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BOARD NOTICE

BOARD NOTICE 129 OF 2004

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

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

SCHEDULE

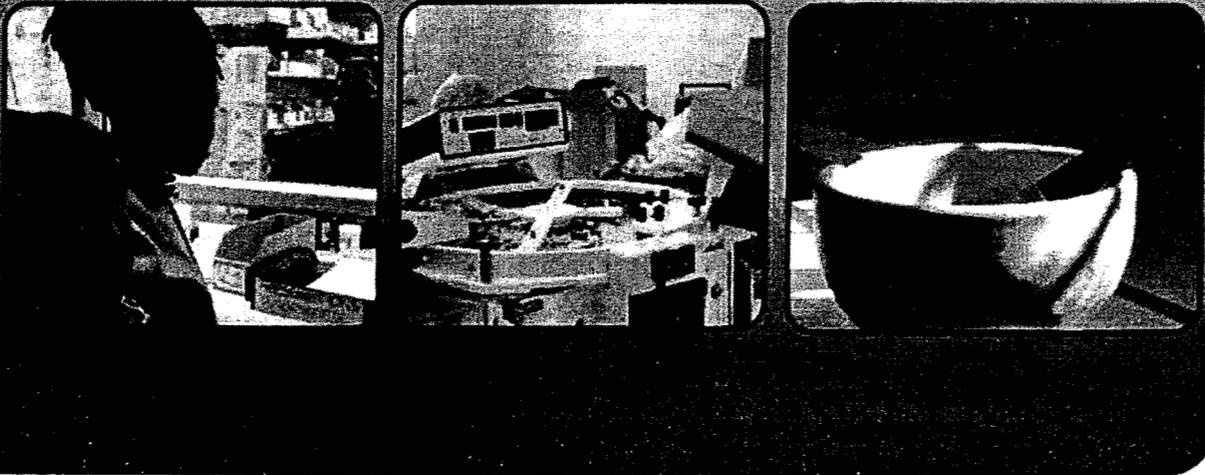
Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy 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 Standards as published herewith as Annexure A shall constitute good pharmacy practice in accordance with section 35A(b)(ii) of the Act.

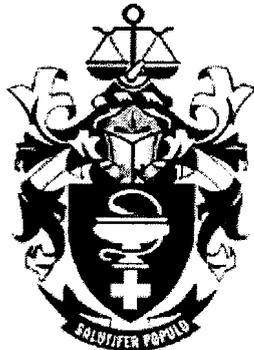


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GOOD PHARMACY PRACTICE IN SOUTH AFRICA



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THE SOUTH AFRICAN
PHARMACY COUNCIL

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THE SOUTH AFRICAN PHARMACY COUNCIL

GOOD PHARMACY PRACTICE IN SOUTH AFRICA

INTRODUCTION

The vision of the South African Pharmacy Council ("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 basis of pharmaceutical sciences there must thus be adequate emphasis on the action and uses of medicines, a reasonable introduction to disease states and the relevant elements of the social and behavioural 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 and complies with Good Pharmacy Practice Standards as published by Council in rules. This document (Good Pharmacy Practice in South Africa) indicates how that obligation can be met. Good Pharmacy Practice is obligatory in terms of Section 35A of the Pharmacy Act 53 of 1974, as amended ("the Pharmacy Act"), Regulation 20(1) of the **Regulations Relating to the Practice of Pharmacy** and Regulation 7(a) of the **Regulations Relating to the Ownership and Licensing of Pharmacies** published in terms of the Pharmacy Act as well as Regulation 18(7)(b) of the General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965, as amended (the "Medicines Act").

THE UNDERLYING PHILOSOPHY

Pharmacy as a dynamic, information-driven, patient-orientated profession, through its infrastructure, competence and skills, is committed to fulfil 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 other members of the health care team in the interest of the patient; and
- (i) profession committed to cost-effective pharmaceutical services.

THE SCOPE OF PRACTICE OF PHARMACISTS

In order to fulfil the needs relating to pharmaceutical care of the people of South Africa, the scope of practice of the pharmacy profession has been prescribed in terms of Section 35A of the Pharmacy Act.

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 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, re-packaging, 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 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 re-packaging of medicines; and
- (i) the initiation and conducting of pharmaceutical research and development.

GOOD PHARMACY PRACTICE REQUIREMENTS

Good pharmacy practice requirements could thus be summarised as follows:

- (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) Where applicable, pharmacists must adhere to Good Manufacturing Practice as determined by the Medicines 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 care 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 regarding 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 from the pharmacist;
- (v) the pharmacist must 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 must be professionally rather than commercially orientated;
- (viii) pharmacists in each field of practice must accept personal responsibility for the self-assessment and maintenance of competence throughout their involvement in the profession;
- (ix) good pharmacy practice as published in rules by Council must be adhered to by all pharmacists practising in South Africa; and
- (x) educational programmes 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.

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

- (a) Professional standards for premises.
- (b) Professional standards for services.
- (c) Professional standards for pharmacy human resources.
- (d) Professional standards for pharmacy management.

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 standards be kept at hand for easy reference in all situations.

It must be noted, however, that in cases where a particular issue is dealt with in terms of other legislation, including for example the acts and regulations dealing with employment, occupational health and safety and the public service, the requirements of the relevant legislation will take precedence over the standards laid down in this document.

GENERAL OBJECTIVES AND REQUIREMENTS OF PHARMACEUTICAL SERVICES

The following broad objectives and requirements are common to pharmaceutical services provided by pharmacists:

- (a) A sound **management structure** must be established to ensure efficient practice. The structure must 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 must be established.
- (b) **Quality assurance** must be an integral part of pharmaceutical practice.
- (c) **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.
- (d) **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 must take into account the need to protect staff from hazardous processes or materials and the safe disposal of all waste.

- (e) Effectivesystems of **drug supply management** must be provided to ensure efficiency and economy.
- (f) A **prescription monitoring service** must be established 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.
- (g) The **counselling of patients** or their caregivers must be undertaken to promote the correct and safe use of medicines. The responsible pharmacist must ensure that patients are counselled before they receive medicines that they are to self-administer, when they are discharged, transferred or treated as outpatients.
- (h) **Medicine information** must 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 and the public.
- (i) Pharmacists must be available to contribute actively to **health education** programmes in schools, community clinics, patient support groups and any area where compliance is particularly important.
- (j) 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 must co-ordinate any adverse reaction reporting service.
- (k) A pharmaceutical service must be readily **available and appropriate** for both advisory and logistical purposes. The service must reflect the level of use of medicines for patient care groups.
- (l) Pharmacists must initiate, conduct, participate in and support **research** into any pharmaceutical subject in the practice environment.
- (m) Pharmacists must be involved in **clinical trials** including for example, the development of protocols, be responsible for medicine supplies, monitor administration protocols and maintain trial registers.

CHAPTER 1

PROFESSIONAL STANDARDS FOR PREMISES

MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

1.1 INTRODUCTION

The keeping, compounding, dispensing or supply of any medicine or scheduled substance by a pharmacist, pharmacist intern or pharmacist's assistant or the provision of services which form part of the scope of practice of a pharmacist, may only take place in or from a pharmacy if the pharmacy complies with minimum standards relating to premises, facilities and equipment and is duly licensed by the Department of Health and recorded in terms of the Pharmacy Act.

In adhering to minimum standards of good pharmacy practice it must 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 medicines and scheduled substances;
- (d) the hygiene, cleanliness and neatness of a pharmacy;
- (e) the appearance of a pharmacy.

Each section sets out minimum standards for premises, facilities and equipment for community, institutional, and mobile pharmacies as well as primary health care facilities, which must be met. Failure to meet the standards could form the basis of a complaint of misconduct and in some instances even the withdrawal of a licence to own a pharmacy in terms of the Pharmacy Act.

Manufacturing pharmacies, wholesale pharmacies and distributors must comply with standards as prescribed in the Guidance Document: Good Manufacturing Practice published by the Medicines Control Council (MCC) (GNR.7659 of 2 May 2003) and Good Wholesale Practice for Wholesalers, Distributors and Bonded Warehouses (MCC 6 June 2003).

Good pharmacy practice standards for persons licensed to dispense in terms of the Medicines Act are provided in section 1.7 of this chapter.

1.2 MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

1.2.1 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 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 displayed conspicuously over the main entrance of a pharmacy.
- (d) The name of the pharmacist(s) on duty must be displayed conspicuously in or outside the pharmacy for purposes of identification of such person(s) by the public.
- (e) The pharmacist(s) on duty must wear a name tag or badge indicating his/her name and designation for the purposes of identification of such person by the public.
- (9)** The external appearance of pharmacies must inspire confidence in the nature of the health care service that is provided and portray a professional image.
- (g) Entrances, dispensing counters and doorways must be accessible to disabled persons.

1.2.2 ANOTHER BUSINESS OR PRACTICE IN A PHARMACY OR A PHARMACY IN ANOTHER BUSINESS

- (a) The responsible pharmacist of a pharmacy must obtain the approval of Council, prior to allowing a person who is not registered with Council, to conduct a separate practice or business in the pharmacy.
- (b) The pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice.

1.2.3 SECURITY IN PHARMACY PREMISES

- (a) Careful consideration must be given to the overall security of the pharmacy. It must be lockable and as far as possible exclude any unauthorised entry.
- (b) A security policy must be implemented which is designed to ensure as far as possible the safety of both staff and medicines, and must take account of local crime prevention advice.

1.2.4 CONTROL OF ACCESS TO PHARMACY PREMISES

- (a) The responsible pharmacist of a pharmacy must ensure that every key, key card 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) Control of access to pharmacy premises, which would include the design and layout of the pharmacy, must be of such a nature that only registered pharmacy personnel have direct access to medicine.
- (c) A procedure must be in place to ensure access to pharmacy premises in an emergency situation in compliance with the Occupational Health and Safety Act 85 Of 1993.

1.2.5 SAFETY OF PHARMACY PREMISES

- (a) Working conditions must be arranged to protect the safety of the public and people working on the premises and comply with relevant legislation relating to safety in the workplace.
- (b) There must be a fire extinguisher in the pharmacy which must be checked regularly
- (c) All staff must be familiar with the fire procedure.
- (d) Electrical equipment must be safe and maintained regularly.

(e) Proper provision must be made for an adequate number of electrical sockets. Care must be taken to avoid trailing wires across floors, work surfaces or sinks.

(9) A health and safety procedure must be available and read and signed by all staff.

1.2.6 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) Countertops, shelves and walls must be finished in a smooth, washable and impermeable material which is easy to maintain in a hygienic condition.

1.2.7 CONSTRUCTION OF PHARMACY PREMISES

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

1.2.8 ENVIRONMENT IN PHARMACY PREMISES

(a) Storage of thermolabile medicines must be in accordance with the storage instructions of the manufacturer.

(b) Refrigerators used for the storage of thermolabile medicine must be calibrated regularly.

(c) Products must be protected from the adverse effects of light, freezing or other temperature extremes and dampness.

(d) Levels of heat, light, noise, ventilation, etc., must exert no adverse effects on pharmaceutical stock as well as personnel.

(e) All parts of the premises must have suitable and effective means of heating or cooling, lighting and ventilation. If windows can be opened, they must be locked securely when the pharmacy is closed.

(9) Background music or other broadcasts in the pharmacy must not be played at such a volume so as to cause distraction.

1.2.9 HYGIENE IN PHARMACY PREMISES

(a) There must be an area where equipment and other utensils can be washed which has a source of hot and cold tap water.

(b) There must be a suitable, clean wash hand basin made of a smooth, washable and impermeable material which is easy to maintain in a hygienic condition and has a source of hot and cold tap water and a closed drainage system.

(c) Toilet facilities must be kept clean and in good order.

(d) 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 and clean towels or other satisfactory means of drying the hands.

(e) Toilet areas must not be used for storage, or as a source of water for dispensing.

1.2.10 STORAGE AREAS IN PHARMACY PREMISES

- (a) Storage areas must have sufficient shelving constructed from a smooth, washable and impermeable material, which is easy to maintain in a hygienic condition for the keeping of medicines above floor level.
- (b) Storage areas for pharmaceuticals must be self-contained and secure.
- (c) Storage areas must be large enough to allow for orderly arrangement of stock and proper stock rotation.

1.2.11 DISPENSARY**1.2.11.1 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 must be designed to accommodate the forecast workload and the maximum available space must be allocated. In existing pharmacies space requirements must be monitored on a continuing basis.

1.2.11.2 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 must be sufficient for the volume of prescriptions dispensed. A clear working surface area of at least 90cm by 1 m must be provided for each pharmacist or other person registered with Council who works in the dispensary.
- (c) The temperature in the dispensing area must be maintained below 25°C and there must be an air conditioner installed in the dispensary which is in good working order.

1.2.11.3 Waste disposal

- (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 must be collected in suitable covered (as applicable) receptacles for removal to collection points.
- (c) Written sanitation procedures must be available detailing schedules, methods, materials and equipment available. Responsibility must be assigned in writing.
- (d) Under no circumstances must substances be disposed of down surface water drains, e.g. storm water drains.
- (e) In all situations, a pharmacist must 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, and bio-medical waste safely and in accordance with regulations.

1.2.11.4 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 standard. Equipment must be specific for each service which may be 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 (if compounding is performed in the pharmacy).
- (c) A range of graduated, stamped glass or plastic measures.
- (d) A refrigerator equipped with a suitable 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. This refrigerator must **be** used only for storing pharmaceutical products. Where applicable, a freezer for the storage of polio and measles vaccines and ice packs must be available.
- (e) A suitable range of dispensing containers for medicinal products. The use of child-resistant closures is 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 **must** be the latest version available.
- (g) An ointment tile and spatula, stirring rods, pestles, mortars and other appropriate equipment (if compounding is performed in the pharmacy).
- (h) Where sterile or aseptic dispensing is to be carried out in accordance with the Medicines Act, suitable facilities must **be** available.
- (i) Where cytotoxic or other hazardous substance preparation is to **be** carried out in accordance with the Medicines Act, a suitable cabinet that complies with generally accepted GMP standards must be provided.
- (j) Suitable means for sterilisation of medicinal products if products that require sterilisation are prepared in the pharmacy.
- (k) Suitable refuse receptacles.

1.2.11.5 Reference sources

The following reference material in the current editions (unless **otherwise** indicated) must **be** available for consultation in all pharmacies:

- (a) one of the last three (**3**) editions of Martindale;
- (b) MIMS;
- (c) Daily Drug Use (Tincture Press Publications) or other drug interactions reference source;
- (d) MDR or SAMF;
- (e) a comprehensive textbook on Pharmacology;
- (**9**) a medical dictionary;
- (g) the latest copy of the Pharmacy Act 53 of **1974**, as amended, and the Medicines and Related Substances Act 101 of **1965**, as amended;

- (h) a Good Pharmacy Practice Manual;
- (i) a comprehensive textbook on complementary medicine (where applicable);
- (j) a Paediatric Dosing Reference Guide (where applicable);
- (k) Pharmacopoeia (BP, USP, EP) (where applicable);
- (l) the latest copy of the Standard Treatment Guidelines and Essential Drug List for the appropriate level of care.

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 in exceptional circumstances apply to Council for a relaxation of the minimum requirements relating to reference books.

1.2.12 WAITING AREA

- (a) A waiting area(s), which is under cover, must be situated near the dispensing area, areas for counselling and the furnishing of information and/or consultation areas.
- (b) Comfortable seating must be provided.
- (c) The amount of seating available in the waiting area must depend on the number of patients expected to arrive in/at the pharmacy any one time.
- (d) Appropriate health-related literature must be provided.

1.2.13 AREAS FOR COUNSELLING AND THE FURNISHING OF ADVICE

A minimum standard for pharmacies where medicines are supplied directly to the public is a suitable area for the furnishing of advice to patients in a reasonably private environment. The following minimum standards apply:

- (a) The area(s) must be easily accessible and, where possible, be close to the dispensary.
- (b) Clear directions must be provided if the area is not close to the dispensary.
- (c) The area(s) 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 area(s) must have a professional appearance and be kept clean and tidy.
- (e) The area(s) must have sufficient space to promote appropriate counselling and demonstration of the correct and safe use of specific medicines as required.

1.2.13.1 Types of areas for the furnishing of information and advice and the counselling of patients

Three types 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;
- (b) a private area;
- (c) a consultation area for the provision of screening and monitoring services.

Every pharmacy must have at least one type of area for the furnishing of information and advice. In cases where a pharmacy only has a semi-private area available, there must in addition be access to another separate room/area (which does not necessarily form part of the pharmacy) where communication can take place between a pharmacist and a patient in private.

Standards for the different types of areas, including the equipment required, are provided below.

1.2.13.2 Semi-private area

This area is for the provision of information and/or advice that may occur 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. Another option is an aperture which is surrounded by a "telephone booth" type structure to prevent other persons from crowding around the patient who is communicating with the pharmacist. Figure 1 is a schematic representation of an example of 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.

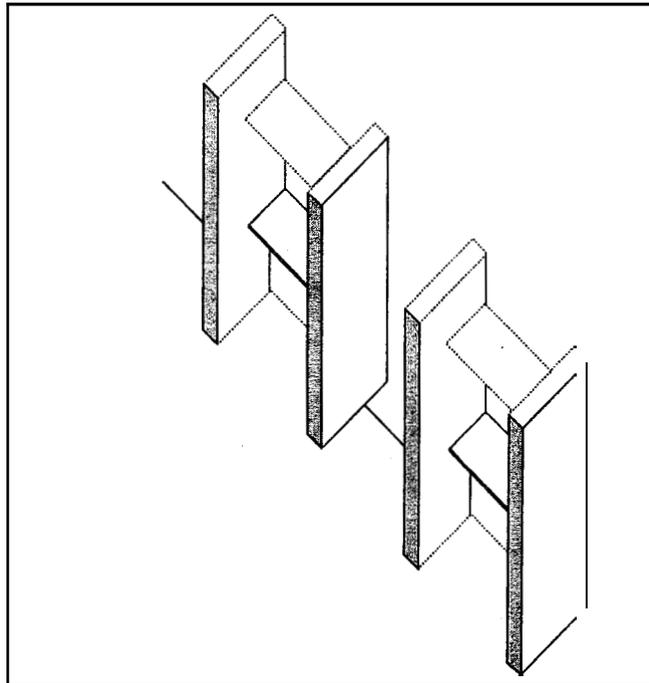


Figure 1: Semi-private counselling area

1.2.13.3 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 to the area 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 an example of a private area for the furnishing of advice.

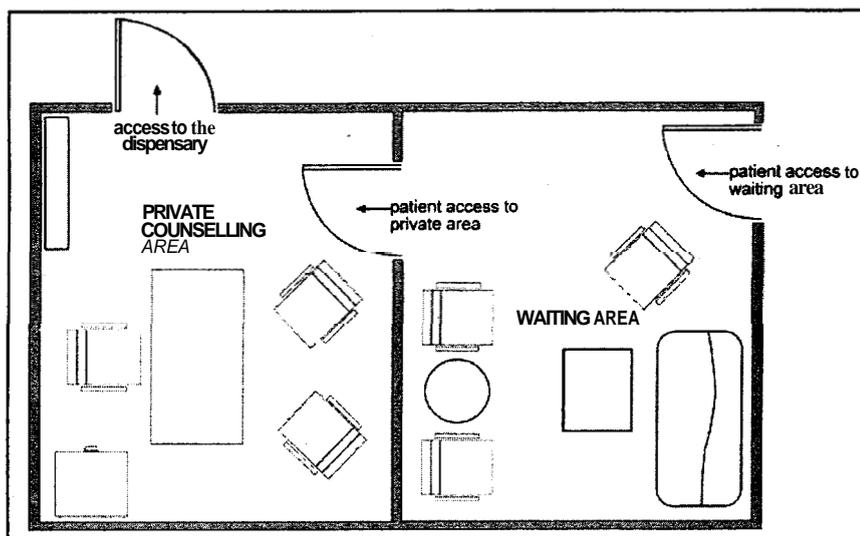


Figure 2: Private Counselling Area

1.2.13.4 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 services, e.g. cholesterol tests or blood pressure monitoring.

1.2.13.4.1 Location

- (a) The consultation area must have a professional appearance and must be kept clean and tidy. Figure 3 is a schematic representation of such a consultation area.
- (b) The consultation area should have sufficient space (at least 15 square meters)
- (c) The working surface in the area must be of impermeable washable material.
- (d) The area must at least have the following:
- (i) an examination couch with spare clean sheets;
 - (ii) a suitable trolley and/or cabinet for the necessary equipment;
 - (iii) an emergency tray;
 - (iv) applicable facilities for the taking and analysis of urine and/or blood samples where necessary;
 - (v) a wash hand basin with hot and cold running water;
 - (vi) a closable rubbish bin with a lid and disposable plastic liners;
 - (vii) effective equipment for record keeping; and
 - (viii) a biohazardous materials bin and sharps container.

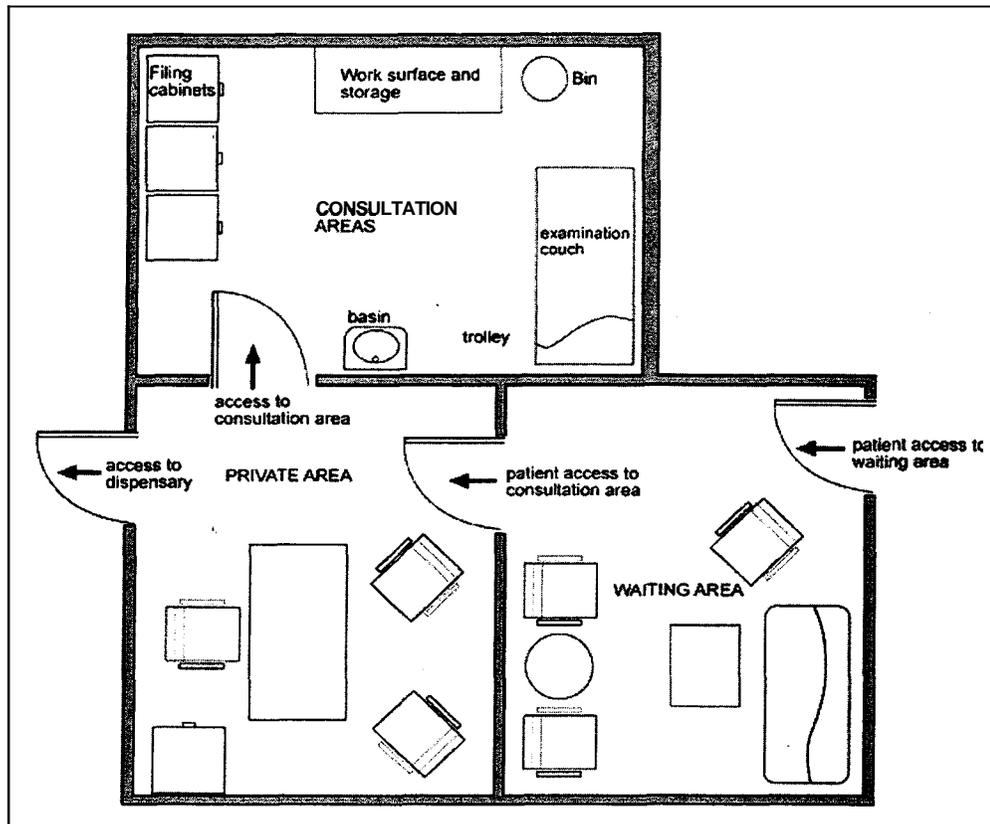


Figure 3: Consultation Area

- (e) It is advisable to have a refrigerator with a freezing compartment in the consultation area, especially when immunisation services are provided.
- (9) 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.

1.2.13.4.2 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;
- (9) 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% gluteraldehyde. 1% halocide, sodium hydrochloride, biodecyl 1%) for equipment and clothing/fabric, ready prepared;
- (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.

1.3 MINIMUM STANDARDS RELATING SPECIFICALLY TO INSTITUTIONAL PHARMACIES

Minimum standards for pharmacy premises, facilities and equipment are stipulated in items 1.2.1 to 1.2.13 above and must be met. The following additional standards relate specifically to institutional pharmacies:

- (a) the pharmacy must be located in an area easily accessible to patients and staff of the hospital/institution;
- (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 must allow proper workflow and segregation of activities;
- (d) there must be sufficient and suitable space and facilities for normal dispensing activities as well as where necessary for ward and clinical services, compounding, pre-packing, parenteral admixture preparation, other aseptic compounding and cytotoxic preparation;
- (e) a suitable area and facilities (space, equipment, journals, books) for providing a medicine information service must be provided where applicable;
- (f) offices should be appropriate for the size of the pharmacy and personnel structure;

- (g) separate service areas for outpatients and staff must be provided that are large enough to allow effective communication. In addition, separate facilities for the provision of information or advice must be provided to ensure confidentiality of discussion;
- (h) where compounding and pre-packing are to be carried out in accordance with the Medicines Act, suitable separate facilities that comply with GMP standards must be provided;
- (i) where radioactive pharmaceuticals are to be prepared in accordance with the Medicines Act, the premises must comply with the requirements for aseptic preparation and be in line with GMP standards. The premises must also meet the requirements for radioactive products and a suitable cabinet that complies with GMP standards must be provided;
- (j) there must be separate and secure goods receiving area(s), which is under cover;
- (k) there must be a separate and secure goods dispatch area.

1.4. MINIMUM STANDARDS FOR PHARMACIES PROVIDING MOBILE PHARMACEUTICAL SERVICES

1.4.1 PRE-REQUISITES FOR CONDUCTING MOBILE PHARMACEUTICAL SERVICES

- (a) Mobile pharmaceutical services may only be provided at the place or places licensed by the Director-General and recorded as such by Council.
- (b) Only medicine, medicinal and relevant products and/or approved supplementary services may be sold/provided from a mobile unit.
- (c) The mobile unit 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.

1.4.2 MOBILE UNIT, FACILITIES AND EQUIPMENT

- (a) The mobile unit must be -
 - (i) insulated with double-sided side panels and ceiling; and
 - (ii) 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) If supplementary services such as approved screening tests are provided, suitable facilities must be available.
- (g) The working surfaces/space within the mobile unit must be large enough to allow at least two persons to perform dispensing functions or the provision of supplementary services under safe conditions.

1.5 MINIMUM STANDARDS FOR PHARMACIES OPERATING INTERNET SITES

Internet websites which sell medicine (S1-6) directly to the public must be operated by and constitute part of a pharmacy licensed by the National Department of Health (NDOH) and recorded with Council. Such a website must fall under the authority of the responsible pharmacist of the pharmacy of which it forms a part, and be operated in compliance with all relevant legislation including the Pharmacy Act, the Medicines Act and Good Pharmacy Practice. An Internet site cannot exist/operate independently of a pharmacy. The following standards apply -

- (a) The decision to sell a medicine must be made by a pharmacist who must be available for consultation with clients.
- (b) The handling of prescriptions must be in compliance with all legislation that applies to the supply of medicine including that -
 - (i) a pharmacist must verify the authenticity of all electronic prescriptions;
 - (ii) a permanent copy of all electronic prescriptions must be recorded and filed;
 - (iii) all electronic prescriptions must be followed by the original prescription within seven working days;
 - (iv) only the prescriptions of persons authorised to prescribe in South Africa may be dispensed (NOTE - prescribers not registered in South Africa are not authorised prescribers in this country);
 - (v) the website must be operated in compliance with all regulations and rules regarding the transparent pricing system for medicine and scheduled substances, the advertising of medicine and the services for which a pharmacist may levy a fee and guidelines for levying of fees.
- (c) The home page of any pharmacy Internet site must identify the website as being operated by a pharmacy licensed by NDOH and recorded with Council and must provide at least the following information:
 - (i) the registration number (Y number) of the pharmacy;
 - (ii) the physical and postal address of the pharmacy;
 - (iii) telephone number(s) to contact the pharmacy;
 - (iv) the name of the responsible pharmacist;
 - (v) the hours that a pharmacist is available for consultation.
- (d) Patient health information must be collected, recorded and used in a manner that protects confidentiality and privacy.
- (e) The Internet site must provide information to the public regarding policies and procedures for the following:
 - (i) counselling patients on new and repeat prescriptions;
 - (ii) counselling patients on medicines sold without a prescription;
 - (iii) delivery of medicine;
 - (iv) return of medicines;

- (v) complaints procedures;
 - (vi) confidentiality of patient information;
 - (vii) hours of provision of service or hours of business of the pharmacy.
- (f) The responsible pharmacist must inform Council of any information as required in terms of the Pharmacy Act as well as the following:
- (i) when a pharmacy is going to be conducting business over the Internet;
 - (ii) the Internet address;
 - (iii) nature of the business (e.g. Rx, OTC or both, specialties, etc.);
 - (iv) the telephone number if different from the pharmacy.
- (g) The Internet operation must be available for onsite inspection by Council inspectors.
- (h) Pharmacists remain professionally liable regardless of any disclaimers which may be posted on the website.

1.6 MINIMUM STANDARDS FOR THE SUPPLY OF MEDICINES IN A PRIMARY HEALTH CARE CLINIC

1.6.1 CLASSIFICATION AND MANAGEMENT OF FACILITY

- (a) The provision of services and/or acts regarded to be acts specially pertaining to the scope of practice of a pharmacist (pharmaceutical services) in a primary health care clinic or mobile clinic must be managed, monitored and supervised by the responsible pharmacist of the institutional pharmacy in a public health facility from which the services are managed or by a pharmacist designated by a province or a local authority, e.g. a district pharmacist, who shall be accountable to Council for compliance with the applicable legislation relating to the services which pertain to the scope of practice of a pharmacist in the primary health care clinic(s) under his or her supervision.
- (b) In cases where the pharmaceutical services in a primary health care clinic or mobile clinic are not provided by a pharmacist, they must be provided by a pharmacist's assistant (post-basic) working under the indirect supervision of a pharmacist or alternatively a person licensed to dispense medicine in terms of Section 22C(1)(a) of the Medicines Act.
- (c) The responsible pharmacist of the institutional pharmacy in a public health facility from which the services are managed/provided or the pharmacist designated by a province or a local authority in 1.6.1 (a) above must submit to Council, a list of the names and details of the primary health care facilities which are managed by the responsible pharmacist or the designated pharmacist on a form approved and provided by Council. Council must be notified in writing by the relevant pharmacist of any change to the information provided, within 30 days of the change taking place.
- (d) The details of the primary health care facilities managed by the responsible pharmacist of an institutional pharmacy in a public health care facility or a pharmacist designated in 1.6.1(a) must be recorded by Council.
- (e) At primary health care clinics where the service is provided by a pharmacist's assistant(s) (post-basic) in accordance with his/her scope of practice, indirect supervision may only take place under the following circumstances:
- (i) a pharmacist must visit and document visits to the clinic for purposes of monitoring, supervision and support at least once a month;

- (ii) a pharmacist based at the pharmacy from which the service is provided or the pharmacist designated in 1.6.1(a) must provide written and updated protocols and Standard Operating Procedures describing clearly the responsibility of the pharmacist's assistant;
 - (iii) re-packaged medicines or patient-ready packs must be provided to the facility.
- (9) The name of the pharmacist's assistant (post-basic) on duty must be displayed conspicuously in or outside the dispensary for purposes of identification of such person(s) by the public.
- (g) The pharmacist's assistant (post-basic) on duty must wear a name tag or badge indicating his/her name and designation for the purposes of identification of such person by the public.
 - (h) At primary health care clinics where the service is provided by licensed dispensers (e.g. doctors or nurses), a pharmacist must visit the clinic for purposes of monitoring and support on a monthly basis.
 - (i) The name of the licensed dispenser(s) on duty must be displayed conspicuously in the primary health care clinic for purposes of identification of such person(s) by the public.
 - (j) The licensed dispenser on duty must wear a name tag or badge indicating his/her name and designation for the purposes of identification of such person by the public.
 - (k) Compounding of medicine may only be performed at a primary health care clinic by a pharmacist or a pharmacist's assistant (post-basic) under the indirect supervision of a pharmacist provided that the necessary equipment for the compounding of medicine as described in Section 1.2.11.4 of this manual is available in the clinic.

1.6.2 DESIGNATION OF DISPENSARY OR MEDICINE ROOM

In a primary health care clinic where -

- (a) the services are provided by a pharmacist's assistant (post-basic) there must be a suitable room assigned for use as a **dispensary**;
- (b) the services are provided by a licensed dispenser in the consulting rooms in the primary health care clinic there must be a suitable room designated as a **medicine room for use as a storage area for medicine**. In such a facility the following standards must be observed:
 - (i) the dispensing must be done in the consulting room(s) and not in the medicine room;
 - (ii) no medicine may be stored in the consulting room(s) except in situations where there is an air-conditioner installed and the temperature is controlled;
 - (iii) where medicine is stored only in the medicine room, medicines or scheduled substances must be transported to the consulting room(s) on a daily basis in, for example, a lockable medicine trolley or tray;
 - (iv) control of access to the medicine room and the consulting room(s) (as applicable) must be of such a nature that only licensed dispenser(s) has direct access to medicines.

1.6.3 CONDITION OF A DISPENSARY OR MEDICINE ROOM

- (a) The walls, floors, windows, ceiling, woodwork and all other parts of the dispensary or medicine room 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 by insects, birds or rodents.
- (b) Countertops, shelves and walls must be finished in a smooth, washable and impermeable material which is easy to maintain in a hygienic condition.-----
- (c) Light conditions, temperature and humidity within the dispensary or medicine room must comply with the requirements for the storage of medicine, other pharmaceutical products, and packaging materials.
- (d) The dispensary, its fittings and equipment must be adequate and suitable for the purpose of dispensing.
- (e) The working surface area in a dispensary must be sufficient for the volume of prescriptions dispensed.
- (9) The temperature in the dispensary/medicine room must be below 25°C.
- (g) The dispensary/medicine room must have the following fixtures/fittings:
 - (i) an air-conditioner in good working order;
 - (ii) a refrigerator in good working order (see below);
 - (iii) a wash hand basin with hot and cold water.
- (h) In facilities where there is a designated dispensary, a suitable area for the furnishing of advice and a waiting area for patients must be provided which comply with the standards laid down in sections 1.2.12 and 1.2.13 respectively.

1.6.4**STORAGE AREAS IN A DISPENSARY OR MEDICINE ROOM**

- (a) Storage areas must have sufficient shelving constructed from smooth, washable and impermeable material, which is easy to maintain in a hygienic condition.
- (b) No medicines may be stored on the floor.
- (c) Storage areas for medicines must be self-contained and secure.
- (d) Storage areas **must** be large enough to allow orderly arrangement of stock and proper stock rotation.

1.6.5**EQUIPMENT FOR DISPENSARY OR MEDICINE ROOM OR CONSULTING ROOM**

There must be adequate, suitable equipment for the dispensing of medicine in the facility. Each item must be clean, in good repair and of suitable material. Equipment must be specific for the medicines which may be dispensed in the primary health care facility. The list given below provides a standard "

- (a) A suitable means of counting tablets and capsules. This equipment must be cleaned regularly so that cross-contamination between products is avoided.
- (b) A range of graduated, stamped glass or plastic measures suitable for the medicines dispensed in the facility.
- (c) A refrigerator equipped with a suitable thermometer and capable of storing medicines at temperatures between 2°C and 8°C. The refrigerator must be cleaned, defrosted and checked periodically to ensure efficient running. This refrigerator must be used only for storing pharmaceutical products. Where applicable, a freezer for the storage of ice packs must be available.

- (d) A suitable range of dispensing containers for medicine. The use of child-resistant closures is encouraged.
- (e) Labels for the dispensing of medicines. Labels and labelling must comply with the requirements of Regulation 8 of the General Regulations published in terms of the Medicines Act.
- (9) Suitable refuse receptacles.

1.6.6 REFERENCE SOURCES:

The following reference sources must be available in a primary health care clinic or a mobile clinic where the dispensing of medicine takes place:

- (a) **EDUSTG**;
- (b) the latest edition of Daily Drug Use (Tincture Press Publications) or another drug interactions reference source;
- (c) the latest edition of either MDR or SAMF;
- (d) a Good Pharmacy Practice Manual;

provided that there is access to a telephone or other means of communication with an institutional or other pharmacy, e.g. district or sub-district hospital if further information is required.

1.6.7 CONTROL OF ACCESS TO DISPENSARY OR MEDICINE ROOM

- (a) The pharmacist's assistant (post-basic) or licensed dispenser in charge must ensure that every key, key card or other device, or the combination of any device, which allows access to a dispensary/medicine room when it is locked, is kept only on his/her person or the person of a pharmacist's assistant (post-basic), licensed dispenser or a pharmacist (as applicable) at all times.
- (b) Control of access to the dispensary, medicine room and/or consulting room(s) (as applicable) must be of such a nature that only authorised personnel have direct access to medicines.
- (c) A procedure must be in place to ensure access to the dispensary, medicine room and/or consulting room(s) (as applicable) in an emergency situation in compliance with the Occupational Health and Safety Act, 1993.

1.7 MINIMUM STANDARDS SPECIFICALLY RELATING TO THE MEDICINE ROOM OF A PERSON LICENSED TO DISPENSE MEDICINE IN TERMS OF THE MEDICINES ACT

1.7.1 DESIGNATION OF THE MEDICINE ROOM

In a premises where the services are provided by a licensed dispenser in the consulting rooms of a health establishment there must be a suitable room designated as a **medicine room for use as a storage area for medicine**. In such a facility the following standards must be observed:

- (a) the dispensing must be done in the consulting room(s) and not in the medicine room;
- (b) no medicine may be stored in the consulting room(s) except in situations where there is air-conditioner installed and the temperature is controlled;

- (c) where medicine is stored only in the medicine room, medicines or scheduled substances must be transported to the consulting room(s) on a daily basis in for example, a lockable medicine trolley or tray.

1.7.2 CONDITION OF THE MEDICINE ROOM

- (a) The walls, floors, windows, ceiling, woodwork and all other parts of the medicine room 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 by insects, birds or rodents
- (b) Countertops, shelves and walls must be finished in a smooth, washable and impermeable material which is easy to maintain in a hygienic condition.
- (c) Light conditions, temperature and humidity within the medicine room must comply with the requirements for the storage of medicine, other pharmaceutical products, and packaging materials.
- (d) The temperature in the medicine room must be below 25°C.
- (e) The medicine room must have the following fixtures/fittings:
- (i) an air-conditioner in good working order;
 - (ii) a refrigerator in good working order (see below).

1.7.3 STORAGE AREAS IN THE MEDICINE ROOM

- (a) Storage areas must have sufficient shelving constructed from smooth, washable and impermeable material, which is easy to maintain in a hygienic condition.
- (b) No medicines may be stored on the floor.
- (c) Storage areas for medicines must be self-contained and secure.
- (d) Storage areas must be large enough to allow for orderly arrangement of stock and proper stock rotation.

1.7.4 EQUIPMENT IN THE MEDICINE ROOM OR PREMISES

There must be adequate, suitable dispensing equipment in the medicine room. Each item must be clean, in good repair and of suitable material. The list below provides a standard for equipment, which must be available

- (a) A suitable means of counting tablets and capsules. This equipment must be cleaned regularly so that cross-contamination between products is avoided.
- (b) A range of graduated, stamped glass or plastic measures suitable for the medicines dispensed in the facility.
- (c) A refrigerator equipped with a suitable thermometer 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. This refrigerator must be used only for storing pharmaceutical products. Where applicable, a freezer for the storage ice packs must be available,
- (d) A suitable range of dispensing containers for medicinal products. The use of child-resistant closures is encouraged.

- (e) 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 must be the latest version available.
- (f) Suitable refuse receptacles.

1.7.5 REFERENCE SOURCES IN THE MEDICINE ROOM OR PREMISES

In addition to any reference sources required by the statutory council of the licensed dispenser, the following must be available on the premises of the licensed dispenser, namely -

- (a) the latest edition of MIMS;
- (b) the latest edition of Daily Drug Use (Tincture Press Publications) or another drug interactions reference source;
- (c) the latest edition of either Mims Desk Reference or South African Medicines Formulary;
- (d) a comprehensive textbook on Pharmacology;
- (e) a medical dictionary;
- (g) a Good Pharmacy Practice Manual;
- (g) the latest copy of the Medicines and Related Substances Act 101 of 1965 as amended;
- (h) a textbook on complementary medicines (where applicable).

1.7.6 CONTROL OF ACCESS TO THE MEDICINE ROOM

- (a) The licensed dispenser must ensure that every key, key card or other device, or the combination of any device, which allows access to a medicine room when it is locked, is kept only on his/her person.
- (b) Control of access to the medicine room and/or consulting room(s) (as applicable) must be of such a nature that only the licensed dispenser(s) has direct access to medicine.
- (c) A procedure must be in place to ensure access to the medicine room and/or consulting room(s) (as applicable) in an emergency situation in compliance with the Occupational Health and Safety Act, 1993.

1.8 MINIMUM STANDARDS SPECIFICALLY RELATING TO A STORAGE AREA FOR PHARMACEUTICALS OUTSIDE THE PHYSICAL PREMISES OF A PHARMACY

1.8.1 MANAGEMENT OF A STORAGE FACILITY

Any storage area, which is not physically an integral part of the premises of a pharmacy, must constitute part of a pharmacy licensed by the Department of Health and recorded with Council. Such a storage area must fall under the authority of the responsible pharmacist of the pharmacy of which it forms a part, and be operated in compliance with Good Pharmacy Practice. Thus, such a storage area cannot exist/operate independently of a pharmacy

1.8.2 CONDITION OF THE STORAGE AREA

- (a) The walls, floors, windows, ceiling, woodwork and all other parts of the storage area 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, washable and impermeable material, which is easy to maintain in a hygienic condition.
 - (c) The storage area must have an air-conditioner in good working order;
 - (d) Light conditions, temperature and humidity within the storage area must comply with the requirements for the storage of medicine, other pharmaceutical products, raw materials and packaging materials.
 - (e) The temperature in the storage area must be below 25°C.
 - (f) Storage areas must have sufficient shelving constructed from a smooth, washable and impermeable material, which is easy to maintain in a hygienic condition.
 - (g) Storage areas for pharmaceuticals must be self-contained and secure.
 - (h) Storage areas must be large enough to allow for orderly arrangement of stock and proper stock rotation.
 - (i) No medicine may stored be on the floor.

1.8.3

CONTROL OF ACCESS TO THE STORAGE AREA

- (a) The pharmacist must ensure that every key, key card or other device, or the combination of any device, which allows access to a storage area when it is locked, is kept only on his/her person.
- (b) Control of access to the storage area must be of such a nature that only a person authorised by the responsible pharmacist has direct access to medicine.
- (c) A procedure must be in place to ensure access to the storage area in an emergency situation in compliance with the Occupational Health and Safety Act, 1993.

CHAPTER 2**PROFESSIONAL STANDARDS FOR SERVICES****MINIMUM STANDARDS FOR SERVICES PROVIDED
IN A PHARMACY****2.1 INTRODUCTION**

The *Regulations relating to the registration of persons and the maintenance of registers* (GNR 1160 of 20 November 2000) published in terms of the Pharmacy Act make provision for the recording of five different categories of pharmacy. The five categories of pharmacy are: manufacturing pharmacy, wholesale pharmacy, consultant pharmacy, community pharmacy and institutional pharmacy. The services which may be provided in the different categories of pharmacy, are prescribed in the *Regulations relating to the practice of pharmacy* (GNR. 1158 of 20 November 2000) published in terms of the Act.

The following minimum standards apply to the provision of the services in the different categories of pharmacy referred to above

2.2 MINIMUM STANDARDS FOR MANUFACTURING OF ANY MEDICINE OR SCHEDULED SUBSTANCE

Manufacturing is 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 accordance with the Medicines Act and in a manner that will ensure compliance with Good Manufacturing Practice (GMP), as described in the Guidance Document: Good Manufacturing Practice for Medicine in South Africa (GNR. 7659 of 2 May 2003), published by the MCC, as well as the relevant provisions of the Pharmacy Act.

2.3 MINIMUM STANDARDS FOR PROCUREMENT, STORAGE AND DISTRIBUTION**2.3.1 RESPONSIBILITY FOR PROCUREMENT**

The pharmaceutical aspects of the purchase of all medicinal products and related materials must be the responsibility of a pharmacist. Written policies for the procurement, storage and distribution of medicine and scheduled substances must be available in the pharmacy. Written policies must 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;
- (9) 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.

2.3.2 SOURCES OF SUPPLY

- (a) The responsible pharmacist has a professional responsibility to exercise control over all medicinal and related products, which are purchased or supplied.
- (b) A purchasing policy must be in place that ensures the safety of medicine.
- (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) The pharmacist must know and select suppliers by applying various quality parameters, in accordance with the MCC's standards of Good Manufacturing Practice.
- (e) A pharmacist must be satisfied that both the supplier and the source of any medicine purchased are 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.
- (9) A MCC registration number must appear on the original container of every medicine in the facility, with the exception of unregistered medicines for which authority for the use thereof has been granted by the MCC.
- (g) Stock rotation must always be done on the "FIRST EXPIRY, FIRST OUT" (FEFO) or "FIRST IN - FIRST OUT (FIFO) basis. Stock that expires first or is received first (where expiry dates are not available) must therefore be used first.
- (h) Patients must receive stock that has been stored suitably and has an appropriate expiry date.

2.3.3 SAFE SYSTEMS OF WORK

A pharmacist must 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 must be taken into consideration:

- (a) Safe systems of work must be established and maintained by a pharmacist to eliminate, as far as possible, errors in any component of the pharmaceutical service.
- (b) Secure storage for medicines must be provided in all premises and approved store-keeping procedures and adequate stock control systems must be maintained.
- (c) A policy for the storage and administration of medicines in hospitals must be defined and updated regularly. A pharmacist must establish systems, and be responsible, for the professional element of the procurement of all medicinal products purchased through the hospital pharmaceutical service.
- (d) Within a multidisciplinary system a pharmacist is responsible for providing advice as needed on the pharmaceutical element of the procurement of surgical dressings.

2.3.4 MEDICAL GASES

The procurement, storage and distribution of medical gases must comply with the requirements as described in the Guidance Document: Good Manufacturing Practice for Medicine in South Africa (GNR. 7659 of 2 May 2003), published by the MCC, which could include but not be limited to the following:

- (a) All equipment supplied for use must be fit for its purpose and must be maintained in a manner that will ensure the safe and proper use thereof.
- (b) Cylinders and other containers of medical gases must be stored in accordance with the current guidelines issued by the manufacturers of the gas.

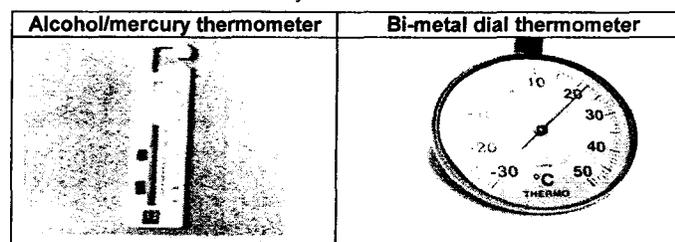
- (c) The supply of medical gases to a patient must be in association with treatment of a medical condition.
- (d) Each patient, and appropriate members of the patient's family or caregiver, must receive full and proper instruction from a pharmacist or suitably trained person in the safe care and handling 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 must be recorded and held in the pharmacy.
- (9) The responsible pharmacist in an institutional pharmacy must ensure that an appropriate Standard Operating Procedure is in place for the handling of medical gases in the institution.

2.3.5 COLD STORAGE OF PHARMACEUTICALS

- (a) Thermolabile medicines must be kept in a refrigerator.
- (b) The refrigerator must be inside the dispensary or clinic and must be readily accessible to the pharmacist.
- (c) The refrigerator must only be used for storing pharmaceuticals.
- (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.
- (e) The refrigerator must be connected to a standby generator or other emergency power system to ensure uninterrupted power supply in case of power (current) failure.

2.3.6 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 must be monitored and charted twice daily
- (c) A WHO approved dial thermometer or alcohol or mercury thermometer must be used. (NOTE: A minimum/maximum thermometer must not be used.) The thermometer must be hung from the middle shelf of the refrigerator. Figure 6 A WHO approved dial thermometer or alcohol or mercury thermometer



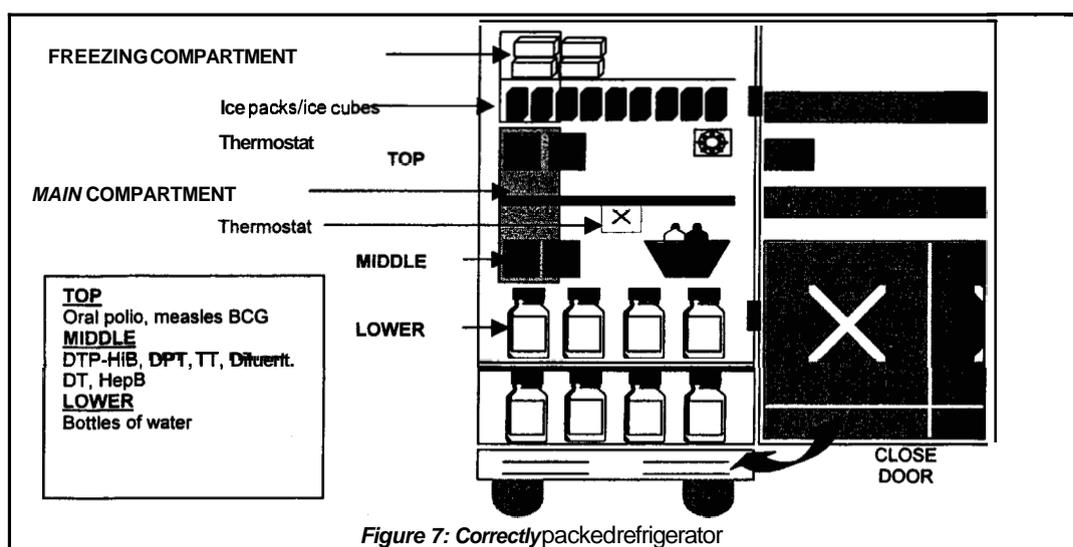
- (d) If the power is off for any length of time, the refrigerator should not be opened until the power supply is restored.
- (e) The refrigerator must be cleaned and defrosted at least once a month.
- (f) The cold chain must be maintained when the refrigerator is cleaned. Cooler boxes should be used to maintain the cold chain.
- (g) The following procedures must be followed when the refrigerator is cleaned:
 - (i) The inside of the refrigerator must be cleaned with an appropriate cleaning solution and wiped dry.

- (ii) The door gasket must be cleaned, especially along the bottom edge on upright units.
- (iii) When applicable 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 condenser coil on the back of the refrigerator should be cleaned and dust removed from the compressor.
- (v) It must be ensured that the door closes tightly.

2.3.7

STORAGE OF 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.
- (c) Various aids can be used to monitor the temperature of vials, e.g. cold chain monitors cards (CCMs) and vaccine vial monitors (VVMs).
- (d) Correct packing of vaccines and diluents in the refrigerator is vital if they are to be kept at safe temperatures. Figure 7 indicates how a refrigerator should be packed.



- (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 refrigerator.
- (f) Vaccines must 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 thermolabile drugs.
- (h) Diluents should be at the same temperature as the vaccine at the point of use.
- (i) Only the designated diluents must be used for specific vaccines.
- (j) All vaccines must 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. All ice packs must be properly conditioned (the ice must rattle in the water inside the ice pack to prevent accidental freezing of the vaccines).

(k) Shake Test:

The Shake Test is designed to determine whether adsorbed vaccines (DPT, DT, Td, TT, DTP-Hib or Hepatitis B) have been frozen. After freezing, the vaccine is no longer a uniform cloudy liquid, but tends to form flakes which gradually settle to the bottom after the vial has been shaken. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen.

Note that individual batches of vaccine may behave differently from one another. Therefore the test procedure described below should be repeated with all suspect batches.

Test procedure:

- Prepare a frozen control sample:** Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer. Freeze the vial until the contents are solid, and then let it thaw. This vial is the **control sample**. Clearly mark the vial **so** that it cannot later **be** used by mistake.
- Choose a test sample:** Take a vial of vaccine from the batch that you suspect has been frozen. This is the **test sample**.
- Shake the control and test samples:** Hold the control sample and the test sample together in one hand and shake vigorously for **10-15** seconds.
- Allow to rest:** Leave both vials to rest.

Compare the vials: View both vials against the light to compare the sedimentation rate. If the test sample shows a much slower sedimentation rate than the control sample, the test sample is probably potent and may be used. If the sedimentation rate is similar and the test sample contains flakes, the vial under test has probably been damaged by freezing and should not be used. Note that some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

Subsequent action: If the test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately. Standard Operating Procedures should then be followed to ensure that all damaged vaccine is identified and that none of this damaged vaccine is distributed or used.

Table 1 depicts the official schedule for the Expanded Programme on Immunisation in South Africa



TABLE 1: RECOMMENDED CHILDHOOD IMMUNISATION SCHEDULE

When should a child be immunised?		
Age of Child	Which Vaccine?	How and where is it given?
At birth	BCG (vaccine against tuberculosis) Polio vaccine	Intradermal injection in upper right arm Drops by mouth
6 weeks old	Polio vaccine DTP* vaccine Hib*** vaccine Hepatitis B vaccine	Drops by mouth Injection in left thigh Injection in left thigh Injection in right thigh
10 weeks old	Polio vaccine DTP* vaccine Hib*** vaccine Hepatitis B vaccine	Drops by mouth Injection in left thigh Injection in left thigh Injection in right thigh
14 weeks old	Polio vaccine DTP* vaccine Hib*** vaccine Hepatitis B vaccine	Drops by mouth Injection in left thigh Injection in left thigh Injection in right thigh
9 months old	Measles vaccine	Injection in right thigh
18 months old	Polio vaccine DTP* vaccine Measles vaccine	Drops by mouth Injection in left arm Injection in right arm
5 years old	Polio vaccine DT** vaccine	Drops by mouth Injection in left arm
DTP* = vaccine against diphtheria, whooping cough and tetanus (lock-jaw) DT** = vaccine against diphtheria and tetanus only Hib*** = vaccine against <i>Haemophilus influenzae</i> type b		

2.4 MINIMUM STANDARDS RELATING SPECIFICALLY TO INSTITUTIONAL PHARMACIES

Minimum standards for procurement, storage and distribution are stipulated in items 2.3.1 to 2.3.7 above and must be met. The following additional standards relate more specifically to institutional pharmacies.

2.4.1 SELECTION OF PHARMACEUTICALS

- (a) A Pharmacy and Therapeutics Committee (PTC) must be in place for the selection of pharmaceuticals and the promotion of rational drug use.
- (b) A pharmaceutical code list and/or formulary and/or the Essential Drug List must 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 as well as a policy and procedures for the approval and provision of medicine not included in the formulary as required.
- (c) The Pharmacy and Therapeutics Committee must be responsible for the formulary.
- (d) Pharmaceutical usage review programmes must be developed to ensure maximum patient benefit on the most cost-effective basis.

2.4.2 PROCUREMENT AND STORAGE

- (a) The pharmaceutical storage area(s) must be under control of the responsible pharmacist.
- (b) Delivery of medicines must be made directly to the pharmacy. Where delivery is not direct to the pharmacy, procedures must be established and followed to ensure secure receipt of medicinal products and their onward passage to the pharmacy.
- (c) 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, which must be updated regularly, covering all activities.
- (d) The responsible pharmacist must establish and maintain adequate records of purchases for inventory control and satisfaction of legal and audit requirements.
- (e) The responsible pharmacist is 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) adherence to central contract or purchasing agreements (as applicable);
 - (iii) the maintenance of up-to-date price records to ensure that the most favourable prices are obtained (as applicable);
 - (iv) establishing and maintaining adequate records of purchases for inventory control and satisfaction of legal and audit requirements;
 - (v) the establishment and maintenance of a system for reporting errors and withdrawing defective products.
- (f) All orders must be on official documents carrying a unique order number. There must be only a small number of authorised signatories. Telephonic orders must be confirmed in writing immediately.
- (g) The responsible pharmacist must ensure that all areas where medicines are stored are of acceptable standard.

- (h) The responsible pharmacist must ensure that all medicine storage areas are inspected regularly (at least monthly) to at least ensure that:
 - (i) medicines and scheduled substances are stored and handled in accordance with the pharmaceutical manufacturer's requirements;
 - (ii) no expired or obsolete medicines are stocked;
 - (iii) medicines requiring special environmental conditions are stored properly;
 - (iv) stock levels are adequate to ensure the continuous supply and accessibility of medicine at all times, including the availability of essential drugs as per the latest edition of the EDL/ Formulary (as applicable);
 - (v) inflammable substances are stored separately and in an appropriate manner;
 - (vi) disinfectants and preparations for external use are stored separately from medicines for internal use; and
 - (vii) medicines are pre-packed only in accordance with the provisions of the Medicines Act.
- (i) Adequate inventory control systems for pharmaceutical stock held in the pharmacy and or pharmacy store as well as for ward and clinic pharmaceutical stock must be maintained by:
 - (i) establishing minimum and maximum stock order levels;
 - (ii) stock control accounting for pharmaceutical products, received into and removed from stock;
 - (iii) identification and proper disposal of expired, 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 (as applicable).

2.4.3**DISTRIBUTION OF PHARMACEUTICALS TO WARDS, DEPARTMENTS, THEATRES, CLINICS (WDTC) AND OTHER OUTLETS**

- (a) Distribution of medicines within a hospital institution must take place under the direction and control of a pharmacist and must be in accordance with Regulation 36 of the General Regulations published in terms of the Medicines Act.
- (b) For each WDTC, and other outlet(s), agreement must be reached with nurses and clinicians for those items, which are to be held as stock. Stock levels must be determined from analysis of previous issues and agreed with nursing staff.
- (c) A stock list must be prepared for WDTC and other outlets.
- (d) A copy of the stock list must be made available to nursing staff who will be responsible for obtaining supplies of stock, and to prescribers servicing the ward.
- (e) Written SOPs must be provided on how supplies of stock medicines are to be obtained from the pharmacy together with an indication of nurses' responsibilities for signing approved requisition documents, which comply with the latest requirements of the Medicines Act.
- (f) Procedures must 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 of each item supplied and each requisition must be dated and signed.
- (h) Procedures must be agreed upon for the return of empty stock packs to deter potential misuse.
- (i) Procedures must 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 must be undertaken at least monthly to ensure that stock rotation is maintained in all medicine storage areas in the hospital institution.
- (k) Where applicable, procedures must be agreed upon 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 must ensure that a thorough stock-check is carried out prior to topping up to agreed stock levels.
- (m) When a topping up list is drawn up by pharmacist's assistants, the order must be signed by the nurse-in-charge or other responsible person. The order must be sent to the pharmacy for processing in accordance with the agreed stock control system, whether electronic or manual.
- (n) Stock must not be returned to the pharmacy without the agreement of the nurse-in-charge or other responsible person. A written record of its removal must be made on the topping-up list.
- (o) Stock rotation must be practised.

2.5 MINIMUM STANDARDS RELATING SPECIFICALLY TO MOBILE PHARMACEUTICAL SERVICES

2.5.1 STORAGE AND CONTROL OF MEDICINE AND SCHEDULED SUBSTANCES

- (a) Medicines and scheduled substances stored 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 labelled correctly.
- (b) Where applicable, 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.

2.6 MINIMUM STANDARDS RELATING SPECIFICALLY TO WHOLESALE PHARMACIES

Minimum standards for procurement, storage and distribution are stipulated in items 2.3.1 to 2.3.7 above and must where applicable be met. Additional minimum standards for wholesale pharmacies or Good Pharmaceutical Wholesale Practice (GPWP) are prescribed in the guidance document: Good Manufacturing Practice for Medicine in South Africa (GNR. 7659 of 2 May 2004), published by the MCC, as well as in Good Wholesale Practice for Wholesalers, Distributors and Bonded Warehouses (MCC 6 June 2003).

Minimum standards for "distributors" are not provided in this GPP document and more information in this regard must be obtained from the MCC.

2.7 MINIMUM STANDARDS FOR THE DISPENSING OF MEDICINE OR SCHEDULED SUBSTANCES ON THE PRESCRIPTION OF AN AUTHORISED PRESCRIBER

"Dispensing" as defined in terms of the Pharmacy Act means *"the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to the Medicines Act and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient and "dispense" has a corresponding meaning"* (GNR. 1158 of 20 November 2000).

2.7.1 DISPENSING PROCEDURES

This section must be read and applied in the context of its relevance and pertinence to the various persons authorised to participate in the dispensing process in terms of their scope of practice.

The dispensing process is divided into three phases, namely:

- Phase 1: Interpretation and evaluation of the prescription.
- Phase 2: Preparation and labelling of the prescribed medicine.
- Phase 3: Provision of information and instructions to the patient to ensure the safe and effective use of medicine.

The three phases may be performed by a pharmacist or pharmacist intern under the direct personal supervision of a pharmacist. Phases 2 and 3 may be performed by pharmacist's assistants (post-basic) under the direct personal supervision of a pharmacist. In terms of the scope of practice of a pharmacist's assistant (post-basic) he/she may read and prepare a prescription, select, manipulate or compound the medicine, label and supply the medicine following the interpretation and evaluation of the prescription by a pharmacist. He/she may also provide instructions regarding the correct use of medicine supplied.

Notwithstanding the above, a pharmacist's assistant (post-basic) working under the indirect supervision of a pharmacist may, under certain conditions, in terms of Regulation 12 of the *Regulations relating to the practice of pharmacy*, read and prepare a prescription, select, manipulate or compound a medicine, label and supply medicine in an appropriate container and provide instructions regarding the correct use of the medicine supplied.

The person who is responsible for the dispensing of a prescription must ensure that all three phases of the dispensing process have been performed by an appropriately authorised person.

2.7.1.1 Phase 1: Interpretation and evaluation of the prescription

- (a) Receipt of the prescription and confirmation of the integrity of the communication. Adequate procedures must exist for:
 - (i) identifying the patient, the prescriber and the entity responsible for payment (as applicable);
 - (ii) ensuring the legality/authenticity of the prescription;
 - (iii) a permanent copy of a faxed, e-mailed, telephonic or other electronically transmitted prescription or order made for record purposes. A faxed, e-mailed, telephonic or other electronically transmitted prescription or order must be followed by the original prescription or order within seven working days;
 - (iv) helping the patient to resolve the problem when the prescription cannot be dispensed;
 - (v) interpreting the type of treatment and the prescriber's intentions;

- (vi) identifying the medicine, and checking the pharmaceutical form, strength, appropriate dosage, presentation, method of administration and duration of treatment;
 - (vii) informing the patient of the benefits and implications of the substitution for a branded medicine of an interchangeable multi-source medicine. Refer Section 7.3.11 of this chapter.
- (b) Assessment of the prescription to ensure the optimal use of medicine. Each prescription must be professionally assessed by a pharmacist with respect to:
- (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 the indication for which the medication is prescribed
 - (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;
 - (ii) questions put to the prescriber where doubts arise or further information is required;
 - (iii) 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.

2.7.1.2 Phase 2: Preparation and labelling of the prescribed medicine

2.7.1.2.1 Selecting or preparing the medicine includes the following activities:

- (a) Patient-ready packs/pre-packed medicines are correctly selected.
- (b) Preparation of extemporaneous preparations. Where applicable, the pharmacy **must** have adequate facilities for the extemporaneous dispensing of individual prescriptions. When medicines are compounded in a pharmacy this must be done in accordance with the details laid down in section 2.18.
- (c) Counting must be done on a clean 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, whether performed by a pharmacist, pharmacist intern or pharmacist's assistant (post-basic), must be carefully checked for accuracy and completeness.
- (9) Signing the prescription. Accountability must be accepted by the pharmacist or other authorised person 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.

2.7.1.2.2 Labels

- (a) Labelling of dispensed products must be clear, legible and indelible. Lettering must as far as possible be mechanically printed.
- (b) The following information must be indicated on the label in accordance with Regulation 8(4) of the General Regulations published 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.

2.7.1.2.3 Record keeping regarding the supply of medicine

Regulation 11 of the General Regulations published in terms of the Medicines Act, specifies the information that must be recorded when medicine is supplied.

2.7.1.2.3.1 SCHEDULE 1 RECORD

According to Regulation 11 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
- (c) the name of the pharmacist, pharmacist intern or pharmacist's assistant who sold it.

2.7.1.2.3.2 PRESCRIPTION BOOK

According to Regulation 11, 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
- (9) 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.

2.7.1.3 Phase 3: Provision of information and instructions to the patient to ensure the safe and effective use of medicine.

2.7.1.3.1 Supply to the patient

- (a) Advising a patient or the patient's agent/caregiver (physical presence is preferred) must be carried out by a pharmacist or other authorised person.
- (b) A patient information leaflet, containing the information as prescribed in the General Regulations published in terms of the Medicines Act should be available at the point of dispensing.
- (c) Information must be structured to meet the needs of individual patients
- (d) Pharmacists must 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.
- (e) Information provided to patients regarding their medicine use must always be done with professional judgement and the prescriber should be contacted when necessary.

2.7.1.3.2.1 Monitoring patient outcomes

- (a) The pharmacist or pharmacist intern under the personal supervision of a pharmacist must 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.

2.7.2 SUPERVISION OF DISPENSING AND SALES/SUPPLY

- (a) Dispensing must be done by or under the supervision of a pharmacist in accordance with applicable legislation.
- (b) In a pharmacy with only one pharmacist present, this pharmacist must be able to supervise activities in the medicines sales area (as applicable) 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 dispense in a pharmacy must be seen by a pharmacist and 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) tasks that he/she is confident can be undertaken by them and fall within the scope of practice of a pharmacist's assistant (post-basic). The pharmacist must be available in the pharmacy to intervene, to advise and to check the dispensing of any prescription under his/her supervision.

- (9) Systems must be developed to ensure that the distribution of medicines is reliable and secure to the point of delivery.

2.7.3 SAFETY IN DISPENSING PROCEDURES

2.7.3.1 Interpretation of prescription

- (a) In cases of uncertainty, the pharmacist or pharmacist intern must make every effort to contact the prescriber. If it is impossible to contact the prescriber, the pharmacist must use his/her professional judgement and decide, in all 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 must be endorsed according to any action taken e.g. telephonic confirmation of an unusual dosage, etc.

2.7.3.2 Forged prescriptions

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

2.7.3.3 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 must be dispensed in a re-closable 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 re-closable container; or
 - (iii) a specific request is made that the product shall not be dispensed in a re-closable container.
- (d) Advice must be given to keep all medicines out of the reach of children.

2.7.3.4 Reuse of containers

- (a) Plastic containers and caps for solid or liquid dose preparations must not be reused.
- (b) Under no circumstances may re-closable child resistant closures be used more than once.
- (c) Glass containers may be reused only after satisfactory cleaning and drying.

2.7.3.5 Reuse of medicines

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

- (a) Medicines brought in by patients remain the patient's own property. Under no circumstances may they be used by any one 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.
 - (iii) The continued use of patients' own medicines while in hospital may be necessary in special circumstances. Appropriate safeguards are required.

2.7.3.6 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 minimum standard can be found in the Code of Conduct as published by Council in rules.

2.7.3.7 Recalls

- (a) A pharmacist must comply immediately, with any warning about or recall of defective medicines.
- (b) Every pharmacy must have a recall policy.
- (c) A pharmacist must actively participate in any arrangements made for warning the profession of problems associated with medicines, and must inform appropriate bodies of hazards which come to their attention.

2.7.3.8 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.

2.7.3.9 Expiry dates

- (a) Expired medicine must not be dispensed or supplied to the public.
- (b) Particular care must 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.
- (c) A record of the expiry dates of all medicine procured by the pharmacy must be **kept**.

- (d) Pharmacists in hospitals/institutions or registered nurses in charge of units must return excessive and short-dated stock to the pharmacy timeously.
- (e) Those items which have expired must be recorded and priced.
- (9) The destruction of expired medicine must only take place in accordance with the General Regulations published in terms of the Medicines Act.

2.7.3.10 Adverse drug reaction reporting

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

2.7.3.1 1 Generic substitution

Section 22F of the Medicines Act states that:

- (1) A pharmacist shall -
 - (a) inform all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; and
 - (b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.
- (2) If a pharmacist is forbidden as contemplated in subsection (1)(b), that fact shall be noted by the pharmacist on the prescription.
- (3) When an interchangeable multi-source medicine is dispensed by a pharmacist, he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.
- (4) A pharmacist shall not sell an interchangeable multi-source medicine -
 - (a) if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;
 - (b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or
 - (c) where the product has been declared not substitutable by the Medicines Control Council.

NOTE: Interchangeable multi-source medicine – is defined in terms of the Medicines Act as medicines that contains the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed.

2.7.4 PRICING OF PRESCRIPTIONS AND SERVICES

- (a) Pricing of the prescription or copy of the prescription (where applicable) must include the following:
 - (i) 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
 - (ii) the final price paid by the patient/member or an indication of the total cost of the account rendered if payment is not effected.

- (b) Pricing of prescriptions must be in accordance with the Regulations relating to a transparent pricing system (GNR. 553 of 30 April 2004).
- (c) Pricing for approved services must be in accordance with the Rules relating to services for which a pharmacist may levy a fee and guidelines for the levying of such fee or fees (once published).
- (d) The advertising of prices must be in accordance with Regulation 45 of the General Regulations published in terms of the Medicines Act. Logos or pack shots may not be used.
- (e) Prices for services, including dispensing, must not be advertised in a manner that -
 - (i) is calculated to suggest that a pharmacist's professional skills or ability or his/her facilities for practising his/her profession or rendering his/her professional services are superior to those of other pharmacies; or
 - (ii) could be construed as touting or attempting to tout for prescriptions or business with regard to the sale of medicines or the provision of approved supplementary services.

2.7.5 DELIVERY OF MEDICINES

- (a) All efforts must be made to enable face-to-face counselling of the patient by a pharmacist.
- (b) When a person other than a pharmacist delivers medicines to a patient or a patient's caregiver, the pharmacist must furnish comprehensive written instructions, that shall include the patient's details and information regarding the correct use of the medicine, as well as the statement and a patient information leaflet
- (c) All medicines should, whenever possible, be delivered to patients at an agreed time.
- (d) In the absence of an adult (a person above 14 years) to receive the medicine, it must be taken back to the pharmacy.

2.8 MINIMUM STANDARDS FOR PATIENT INFORMATION AND ADVICE

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.

2.8.1 PURPOSE

Patient information must 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 health care providers; and
- (c) aiding and encouraging effective use of medicines.

2.8.2 GENERAL CONSIDERATIONS

- (a) Pharmacists and other persons registered with Council must (within their scope of practice) give advice and information to patients on how to use medicines safely and effectively to maximise therapeutic outcomes.

- (b) Pharmacists must have access to as much information as they require within their ethical and professional judgement to meet the individual needs of patients. Such information should include the patient's medical/clinical records.
- (c) Although specific presentation and language must be adapted to local communities and public comprehension, information presented to patients must as far as possible be nationally consistent.
- (d) Pharmacists must assess and, where appropriate, comment on promotional materials for medicines and other products associated with health.
- (e) Upon receipt of a prescription, or a request for dispensing of medicine on own initiative, a pharmacist must counsel each patient or patient's caregiver on matters which, in the pharmacist's professional judgement, will enhance or optimise the medicine therapy prescribed.
- (g) Care must be taken to assess the wishes of the prescriber and the information and counselling needs of individual patients.
- (h) Written information must be used to supplement verbal communication as appropriate.
- (i) The pharmacist must assess each patient's ability to understand the information imparted by question and answer and must be able to modify his/her approach accordingly. Care should be taken with counselling where understanding is likely to be a problem.
- (j) Confidentiality of the patient must be respected.
- (k) The provision of advice must take place in a suitable environment and the patient should be put at ease, especially with regard to sensitive information.

2.9. MINIMUM STANDARDS FOR RECORD KEEPING PROCEDURES

Patient medication records must be kept in the pharmacy, except in institutional pharmacies where the pharmacist has access to the necessary information in the patient's medical/clinical records.

2.9.1 PATIENT MEDICATION RECORDS

- (a) Patient medication records must be developed, preferably using computer technology.
- (b) Patient medication records must respect the patient's privacy.
- (c) The following information must be captured in a patient medication 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) current mass of the patient;
 - (vi) medical aid details;
 - (vii) the name of the prescriber and date of consultation;
 - (viii) 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;

- (ix) the number allocated to each prescription dispensed and the date thereof;
 - (x) any known allergies of the patient;
 - (xi) any possible reactions of the patient towards medicine; _____
 - (xii) family history;
 - (xiii) idiosyncrasies or negative reactions of the patient towards medicine;—
 - (xiv) the presence of other factors, e.g. smoking;
 - (xv) chronic conditions or disease states of the patient; and
 - (xvi) the identity of any other medicine or devices currently being used by the patient, and any related information indicated by a medical or other health care professional.
- (d) Patient medication records must:
- (i) be readily retrievable by manual or electronic means;
 - (ii) enable the pharmacist to identify medicine dispensed previously and known disease conditions; and
 - (iii) enable the pharmacist to determine the impact of medicine dispensed previously and known disease conditions upon the newly submitted prescription or other medicine sold or supplied to the patient.
- (e) The pharmacist must ensure a system is in place to guarantee the confidentiality of data relating to individual patients.

2.9.2 DOCUMENTATION OF PROFESSIONAL ACTIVITIES

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

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

2.10. MINIMUM STANDARDS FOR DISPENSING SPECIFICALLY IN INSTITUTIONAL PHARMACIES

Section 2.7.1 of this Chapter provides minimum standards for the dispensing of medicines on the prescription of an authorised prescriber. The following additional minimum standards relate specifically to the dispensing of medicine in institutional pharmacies.

2.10.1 INDIVIDUAL PATIENT DISPENSING (IPD)

- (a) In the case of medicines dispensed for individual patients, 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) A suitable lockable trolley for patient's medication must be available. 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 to wards, departments, theatres and clinics but not used must be returned to the pharmacy. Procedures must be established to ensure that the inspection of returned medicines, their return to stock (if appropriate) and crediting take place in accordance with local policy.
- (d) The responsible pharmacist must ensure that medicines prescribed outside normal pharmacy hours are made available either by the use of an emergency medicine cupboard or are provided by a pharmacist who is on call.
- (e) The responsible pharmacist must also ensure that an on-call pharmacist is available to provide other services as necessary.
- (9) Policies must be agreed upon, in conjunction with the Pharmacy and Therapeutics Committee at local and/or provincial level as applicable, regarding the quantity of individually dispensed items to be supplied
- (g) The pharmacist must be responsible for ensuring that medicines dispensed for individual patients are labelled in accordance with Regulation 8(4) of the General Regulations published in terms of the Medicines Act and in addition must contain the following minimum detail:
 - (i) name of ward;
 - (ii) the proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
 - (iii) the directions with regard to the manner in which such medicine should be used;
 - (iv) number of dose units in container;
 - (v) name of patient and hospital number;
 - (vi) date of dispensing;
 - (vii) expiry date and batch number where appropriate; and
 - (viii) additional labels, warnings and storage instructions according to local policy.
- (h) The frequency of ward visits should be determined by the needs of patients in individual wards.

2.10.2**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 or anaphylactic shock.
- (b) The responsible pharmacist must implement procedures to ensure adequate control over medicine kept on the emergency trolley(ies).
- (c) Policies must be agreed upon, in conjunction with the Pharmacy and Therapeutics Committee at local and/or provincial level as applicable, specifying those medicines to be included in emergency stocks.
- (d) Procedures must be instituted to review the contents and expiry dates of these trolleys/trays periodically.

2.11. MINIMUM STANDARDS FOR CLINICAL PHARMACEUTICAL SERVICES IN INSTITUTIONAL PHARMACIES

2.11.1. INTRODUCTION

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

2.11.2. WARD PHARMACY SERVICES

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

- (a) Ward pharmacists must utilise their knowledge and skills of pharmaceutical sciences and product awareness to promote safety, efficacy and economy in the use of medicines.
- (b) Ward pharmacists must 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 must co-operate with clinicians in determining the minimum number of ward rounds to be attended to ensure that the ward 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.
- (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) Where a local formulary is in operation the ward pharmacist in close co-operation with other health care professionals is responsible for ensuring that all new treatment prescribed takes account of the recommendations of the formulary.
- (g) Ward pharmacists must provide a patient counselling service where the need arises.
- (h) In order to safeguard the patient and ensure that documents relating to prescribing and administration remain at ward level, a prescription monitoring service must be provided. It should be tailored to the individual needs of patients on each type of ward.

2.11.3. PRESCRIPTION MONITORING

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

- (a) A multi-disciplinary approach must 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 must be communicated to the prescriber 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 must be discussed with the clinician(s) 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 must be documented by a pharmacist, clinician or nurse and must become a permanent record in the patient's notes. Confidentiality must be respected at all times.
- (f) Prescriptions must 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;
 - (ix) problems relating to intravenous administration, including potential incompatibilities, medicine stability, volume of intravenous fluid for medicine administration and rate of administration;
 - (x) compliance with any applicable formulary/treatment guidelines, e.g. appropriate EDUSTG.
- (g) Patients and their medicine therapy must be monitored for the following:
 - (i) the manifestation of adverse reactions or drug toxicity. The pharmacist should attempt to detect these adverse effects at an early stage. Any recognised reaction or adverse effect whether possibly or definitely drug-related, must be investigated and reported according to the guidelines published by the MCC;
 - (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 therapeutic efficacy of medicines, will require more intensive monitoring, according to the following criteria:
- (i) patients whose age, weight, 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 must be set at a frequency suitable for the patient mix and prescribing practice.
- (j) All pharmacists monitoring prescriptions must be able to provide appropriate information on request using local or other information sources.

2.11.4 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 for an individual patient.

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. If a drug information service is established, it must comply with the standards as set out hereunder.

2.11.4.1 Minimum requirements for a drug information service

- (a) Allocated space should be sufficient for reference collection and provision of the service.
- (b) Minimum essential furniture and equipment including a dedicated telephone, computer and lockable filing cabinets must be available.
- (c) The unit should maintain a current collection of reference materials appropriate to the scope and nature of the service provided. These references should include books, journals, drug profiles, relevant formularies and manufacturers' 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.

- (9) Access to a medical library with an inter-library loan facility is recommended. .
- (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 institution and the number of enquiries must be employed.
- (i) The personnel must develop and maintain a current Standard Operating Procedure manual outlining procedures appropriate to the services provided.
- (j) The service must be available during normal pharmacy hours. If provided, a toxicology service must be available 24 hours a day.
- (k) Methods must be in place for:
- (i) the receiving, researching, answering, referencing, logging and storing of medicine information queries;
 - (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 personnel of the hospital/institution; and
 - (x) quality assurance.

2.12. MINIMUM STANDARDS FOR PHARMACIST-INITIATED THERAPY

2.12.1 SERVICES RELATING TO A SPECIFIC PATIENT

2.12.1.1 Response to symptoms

When called upon by a member of the public to advise on symptoms, the request must be dealt with by a pharmacist or another member of staff in the pharmacy who is appropriately registered with Council or is an appropriate health care professional. Where necessary, arrangements must be in place to ensure that an intervention by a pharmacist can be made at an appropriate stage. The following steps must be taken:

- (a) Sufficient information must be obtained to enable a proper assessment of the situation to be made. This should include information about who has the problem, what the symptoms are, how long the condition has persisted, any action that has already been taken, and which medicines the person concerned is already using.

- (b) It must be decided whether the symptoms might be associated with a serious condition, and in such circumstances the patient must be referred for immediate medical advice.
- (c) In the case of a minor self-limiting health problem, appropriate advice must be given and a medicine recommended only when necessary.
- (d) The patient record must be updated, whether medicine has been supplied or not and the patient advised to consult a doctor should the symptoms persist beyond a stated time.

2.12.1.2 Self-Care Products, including the supply of Schedule 0, Schedule 1 and Schedule 2 medicines

- (a) The pharmacist must utilise experience to select medicines taking into account their quality, efficacy and safety.
- (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 contraindications 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 must be indicated in the patient's profile.
- (d) For each type of health problem that can be treated within the framework of self-care, protocols for the action of pharmacist's assistants and members of staff who are not registered with Council must be established.
- (e) The protocol must define when referral to a pharmacist is necessary.

2.12.1.3 Follow-up

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

2.13. MINIMUM STANDARDS FOR SCREENING AND MONITORING SERVICES IN PHARMACIES**SCREENING AND TESTING BIOCHEMICAL AND PHYSIOLOGICAL PARAMETERS**

- (a) A pharmacy can offer services relating to screening and testing a patient's biochemical and physiological parameters. Pharmacists who are competent to do so may provide such screening and monitoring services.
- (b) Protocols must 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 must be effective communication with the patient's doctor and other relevant health care professionals.
- (d) Pharmacists and members of staff involved must have sufficient training to enable them to give appropriate and sound advice.
- (e) 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.
 - (i) Pharmacists are entitled to inform the public of the availability of screening and monitoring tests.
 - (ii) According to the code of conduct of pharmacists, the advertisement must be factually correct, must not be misleading and must not bring the profession into disrepute.
- (9) With the exception of screening tests for **HIV**, 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 levy a professional fee and guidelines for levying such a fee or fees).

2.13.1 MINIMUM STANDARDS ON PROMOTION OF PUBLIC HEALTH**2.13.1.1 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 must comply with the requirements described in 1.2.13 of Chapter 1 of this manual.

2.13.1.2 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 must 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 must 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, must 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 practice should, however, be avoided and results should be confirmed in writing.
- (g) The pharmacist must comply with any request from the patient that patient records and test results be made available to other health care professionals caring for the patient.
- (h) The following information must 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), a record of advice given to patients.

2.13.1.3 Professional and ethical aspects

- (a) Pharmacists must ensure that they have adequate training, knowledge and skills to perform screening tests and interpret and discuss the results thereof.
- (b) Confidentiality of patient information must be ensured throughout.
- (c) Patient information must 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.
- (d) The pharmacist must always act in the best interest of the patient.
- (e) Pharmacists must establish criteria for the referral of patients. It is preferable that these criteria are determined in consultation with local medical practitioners.

2.13.2 MINIMUM STANDARDS REGARDING TESTING

- (a) A person suffering from a communicable disease should not treat patients.
- (b) Disposable units must **be used** for biohazardous substances. Puncture-resistant containers must be used that are located as close as possible to the area of use.
- (c) Suitable procedures must be adopted for the disposal of waste material, bearing in mind the risks associated with materials contaminated with blood.
- (d) Needles or other sharp objects must not be recapped, bent or broken.

2.13.2.1 Minimum standards regarding test materials and instruments

- (a) Reliable tests and instruments must be used at all times.
- (b) Pharmacists performing the tests must be familiar with the instructions and requirements of individual products on the market, and **must** be aware of the limitations of the tests and realise that no test is 100% accurate.
- (c) The storage requirements of the test material must be noted and the product **stored** according to the manufacturer's instructions.

- (d) All unused material must be stored in the original containers.
- (e) If applicable, the drying material should not be removed from the original container. Lids must be replaced immediately after use.
- (9) Contamination of material and samples must be prevented.
- (g) The testing areas of reagent strips must not be touched.
- (h) Any discoloration or darkening of material can be an indication of deterioration of the reagent strips.
- (i) Expiry dates of material must be checked before use.
- (j) Instruments must be kept clean and in good working order and be calibrated regularly.

2.13.2.2 Minimum standards regarding the taking of samples

- (a) Correct methods for sample collection must be followed.
- (b) Samples must be collected in clean, dry containers not contaminated with cleansers. If manufacturers supply containers, these must be used.
- (c) Gloves must be worn in the following instances:
 - (i) when touching blood and body fluids, mucous membranes or non-intact skin of patients; and
 - (ii) when handling items or surfaces soiled with blood or body fluids.
- (d) Gloves must be changed after contact with each patient and hands washed.
- (e) Masks and protective eyewear or face shields must be worn during procedures that are likely to generate droplets of blood or body fluids.
- (9) Plastic aprons and gowns must be worn during procedures where blood or body fluid splashes are likely.
- (g) Hands and other skin surfaces must be washed immediately and thoroughly if they become contaminated with blood or body fluids.
- (h) All blood and body fluid specimens must be placed in sturdy containers with a secure lid and contamination of the outside of the container avoided.

2.13.3 MINIMUM STANDARDS FOR BLOOD PRESSURE MONITORING SERVICES

The following standards must be considered when a blood pressure monitoring service is established in a community pharmacy.

2.13.3.1 Equipment

- (a) Equipment needed for the performance of blood pressure monitoring is blood pressure monitors and stethoscopes and/or electronic monitors.
- (b) Equipment must 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 of apparatus that are used, must be implemented and applied on a regular basis.

2.13.3.2 Procedure and interpretation of results

The following aspects must be considered in blood pressure monitoring:

- (a) The procedure must be explained to the patient, his/her permission obtained and the patient made to feel comfortable.
- (b) The person monitoring blood pressure must 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 must be rounded off to the nearest whole number. This rounding off must 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 must 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 must be noted. Presence of arrhythmias and unusual circumstances such as anxiety must be noted.

2.13.3.3 Documentation and record keeping

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

2.13.4 MINIMUM STANDARDS 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, for referral to a medical practitioner, and secondly it provides an opportunity to advise asthma patients and other patients with respiratory diseases receiving medication on a chronic basis, about the control of their condition with the help of peak flow tests. The following standards must be used when such a service is provided in the pharmacy.

2.13.4.1 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 must be followed for the cleaning procedures. Instruments must be cleaned at least once a week. Peak flow meters must be checked regularly to ensure that they function correctly. A damaged instrument must never be used.
- (d) Pharmacists must implement a suitable quality assurance programme and apply it regularly to instruments to ensure the reliability of the determinations.

2.13.4.2 Procedure and interpretation of results

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

- (a) The procedure must 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.
- (9) 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 must 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 must 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 must be reevaluated 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 respiratory diseases involving airway obstruction must be confirmed through the determination of lung function with the help of a spirometer by a medical practitioner.
- (i) The patient's medical practitioner must be consulted in the case of reduced lung function, concerning the criteria for referral of the patient or adjustment of drug therapy.

2.13.4.3 Documentation and record keeping

For regular monitoring of a patient's peak expiration flow it is essential that a complete patient profile system is kept. Apart from general information that must be kept, the following information must 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
- (g) results of peak flow measurements must be kept for at least three years.

2.13.5 MINIMUM STANDARDS 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. The following standards must be applied when such a service is provided in the pharmacy.

2.13.5.1 Physical facilities and equipment

- (a) Consultation area
 - (i) Taking of samples and the performance of HIV antibody tests must be done in a private allocated area in the pharmacy.
 - (ii) The consultation area must comply with the requirements laid down in section 1.2.13 of this manual.
 - (iii) The following minimum furniture and fittings must be available in the consultation area:
 - a desk with seating;
 - a working surface of impermeable washable material;
 - a wash hand 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 biohazardous materials;
- access to a fridge (for storage of test materials).

Note: It is advisable that the fridge is situated in the consultation area, **so** that observers / bystanders 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) Reliable tests must 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).
- (c) The following equipment must be available:
- (i) a reliable HIV antibody test with its sample containers, diluents, etc. that is recommended by the MCC* and purchased from a reputable company;
 - (ii) requirements for the collecting of samples (e.g. blood tubes, etc);
 - (iii) disposable latex gloves;
 - (iv) alcohol swabs or 70% alcohol solutions;
 - (v) tissues;
 - (vi) paper towels;
 - (vii) 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 must be purchased from reputable companies. It is recommended that it be ascertained whether the test is registered in the country of origin.
- (d) Pharmacists must 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 must be aware of the limitations of tests used and realise that no test is 100% accurate.
- (9) Expiry dates of HIV antibody tests must be checked.
- (g) The manufacturer's storage requirements for the test material must be followed.

2.13.5.2 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 must be implemented. Contamination of blood samples must be prevented. The samples must be clearly and correctly marked if they are sent to a laboratory.
- (c) Samples must 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 must be aware of his/her own physical limitations which could influence the interpretation of the results, for example, colour blindness.
- (g) Pharmacists must 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 as follows:

Wear gloves in the following situations:

- (i) when touching blood and body fluids, mucous membranes or non-intact skin of all patients;
- (ii) when handling items or surfaces soiled with blood or body fluids;
- (iii) 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 large-bore re-useable needles in a puncture-resistant container for transport to reprocessing areas.

Make mouthpieces, 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 must seek counselling from other health care professionals if he/she incurs a needle stick injury during the performance of his/her duties. The **HIV** test must be done by another health care professional.

- (b) In a case of rape, the pharmacist must refer patients to a centre where post-exposure prophylaxis is available. Pharmacists in community pharmacy who are able to recover their cost on medicines for HIV post-exposure prophylaxis (PEP) may provide these medicines in accordance with the provisions of the Medicines Act and the guidelines of the National Department of Health.

2.13.5.3 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 counselling 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.

2.13.5.4 Counselling

- fa) —HIV testing needs to be done with much care and consideration. Due to the implications of receiving a positive result a person must 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 must 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 Counselling

Pre-test counselling is 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 must include discussions on:

- (a) ensuring confidentiality;
- (b) the definition of HIV and **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, psychosocial 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 results;
- (m) coping with a positive test result, including whom to tell and identifying needs and support services;
- (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 must include discussions on:

- (a) feedback and understanding of results;
- (b) if the result is negative:
 - (i) strategies for risk reduction;
 - (ii) possibility of infection in the 'window' period;
 - (iii) suggest retesting in three months' time;
- (c) if the result is positive:
 - (i) immediate emotional reaction and concerns;
 - (ii) personal, family and social implications;
 - (iii) difficulties a client may foresee and possible coping strategies;
 - (iv) who the client wants to share the results with;
 - (v) immediate needs and social support identification;
 - (vi) follow-up supportive counselling; and
 - (vii) follow-up medical care;
 - (viii) possible routes of transmission;
 - (ix) explain that the person is both infected and infectious;
 - (x) the importance of notifying sexual partners;

- (xi) the likely progression of infection;
 - (xii) the availability of care programmes, such as Aid for AIDS.
- (d) The counsellor must 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 caregivers in the community. Meet with them to discuss this very important matter and establish whether they are knowledgeable about HIV and AIDS and whether they are prepared to collaborate with you.
- (9) Monthly statistics of all pre-test and ongoing counselling sessions as well as the number of tests completed during the month must be kept.

2.13.5.5 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 breastfeeding. 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 counselling (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 counselling. Only rapid tests which use a blood sample must be performed in a pharmacy.

The following precautions and procedures must be borne in mind:

- (i) Follow the test instructions exactly.
- (ii) Screening tests alone cannot be used to diagnose AIDS.
- (iii) If the test is positive, the patient must 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 must be done at least 12 weeks after any likely infection.

- (b) 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 in the past 3 months.
- (c) 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.

2.13.5.6 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 must be considered:
 - (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 must **be** considered infected and contagious.

2.13.5.7 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 must 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 must 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, must appear on all referral documents.
- (e) Results must not be given telephonically.
- (f) The following information must 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 the pharmacist/health care professional;
 - (vii) the name of the pharmacist/health care professional who performed the test.

2.13.5.8 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 must be ensured throughout. Patient information must 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 must 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.

2.13.5.9**Training**

- (a) According to the "ethical rules", 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 must 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 and 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) the role of the pharmacist in the prevention of HIV and AIDS.

2.13.5.10**Advertising the service**

- (a) The specific service should be introduced to local members of the health care professions (such as local pathology laboratories, doctors, local clinics, private registered nurses, etc).
- (b) Pharmacists are entitled to inform the public about the availability of HIV antibody tests. The advertisement must be factually correct, must not be misleading and must not harm the dignity of the profession.

- (c) The following methods can be used:
- (i) oral information given to people visiting the pharmacy;
 - (ii) enclosures in accounts;
 - (iii) newsletters to regular clients;
 - (iv) posters in the pharmacy, etc.

2.14 MINIMUM STANDARDS FOR IMMUNISATION SERVICES

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 care 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 an underlying disease state;
- (e) administering immunisation agents;
- (9)** recording immunisation data; and
- (g) using the immunisation database to generate reminder letters for booster doses.

2.14.1 PHYSICAL FACILITIES AND EQUIPMENT

If immunisation services are provided the following standards are applicable:

- (a) Counselling and administration of immunisation agents must be done in a private allocated area in the pharmacy. The consultation area must comply with the requirements described in Section 1.2.13 of this manual.
- (b) The correct storage procedures for vaccines must be adhered to according to the standards for the cold storage of pharmaceuticals described in Chapter 2 of this manual.
- (c) The following equipment must be available:
 - (i) syringes and administering devices; and
 - (ii) biohazardous materials and sharps disposal container(s).
- (d) Adequate drugs for use in emergencies 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.) must be available.

2.14.2 PROCEDURE

- (a) Pharmacists must be familiar with the instructions, requirements and guidelines of the National Expanded Programme on Immunisation (EPI) policy.
- (b) Pharmacists must 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 must be noted and products must be stored according to the manufacturer's instructions. Refer Chapter 2 for standards for the storage of vaccines.

- (d) The cold chain (system of ensuring that a product is stored at the correct temperature during transport and storage up until the moment of immunisation) must be maintained.
- (e) Live virus vaccines may be used after they have been frozen, but repeated freezing and thawing must be avoided. The National open vial policy must 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 must never be used beyond the expiry date.
- (g) If required, reconstitution of vaccines must 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 must be discarded at the end of the working day.
- (h) Prior to the administration of immunisation agents, patients must 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 tuberculosis, 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 must be familiar with the National and Provincial schedules for immunisation of infants, children and travellers.
- (l) Pharmacists performing immunisations must be familiar with the WHO guidelines for the prevention of HIV and Hepatitis virus. 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 must 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 must be followed:
- (i) Ensure privacy.
 - (ii) Strict aseptic technique must 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 to vaccines.
 - (ii) The recommended time and route of administration of the different vaccines.
 - (iii) The contra-indications 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 must carefully review package inserts before deciding to administer a vaccine as some contain preservatives (e.g. thiomersal) 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.

2.14.3**DOCUMENTATION AND RECORD KEEPING**

- (a) Immunisation cards must be completed to keep a record of immunisations. This information must be kept for a period of at least five years. The record cards must contain the following details:
 - (i) patient name, and address, and 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 sensitivity to eggs, antibiotics and preservatives which may be contained in vaccines.
- (b) Immunisation of children must 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 must be complied with.
- (d) Co-operation with local clinics must be maintained.
- (e) The pharmacist must provide immunisation statistics to the local District Health Co-ordinator for epidemiological purposes and for proper stock control.

2.14.4 ETHICAL ASPECTS

- (a) Confidentiality of patient information must be ensured throughout. Patient information must 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 must always act in the best interest of the patient.

2.14.5 TRAINING

- (a) Pharmacists must ensure that they have adequate training, knowledge and skills to provide the service.
- (b) Pharmacists must be competent in cardio-pulmonary resuscitation techniques.
- (c) Pharmacists involved in this service must 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.

2.15 MINIMUM STANDARDS FOR REPRODUCTIVE HEALTH SERVICES

A community/institutional pharmacist may render a comprehensive reproductive health service if he/she has obtained the necessary training and has registered his/her supplementary training with Council. Contraceptives may be sold/supplied in accordance with the provisions of the Medicines Act. Pharmacists can administer injectable contraceptives and hormone injections, if the pharmacist is competent in injection techniques. If a reproductive health service is provided the following standards are applicable.

2.15.1 PHYSICAL FACILITIES AND EQUIPMENT

Reproductive health counselling must be done in a private designated area in the pharmacy. The consultation area must comply with the requirements as described in Section 1.2.13 of this manual.

2.15.2 PROCEDURE

- (a) Requirements of registration of the applicable supplementary training with Council must be finalised.
- (b) Co-operation must be maintained with local reproductive health 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 reproductive health clinic at least once a year for a full physical evaluation.

2.15.3 DOCUMENTATION AND RECORD KEEPING

Client records must be completed and updated.

2.15.4 LEGAL AND ETHICAL ASPECTS

- (a) The authorisation for reproductive health 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 reproductive health service, which is rendered under the auspices of his/her registration as pharmacist with supplementary training in family planning.
- (b) Confidentiality of patient information must be ensured throughout. More standards regarding patient confidentiality can be found in the Code of Conduct as published by Council in rules.
- (c) In the provision of the service, the pharmacist must always act in the best interest of the patient.
- (d) Reasonable privacy must 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 must receive information (oral and written) about reproductive health.
- (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 must be kept for a period of at least five years.

2.15.5 TRAINING

- (a) Pharmacists must ensure that they have adequate training, knowledge and skills to provide the service.
- (b) No pharmacist may render a reproductive health service unless he/she has obtained specific training and such supplementary training is registered with Council.
- (c) Pharmacists involved in this service must 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 reproductive health through self-training, training by suppliers and continuing education courses.

2.16 MINIMUM STANDARDS FOR OTHER HEALTH CARE SERVICES**2.16.1 RESIDENTIAL AND NURSING HOMES**

Pharmacists are in a unique position to provide pharmaceutical care to residential and nursing homes. Where pharmaceutical care is provided in residential and nursing homes, the following standards are applicable:

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

2.16.2 SMOKING CESSATION

Pharmacists should advise patients to stop smoking and give patients information regarding pharmaceutical products that can assist them with this process. The following standards are applicable where a pharmacist is participating in anti-smoking campaigns:

The following standards must be followed where a pharmacist is participating in anti-smoking campaigns:

- (a) The pharmacy must have written information on how to stop/reduce smoking.
 - (b) The pharmacist involved in assisting patients in smoking cessation must 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.
 - (c) All anti-smoking products must be sold with an invitation to come back and report progress.
 - (d) Supporting information must be readily available.
 - (e) Counselling sessions to stop smoking must be available from the pharmacist by appointment or a suitable system must exist for referral.
- (9) Smoking must not be permitted in the pharmacy.**

2.16.3 NUTRITION ADVICE

Pharmacists are in a position to provide patients with up-to-date information regarding healthy nutrition and lifestyles. Where a pharmacist is providing nutrition advice, the following standards must be followed:

Where a pharmacist is providing nutrition advice, the following standards must be followed:

- (a) Pharmacists must provide advice regarding vitamin and mineral supplementation for patients with nutritional deficiencies.

- (b) Where applicable, pharmacists must explain to patients the benefits of high fibre diets.
- (c) Pharmacists must be informed on the signs and symptoms of anorexia.
- (d) Pharmacists must be informed on nutrition advice to be given during pregnancy, e.g. the supplementary folic acid intake.
- (e) Requests for weight reduction advice and products must be met in a structured manner.
- (f) A policy must exist to ensure that weight reduction advice is not given to those who do not require it.
- (g) A weight reduction guide must be available in the pharmacy and be provided to appropriate patients.
- (h) Those who need to lose weight must be given advice on healthy eating and exercise.
- (i) Slimming mixtures and unhealthy slimming medicines/techniques must not be promoted in 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.

2.16.4**BABY AND CHILD HEALTH**

Where a pharmacist is providing baby and child health services, the following standards are applicable:

- (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 must 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 must provide advice regarding sugar intake and dental care.
- (f) All parasitic worm preparations must be sold with advice on hygiene and treating all family members.
- (g) Pharmacists must know the principles of vitamin supplementation for infants.
- (h) Pharmacists must actively promote immunisation programmes.
- (i) Pharmacists must provide patient information and advice on the benefits of breastfeeding and alternative milk products in line with WHO guidelines for substitute milk products and policies of the DOH:
 - (i) The pharmacy should stock a range of accessories and equipment to facilitate breastfeeding.
 - (ii) The pharmacist and pharmacy support personnel must actively encourage mothers to continue breastfeeding when appropriate.
 - (iii) The pharmacist must refer mothers experiencing difficulty with breastfeeding for specialist professional help.
 - (iv) The pharmacist must give advice on the use of medicines in association with breastfeeding.
 - (v) Pharmacy support personnel must know the range of formula milk and its relative advantages and mixing and storage procedures.

2.17 MINIMUM STANDARDS FOR ASEPTIC DISPENSING SERVICE

An aseptic dispensing service provides, in response to a clinician's prescription, a sterile product prepared by the admixture of sterile components. If **any** aseptic dispensing service is provided, the following standards are applicable:

- (a) 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.
- (b) A safe system of work must apply throughout preparation and there must be safeguards to ensure that the final product is stable and safe throughout its shelf life.
- (c) Only staff trained in pharmaceutical aseptic technique must provide this service, provided that it falls within their scope of practice.
- (d) Procedures must be introduced to ensure that dosage calculations are correct and that final containers are appropriate for the route of administration to be employed.
- (e) Procedures must be established to ensure that principles of Good Manufacturing Practice are applied to the aseptic dispensing service.
- (f) Particular attention must be paid to ensuring that validated procedures are used, Prescription details, work sheets, labels and ingredients must be checked prior to preparation. The final product, documentation and label details must be checked prior to release.
- (g) Accurate records must be kept for each product prepared, including label details. These must 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.
- (h) Quality control procedures must ensure that new formulations undergo stability testing, preferably prior to use. Microbiological and particulate monitoring must be carried out even though results may be retrospective.

2.17.1 INTRAVENOUS ADDITIVE SERVICE

- (a) Standard policies and procedures must 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 must handle such solutions, provided that it falls within their scope of practice.
- (d) Procedures must be introduced to ensure that dosage calculations are correct and that the addition will not result in any chemical or physical incompatibility.
- (e) Procedures must be instituted to ensure that safe systems of work are applied throughout the admixture process and there must be safeguards to ensure that the solution is stable and safe throughout administration to the patient.
- (f) Policies and procedures must be established for the addition of medicines to intravenous fluids and their administration. The pharmacy must have access to adequate information sources concerning the intravenous administration of medicines and related compatibilities and stabilities.
- (g) Accurate records must be kept of each admixture including label details. In addition to the requirements for labelling prescribed in Regulation 8(4) of the General Regulations published in terms of the Medicine Act, the following information must 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 must be stated; and
 - (vi) rate of administration.
- (h) All admixtures must be inspected for particulate matter before they are supplied for administration.
- (i) Quality control testing must be conducted to monitor IV additive procedures. The quality assurance programme must 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.

- (j) The pharmacy must provide an efficient system for distribution of ready-prepared admixture solutions.
- (k) The pharmacist should, where possible, ensure that intravenous additives are used appropriately, e.g. within the specified shelf life. Unwanted admixtures must be removed from the ward area.

2.17.2 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 **must** apply throughout preparation and there must be safeguards to ensure that the solution is stable and safe throughout administration to the patient.
- (c) Accurate batch control records must be kept of all TPN solutions issued for administration to patients.
- (d) There must be a uniform standard for labelling TPN solutions. In addition to the requirements for labelling prescribed in Regulation 8(4) of the General Regulations published in terms of the Medicines Act the following information must be included on 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 must be used for the named patient only;
 - (x) the expiry date of the solution; and
 - (xi) that additives are prohibited.

2.17.3 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 must 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 minimise 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 must ensure that cytotoxic drug handling policies are regularly revised.
- (f) The responsible person must ensure that facilities are suitable for the type of preparation.
- (g) Equipment must be designed to minimise the risk of contamination of the product as well as the operator. Procedures must 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 must 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 must 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 must not be used.
- (j) The pharmacist must ensure that there are procedures in place to control that final containers are suitable for the purpose and that they are adequately labelled. Full documentation of each preparation must 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 must 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 must be available and there must 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 must be employed throughout for injectable preparations.
- (l) Protective clothing must 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) The pharmacist must ensure that there are procedures in place to control that a broad-edged tray is used to contain any accidental spillage and Luer-lock syringes must be used. Whenever possible, for reconstitution purposes, a wide-bore needle (18 gauge) should be used and steps must **be** taken to ensure that excess pressure build-up does not cause leakage or the formation of an aerosol. Care must 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) The pharmacist must ensure that there are procedures in place to control that syringes are protected during transport to the patient. Individual syringes must be labelled. The label must 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 must 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 must be thoroughly cleaned immediately after use according to local procedures.
- (r) All excess medicine, equipment and protective clothing used in the preparation must be disposed of and dealt with according to local procedures.
- (s)** Procedures for administration of cytotoxic medicines to patients must strike a balance between protecting the operator and alarming the patient. They must 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 must be designed to ensure that all products achieve the required standard of quality.
- (u) All personnel must receive special training in working with cytotoxic medicines and be monitored regularly to ensure compliance with all procedures.
- (v) A permanent register must be maintained of all employees who routinely handle cytotoxic medicines. Acute exposure episodes must **be** documented and the employee must be referred for appropriate medical examination. Routine medical examination and blood tests must be performed on personnel handling cytotoxic medicine.
- (w) Personnel working in a cytotoxic reconstitution service must be rotated regularly.

2.18

COMPOUNDING

- (a) Compounding must be done under the direct supervision of a pharmacist, **except** in circumstances where specific exemption is granted in terms of the applicable legislation.

- (b) All compounding processes must be in accordance with SOPs authorised by a pharmacist.
- (c) All the necessary requirements must 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 must be written in instructional form and be applicable to the facilities provided.
- (e) Compounding may be done by pharmacy support personnel registered with Council who have the appropriate scope of practice and who are competent 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 must be in place to recall any batch or product, should it be necessary.
- (h) High standards of personal cleanliness must be observed by all those concerned with the compounding process.
- (i) Hand-washing facilities must be conveniently available to the personnel involved.
- (j) Storage areas must provide adequate space and must 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 compounding must be designed and maintained in such a way as to:
 - (i) be suitable for its intended use;
 - (ii) facilitate thorough cleaning when necessary;
 - (iii) minimise any contamination of drugs and their containers; and
 - (iv) minimise the risk of confusion or the omission of a processing step such as filtration or sterilisation.
- (l) Equipment and utensils must be thoroughly cleaned and, if necessary, sterilised and maintained in accordance with specific written directions.
- (m) Before the commencement of any compounding, a check must be made to ensure that all apparatus and equipment to be used have been cleaned/sterilised.

2.19

PRE-PACKING

- (a) Pre-packing entails the repacking of medicines from bulk packs into smaller packs suitable for patient use and must be performed in terms of the provisions of the

Medicines Act and in accordance with Good Manufacturing and Distribution Practices as determined by the MCC as well as the standards provided below.

- (b) Pre-packing may 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 standards provided in this document and the General Regulations published in terms of 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 must 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.

2.19.1 MINIMUM STANDARDS FOR PRE-PACKING

To comply with the above requirements, the following minimum standards must be complied with in the packaging of medicines in patient-ready packs:

- (a) All pre-packing operations must 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 must be effectively lit and ventilated with temperature and humidity control facilities. Conditions must be such that there is no adverse effect on the product or equipment either directly or indirectly.
- (c) All equipment must be kept clean and before each production run checked for efficiency and accuracy.
- (d) Electronic tablet counters must preferably be fitted with dust covers and extractor fans.
- (e) The personnel operating the equipment must be competent to do so and appropriately registered with Council (i.e. pharmacist's assistants).
- (f) Personnel must be adequately protected from possible exposure to health hazards (e.g. oncolytics, penicillin, etc.)
- (g) A master pre-packing document must 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 speed of the turntable and vibrator where applicable.
- (h) A batch number must be assigned to each batch of medicine packed.
- (i) A packaging record must be kept for each batch of medicine packed for a period of three years. The following details must 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 must **be** given to the security of all stored labels, plastic bags and pre-printed 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 must be discarded after annotating the number thereof on the packaging record.
- (l) The following information must 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, e.g. 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.

2.20

MINIMUM STANDARDS FOR A TOTAL PARENTERAL NUTRITION (TPN) CONSULTATION SERVICE

If a total parenteral nutrition (TPN) consultation service is provided the following standards are applicable:

- (a) Intravenous feeding should only be used when nutritional support by the gastrointestinal 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 Council must 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 must 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 must be assessed by the team to ensure that TPN is appropriate and adequate baseline laboratory data has been obtained.
- (g) The pharmacist must 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 must 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 must be inspected, where appropriate, for particulate matter before they are issued for administration to the patient.
- (n) The pharmacist must 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 must be conducted to monitor TPN procedures. The quality assurance programme must 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.

2.21 MINIMUM STANDARDS 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. If a therapeutic medicine monitoring service is provided the following standards are applicable:

- (a) The role of the pharmacy, the pathology and, if appropriate, the clinical pharmacology departments must 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 must be involved in the interpretation of results from medicine assays.
- (c) Policies and procedures must 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, must be designed and agreed upon by the Pharmacy and Therapeutics Committee. Explanatory notes must be provided on the use of these forms.
- (e) Results from therapeutic medicine monitoring and interpretation of these results must be communicated to the clinician by a pharmacist on the approved form to become part of the patient's permanent records.
- (9) Quality assurance procedures must be introduced to ensure that results are consistent and reproducible. This should involve participation in rational quality control schemes if these are available.

2.22 MINIMUM STANDARDS FOR THE PROVISION OF COMPLEMENTARY MEDICINE

- (a) Where complementary medicines are offered for sale, staff involved must 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.

- (d) The client must be informed of possible adverse reactions and drug/drug and drug/food interactions.
- (e) Medicines acquired and sold must comply with MCC requirements.

Guidance

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

2.23 MINIMUM STANDARDS FOR 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 care service must have a separate entrance from the pharmacy entrance.
- (b) Transmission of infection between animals and from animals to humans must be avoided.
- (c) Stringent hygiene must 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 owners' details must 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.

2.24 MINIMUM STANDARDS FOR AIDS RESOURCE CENTRES IN A PHARMACY**2.24.1 FACILITIES**

Since confidentiality and privacy are essential, a separate consulting room may be utilised as the AIDS Resource Centre in a pharmacy. The AIDS Resource Centre must have similar equipment to a consultation area room for the performance of supplementary services (refer 1.2.13 of this manual).

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

- (a) **Prevention**, which could include –
 - (i) the promotion of safe and healthy sexual behaviour;
 - (ii) the management and control of STIs, 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 the Medicines Act and the 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 trained and sufficiently experienced in providing the services concerned.

2.24.3 RESPONSIBILITIES

- (a) Pharmacists must ensure that the dignity of the patient is maintained.
- (b) Pharmacists must ensure that patients' rights are maintained.
- (c) Pharmacists must ensure that confidentiality is maintained throughout treatment.

2.25 REVIEW OF THE OVERALL MEDICATION REQUIREMENTS OF A PATIENT

A pharmacist may review a patient's overall medication requirements to ensure the effective use of medicine, following a diagnosis(es) made by another health care professional, in order to maximise therapeutic outcomes. A review of the patient's overall medication requirements involves analysing the patient's medication record to assess the appropriateness and cost-effectiveness of treatment to ensure rational drug use, and to identify possible interactions and adverse drug reactions. It also involves developing a plan of action in collaboration with other health care professionals and the patient as well as the necessary follow-up. Such a review may involve a consultation with the patient. Full records must be kept.

The responsibility of the pharmacist who provides such a review is to care for a patient's medicine-related needs by making sure that all of a patient's medicine therapy is appropriate, the most effective available, the safest possible and is used as indicated. This is accomplished by identifying, resolving and preventing medicine therapy problems that could interfere with meeting a patient's medicine therapy goals successfully and producing positive patient outcomes.

It is not necessary to provide an overall review of all patients' medication requirements every time they visit a pharmacy. Situations that would justify such a review are any of the following:

- (a) a patient with a new prescription;
- (b) patients on chronic therapy, depending on the disease, the medicines prescribed, and the patient's needs;
- (c) situations where a medicine therapy problem is identified and/or a potential medicine-related problem is anticipated to occur in the future;
- (d) the patient has questions regarding his or her medicine therapy, concerns about an adverse drug reaction or requests a review of his/her medication.

A patient can request a review of his/her medication by asking the pharmacist for help with regard to a medicine-related problem. Another health care provider, for example a medical practitioner, nurse, dentist or another pharmacist, might refer a patient for a medication review or a pharmacist's assistant or another pharmacist dispensing medicine to a patient

might identify some need for care.

The review process must be systematic, structured, ongoing and documented. It consists of three important steps:

- (a) an **assessment phase** (start care, work-up, assessment) where the pharmacist assesses the patient's medicine-related needs, including the identification of any medicine therapy problems that exist, or need to be prevented in the future;
- (b) the **development of a care plan** (care planning, interventions) by the pharmacist and patient in consultation with the prescriber (as necessary), together with goals of medicine therapy and appropriate interventions; and
- (c) a **follow-up evaluation** to determine the actual patient outcomes that have resulted from the care provided.

Where a pharmacist performs an overall review of the patient's medication, the following standards are applicable:

2.25.1 PATIENT INFORMATION/DATABASE

Regardless of the practice environment, a common set of information should be collected for each patient. The following information should be included in a comprehensive pharmaceutical care database:

- (a) **Demographic data** including the patient's name, date of birth, gender, height, weight, body weight index, ethnic group, address, phone number, health care providers, (for example medical practitioners), source of payment, occupation, medical record number (if applicable), date of hospital admission (if applicable).
- (b) **Living arrangements** of the patient (for example, who lives with the patient, who administers medication)
- (c) **Allergy history** including a description of every food or drug reaction, the time of onset, the route of medicine administration, and the treatment.
- (d) Information regarding **adverse drug reactions** or predictable side effects from a drug or medicine product.
- (e) Descriptions of the **family health history** of certain diseases, conditions or risk factors for medicine therapy problems.
- (f) **Special and unique needs** such as physical limitations, special health care beliefs, language, compliance problems, diet and sleeping habits, and exercise.
- (g) **Current medical problem list** (both acute and chronic) including the patient's current complaints, symptoms, diagnoses, conditions, illnesses and how each of these problems is being treated.
- (h) **Complete medicine history** including:
 - (i) All prescription medicines, non-prescription medicines, medication obtained from friends and family members, use of home remedies or traditional medicine, vitamins, natural and homeopathic remedies.
 - (ii) The indication for every medication that the patient is taking.
 - (iii) The person responsible for administering the medication.
 - (iv) Health beliefs related to medicine use. During the initial interview, the pharmacist should determine the cultural issues that might influence the patient's compliance, attitudes towards the health care system and response to therapy. This profile could facilitate an effective pharmacist-patient relationship that ultimately results in positive outcomes.
 - (v) Patient's level of understanding of the medication.
 - (vi) The goals of the medicine therapy and any evidence of the patient's response to his or her particular medicine therapy.
- (i) **Past medical history** including any surgical procedures, hospitalisation and a list of all other medical problems that might have an impact on the patient's present and

future care, medicine therapy problems, incidence of side-effects and history of poor response to specific agents or treatments.

- (j) Social history including tobacco, caffeine and alcohol use (including quantity used and length of use) and any history of illicit drug use.
- (k) Health maintenance information including information on cancer screening, immunisation history, history of sexually transmitted diseases, etc.
- (l) Information regarding the review of systems, for example vital signs (such as temperature, blood pressure and pulse rate), descriptions and experiences offered by the patient regarding the medical problems and laboratory information (for example, electrolyte concentrations, haemolytic profile, and liver and renal function tests).

2.25.2 ASSESSMENT

During the assessment phase the pharmacist should evaluate the patient's **medicine** therapy including any new prescription of a patient with the aid of all the information gathered in order to ascertain any of the following:

- (a) the over-utilisation of medicine (i.e. the use of a medicine by a patient in quantities or for durations that are or can be regarded as not being in the interests of the patient);
- (b) the under-utilisation of medicine (i.e. the use of a medicine by a patient in an insufficient quantity to achieve a desired therapeutic goal);
- (c) therapeutic duplication of medicine (i.e. the use of **two** or more medicines from the same therapeutic class in such a way that the combined daily dose puts the patient at risk of an adverse medical result);
- (d) medicine/disease contra-indication (i.e. the potential for or the occurrence of an undesirable alteration of the therapeutic effect of a given medicine because of the presence of a disease condition in the patient or an adverse effect of the medicines on the patient's disease conditions);
- (e) adverse medicine interactions (i.e. the potential for or the occurrence of an adverse medical effect as a result of the patient using two or more medicines together);
- (f) incorrect medicine dosage(s);
- (g) incorrect duration of medicine treatment;
- (h) medicine/allergy interactions (i.e. the significant potential for or the occurrence of an allergic reaction as a result of medicine therapy);
- (i) clinical abuse or misuse of medicine; and
- (j) patient adherence/compliance.

Where a new prescription must be dispensed this must be done in accordance with **the** standards laid down in section 2.7 of this manual.

2.25.3 DEVELOPMENT OF A CARE PLAN (TAKING APPROPRIATE ACTIONS)

The pharmacist must upon recognising any problem/situation as described above, take the appropriate steps which could include the development of a care plan to avoid or resolve the problem(s). Care plans are developed to define goals, determine appropriate interventions and to assess whether the patient's needs have been met. It also defines responsibilities of the patient and pharmacist for three different purposes:

- (a) To resolve the medicine therapy problems identified during the assessment phase.
- (b) **To** meet the goals of the medicine therapy for each of the patient's medical conditions, thereby achieving the desired outcomes.
- (c) To prevent future medicine therapy problems from developing.

The pharmacist must consult with the prescriber and/or the patient's medical practitioner when it is deemed necessary by the pharmacist to resolve a medicine-related problem. During this step it is also the responsibility of the pharmacist to provide adequate advice to the patient to ensure the safe and efficacious use of medicines. The patient should receive an unequivocal understanding of the instructions for use, and any distinct characteristics or requirements of the medicine. Counselling should cover matters that will enhance or optimise medicine therapy. Counselling of patients or their caregivers should thus include at least the following information-

- (a) name and description of the medicine(s) used;
- (b) dosage form, dose, route of administration and duration of medicine therapy;
- (c) intended use of the medicine(s) and expected action;
- (d) special directions and precautions for preparation, administration and use by the patient;
- (e) common severe side or adverse effects *or* interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (f) techniques for self-monitoring medicine therapy;
- (g) proper storage of medicine(s);
- (h) prescription repeat information;
- (i) action to be taken in the event of a dose not being taken;
- (j) any additional information which may be necessary.

When the patient or the patient's caregiver is present, the pharmacist should consult with the patient/caregiver in person. Such a consultation should take place in an environment that allows for confidential conversation (refer section 1.2.13).

The care plan is completed when goals have been set, interventions agreed upon, and responsibilities of the patient and pharmacist are accepted. The pharmacist is then able to establish outcomes to be assessed during follow-up. The last step of the care-planning process is to schedule a time to conduct a follow-up evaluation.

2.25.4

Follow-up evaluation

The final step in the review process is the follow-up evaluation of the patient to determine actual patient outcomes. A follow-up evaluation is a patient encounter, either in person or by telephone, which allows the pharmacist to collect necessary information to determine whether the actions and interventions taken during the assessment and care planning have produced positive results. Since medicine therapy could produce both positive and negative results, a follow-up evaluation is vital. In addition, routine discussions with the patient's medical practitioner or other health care professionals might also be necessary.

These three steps provide the pharmacist with an organised logical mechanism to structure the provision and evaluation of care to patients. The above three steps occur continuously for a patient during treatment. The amount and type of work required at each step varies with the particular step and the specific needs of a patient. Other health care providers must be included in the patient care process when their input is needed to meet the patient's medicine-related needs. A pharmacist providing this service to patients is required to maintain the data base as per the standard and in addition to create and maintain reports reflecting each of the three steps of the pharmaceutical care service rendered.

CHAPTER 3

**PROFESSIONAL STANDARDS FOR PHARMACY
HUMAN RESOURCES****MINIMUM STANDARDS FOR HUMAN
RESOURCES IN PHARMACY****3.1 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 published in terms of the Pharmacy Act. Anyone who performs any of the functions prescribed must be registered with Council. The relevant regulations are included in **Annexure A**.

3.2 RECOMMENDED STANDARDS 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 practice. Staff selection, appraisals and training must be performed in accordance with the provisions of the applicable legislation, e.g. the Labour Relations Act 66 of 1995.

3.2.1 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 should ensure that written job descriptions are prepared for **all** staff and that all staff are acquainted with their job descriptions and responsibilities.
- (b) All staff must be appropriately qualified, competent and fit to work in the pharmacy.
- (c) All staff should receive appropriate training, information and orientation when newly appointed to a position in the pharmacy.
- (d) The requirements of the Pharmacy Act and the Medicines Act with respect to persons handling medicines and related products must be observed.
- (e) The provisions of the Employment Equity Act and other legislation relating to human resources must 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.

3.2.2 STAFF APPRAISAL AND DEVELOPMENT

An ongoing staff appraisal and development process should be established which contributes to the maintenance of well-trained, motivated and loyal staff.

- (a) The responsible pharmacist should set performance objectives at least annually, in consultation with each staff member. Performance is monitored and evaluated against the job descriptions and established objectives. Results should be 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, should be 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 should be 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 should be 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.

3.2.3**STAFF TRAINING**

Training should be sufficient to enable staff to provide comprehensive and effective pharmaceutical service.

- (a) The pharmacy should maintain a staff development programme and training plan which ensure 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 should continually review their level of professional knowledge and expertise. They should 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, pharmacist interns, and/or pharmacist's assistants is provided, there must be a sufficient number of experienced pharmacists to supervise training.
- (g) Appropriate staff members should be encouraged to participate in inter-professional activities which will further the practice of pharmacy and will assist in the provision of better patient care.

3.3 LEGISLATIVE REQUIREMENTS REGARDING THE TRAINING OF PHARMACIST INTERNS AND PHARMACIST'S ASSISTANTS

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

3.3.1 PHARMACIST INTERNS/ PRE-REGISTRATION EXPERIENCE

- (a) The purpose of the pharmacist **internship/pre-registration** experience is to enable the pharmacist 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 prior to the end of the **internship/pre-registration** experience before registration as a pharmacist for purposes of performing community service can take place.

3.3.1.1 Objectives of the internship

During the completion of the pharmacist internship the pharmacist intern must 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.

3.3.1.2 Pre-requisites for training

- (a) The internship year is regulated by the following:
 - (i) may only be undertaken at pharmacies which conform with the minimum requirements as determined by Council;
 - (ii) must 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) must 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.

3.3.2 PHARMACIST'S ASSISTANTS

- (a) Pharmacist's assistants are legally allowed to perform certain functions under the supervision of pharmacists.
- (b) The pharmacist must supervise and monitor tasks delegated to support staff. Arrangements must ensure that an intervention by the pharmacist can be made at an appropriate level when necessary.
- (c) The pharmacist must ensure that all pharmacy staff have current competence for the tasks they undertake.

3.3.2.1 Pre-requisites for training

- (a) The tutor pharmacist must conduct the training in the in-service training component and must 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.

3.4 MINIMUM STANDARDS FOR PHARMACEUTICAL HUMAN RESOURCE DEVELOPMENT**3.4.1 STANDARDS FOR CONTINUING PROFESSIONAL DEVELOPMENT OF PHARMACEUTICAL PERSONNEL**

Minimum standards regarding the professional development of pharmacists can be found in the Code of Conduct.

3.4.1.1 Competency

- (a) Each pharmacy must have a responsible pharmacist who has appropriate knowledge and experience of the practice of pharmacy and who assumes 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 must 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 must be recorded so that the pharmacist's portfolio of learning activities is kept up to date on a permanent basis.
- (h) A pharmacist must ensure that any services provided, comply with standards and guidelines issued by 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 must be clearly defined.

3.4.1.2 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.

3.4.1.3 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.

3.4.1.4 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.

3.4.1.5 Other health care professionals

Pharmacists should play 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.

3.5 PROFESSIONAL INDEMNITY

A pharmacist must ensure that he/she is covered by his/her own indemnity insurance.

3.6 MINIMUM STANDARDS FOR *LOCUM*/RELIEF PHARMACISTS

- (a) The qualifications and registration status of *locum* pharmacists must be checked and displayed to ensure patients' safety.
- (b) *Locum* pharmacists must have the necessary information to ensure the smooth running of the pharmacy. Written information must therefore exist to enable *locum* pharmacists to locate key Standard Operating Procedures.
- (c) Basic operational information must be available to *locum* pharmacists. This information must include the following:
 - (i) computer instructions (as applicable);
 - (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,
 - (vi) ordering systems and wholesalers used;
 - (vii) instructions on use of alarm system (as applicable);
 - (viii) cash register instructions and cashing up procedure (as applicable);
 - (ix) emergency contact numbers;

- (x) collection and delivery service details;
- (xi) list of outstanding work;
- (xii) local map: and
- (xiii) smoking policy.

3.7 MINIMUM STANDARDS FOR THE MANAGEMENT OF HUMAN RESOURCES IN WHOLESALE AND MANUFACTURING PHARMACIES.

3.7.1 GENERAL

The management of human resources is of major importance in the assurance of good wholesale, distribution and manufacturing practices. Minimum standards for pharmacy human resources development are provided in Section 3.2 of the manual. The following standards relate more specifically to wholesale and manufacturing pharmacies:

- (a) Wholesale and manufacturing pharmacies must 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 must possess the necessary knowledge, experience, professional qualifications and authority to perform their duties efficiently.
- (c) Every wholesale and manufacturing 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 subject to such conditions as may be prescribed at all times be conducted under the continuous personal supervision of a pharmacist.
- (e) A pharmacist must be appointed in each area where the need exists to sign off certain procedures.
- (f) Every wholesale and manufacturing pharmacy must have an organisational chart and written job descriptions for all the personnel.
- (g) The authority of the responsible pharmacist, must be such that decisions relating to quality assurance and compliance with the Pharmacy Act remain his/hers and can only be altered by agreement with the said pharmacist(s).

3.7.2 PHARMACY SUPPORT PERSONNEL

All pharmacy support personnel employed by wholesale and manufacturing 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.

3.7.3 RESPONSIBLE PHARMACIST

- (a) The responsible pharmacist of a wholesale and manufacturing pharmacy must have expert knowledge with regard to the wholesale distribution of medicine and scheduled substances.
- (b) 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.
- (c) The responsible pharmacist must ensure that the conditions of the wholesale and manufacturing pharmacy's licence are met and that there is compliance with the standards and guidelines on pharmacy practice.

3.7.3.1 Duties and responsibilities of the responsible pharmacist

Refer to Annexure A of the manual for the duties and responsibilities of the responsible pharmacist. In addition, the responsible pharmacist of a wholesale or distribution pharmacy must:

- (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.

3.7.4 TRAINING

- (a) Wholesale and manufacturing pharmacies must provide training for all personnel whose activities could affect the quality of the product.
- (b) All newly recruited personnel must 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, e.g. areas where toxic substances are handled, must 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 must be kept.

3.7.5. HYGIENE

- (a) Detailed programmes relating to hygiene must be established and adapted to the different needs within the wholesale, distribution and manufacturing pharmacy. They must include procedures relating to the health, hygiene practices and clothing of personnel.
- (b) Steps must 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 in the pharmacy, or the storage of food, drink, smoking materials or personal medication in the storage areas must be prohibited. In general, any unhygienic practice within the facility where medicine or scheduled substances might be adversely affected, must be forbidden.
- (d) Personnel must be instructed to use the hand-washing facilities regularly.

CHAPTER 4**PROFESSIONAL STANDARDS FOR PHARMACY
MANAGEMENT****MINIMUM STANDARDS FOR MANAGEMENT OF
THE PHARMACY/PHARMACEUTICAL SERVICE****4.1 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 the efficient provision of services. 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 must 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) The responsible pharmacist must ensure that there are sufficient pharmacists and pharmacy support personnel to undertake the pharmaceutical services provided by the institution or pharmacy concerned.

4.2 MINIMUM STANDARDS 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.

4.2.1 PHARMACY MANAGEMENT

- (a) The responsible pharmacist must demonstrate a high standard of professionalism and a commitment to quality development.
- (b) The management structure of the pharmacy should be documented with a clear allocation of duties and responsibilities established and properly recorded.
- (c) The responsible pharmacist must ensure that all regulations covering the operations of the pharmacy are complied with.
- (d) The pharmacy operation must comply with all relevant legislation rules, regulations, codes, standards and guidelines of the South African Pharmacy Council.
- (e) The responsible pharmacist must review his or her level of professional knowledge and expertise continually and documents an appropriate self-development plan.
- (f) The responsible pharmacist must participate regularly in continuing professional development programmes.
- (g) The extent and content of any documentation of pharmacy structures and processes will vary with the size and complexity of the pharmacy operation.
- (h) Quality service will be best achieved if all pharmacy staff are aware of the total commitment of the pharmacy owner and the responsible pharmacist to quality improvement.

- (i) A collection of all legislation and guidelines relevant to the pharmacy must be maintained in a current state and be accessible by all pharmacy staff.
- (j) Procedures must exist to ensure that pharmacy staff are informed of any changes to legislation or other relevant codes or regulations.
- (k) Documented procedures must be in place to ensure that pharmacy staff are aware of relevant legislation, and apply this to the handling, sale and required record keeping of medicines available for sale in the pharmacy.

4.2.1.1 Pharmacy Planning

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

- (a) The pharmacy's mission statement and/or statement of purposes should be documented, regularly reviewed and understood by all staff.
- (b) Business and quality objectives should be established, documented and form the basis of the pharmacy business plan. The objectives and plan should be reviewed at least annually.
- (c) Contracts should be established between the pharmacy and the health care provider being served which specify the terms of the relationship and the services provided.
- (d) The responsible pharmacist must 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 must encompass the services being offered, by whom the services are provided, the clients and the pharmacy's intended impact on the community.
- (9) The pharmacy's mission should be consistent with the principles of pharmaceutical care and the quality requirements of the appropriate health care 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.

4.2.2 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.

4.2.2.1 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 should include 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:
- (i) the quality standards for services supplied by the pharmacy;
 - (ii) processes that operate in the pharmacy and the resources devoted to them (including staff);
 - (iii) how customer feedback will be obtained for services provided;
 - (iv) how other evidence supporting the achievement of quality standards will be obtained and recorded;
 - (v) how resources and training relevant to the quality management responsibilities of each staff member are allocated;
 - (vi) the frequency of assessment of the plan to ensure that it is producing a continuous improvement of service.
- (b) The responsible pharmacist should develop, documents and approves the quality improvement plan for the pharmacy. This provides a systematic plan for each of the service areas in the pharmacy.
- (c) The quality improvement programme should be assessed regularly.
- (d) A documented risk management system should be integrated into the quality improvement process.
- (e) Standard Operating Procedures must be developed, documented and used in the pharmaceutical and retail activities of the pharmacy and be reviewed on a regular basis.
- (f) Documentation of all pharmacy standards, procedures, policies and guidelines should be comprehensive, current and readily available to all pharmacy staff. It is reviewed regularly.
- (g) Pharmacy staff should be trained in the aspects of service quality management which are relevant to their work responsibilities.
- (h) All quality improvement planning, implementation and auditing must be appropriately documented.
- (i) 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.
- (j) Pharmacy documentation must cover: legislative and professional requirements applicable to the operations of the pharmacy, Standard Operating Procedures, contractual details and supply of goods and services.
- (k) All staff must be trained in the use of Standard Operating Procedures.
- (l) The responsible pharmacist must ensure that standards for the operation of pharmacy services are established and that performance against these standards is monitored.
- (m) 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.
- (n) Staff training in the quality area should be aimed at establishing familiarity with the quality improvement cycle, and confidence in its use.

4.2.2.2 Pharmacy effectiveness

The pharmacy should evaluate 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 should monitor client satisfaction and analyse the degree to which it is being maintained.
- (a) Contracts with third parties should 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 should participate in regular professional audit activities to review the standard of clinical and non-clinical services. From the review process strategies should be developed, documented and employed to improve performance.
- (c) Information from business, quality and outcome monitoring should be utilised in the assessment of pharmacy effectiveness.
- (d) Client satisfaction should be 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 health care providers which have a contractual or less formal relationship.
- (9) The pharmacist(s) should participate in any clinical review and audit carried out by health care 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 must be developed to enable the pharmacy to collect reliable and valid data on health outcomes resulting from the pharmacist's clinical observation.

4.2.3 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.

4.2.3.1 Inter-professional relationships

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

- (a) The pharmacist should participate in medicine utilisation reviews, medical audits, medical care evaluations and clinical studies of medicines.
- (b) The pharmacist should ensure that other health care professionals are provided with medicine information and information concerning prescribing and dispensing practices.
- (c) Pharmacists should seek opportunities to provide information to other health care professionals and groups on developments concerning medicines, the general role of pharmacists, contents, packaging and processing of medicines, and 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.

4.2.3.2 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.

4.2.3.3 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 responsible for the existence of **SOPs** in a pharmacy and must be involved in the compilation of SOPs.

SOPs must -

- (a) provide personnel with all the safety, health, environmental and operational information necessary to perform a job properly;
- (b) ensure that operations are performed consistently to maintain quality control of processes and products;
- (c) ensure that processes continue uninterrupted and are completed timeously;
- (d) ensure that no failures occur that could harm anyone;
- (e) ensure that approved procedures are followed in compliance with legislation;
- (f) serve as a training document, e.g. pharmacist interns or pharmacist's assistants;
- (g) serve as a historical record of the how, why, when of steps in an existing process;
- (h) 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:

4.2.3.3.1 Community pharmacy -

- (a) good housekeeping (cleaning procedures, etc);
- (b) daily routine and working hours;
- (c) enquiry or complaint procedure;
- (d) pest (insects, rodents, etc.) elimination;
- (e) effective stock rotation;

- (f) stock-taking;
- (g) disposal or removal of **S1-S6** expired, damaged and/or contaminated stock as required in Regulation 27 published in terms of the Medicines Act;
- (h) obsolete or unusable stock;
- (i) product types requiring special storage or handling instructions;
- (j) separation and handling of goods returned from patients;
- (k) recall of medicine;
- (l) delivery of medicines;
- (m) receiving of medicines;
- (n) storage of medicine;
- (o) procurement of medicine;
- (p) handling of product complaints;
- (q) pre-packing (including quality assurance procedures) (where applicable);
- (r) procedures for a locum or relief pharmacist(s) (where applicable);
- (s) handling of **S5** and **S6** medicines; and
- (t) cold chain management (including procedures to be followed in the event of a refrigerator power failure).

4.2.3.3.2 Institutional pharmacy:—

- (a) good housekeeping (cleaning procedures, etc);
- (b) daily routine and working hours;
- (c) enquiry or complaint procedure;
- (d) pest (insects, rodents, etc.) elimination;
- (e) effective stock rotation;
- (f) stock-taking;
- (g) disposal or removal of **S1-S6** expired, damaged and/or contaminated stock as required in Regulation 27 published in terms of the Medicines Act;
- (h) obsolete or unusable stock
- (i) product types requiring special storage or handling instructions;
- (j) separation and handling of goods returned from patients, wards, clinics etc;
- (k) recall of medicine;
- (l) delivery of medicines;
- (m) receiving of medicines;
- (n) storage of medicine;

- (o) procurement of medicine;
- (p) handling products complaints
- (q) handling of **S5** and **S6** medicines;
- (r) procedures for a locum or relief pharmacist(s) (where applicable);
- (s) cold chain management (including procedures to be followed in the event of a refrigerator power failure);
- (t) pre-packing (including quality assurance procedures) (where applicable);
- (u) compounding operations (including quality assurance procedures);
- (v) preparation of **TPN**/large volume parenterals (including quality assurance procedures) (where applicable);
- (w) oncology mixing (including quality assurance procedures) (where applicable);
- (x) preparation of IV additives (including quality assurance procedures) (where applicable);
- (y) 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).

4.2.3.3.3**Wholesale pharmacy -**

- (a) good housekeeping (cleaning procedures, etc);
- (b) daily routine and working hours;
- (c) enquiry or complaint procedure;
- (d) pest (insects, rodents, etc.) elimination;
- (e) effective stock rotation;
- (**9**) stock-taking;
- (g) disposal or removal of **S1-S6** expired, damaged and/or contaminated stock as required in Regulation **27** published in terms of the Medicines Act;
- (h) obsolete or unusable stock
- (i) product types requiring special storage or handling instructions;
- (j) separation and handling of returned goods;
- (k) recall of medicine;
- (l) delivery of medicines;
- (m) receiving of medicines;
- (n) storage of medicine;
- (o) procurement of medicine;
- (p) procedures for locum/relief pharmacist(s) (where applicable);

- (q) handling of S5 and S6 medicines;
- (r) cold chain management (including procedures to be followed in the event of a refrigerator power failure);
- (s) pre-packing (including quality assurance procedures) (where applicable);
- (t) handling of product complaints.

4.2.3.3.4 Primary health facility –

- (a) good housekeeping (cleaning procedures, etc);
- (b) daily routine and working hours;
- (c) enquiry or complaint procedure;
- (d) pest (insects, rodents, etc.) elimination;
- (e) effective stock rotation;
- (g)** stock-taking;
- (g) disposal or removal of S1-S6 expired, damaged and/or contaminated stock as required in Regulation 27 published in terms of the Medicines Act;
- (h)** obsolete or unusable stock;
- (i) product types requiring special storage or handling instructions;
- (j) separation and handling of goods returned from patients,
- (k) recall of medicine;
- (l) receiving of medicines;
- (m) storage of medicine;
- (n) procurement of medicine;
- (o) handling products complaints;
- (p) handling of S5 & S6 medicines;
- (q) cold chain management (including procedures to be followed in the event of a refrigerator power failure).

The following policies must be available in all pharmacies

- (a) Sanitation policy
- (b) Health safety policy
- (c) Security policy
- (d) Post exposure policy (where applicable)
- (e) HIV and AIDS policy

4.3 .. **MINIMUM STANDARDS FOR QUALITY MANAGEMENT IN AN 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.

4.3.1 **MANAGEMENT**

- (a) An updated manual reflecting all relevant policies must be available. All pharmacy personnel must have a sound knowledge thereof and apply policies 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 must 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 to 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 must be familiar with the contents of such a manual and must practise in accordance with the manual.
- (g) Cost-effective and service-orientated work schedules, systems and procedures which utilise pharmacy personnel and resources most effectively should be instituted and subjected to regular re-evaluation and in this way establish an acceptable standard of practice.
- (h) Policies and procedures must 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 must 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 must be held. Such meetings will promote improved administration and service.
- (l) The hospital pharmacy or institution must establish its own professional quality assurance committee. Quality assurance cannot be acquired without collaboration with other health care professionals for those areas of mutual responsibility.

4.3.2 **PHARMACY AND THERAPEUTIC COMMITTEES**

- (a) The Pharmacy and Therapeutics 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 must be maintained to develop policies and procedures relating to the selection and the rational, safe and effective use of medical products, surgical dressings and medicine administration systems within the hospital's boundaries.
- (c) The Pharmacy and Therapeutics Committee(s) must be a multi-disciplinary focal point for all policy decisions relating to the control of medicines within the hospital environment.
- (d) Membership must be representative and could comprise (where available) 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.

4.3.3 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 MCC (GNR. 7659 of 2 May 2003).

4.3.4 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 institution and must reflect the current judgement of clinicians and pharmacists on the basis of efficacy, safety and costs. The formulary must be produced in co-operation with the Pharmacy and Therapeutics Committee.
- (b) The minimum requirements for a formulary must 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 must be agreed procedures for medicines **to** be added to, or deleted from the formulary.
- (d) The responsible pharmacist must update, maintain and monitor the formulary system on behalf of the Pharmacy and Therapeutics Committee.

4.3.5 MINIMUM STANDARDS FOR VISITS BY PHARMACEUTICAL REPRESENTATIVES

Pharmaceutical representatives can play an important role in the introduction and marketing of medicinal products in hospitals/institutions. 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 to the benefit of hospitals if representatives and the responsible pharmacist work together closely.

The following standards apply **to** visits by representatives:

- (a) Representatives on their first visit to a hospital/institution 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 must only visit a **hospital/institution** by appointment and the pharmacist must be kept fully informed as **to** the programme of appointment, meetings, etc. that representatives may have in the **hospital/institution**, including visits **to be** made to the pharmacy department, for the detailing of products.
- (c) Representatives must inform the responsible pharmacist of any new products before detailing to other personnel.
- (d) Representatives must 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 must not be permitted access to pharmacy stock, medicine cupboards, etc. for any reason.
- (9) Derogatory and inflammatory remarks about competitors' products, companies, the award of tenders and personnel must be avoided.
- (g) Representatives must be aware that it is a privilege and not a right to conduct business in hospitals/institutions and must at all times **be** sensitive to the working pressures and environment of personnel.

4.3.6 MINIMUM STANDARDS FOR CONTINUOUS SUPPLY OF MEDICINES

- (a) A community and institutional pharmacy must have a pharmacist available to provide a pharmaceutical service **to** the public on a 24-hour basis.
- (b) If a pharmacy is not open on a 24-hour basis, a designated **pharmacist(s)** must be available for the emergency supply of pharmaceutical services.
- (c) Contact details of the pharmacist-on-duty must be displayed conspicuously at the pharmacy premises.

ANNEXURE A

SCOPE OF PRACTICE OF PHARMACY PERSONNEL**1. PHARMACY HUMAN RESOURCES****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 72 of the Regulations 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 Council.

1.4 PHARMACIST INTERN

The scope of practice of a pharmacist intern –

- (a) A pharmacist intern 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.
- (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, re-packaging, 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 re-packaging of medicines;
- (e) the initiation and conducting of pharmaceutical research and development; and
- (9) 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 may be prescribed, 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 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
- (9) 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.

2.1.1 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:

2.1.1.1 Circumstances

The responsible pharmacist may be absent from his/her pharmacy subject to the conditions mentioned in paragraph 2.1.1.2 hereunder to –

- (a) fulfil his or her 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.

2.1.1.2 Conditions

A responsible pharmacist may be absent from his or her pharmacy under the circumstances as mentioned in item 2.1.1.1 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 her pharmacy, the responsible pharmacist may be absent only if -
 - (i) schedule 1 substances are 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);
 - (ii) schedule 2 to 6 substances are locked away in an area of which the key must be in the personal possession of the responsible pharmacist;
 - (iii) in the case of written prescriptions a locked box is provided to ensure the confidentiality of prescriptions;
 - (iv) no verbal prescriptions are received in the pharmacy for the period in question; and
 - (v) a sign informing members of the public that no pharmacist is present is 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 performs 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.