification of the product i.e. "Parenteral Nutrition Solution";
 - (ii) the patient's name and ward;
 - (iii) the name and amount of each constituent;
 - (iv) storage conditions;
 - (v) the total volume;
 - (vi) the time and date of preparation;
 - (vii) the rate of administration;
 - (viii) the batch control number;
 - (ix) statements to the effect that the solution remains sterile if unopened and that the bag should be used for the named patient only;
 - (x) the expiry date of the solution; and
 - (xi) that additives are prohibited.

18.4 CYTOTOXIC PREPARATION AND RECONSTITUTION SERVICE

- (a) Cytotoxic medicines have a potential for being mutagenic, teratogenic and carcinogenic. It is prudent that every reasonable precaution should be taken by staff handling cytotoxic medicines to ensure that absorption does not occur,

especially as no adequate means of monitoring or measuring inadvertent absorption have been devised.

- (b) Due to the potential hazards to patients, staff and visitors, staff involved in the preparation, administration and disposal of these agents must be adequately trained.
- (c) Procedures should be established to ensure that the hazards associated with the handling, preparation and administration of cytotoxics are kept to a minimum by ensuring that:
 - (i) the correct technique is used;
 - (ii) staff are properly trained and aware of the various hazards;
 - (iii) appropriate protective clothing is provided and used;
 - (iv) correct action is taken following any accidental spillage or contamination of the person; and
 - (v) suitable equipment for waste is provided to minimize the risk of contamination.
- (d) The responsible pharmacist must ensure that facilities are suitable for the type of preparation irrespective of the scale of preparation and that proper records of prescribing, dispensing and administration are maintained.
- (e) A nominated pharmacist should ensure that cytotoxic drug handling policies are regularly revised.
- (f) The responsible person should ensure that facilities are suitable for the type of preparation and should not depend upon the scale of preparation.
- (g) Equipment should be designed to minimise the risk of contamination of the product as well as the operator. Procedures should lay down standards for protective clothing as well as safety cabinets and single-use medical and surgical sundries.
- (h) The preparation and reconstitution of cytotoxic medicines should be carried out by appropriately trained staff within an approved safety cabinet, designed to protect the operator from exposure to any concentration of the medicines and also to protect the product from microbiological contamination. This service should take place either within a designated area of the pharmacy or on a centralised basis within e.g. an oncology unit.
 - (i) Horizontal laminar flow cabinets should not be used.
 - (j) Procedures should ensure that final containers are suitable for the purpose and that they are adequately labelled. Full documentation of each preparation should be carried out according to standardised procedures so that individual constituents are readily traceable.
- (k) Where reconstitution has to take place in a hospital ward a clean, quiet, well-lit and well ventilated area should be chosen for the purpose, where the operation will be subject to the minimum of interruptions, be well away from food and passing people. Hot and cold water should be available and there should be immediate access to eye wash facilities and treatment agents. If possible, in wards, part of this area should be dedicated exclusively to the preparation of cytotoxic medicines. Strict aseptic technique should be employed throughout for injectable preparations.

- (l) Protective clothing should include the following:
 - (i) gloves that are of material appropriate to the product being handled;
 - (ii) safety spectacles with side pieces or locally approved alternatives;
 - (iii) a single use plastic apron (specially designed coats, with long sleeves and cuffs are preferable); and
 - (iv) a single use surgical mask.
- (m) Procedures should ensure that a broad-edged tray is used to contain any accidental spillage and that Luer-Lock syringes should be used. Whenever possible, for reconstitution purposes, a wide bore needle (18 gauge) should be used and steps should be taken to ensure that excess pressure build-up does not cause leakage or the formation of an aerosol. Care should be taken to ensure that the operator is not at risk when reconstituting open vials or ampoules, opening ampoules or expelling air from syringes.
- (n) Procedures should ensure that syringes are protected during transport to the patient. Individual syringes must be labelled. The label should contain at least the following information:
 - (i) the name and strength of the medicine;
 - (ii) the total quantity of the medicine;
 - (iii) the name of the patient;
 - (iv) the date of preparation;
 - (v) the expiry date; and
 - (vi) the batch number of the preparation.
- (o) Any special recommendations from the manufacturer should be observed.
- (p) Any accidental spillage or contamination of the operator must be dealt with immediately and procedures must be established for treatment of the skin, eyes and other surfaces.
- (q) The working area used for the preparation or reconstitution of cytotoxic medicines should be thoroughly cleaned immediately after use according to local procedures.
- (r) All excess medicine, equipment and protective clothing used in the preparation should be disposed of and dealt with according to local procedures.
- (s) Procedures for administration of cytotoxic medicines to patients should strike a balance between protecting the operator and alarming the patient. They should include details of action to be taken in the case of extravasation and for the disposal of excreta from patients receiving cytotoxic medicines.
- (t) All procedures should be designed to ensure that all products achieve the required standard of quality.
- (u) All personnel should receive special training in working with cytotoxic medicines and be monitored regularly to ensure compliance with all procedures.

- (v) A permanent register should be maintained of all employees who routinely handle cytotoxic medicines. Acute exposure episodes should be documented and the employee should be referred for appropriate medical examination. Routine medical examination and blood tests should be performed on personnel handling cytotoxic medicine.
- (w) Personnel working in a cytotoxic reconstitution service should be rotated regularly.

18.5 COMPOUNDING

- (a) Compounding must be done under the direct supervision of a pharmacist.
- (b) All compounding procedures should be prepared by a pharmacist with the necessary authority and clearly defined and known to be capable of achieving the desired outcomes.
- (c) All the necessary requirements should be provided, including:
 - (i) appropriately trained personnel;
 - (ii) adequate premises and space;
 - (iii) suitable equipment and services;
 - (iv) correct materials, containers and labels;
 - (v) approved procedures (including cleaning procedures); and
 - (vi) suitable storage and transport.
- (d) Procedures should be written in instructional form and be applicable to the facilities provided.
- (e) Compounding may be done by pharmacy support personnel who have been trained to perform the procedures concerned.
- (f) Records must be kept during the process which demonstrate that all the steps required by the defined procedures were taken and that the quantity and quality produced were those expected.
- (g) A system should be in place to recall any batch or product should it be necessary.
- (h) High standards of personal cleanliness should be observed by all those concerned with the bulk compounding process.
- (i) Hand-washing facilities should be conveniently available to the personnel involved.
- (j) Storage areas should provide adequate space and should be arranged and equipped to allow dry, clean and orderly placement of store materials and products under controlled conditions of temperature and humidity.
- (k) Equipment used for bulk compounding should be designed and maintained in such a way as to:
 - (i) be suitable for its intended use;
 - (ii) facilitate thorough cleaning when necessary;

- (iii) minimize any contamination of drugs and their containers during manufacture; and
- (iv) minimize the risk of confusion or the omission of a processing step such as filtration or sterilization.
- (l) Equipment and utensils should be thoroughly cleaned and if necessary sterilised and maintained in accordance with specific written directions.
- (m) Before the commencement of any bulk-compounding, a check should be made to ensure that all apparatus and equipment to be used have been cleaned/sterilised.
- (n) Prior to packaging and labelling of a batch of medicine, the records should show that the batch has been duly checked and approved for release.

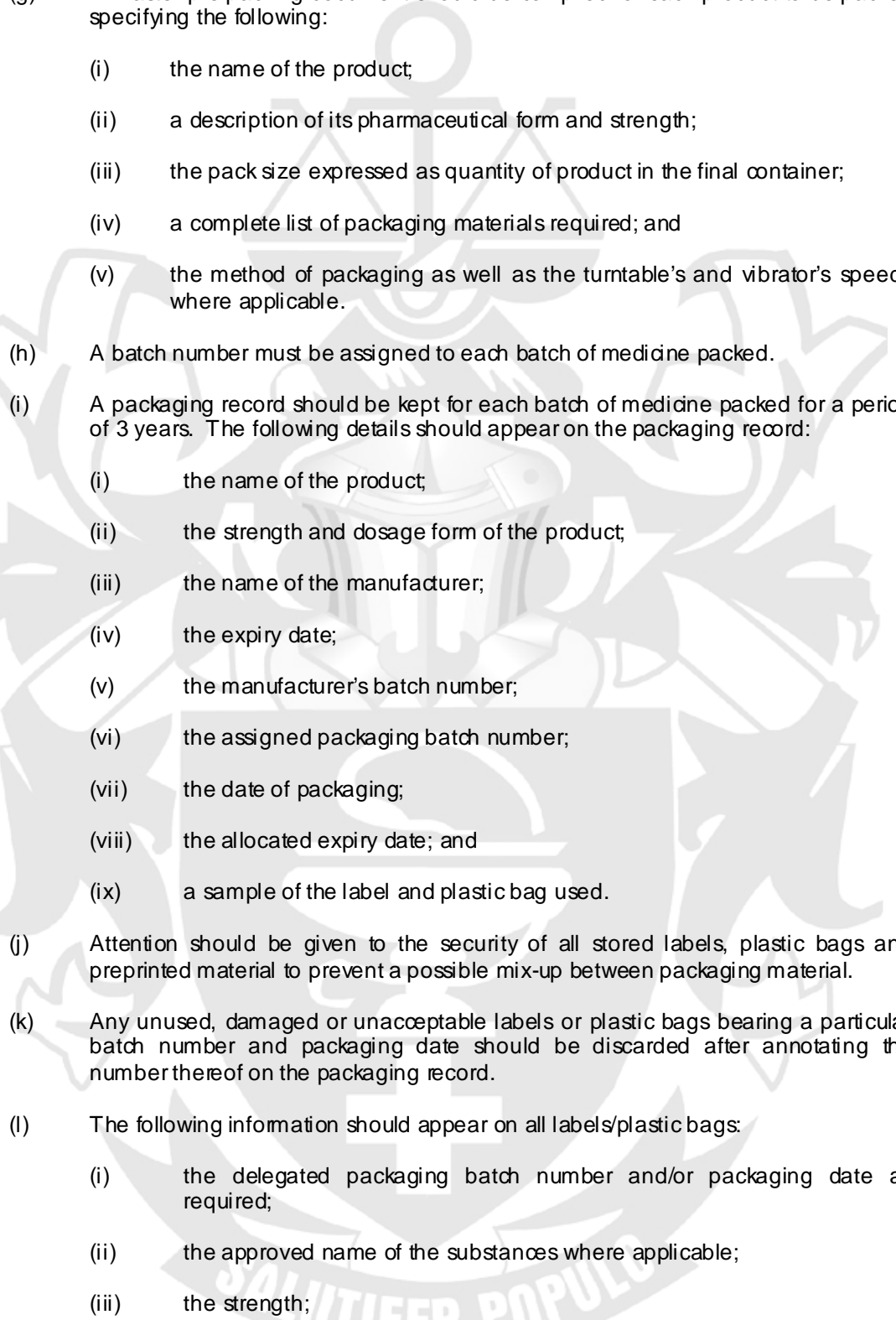
18.6. PRE-PACKING

- (a) Pre-packing entails the repacking of medicines from bulk packs into smaller packs suitable for patient use.
- (b) Pre-packing must only be performed by a pharmacist or under the supervision of a pharmacist under strictly controlled conditions and according to a clearly designed system of quality assurance based on the guidelines provided in this document and the general regulations to the Medicines Act.
- (c) Where tablets are pre-packed they must be manually counted, weighed, or electronically counted. Measuring by volume is not permitted.
- (d) Pre-packing must take place only under the required conditions of temperature and humidity.
- (e) A batch numbering system should be used which gives ready access to all information required to ascertain the ingredient(s) and the procedure(s) used in preparing the finished product
- (f) Pre-packing must be carried out in accordance with good manufacturing and distribution practices (refer general regulations to the Medicines Act)

18.6.1 Minimum standards for pre-packing

To comply with the above requirements the following minimum standards should be complied with in the packaging of medicines in patient ready packs.

- (a) All pre-packing operations should be confined to a separate area intended for such purposes and physically partitioned off from all other working areas, with limited access.
- (b) The pre-packing area should be effectively lit and ventilated with temperature and humidity control facilities. Conditions should be such that there is no adverse effect on the product or equipment either directly or indirectly.
- (c) All equipment should be kept clean and before each production run checked for efficiency and accuracy.
- (d) Electronic tablet counters should preferably be fitted with dust covers and extractor fans.
- (e) The personnel operating the equipment should be adequately trained by *inter alia* in-service training and be registered with the Council (i.e. pharmacist's assistants)

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- (f) Personnel must be adequately protected from the possible exposure to health hazards (eg. oncolytics, penicillin, etc.)
 - (g) A master pre-packing document should be compiled for each product to be packed specifying the following:
 - (i) the name of the product;
 - (ii) a description of its pharmaceutical form and strength;
 - (iii) the pack size expressed as quantity of product in the final container;
 - (iv) a complete list of packaging materials required; and
 - (v) the method of packaging as well as the turntable's and vibrator's speeds where applicable.
 - (h) A batch number must be assigned to each batch of medicine packed.
 - (i) A packaging record should be kept for each batch of medicine packed for a period of 3 years. The following details should appear on the packaging record:
 - (i) the name of the product;
 - (ii) the strength and dosage form of the product;
 - (iii) the name of the manufacturer;
 - (iv) the expiry date;
 - (v) the manufacturer's batch number;
 - (vi) the assigned packaging batch number;
 - (vii) the date of packaging;
 - (viii) the allocated expiry date; and
 - (ix) a sample of the label and plastic bag used.
 - (j) Attention should be given to the security of all stored labels, plastic bags and preprinted material to prevent a possible mix-up between packaging material.
 - (k) Any unused, damaged or unacceptable labels or plastic bags bearing a particular batch number and packaging date should be discarded after annotating the number thereof on the packaging record.
 - (l) The following information should appear on all labels/plastic bags:
 - (i) the delegated packaging batch number and/or packaging date as required;
 - (ii) the approved name of the substances where applicable;
 - (iii) the strength;
 - (iv) the quantity or volume of medicine;

- (v) the expiry date;
 - (vi) the name and address of the packaging institution; and
 - (vii) any necessary additional information eg. storage conditions, warnings, etc.
- (m) Space on the label must be provided for:
- (i) the directions for use;
 - (ii) the name and reference number of the patient; and
 - (iii) the name and address of the hospital.
- (n) Containers and packaging material must conform to the following requirements:
- (i) protecting the product from light and moisture;
 - (ii) preventing contamination of the product, including possible microbial contamination; and
 - (iii) prevention of product deterioration.

19. GUIDELINES FOR A TOTAL PARENTERAL NUTRITION (TPN) CONSULTATION SERVICE

- (a) Intravenous feeding should only be used when nutritional support by the gastro-intestinal tract is impossible or inadequate.
- (b) A multi-disciplinary Nutrition Advisory Team may be formed in each hospital to develop policies for nutrition support. Prior to initiation of TPN therapy, a member of the Nutrition Advisory Team should assess whether TPN is appropriate and the adequate base-line laboratory data should have been obtained.
- (c) Parenteral nutrition compounding services form part of the range of services available to the Nutritional Advisory Team. Specialist knowledge is required for the formulation and preparation of TPN solutions and for monitoring TPN therapy. Only personnel trained in pharmaceutical aseptic technique and registered with the Council should prepare such solutions (refer previous chapter).
- (d) The Nutrition Advisory Team may comprise clinicians, pharmacists, nurses and dieticians. Other disciplines may be included to reflect local requirements.
- (e) The Nutritional Advisory Team should develop policies for:
 - (i) the indications for TPN therapy;
 - (ii) the education of personnel involved in TPN therapy;
 - (iii) the prescribing of TPN therapy;
 - (iv) the formulation, preparation and administration of TPN solutions;
 - (v) the monitoring of patients receiving TPN therapy; and
 - (vi) the care of central venous catheters.

- (f) Prior to initiation of TPN therapy individual patients should be assessed by the team to ensure that TPN is appropriate and adequate baseline laboratory data has been obtained.
- (g) The pharmacist should check the TPN prescription for the following:
 - (i) correct route and rate of administration;
 - (ii) formulation;
 - (iii) stability and/or compatibility of constituents; and
 - (iv) interaction with other medicines.
- (h) The pharmacist should be responsible for ensuring that the dosage calculations are correct and that the mixture will not result in any chemical or physical incompatibility.
- (i) Completed TPN solutions should be inspected, where appropriate, for particulate matter before they are issued for administration to the patient.
- (n) The pharmacist should take an active part in monitoring the progress of patients receiving TPN therapy including:
 - (i) the response to TPN therapy to determine if it is adequate;
 - (ii) the detection and/or prevention of complications;
 - (iii) the adherence to correct IV administration procedures;
 - (iv) that batch control records are complete; and
 - (v) that solutions are protected from light during administration when appropriate.
- (k) Quality control testing should be conducted to monitor TPN procedures. The quality assurance programme should be designed to evaluate the performance of equipment, personnel and procedures and include where applicable testing of the final product and remnants returned from the ward.

20. GUIDELINES FOR THERAPEUTIC MEDICINE MONITORING SERVICE

A therapeutic medicine monitoring service is designed to allow adjustment to the dose of a medicine to obtain maximum clinical benefit and avoid unnecessary toxicity. This is achieved by the measurement of plasma concentrations of a medicine in specific conditions coupled with the interpretation of the results obtained.

- (a) The role of the pharmacy, the pathology and, if appropriate, the clinical pharmacology departments should be clearly defined locally. It is important to promote good relations and ensure that equipment is not duplicated and that analysis and the taking of samples is carried out by suitably trained people observing health and safety procedures.
- (b) Pharmacists should be involved in the interpretation of results from medicine assays.
- (c) Policies and procedures should include:

- (i) guidance on the types of medicine of which therapeutic medicine monitoring has been shown to be of value and those medicines where plasma level measurements are unnecessary;
 - (ii) indications for therapeutic medicine monitoring;
 - (iii) detailed guidelines on the application of therapeutic medicine monitoring to all the medicines for which the service is available; and
 - (iv) guidelines on sampling.
- (d) A pharmacokinetic profile form/reporting sheet, should be designed and agreed by the Pharmacy and Therapeutics Committee. Explanatory notes should be provided on the use of these forms.
- (e) Results from therapeutic medicine monitoring and interpretation of these results should be communicated to the clinician by a pharmacist on the approved form to become part of the patient's permanent records.
- (f) Quality assurance procedures should be introduced to ensure that results are consistent and reproducible. This should involve participation in rational quality control schemes if these are available.

21. GUIDELINES FOR THE PROVISION OF COMPLEMENTARY MEDICINE

- (a) Where complementary medicines are offered for sale, staff involved should be trained in the use thereof.
- (b) The pharmacy must stock only those complementary medicines, which are judged by the pharmacist to be effective and appropriate for the treatment of stated conditions.
- (c) The client must be given appropriate information about the use and effectiveness of complementary medicine sold to them.

Guidance

Information about complementary medicine should be suitable for the needs of specific groups of clients and should not make claims, which in the pharmacist's judgement, are misleading or speculative.

22. ANIMAL HEALTH CARE SERVICES

Pharmacists with the necessary competence may provide animal health care services in accordance with his/her scope of practice and the services that may be provided in a community or institutional pharmacy.

The following principles must be adhered to:

- (a) The consultation room applicable to the animal health service must have a separate entrance than the pharmacy entrance.
- (b) Transmission of infection between animals and from animals to humans must be avoided.

- (c) Stringent hygiene should also be followed which includes the provision of necessary advice and equipment when any veterinary medicine is sold and applied by an owner.
- (d) Comprehensive record of the service provided together with owner details should be kept.
- (e) A pharmacist providing an animal health care service must advise owners of animals that a veterinarian must be consulted to confirm a diagnosis made by a pharmacist in an emergency situation.

23. GENERAL GUIDELINES FOR AIDS RESOURCE CENTRES IN A PHARMACY

23.1 FACILITIES

Since confidentiality and privacy are essential, a separate consulting room (as described in the Good Pharmacy Practice guidelines) should be utilised as the AIDS Resource Centre in a pharmacy. The AIDS Resource Centre should have similar equipment to a consulting room for performance of supplementary services as stipulated in the Good Pharmacy Practice guidelines.

23.2 SERVICES THAT MAY BE PERFORMED IN AN AIDS RESOURCE CENTRE IN A PHARMACY

- (a) **Prevention**, which could include –
 - (i) the promotion of safe and health sexual behaviour;
 - (ii) the management and control of STI's, in accordance with guidelines of the Department of Health in this regard;
 - (iii) the provision of antiretroviral therapy to reduce mother-to-child transmission (MTCT), in accordance with the Medicines Act;
 - (iv) the provision of appropriate post-exposure prophylaxis, in accordance with guidelines of the Department of Health in this regard;
 - (v) HIV testing and counselling to improve access to voluntary testing and counselling;
- (b) **Treatment, care and support**, which could include –
 - (i) the provision of treatment, care and support services, in accordance with guidelines of the Department of Health in this regard and the provisions of the Medicines Act;
 - (ii) assistance with research, monitoring and surveillance;
 - (iii) routine surveillance;
- (c) Pharmacists must in all instances be adequately training and sufficiently experienced in providing the services concerned.

23.3 RESPONSIBILITIES

- (a) Pharmacists should ensure that the dignity of the patient is maintained;
- (b) Pharmacists should ensure that patients' rights are maintained; and

- (c) Pharmacists should ensure that confidentiality is maintained throughout treatment.



CHAPTER 4

GUIDELINES FOR HUMAN RESOURCES IN PHARMACY

1. SCOPE OF PRACTICE OF PHARMACY PERSONNEL

The scope of practice of the various categories of persons who may practise in a pharmacy is prescribed in the Regulations relating to the practice of pharmacy. These provisions have provided certainty with regard to the services, which can be provided and the acts that can be performed by the various categories of person. Anyone who performs any of the functions prescribed must be registered with Council. The relevant regulations are included here for information.

1.1 PHARMACIST'S ASSISTANT (BASIC)

A pharmacist's assistant registered in the category pharmacist's assistant (basic) may perform the following services or acts under the direct personal supervision of a pharmacist in a pharmacy:

- (a) the sale of Schedule 1 medicines or scheduled substances;
- (b) assist with the compounding, manipulation or preparation of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;
- (c) assist with the manufacturing of a non-sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;
- (d) the re-packaging of medicine;
- (e) the distribution and control of stock of Schedule 1 to Schedule 5 medicines or scheduled substances; and
- (f) the provision of information to individuals in order to promote health.

1.2 PHARMACIST'S ASSISTANT (POST- BASIC)

A pharmacist's assistant registered in the category pharmacist's assistant (post-basic) may perform the following services or acts under the direct personal supervision of a pharmacist in a pharmacy:

- (a) the sale of Schedule 1 and Schedule 2 medicines or scheduled substances;
- (b) assist with the compounding, manipulation or preparation of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;
- (c) assist with the manufacturing of a non-sterile or sterile medicine or scheduled substance according to a formula and standard operating procedures approved by the responsible pharmacist;
- (d) the re-packaging of medicine;

- (e) the distribution and control of stock of Schedule 1 to Schedule 6 medicines or scheduled substances;
- (f) the ordering of medicine and scheduled substances up to and including Schedule 6 according to an instruction of a person authorised in terms of the Medicines Act to purchase or obtain such medicine or scheduled substance;
- (g) the reading and preparation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container following the interpretation and evaluation of the prescription by a pharmacist;
- (h) the provision of instructions regarding the correct use of medicine supplied; and
- (i) the provision of information to individuals in order to promote health.

In terms of *Regulation 12 of the Regulation relating to the practice of pharmacy*, a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) may perform the acts or provide services as prescribed in (e), (f), (g), (h) and (i), as well as the reading and preparation of a prescription, the selection, manipulation or compounding of medicine and the labelling and supply of medicine in an appropriate container under the indirect personal supervision of a pharmacist: provided that such indirect personal supervision will take place only under the following circumstances:

- (a) the services are provided or acts are performed at a primary health care clinic or any other facility as approved by council;
- (b) only re-packaged medicines or patient ready packs are provided;
- (c) written and up-dated protocols and standard operating procedures are available describing clearly the responsibility of the pharmacist's assistant and pharmacist under whose indirect personal supervision the pharmacist's assistant performs the acts and provides the services; and
- (d) the pharmacist under whose indirect personal supervision the pharmacist's assistant performs the acts and provides the services visits the pharmacist's assistant at the primary health care clinic or other facility as approved by council for purposes of supervision and support, which visits must be documented and take place at least once a month.

1.3 PHARMACY STUDENT

The scope of practice of a student –

- (a) A pharmacy student may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (basic) under the direct personal supervision of a pharmacist in a pharmacy;
- (b) A pharmacy student who has successfully completed his or her second year of study may provide or perform all the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist in a pharmacy;
- (c) A pharmacy student may, for purposes of education and training, and under the auspices of a provider approved to offer education and training for a qualification in pharmacy and with whom such student is enrolled, provide or

perform all the services or acts pertaining to the scope of practice of a pharmacist under the direct personal supervision of a pharmacist;

- (d) The services or acts referred to in (c) must be provided or performed in accordance with a programme developed by the provider and approved by the council.

1.4 PHARMACIST INTERN

The scope of practice of a pharmacist intern –

- (a) A pharmacist intern may provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist's assistant registered in the category pharmacist's assistant (post-basic) under the direct personal supervision of a pharmacist in a pharmacy.
- (b) A pharmacist intern may, for the purposes of education and training, provide or perform all of the services or acts pertaining to the scope of practice of a pharmacist under the direct personal supervision of a pharmacist in a pharmacy.

1.5 PHARMACIST

1.5.1 The following services and/or acts are regarded to be acts specially pertaining to a pharmacist –

- (a) The provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions:
 - (i) evaluation of a patient's medicine related needs by determining the indication, safety and effectiveness of the therapy;
 - (ii) dispensing of any medicine or scheduled substance on the prescription of a person authorised to prescribe medicine;
 - (iii) furnishing of information and advice to any person with regard to the use of medicine
 - (iv) determining patient compliance with the therapy and follow up to ensure that the patient's medicine related needs are being met; and
 - (v) the provision of pharmacist initiated therapy;
- (b) the compounding, manipulation, preparation or packaging of any medicine or scheduled substance or the supervision thereof;
- (c) the manufacturing of any medicine or scheduled substance or the supervision thereof;
- (d) the purchasing, acquiring, importing, keeping, possessing, using, releasing, storage, packaging, repackaging, supplying or selling of any medicine or scheduled substance or the supervision thereof; and
- (e) the application for the registration of a medicine in accordance with the Medicines Act.

1.5.2 The scope of practice of a pharmacist is as follows:

- (a) the Acts specially pertaining to the profession of a pharmacist as prescribed in (1.5.1) above;
- (b) the formulation of any medicine for the purposes of registration as a medicine;
- (c) the distribution of any medicine or scheduled substance;
- (d) the repackaging of medicines;
- (e) the initiation and conducting of pharmaceutical research and development; and
- (f) the promotion of public health.

2. AUTHORITY, DUTIES AND RESPONSIBILITIES OF A RESPONSIBLE PHARMACIST

In terms of the Pharmacy Act, every pharmacy must, except in such circumstances and subject to such conditions as indicated in paragraph 2.2 hereunder, be conducted under the direct personal supervision of a responsible pharmacist, whose name must be displayed conspicuously over the main entrance of such pharmacy and who must be registered as such with the Council.

2.1 DUTIES AND RESPONSIBILITIES OF THE RESPONSIBLE PHARMACIST

The responsible pharmacist must –

- (a) ensure that he or she in fact continuously supervises the pharmacy in which he or she has been appointed;
- (b) have appropriate qualifications and experience in the services being rendered by such pharmacy;
- (c) ensure that persons employed in such pharmacy and who provide services forming part of the scope of practice of a pharmacist are appropriately registered with council;
- (d) notify council immediately upon receiving knowledge that his/her services as responsible pharmacist have been or will be terminated;
- (e) take corrective measures in respect of deficiencies with regard to inspection reports of council or in terms of the Medicines Act; and
- (f) in addition to the general responsibilities also:
 - (i) ensure that unauthorised persons could not by lawful means obtain access to medicines or scheduled substances or the pharmacy premises outside of normal trading hours;
 - (ii) establish policies and procedures for the employees of the pharmacy with regard to the acts performed and services provided in the pharmacy;
 - (v) ensure the safe and effective storage and keeping of medicine or scheduled substances in the pharmacy under his or her direct personal supervision; and

- (vi) ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.

2.2 CIRCUMSTANCES AND CONDITIONS UNDER WHICH A RESPONSIBLE PHARMACIST MAY BE ABSENT FROM HIS/HER PHARMACY

The following are circumstances and conditions under which a responsible pharmacist may be absent from his/her pharmacy:

2.2.1 Circumstances

The responsible pharmacist may be absent from his/her pharmacy subject to the conditions mentioned in paragraph 2.2.2 hereunder to –

- (a) fulfil his or duties and responsibilities as prescribed in terms of the Pharmacy Act (refer paragraph 2.1 above);
- (b) provide pharmaceutical services at a pharmacy of which he or she is not the responsible pharmacist;
- (c) undertake the overall management of the pharmacy concerned, which could include but is not limited to the regulation of pharmacy matters, human resources, or matters relating to processes regarding medicines or scheduled substances including procedures and record keeping, as well as compliance with relevant labour legislation.

2.2.2 Conditions

A responsible pharmacist may be absent from his or her pharmacy under the circumstances as mentioned in item 2.2.1 above, but subject to the following conditions:

- (a) When the responsible pharmacist is the only pharmacist employed by the pharmacy concerned and no *locum* could be employed for the period that the responsible pharmacist would be absent from his or pharmacy, the responsible pharmacist may be absent only if -
 - (ii) schedule 1 substances were inaccessible to the public and not supplied during the absence of the pharmacist except by a pharmacist intern or pharmacist's assistant (basic) or pharmacist's assistant (post-basic);
 - (iii) schedule 2 to 6 substances were locked away in an area of which the key must be in the personal possession of the responsible pharmacist;
 - (iv) in the case of written prescriptions a locked box was provided to ensure the confidentiality of prescriptions;
 - (v) no verbal prescriptions were received in the pharmacy for the period in question; and
 - (vi) a sign informing members of the public that no pharmacist was present was displayed conspicuously.
- (b) If another pharmacist or a *locum* is available in the pharmacy concerned to provide pharmaceutical services in the absence of the responsible pharmacist, the responsible pharmacist may be absent only if suitable mechanisms or procedures or policies were in place-

- (i) to ensure that no person perform any act falling outside the scope of practice of the category in which such person is registered or which he/she was not authorised to perform in terms of the Act;
 - (ii) to ensure that unauthorised persons do not obtain access to medicines or scheduled substances or the pharmacy premises outside of normal trading hours;
 - (iii) for the employees of the pharmacy with regard to the acts performed and services provided in the pharmacy;
 - (iv) to ensure the safe and effective storage and keeping of medicine or scheduled substances in the pharmacy; and
 - (v) to ensure correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances.
- (c) The responsible pharmacist will remain responsible to Council for any act performed by or on behalf of the responsible pharmacist, including any omission to perform an act required to be performed by or on behalf of the responsible pharmacist which may involve disciplinary action by Council.

3. GENERAL GUIDELINES REGARDING STAFF SELECTION, APPRAISAL AND TRAINING

The selection and management of staff are directed towards providing quality of service and meeting the objectives of the pharmacy.

3.1 STAFF SELECTION

Staff recruitment is an objective process, which leads to the employment of staff who are suitable for the specifications of the position.

- (a) The responsible pharmacist ensures that written job descriptions are prepared for all staff and that all staff are acquainted with their job descriptions and responsibilities.
- (b) All staff are appropriately qualified, competent and fit to work in the pharmacy.
- (c) All staff receive appropriate training, information and orientation when newly appointed to a position in the pharmacy.
- (d) The requirements of the Medicines and Related Substances Control Act, 1965 as amended with respect to persons handling medicines and related products must be observed.
- (e) The provisions of the Employment Equity and other legislation relating to human resources need to be incorporated in the pharmacy's staff selection and employment policies.
- (f) Staff selection and placement policies should note the importance of assessing the individual's capability to perform a job. Some positions require particular standards of hygiene, place significant physical demands on the individual, or preclude sensitive infection tolerances. The maintenance of the individual's capability to perform a job is equally important.

3.2 STAFF APPRAISAL AND DEVELOPMENT

An ongoing staff appraisal and development process is established which contributes to the maintenance of well-trained, motivated and loyal staff who are of high quality.

- (a) The responsible pharmacist sets performance objectives at least annually, in consultation with each staff member. Performance is monitored and evaluated against the job descriptions and established objectives. Results are discussed with the staff member and clearly documented on their personal record.
- (b) Personnel records containing professional and personal information which is essential for carrying out their job responsibilities, are maintained for each staff member. They are stored in a manner which preserves confidentiality.
- (c) The establishment of high standards in the provision of service should be a significant factor in appraising a staff member's performance.
- (d) Staff members should be involved in the appraisal of their performance and the extent of their involvement documented.
- (e) Performance appraisal should assist pharmacy management in identifying a staff member's training needs.
- (f) If performance is considered inadequate, the factors leading to the judgement are documented and placed on the individual's personal record along with the details of an agreed strategy to improve and evaluate performance.
- (g) Rewards for performance should reflect the outcome of the individual's performance.
- (h) Staff should be encouraged to participate in the activities of their professional bodies, particularly in those which will further the development of their professional skills.

3.3 STAFF TRAINING

Training is sufficient to enable staff to provide competent and informative advice and assistance to clients.

- (a) The pharmacy maintains a staff development programme and training plan which ensures that staff are properly trained, relevant to their identified needs and to the current and the future work plans of the pharmacy.
- (b) All staff continually review their level of professional knowledge and expertise. They document an appropriate self-development plan.
- (c) Qualifications must be kept current while staff are working in the pharmacy.
- (d) Where a staff member is required to show proof of continuing competency, an appropriate education programme should be established, documented and pursued for the individual concerned.
- (e) A sufficient number of staff should be trained in simple health emergency procedures to enable the provision of advice or treatment when the pharmacy is open to the public.
- (f) When training for pharmacy students, interns, and/or pharmacist's assistants is provided, there should be a sufficient number of experienced pharmacists to supervise training.

- (g) Appropriate staff members should be encouraged to participate in interprofessional activities which will further the practice of pharmacy and will assist in the provision of better patient care.

4. GENERAL GUIDELINES REGARDING THE TRAINING OF INTERNS AND PHARMACIST'S ASSISTANTS

Pharmacists responsible for the practical training of a pharmacist intern or pharmacist's assistant must comply with the necessary responsibilities.

4.1 PHARMACIST INTERNS / PRE-REGISTRATION EXPERIENCE

- (a) The purpose of the pharmacist internship/pre-registration experience is to enable the intern to apply in practice his/her theoretical knowledge and also to gain practical experience.
- (b) The pharmacist internship/pre-registration experience extends over a period of at least twelve (12) months in accordance with the structured practical training programme of Council.
- (c) A pre-registration evaluation, based on the competencies necessary in the practice environment, must be passed by the pharmacist intern at the end of the internship/pre-registration experience before registration as a pharmacist for purposing of performing community service can take place.

4.1.1 Objectives of the internship

During the completion of the pharmacist internship the pharmacist intern should be exposed to the following:

- (a) Obtaining knowledge and expertise in the conducting of a patient-orientated health service.
- (b) Developing communication with patients and other members of the health care team, in order to render a comprehensive pharmaceutical service.
- (c) Practical application of legal and ethical aspects of professional practice.
- (d) Obtaining knowledge with regard to the general aspects of health care, with particular emphasis on the South African situation and the role of the pharmacist in the promotion of health and prevention of illness.

4.1.2 Prerequisites for training

- (a) The internship year is subject to the following criteria:
 - (i) may only be undertaken at pharmacies which conform with the minimum requirements determined by Council;
 - (ii) shall be conducted by tutors who have been approved by Council to act as such. Such a tutor must be a person of experience who, by virtue of such experience, is in a position to conduct the training of the pharmacist intern at the level as laid down by Council; and
 - (iii) shall furthermore be conducted in accordance with a practical programme laid down by Council.

- (b) Both the pharmacy and the prospective tutor must be approved for the purposes of training.
- (c) Progress reports must be submitted at the stipulated intervals.

4.2 PHARMACIST'S ASSISTANTS

- (a) Pharmacist's assistants are legally allowed to perform certain functions under the supervision of pharmacists.
- (b) The pharmacist should supervise, check and assess each task delegated to support staff. Arrangements should ensure that an intervention by the pharmacist can be made at an appropriate level when necessary.
- (c) The pharmacist should ensure that all pharmacy support staff have up-to-date training for the tasks they undertake.

4.2.1 Prerequisites for training

- (a) The tutor pharmacist shall comply with the same requirements as a tutor in the case of pharmacist interns.
- (b) The trainer pharmacist shall conduct the training in the in-service training component and shall also, when applying to act as a tutor, give an undertaking that he/she will assume responsibility for assisting the pharmacist's assistant (learner basic) or (learner post-basic) in his/her study of the theoretical component of the programme.

5. GENERAL GUIDELINES ON PHARMACEUTICAL HUMAN RESOURCE DEVELOPMENT

5.1. STANDARDS FOR CONTINUING PROFESSIONAL DEVELOPMENT OF PHARMACEUTICAL PERSONNEL

Guidelines regarding the professional development of pharmacists can be found in Chapter 1 of this manual.

5.1.1 Competency

- (a) Each pharmacy must have a responsible pharmacist with appropriate knowledge and experience of the practice of pharmacy who has professional responsibility for the conduct of that pharmacy.
- (b) Pharmacists and pharmacy support personnel must receive sufficient education and training to enable them to provide competently the professional services being offered.
- (c) Possession of a qualification, either as a pharmacist or pharmacist's assistant, should not automatically be assumed to confer ability on an individual to carry out all functions in a pharmacy. Additional in-service training will often be required in specific/certain areas.
- (d) The pharmacist should remain informed (scientifically and legally) and maintain a level of competence sufficient to provide the professional services effectively and efficiently.
- (e) Continuing professional development is a professional obligation.

- (f) Continuing education and training will include attending courses, symposia, congresses, scientific and professional meetings, participating in distance learning, workplace learning experience and reading scientific journals and reviews.
- (g) Professional learning or training activities which are of relevance to pharmacy practice should be recorded so that the pharmacist's portfolio of learning activities is kept up to date permanently.
- (h) A pharmacist should ensure that any services provided comply with guidelines issued by the Council or other appropriate bodies.
- (i) A practising pharmacist is the trainer of choice for other pharmacists on professional matters. This does not preclude the use of persons from other professions where their expertise is relevant to the training objective.
- (j) A responsible pharmacist has the responsibility to assess the educational needs of all pharmaceutical staff. Training should relate to the work to be undertaken by the individual.
- (k) The responsibilities of the pharmacist and the personnel working in a pharmacy should be clearly defined.

5.1.2 Self-assessment (self-audit)

A pharmacist must continually review his/her level of professional knowledge and expertise, by self-assessment, and continuously update his/her knowledge.

5.1.3 Legislative changes

In addition to keeping abreast of pharmaceutical matters, it is the pharmacist's duty to be aware of and implement as soon as possible legislative changes, which affect pharmacy.

5.1.4 New services

The pharmacist who provides a new service must acquire the necessary expertise to provide a competent service to a safe standard, and must ensure that the relevant staff are also competent to perform their duties to a high standard.

5.1.5 Other health professionals

Pharmacists should have an active role in the education of clinicians, nurses and other health care professionals in all matters relating to the safe and effective use of medicines.

5.2 PROFESSIONAL INDEMNITY

A pharmacist must either carry his/her own indemnity insurance or must practise only in an establishment which is covered by indemnity insurance or an equivalent arrangement for the protection of the recipients of the service provided from that establishment

6. GUIDANCE FOR "LOCUM"/RELIEF PHARMACISTS

- (a) The qualifications and registration status of "locum" pharmacists should be checked and displayed to ensure patients' safety.
- (b) "Locum" pharmacists should have the necessary information to ensure the smooth running of the pharmacy. Written information should therefore exist to enable "locum" pharmacists to locate key standard operating procedures.

- (c) Basic operational information should be available to “locum” pharmacists. This information should include the following:
- (i) Computer instructions;
 - (ii) Names, addresses and telephone numbers of key staff;
 - (iii) List of medical practitioners with telephone numbers;
 - (iv) Plan of the pharmacy;
 - (v) Copies of all standard operating procedures e.g. dispensing;
 - (vi) Ordering systems and wholesalers used;
 - (vii) Instructions on use of alarm system;
 - (viii) Cash register instructions and cashing up procedure;
 - (ix) Emergency contact numbers;
 - (x) Collection and delivery service details;
 - (xi) List of outstanding work;
 - (xii) Local map; and
 - (xiii) Smoking policy.

7. SPECIFIC GUIDELINES FOR THE MANAGEMENT OF HUMAN RESOURCES IN WHOLESALE PHARMACIES.

7.1. GENERAL

The management of human resources is of major importance in the assurance of good wholesale and distribution practices. General guidelines on pharmacy human resource development are provided in Section 3 of this Chapter. The following guidelines relate more specifically to wholesale pharmacies.

- (a) Wholesale pharmacies should have an adequate number of appropriately trained personnel to perform the required functions.
- (b) Key supervisory and control personnel involved in the storage and distribution of medicine and scheduled substances should possess the necessary knowledge, experience, professional qualifications and authority to perform their duties efficiently.
- (c) Every wholesale pharmacy must have a responsible pharmacist, who must comply with the authorities, duties and responsibilities as prescribed in terms of the Pharmacy Act.
- (d) The pharmacy must at all times be conducted under the continuous personal supervision of a pharmacist.
- (e) A pharmacist should be appointed in each area where the need exists to sign off certain procedures.

- (f) Every wholesale pharmacy should have an organisational chart and written job descriptions for all the personnel.
- (g) The authority of the responsible pharmacists, must be such that decisions relating to quality assurance and compliance with the Pharmacy Act remain theirs and can only be altered by agreement with the said pharmacist(s).

7.2. PHARMACY SUPPORT PERSONNEL

All pharmacy support personnel employed by wholesale pharmacies who perform functions which fall within the scope of practice of pharmacist's assistants and whose functions include the direct handling of medicine must receive the prescribed in-service training and be registered with Council as pharmacist's assistants.

7.3. RESPONSIBLE PHARMACIST

- (a) Every wholesale pharmacy must have a responsible pharmacist registered as such with the Council.
- (b) The responsible pharmacist of a wholesale pharmacy should have expert knowledge with regard to the wholesale distribution of medicine and scheduled substances.
- (c) The responsible pharmacist is responsible for safe-guarding product users against potential hazards arising from poor distribution practices – as a result of, for example, purchasing suspect products, poor storage or failure to establish the *bona fides* of purchasers.
- (d) The responsible pharmacist should ensure that the conditions of the wholesale pharmacy's licence are met and that there is compliance with the guidelines on pharmacy practice.

7.3.1 Duties and responsibilities of the responsible pharmacist:

Refer section 2 of this Chapter for the duties and responsibilities of the responsible pharmacist. In addition, the responsible pharmacist of a wholesale or distribution pharmacy should:

- (a) Have a direct line of communication with and be part of management.
- (b) Have access to all areas, sites, stores and records which relate to the activities being performed.
- (c) Regularly review and monitor all such areas, sites, etc. or have delegated arrangements whereby he/she receives written reports that such actions have been carried out on his/her behalf.
- (d) Keep appropriate records relating to the discharge of his/her responsibilities.
- (e) Ensure the physical security of the stock or have written assurance from the manager responsible for security that administrative and physical security systems are in place and are adhered to by all personnel.

7.4. TRAINING

- (a) Wholesale pharmacies should provide training for all personnel whose activities could affect the quality of the product.

- (b) All newly recruited personnel should receive orientation regarding the organisation and specific training appropriate to the duties assigned to them.
- (c) Personnel working in areas where contamination is a hazard, eg. areas where toxic substances are handled, should be given specific training.
- (d) Ongoing training should be provided to all personnel and the practical effectiveness thereof should be assessed periodically.
- (e) Records of training should be kept.

7.5. HYGIENE

- (a) Detailed programmes relating to hygiene should be established and adapted to the different needs within the wholesale or distribution pharmacy. They should include procedures relating to the health, hygiene practices and clothing of personnel.
- (b) Steps should be taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on an exposed surface of the body is engaged in the handling of medicine or scheduled substances.
- (c) Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or personal medication in the storage areas should be prohibited. In general, any unhygienic practice within the facility where medicine or scheduled substances might be adversely affected, must be forbidden.
- (d) Personnel should be instructed to use the hand-washing facilities regularly

GUIDELINES FOR MANAGEMENT OF THE PHARMACY/PHARMACEUTICAL SERVICE

1. INTRODUCTION

Sound management structures and clearly defined responsibilities must be defined for pharmacy administration and management. A sound management structure should be established to ensure efficient working. The structure should reflect the requirements of various stakeholders, the organisational needs of the company/organisation and the range and level of activity within the pharmaceutical service. Lines of professional and managerial accountability should be established and be subject to regular review.

- (a) A pharmacist employed in administrative, management or advisory positions must have a clearly defined role and responsibility.
- (b) A pharmacy manager should ensure that there are sufficient pharmacists and pharmacy support personnel to undertake the pharmaceutical services provided by the institution or pharmacy concerned.

2. GENERAL GUIDELINES FOR PHARMACY ADMINISTRATION AND MANAGEMENT

The intent of these standards is to have the pharmacy organised in such a way that its services and processes contribute to the highest quality of pharmaceutical care. The pharmacy plans the development and implementation of its goals and evaluates its effectiveness in achieving them.

2.1 PHARMACY MANAGEMENT

- (a) The responsible pharmacist demonstrates a high standard of professionalism and a commitment to and the leadership of quality development.
- (b) The management structure of the pharmacy is documented with a clear allocation of duties and responsibilities established and properly recorded.
- (c) The responsible pharmacist is responsible for establishing and leading the quality work in the pharmacy.
- (d) The responsible pharmacist ensures that all regulations covering the operations of the pharmacy are complied with.
- (e) The pharmacy operation complies with all relevant legislation rules, regulations, codes, and guidelines of the South African Pharmacy Council.
- (f) The responsible pharmacist continually reviews his or her level of professional knowledge and expertise and documents an appropriate self-development plan.
- (g) The pharmacy manager participates regularly in continuing professional development programmes.
- (h) The extent and content of any documentation of pharmacy structures and processes will vary with the size and complexity of the pharmacy operation.

- (i) Quality service will be best achieved if all pharmacy staff are aware of the pharmacy owner/ responsible pharmacist's total commitment to quality improvement.
- (j) A collection of all legislation and guidelines relevant to the pharmacy is maintained in a current state and is accessible by all pharmacy staff.
- (k) Procedures exist to ensure that pharmacy staff are informed of any changes to legislation or other relevant codes or regulations.
- (l) Documented procedures are in place to ensure that pharmacy staff are aware of relevant legislation, and apply this to the handling, sale and required record keeping for medicines available for sale in the pharmacy.

2.1.1 Pharmacy Planning

The pharmacy, having established its mission and/or purposes engages in ongoing planning to achieve its strategic objectives.

- (a) The pharmacy's mission statement and/or statement of purposes are documented, regularly reviewed and understood by all staff.
- (b) Business and quality objectives are established, documented and form the basis of the pharmacy business plan. The objectives and plan are reviewed at least annually.
- (c) Contracts are established between the pharmacy and the healthcare provider being served which specify the terms of the relationship and the services provided.
- (d) The responsible pharmacist should be responsible for the preparation of: the mission statement and/or statement of purposes, the pharmacy strategic plan, contracts for the supply of services and the pharmacy's client profile and client expectations.
- (e) The mission statement and/or purpose statement should encapsulate the basic purpose of the pharmacy and include the vision, values and principles being followed in the pharmacy. It should encompass the services being offered, who provides the services, the clients and the pharmacy's intended impact on the community.
- (f) The pharmacy's mission will be consistent with the principles of pharmaceutical care and the quality requirements of the appropriate healthcare purchasers.
- (g) Through the planning process, the pharmacy staff should evaluate its mission and/or purposes. It should decide how these are to be met and assess progress, if necessary revising its goals, objectives, products and services.
- (h) A suitable planning process will allow for input from staff, clients and other groups or organisations involved with the pharmacy.
- (i) The planning process will incorporate research on pharmacy effectiveness, patient outcomes, demographics and other relevant areas.

2.2 QUALITY STANDARDS FOR PHARMACY

The pharmacy's quality objectives should reflect the need for both the provision of customer-focused services and the continuous improvement of quality.

The planning process will identify the human, financial and physical resources required for the pharmacy. This will influence the acquisition of resources and their allocation.

2.2.1 Quality Management

The pharmacy provides high quality service to its clients. Its management pursues continuous improvement in service quality through its assessment and improvement efforts. The process of quality improvement includes: monitoring the activity, assessing how well the activity is being carried out, establishing the areas where improvement is possible, taking action aimed at achieving improvement, evaluating the effectiveness of the action and the outcome.

- (a) The Quality Improvement Plan should detail:
 - the quality standards for services supplied by the pharmacy;
 - processes that operate in the pharmacy and the resources devoted to them (including staff);
 - how customer feedback will be obtained for services provided;
 - how other evidence supporting the achievement of quality standards will be obtained and recorded;
 - how resources and training relevant to the quality management responsibilities of each staff member are allocated;
 - the frequency of assessment of the plan to ensure that it is producing a continuous improvement of service
- (b) The responsible pharmacist develops, documents and approves the quality improvement plan for the pharmacy. This provides a systematic plan for each of the service areas in the pharmacy.
- (e) The quality improvement programme is assessed regularly.
- (f) A documented risk management system is integrated into the quality improvement process.
- (g) Standard operating procedures are developed, documented and used in the pharmaceutical and retail activities of the pharmacy and are reviewed on a regular basis.
- (h) Documentation of all pharmacy standards, procedures, policies and guidelines is comprehensive, current and readily available to all pharmacy staff. It is reviewed regularly.
- (i) Pharmacy staff are trained in the aspects of service quality management which are relevant to their work responsibilities.
- (j) All quality improvement planning, implementation and auditing should be appropriately documented.
- (k) Pharmacy staff should be involved to the maximum extent possible in the development and execution of the quality improvement plan and should be given regular feedback on the outcomes being achieved in quality improvement.
- (l) Pharmacy documentation should cover: legislative and professional requirements applicable to the operations of the pharmacy, standard operating procedures, contractual details and supply of goods and services.
- (m) All staff should be trained in the use of standard operating procedures.

- (n) The pharmacy manager should ensure that standards for the operation of pharmacy services are established and that performance against these standards is monitored.
- (o) The proper management of risk and the effort made to reduce risk levels, will contribute to the pharmacy's operation as a high quality enterprise.
- (p) Staff training in the quality area should be aimed at establishing familiarity with the quality improvement cycle, and confidence in its use.

2.2.2 Pharmacy Effectiveness

The pharmacy evaluates how well it is accomplishing its purposes and uses the results of these evaluations as a basis for broad-based continuous planning and development.

- (a) Pharmacy management monitors client satisfaction and analyses the degree to which it is being maintained.
- (a) Contracts with third parties specify a system of monitoring and review which is aimed at ensuring that the terms of the contract are met.
- (b) The responsible pharmacist and appropriate staff participate in regular professional audit activities to review the standard of clinical and non-clinical services. From the review process strategies are developed, documented and employed to improve performance.
- (c) Information from business, quality and outcome monitoring is utilised in the assessment of pharmacy effectiveness.
- (d) Client satisfaction is assessed from a variety of sources including complaints mechanisms, satisfaction surveys, outcome monitoring, informal feedback and indicators of service efficiency.
- (e) Lines of communication should be clearly specified between the pharmacy and healthcare providers which have a contractual or less formal relationship.
- (f) The pharmacist/pharmacists should participate in any clinical review and audit carried out by healthcare providers with whom the pharmacy has a contractual relationship.
- (g) Data on the content and frequency of use of the services being provided by the pharmacy should be recorded and available for analysis.
- (h) Systems should be developed to enable the pharmacy to collect reliable and valid data on health outcomes resulting from the pharmacist's clinical observation.

2.3 ETHICS AND PROFESSIONAL STANDARDS

A system should be in place, which enables staff to be kept informed about pharmacy business performance and developments in the economic and political environment, which could impact significantly on the pharmacy. The pharmacist and staff members should carry out, or participate in, research activities aimed at improving the effectiveness and efficiency of the pharmacy and the further development of pharmaceutical care.

2.3.1 Interprofessional relationships

The pharmacist maintains good working relationships with other health professionals in the healthcare team and participates in activities involving the effective supply of pharmacy services.

- (a) The pharmacist participates in medicine utilisation reviews, medical audits, medical care evaluations and clinical studies of medicines.
- (b) The pharmacist ensures that other health professionals are provided with medicine information and information concerning prescribing and dispensing practices.
- (c) Pharmacists should seek opportunities to provide information to other health professionals and groups on: developments concerning medicines, the general role of pharmacists, contents, packaging and processing of medicines, the ancillary services offered by the pharmacy.
- (d) A major emphasis of inter-professional teamwork should be the development of more effective and rational prescribing policies. The pharmacist has a major role in influencing such policies.

2.3.2 Closure of Pharmacies

When a pharmacy is closed the following information must be made available to members of the public-

- (a) the contact details of a pharmacist practising in the pharmacy in question;
- (b) information as to alternate facilities where pharmaceutical services can be obtained in an emergency;
- (c) details relating to when the pharmacy will be opened/closed, and that furthermore, as far as possible, the health of patients should not be compromised as result of the closure of a pharmacy.

2.3.3 Conditions under which a pharmacist may be absent from a pharmacy

Refer paragraph 2.2 of Chapter 4 for further details.

2.3.4 Standard Operating Procedures

A Standard Operating Procedure (SOP) is that set of instructions or steps which must be followed in order to complete a specific job or task safely, with no adverse impact on the environment, and in a way that maximises operational and production requirements. SOPs can be written for virtually any task undertaken in a pharmacy that has to be performed regularly and in a pre-determined way.

The responsible pharmacist is accountable for the existence of SOPs in a pharmacy and should be involved in the compilation of SOPs.

SOPs should –

- (i) provide personnel with all the safety, health, environmental and operational information necessary to perform a job properly;
- (ii) ensure that operations are performed consistently to maintain quality control of processes and products;
- (iii) ensure that processes continue uninterrupted and are completed timeously;
- (iv) ensure that no failures occur that could harm anyone;
- (v) ensure that approved procedures are followed in compliance with legislation;

- (vi) serve as a training document e.g. pharmacist interns or pharmacist's assistants;
- (vii) serve as a historical record of the how, why, when of steps in an existing process;
- (viii) serve as an explanation of steps in a process so they can be reviewed in incident investigation.

The following SOPs are required to be in place in

2.3.4.1 a community pharmacy –

- (a) pest elimination;
- (b) effective stock rotation;
- (c) destroying or removal of expired, damaged and/or contaminated stock;
- (d) product types requiring special storage or handling instructions;
- (e) separation and handling of goods returned from patients;
- (f) recall of medicine;
- (g) delivery of medicines;
- (h) handling of S6 medicines; and
- (i) cold chain management (including procedures to be followed in the event of a refrigerator power failure);

2.3.4.2 an institutional pharmacy -

- (a) pest elimination;
- (b) effective stock rotation;
- (c) destroying or removal of expired, damaged and/or contaminated stock;
- (d) product types requiring special storage or handling instructions;
- (e) separation and handling of goods returned from patients, wards, clinics, etc;
- (f) recall of medicine;
- (g) delivery of medicines;
- (h) handling of S6 medicines; and
- (i) cold chain management (including procedures to be followed in the event of a refrigerator power failure);
- (j) pre-packing (including quality assurance procedures);
- (k) compounding operations (including quality assurance procedures);
- (l) preparation of TPN/large volume parenterals (including quality assurance procedures);

- (m) oncology mixing (including quality assurance procedures);
- (n) preparation of IV additives (including quality assurance procedures);
- (o) control over medicine kept in places other than the pharmacy, e.g. wards, theatres, etc. (including controls over issuing ward stock and medicine per patient to the wards);

2.3.4.3 a wholesale pharmacy -

- (a) pest elimination;
- (b) effective stock rotation;
- (c) destroying or removal of expired, damaged and/or contaminated stock;
- (d) product types requiring special storage or handling instructions;
- (e) separation and handling of goods returned from patients;
- (f) recall of medicine;
- (g) delivery of medicines;
- (h) handling of S6 medicines;
- (i) cold chain management (including procedures to be followed in the event of a refrigerator power failure);
- (j) pre-packing (including quality assurance procedures);
- (k) handling of product complaints.

3. SPECIFIC GUIDELINES FOR QUALITY MANAGEMENT IN THE INSTITUTIONAL PHARMACY.

The responsible pharmacist or any other person licensed to dispense in terms of the medicines act, shall supervise the safety, security, purchasing, storage, and dispensing of medicines in a hospital.

3.1. MANAGEMENT

- (a) An updated manual reflecting all relevant policies must be available. All pharmacy personnel must have a sound knowledge thereof and apply them accordingly.
- (b) Short, medium and long-term planning for an effective and cost-effective pharmaceutical service should be done on a regular basis with priorities set out within financial and personnel structures.
- (c) The responsible pharmacist should be responsible for the annual estimates and budgets for medicine, and should take all the necessary measures to, as far as possible, ensure that expenditure remains within the budget.
- (d) Data for statistical analysis and financial information must be gathered and regular reports be made reflecting the methods employed to economise.
- (e) Lines of authority and areas of responsibility must be clearly defined and conform with labour legislation.

- (f) A manual with standard operating procedures governing all pharmacy functions must be prepared and revised in accordance with changing circumstances and needs. All pharmacy personnel should be familiar with the contents of such a manual and should practise in accordance with such manual.
- (g) Cost-effective and service orientated work schedules, systems and procedures which most effectively utilise pharmacy personnel and resources should be instituted and subjected to regular re-evaluation and in this way establish an acceptable standard of practice.
- (h) Policies and procedures should be developed for the provision of, or access to a pharmacy service on a twenty-four hour basis. Content of emergency cupboards and the supplying of medicine by persons other than pharmacists should be reduced to the absolute minimum and must be fully controlled by the pharmacy.
- (i) Medicines must only be provided for dispensing by persons other than pharmacists if such persons are duly licensed to dispense in terms of the Medicines Act.
- (j) The pharmacy must be represented on and actively involved in all appropriate hospital committees (e.g. the Infection Control Committee, Pharmacy and Therapeutics Committee, the Management Committee and the Financial Committee) where such committees exist.
- (k) Regular staff meetings of pharmacists should be held. Such meetings will promote improved administration and service.
- (l) The hospital pharmacy or institution should establish its own professional quality assurance committee. Quality assurance cannot be acquired without collaboration with other health professionals for those areas of mutual responsibility.

3.2. PHARMACY AND THERAPEUTICS COMMITTEES

- (a) The Pharmacy and Therapeutic Committee(s) has the primary purpose of advising and educating professional staff on all matters pertinent and relevant to the use of medical products in the hospital environment.
- (b) Regular liaison should be maintained to develop policies and procedures relating to the selection, rational, safe and effective use of medical products, surgical dressings and medicine administration systems within the hospital's boundaries.
- (c) Pharmacy and Therapeutic Committee(s) should be a multi-disciplinary focal point for all policy decisions relating to the control of medicines within the hospital environment.
- (d) Membership should be representative and could comprise clinicians (at least one physician and one surgeon), pharmacists, a nursing representative, and may also include a management representative, a junior hospital doctor and a general practitioner. Other disciplines may be included to reflect local requirements.
- (e) Terms of reference could include:
 - (i) The development of medicine policies;
 - (ii) The approval of a local formulary;
 - (iii) The pursuit of safety and economy in the use of medicines and prevention of medicine abuse;

- (iv) The provision of information on medicine costs and efficacy;
- (v) The monitoring of medicine use and expenditure; and
- (vi) The provision of information on new medicines.

3.3. ADVERSE REACTION REPORTING

Adverse drug reaction reporting must be done in accordance with the guidelines for reporting adverse drug reactions in South Africa as published by the Medicines Control Council (GNR. 7659 of 2 May 2003).

3.4. MANAGING FORMULARIES, CLINICAL GUIDELINES AND TREATMENT PROTOCOLS

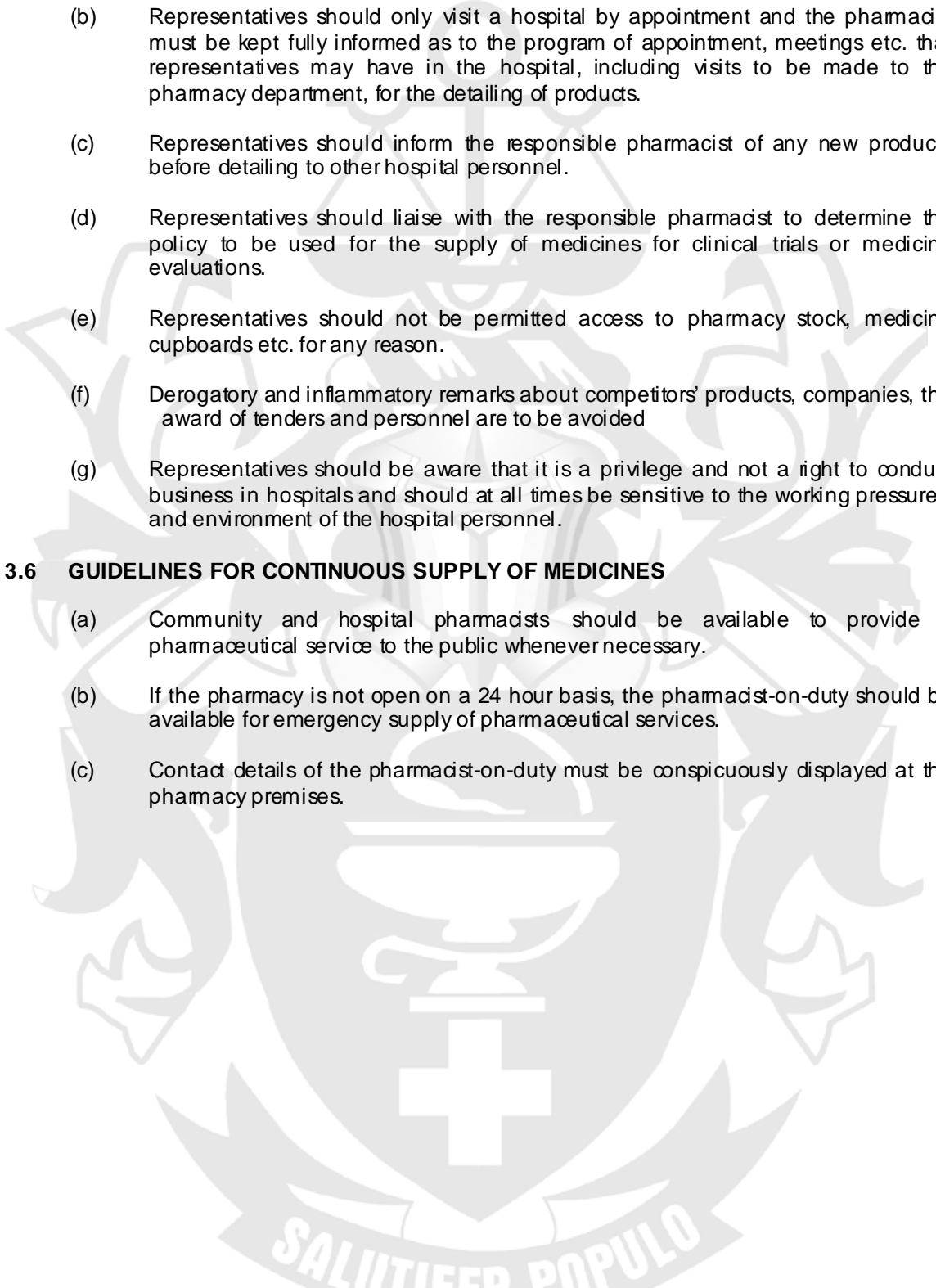
The effective management of formularies, clinical guidelines and treatment protocols promotes rational use of drug therapy in groups of patients. This important component of medicine resource management aims to improve the safety, efficacy and efficiency of medicine use in patient populations.

- (a) A local formulary is a compilation of medicines approved for use within the hospital and should reflect the current judgement of clinicians and pharmacists on the basis of efficacy, safety and costs. The formulary should be produced in co-operation with the Pharmacy and Therapeutic Committee.
- (b) The minimum requirements for a formulary should be a written list of approved medicines classified according to therapeutic use. The formulary can also contain:
 - (i) information on the method of use of the formulary;
 - (ii) local procedures governing the prescribing of medicines;
 - (iii) relevant pharmaceutical policies and procedures controlling medicine distribution;
 - (iv) advice on the selection of medicines from within the formulary;
 - (v) information on special aspects on the use of medicines;
 - (vi) the procedure for amending the formulary;
 - (vii) the procedure for obtaining a non-formulary item for an individual patient.
- (c) There should be agreed procedures for medicines to be added to, or deleted from the formulary.
- (d) The responsible pharmacist should update, maintain and monitor the formulary system on behalf of the Pharmacy and Therapeutics Committee.

3.5. GUIDELINES FOR VISITS BY PHARMACEUTICAL REPRESENTATIVES

Pharmaceutical representatives can play an important role in the introduction and marketing of medicinal products in hospitals. They can also provide a valuable educational service and supply up-to-date information on the latest developments in the pharmaceutical field. It is therefore in the interest and benefit of hospitals if representatives and the responsible pharmacist work closely together.

The following guidelines apply to visits by representatives:

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- (a) Representatives on their first visit to a hospital must consult with the responsible pharmacist on the internal rules and regulations regarding visits by pharmaceutical representatives to the particular hospital, as procedures may vary.
 - (b) Representatives should only visit a hospital by appointment and the pharmacist must be kept fully informed as to the program of appointment, meetings etc. that representatives may have in the hospital, including visits to be made to the pharmacy department, for the detailing of products.
 - (c) Representatives should inform the responsible pharmacist of any new products before detailing to other hospital personnel.
 - (d) Representatives should liaise with the responsible pharmacist to determine the policy to be used for the supply of medicines for clinical trials or medicine evaluations.
 - (e) Representatives should not be permitted access to pharmacy stock, medicine cupboards etc. for any reason.
 - (f) Derogatory and inflammatory remarks about competitors' products, companies, the award of tenders and personnel are to be avoided
 - (g) Representatives should be aware that it is a privilege and not a right to conduct business in hospitals and should at all times be sensitive to the working pressures and environment of the hospital personnel.

3.6 GUIDELINES FOR CONTINUOUS SUPPLY OF MEDICINES

- (a) Community and hospital pharmacists should be available to provide a pharmaceutical service to the public whenever necessary.
- (b) If the pharmacy is not open on a 24 hour basis, the pharmacist-on-duty should be available for emergency supply of pharmaceutical services.
- (c) Contact details of the pharmacist-on-duty must be conspicuously displayed at the pharmacy premises.

CHAPTER 6

GUIDELINES FOR INSPECTIONS OF PHARMACIES BY INSPECTORS OF COUNCIL

1. INTRODUCTION

In adhering to Good Pharmacy Practice standards it should be taken into consideration that pharmacists are obliged to exercise proper and/or reasonable care in respect of and control over –

- (a) the acquisition, storage, manufacture, dispensing, sale, supply or disposal of medicines, or of raw materials for the manufacture of medicines, for human or veterinary use;
- (b) chemical and hazardous substances;
- (c) access of the public to scheduled substances;
- (d) the hygiene, cleanliness and neatness of a pharmacy;
- (e) the appearance of a pharmacy, which failure may result in the dignity of the profession being harmed or potentially harmed.

Each section sets out standards for pharmaceutical facilities which must be met. Failure to meet the standards could form the basis of a complaint of misconduct.

2. COUNCIL INSPECTIONS

The duties of pharmacists appointed by Council as inspectors include the performance of routine inspections of pharmacies and pharmacy departments.

- (a) The powers of inspectors are derived from Sections 38A and 49(1)(l) of the Pharmacy Act, 1974 wherein Council is authorised to make regulations determining the powers, duties and functions of officers of Council.
- (b) Routine inspections are carried out in order to -
 - (i) educate pharmacists by regularly drawing attention to the regulations and guidelines which govern the practice of pharmacy; and
 - (ii) detect areas of non-compliance with the regulations and guidelines.
- (c) A routine inspection may be the main reason for a visit by an inspector. Inspections may also be carried out in conjunction with an investigation into the conduct of a pharmacist or to approve the pharmacy for training purposes.
- (d) It is the aim of Council to inspect pharmacies routinely approximately every two years.
- (e) On completion of the inspection, a copy of the report is made available to the responsible pharmacist. In the comments section of the report any matters, which need prompt attention are mentioned. The responsible pharmacist is expected to take prompt steps to comply with the inspector's suggestions.
- (f) When the points noted on the report are relatively minor, Council takes no further action. For more serious breaches, however, a re-inspection is carried out within the next few weeks (when it is expected that the matters referred to in the report

will be rectified). In the event that the matters noted have not been rectified at the time of the second inspection, Council then considers taking more formal disciplinary action.

REGISTRAR
December 2003

