

# PHARMACY ACT

Act 53 of 1974.

## RULES RELATING TO GOOD PHARMACY PRACTICE

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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.

(Signed)

**TA MASANGO**

**ACTING REGISTRAR**

*(Please note that the image and logo of the South African Pharmacy Council on page 4 of GG 27112 will be supplied on request. Kindly refer to our website for our contact details.)*

[Page 4 of BN 129 in G. 27112 subs by BN 15 in G. 27229.]

## **ARRANGEMENT OF RULES**

### **INTRODUCTION**

THE UNDERLYING PHILOSOPHY

THE SCOPE OF PRACTICE OF PHARMACISTS

GOOD PHARMACY PRACTICE REQUIREMENTS

GENERAL OBJECTIVES AND REQUIREMENTS OF PHARMACEUTICAL SERVICES

### **CHAPTER 1**

#### **PROFESSIONAL STANDARDS FOR PREMISES**

##### **MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT**

#### **1.1 INTRODUCTION**

#### **1.2 MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT**

1.2.1 APPEARANCE OF PHARMACY PREMISES

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

1.2.3 SECURITY IN PHARMACY PREMISES

1.2.4 CONTROL OF ACCESS TO PHARMACY PREMISES

1.2.5 SAFETY OF PHARMACY PREMISES

1.2.6 CONDITION OF PHARMACY PREMISES

1.2.7 CONSTRUCTION OF PHARMACY PREMISES

1.2.8 ENVIRONMENT IN PHARMACY PREMISES

1.2.9 HYGIENE IN PHARMACY PREMISES

1.2.10 STORAGE AREA IN PHARMACY PREMISES

1.2.11 DISPENSARY

1.2.11.1 Size of dispensary

1.2.11.2 Suitability of dispensary

1.2.11.3 Waste disposal

1.2.11.4 Dispensing equipment

1.2.11.5 Reference sources

1.2.12 WAITING AREA

1.2.13 AREAS FOR COUNSELLING AND THE FURNISHING OF ADVICE

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

1.2.13.2 Semi-private area

1.2.13.3 Separate private area

1.2.13.4 Consultation area for the provision of screening and monitoring services

1.2.13.4.1 Location

1.2.13.4.2 Equipment

**1.3 MINIMUM STANDARDS RELATING SPECIFICALLY TO INSTITUTIONAL PHARMACIES**

**1.4 MINIMUM STANDARDS FOR PHARMACIES PROVIDING MOBILE PHARMACEUTICAL SERVICES**

1.4.1 PRE-REQUISITES FOR CONDUCTING MOBILE PHARMACEUTICAL SERVICES

1.4.2 MOBILE UNIT, FACILITIES AND EQUIPMENT

**1.5 MINIMUM STANDARDS FOR PHARMACIES OPERATING INTERNET SITES**

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

1.6.1 CLASSIFICATION AND MANAGEMENT OF FACILITY

1.6.2 DESIGNATION OF DISPENSARY OR MEDICINE ROOM

1.6.3 CONDITION OF A DISPENSARY OR MEDICINE ROOM

1.6.4 STORAGE AREA IN DISPENSARY OR MEDICINE ROOM

1.6.5 EQUIPMENT FOR DISPENSARY OR MEDICINE ROOM

1.6.6 REFERENCE SOURCES

1.6.7 CONTROL OF ACCESS TO DISPENSARY OR MEDICINE ROOM

**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

1.7.2 CONDITION OF THE MEDICINE ROOM

1.7.3 STORAGE AREAS IN THE MEDICINE ROOM

1.7.4 EQUIPMENT IN THE MEDICINE ROOM OR PREMISES

1.7.5 REFERENCE SOURCES IN THE MEDICINE ROOM OR PREMISES

1.7.6 CONTROL OF ACCESS TO THE MEDICINE ROOM

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

1.8.1 MANAGEMENT OF STORAGE FACILITY

1.8.2 CONDITION OF THE STORAGE AREA

1.8.3 CONTROL OF ACCESS TO THE STORAGE AREA

**1.9 MINIMUM STANDARDS RELATING TO AUTOMATED DISPENSING UNITS FOR THE PURPOSE OF DISPENSING MEDICINES AND MEDICAL DEVICES**

**CHAPTER 2**

**PROFESSIONAL STANDARDS FOR SERVICES**

**MINIMUM STANDARDS FOR SERVICES PROVIDED IN A PHARMACY**

**2.1 INTRODUCTION**

**2.2 MINIMUM STANDARDS FOR MANUFACTURING OF ANY MEDICINE OR SCHEDULED SUBSTANCE**

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

2.3.1 RESPONSIBILITY FOR PROCUREMENT

2.3.2 SOURCES OF SUPPLY

2.3.3 SAFE SYSTEMS OF WORK

2.3.4 MEDICAL GASES

2.3.5 MINIMUM STANDARDS FOR THE PROCUREMENT, STORAGE AND DISTRIBUTION OF THERMOLABILE PHARMACEUTICAL PRODUCTS

2.3.6 MAINTENANCE OF THE REFRIGERATOR

2.3.7 STORAGE PRINCIPLES FOR VACCINES

**2.4 MINIMUM STANDARDS RELATING SPECIFICALLY TO INSTITUTIONAL PHARMACIES**

2.4.1 SELECTION OF PHARMACEUTICALS

2.4.2 PROCUREMENT AND STORAGE

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

**2.5 MINIMUM STANDARDS RELATING SPECIFICALLY TO MOBILE PHARMACEUTICAL SERVICES**

2.5.1 STORAGE AND CONTROL OF MEDICINE AND SCHEDULED SUBSTANCES

## **2.6 MINIMUM STANDARDS RELATING SPECIFICALLY TO WHOLESALE PHARMACIES**

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

### **2.7.1 DISPENSING PROCEDURES**

2.7.1.1 Phase 1: Interpretation and Evaluation of the prescription

2.7.1.2 Phase 2: Preparation and labeling of the prescribed medicine

2.7.1.2.1 Selecting or preparing the medicine

2.7.1.2.2 Labels

2.7.1.2.3 Record keeping regarding the supply of medicine

2.7.1.2.3.1 Schedule 1 record

2.7.1.2.3.2 Prescription Book

2.7.1.3 Phase 3: Provision of information and instructions to the patient to ensure the optimum use of medicine

2.7.1.3.1 Supply to the patient

2.7.1.3.2.1.1 Monitoring patient outcomes

### **2.7.2 SUPERVISION OF DISPENSING AND SALES / SUPPLY**

### **2.7.3 SAFETY IN DISPENSING PROCEDURES**

2.7.3.1 Interpretation of prescription

2.7.3.2 Forged prescriptions

2.7.3.3 Dispensing containers

2.7.3.4 Reuse of containers

2.7.3.5 Reuse of medicines

2.7.3.6 Confidentiality

2.7.3.7 Recalls

2.7.3.8 Personal hygiene

2.7.3.9 Expiry dates

2.7.3.10 Adverse drug reaction reporting

2.7.3.11 Generic substitution

### **2.7.4 PRICING OF PRESCRIPTIONS AND SERVICES**

### **2.7.5 DELIVERY OF MEDICINES**

## **2.8 MINIMUM STANDARDS FOR PATIENT INFORMATION AND ADVICE**

- 2.8.1 PURPOSE
- 2.8.2 GENERAL CONSIDERATIONS
- 2.9 MINIMUM STANDARDS FOR RECORD KEEPING PROCEDURES**
- 2.9.1 PATIENT MEDICATION RECORDS
- 2.9.2 DOCUMENTATION OF PROFESSIONAL ACTIVITIES
- 2.10 MINIMUM STANDARDS FOR DISPENSING SPECIFICALLY IN INSTITUTIONAL PHARMACIES**
- 2.10.1 INDIVIDUAL PATIENT DISPENSING (IPD)
- 2.10.2 EMERGENCY MEDICINE TROLLEY
- 2.11 MINIMUM STANDARDS FOR CLINICAL PHARMACEUTICAL SERVICES IN INSTITUTIONAL PHARMACIES
- 2.11.1 INTRODUCTION
- 2.11.2 WARD PHARMACY SERVICES
- 2.11.3 PRESCRIPTION MONITORING
- 2.11.4 PROVISION OF DRUG INFORMATION AND ADVICE
- 2.11.4.1 Minimum requirements for a drug information service
- 2.12 MINIMUM STANDARDS FOR PHARMACIST INITIATED THERAPY**
- 2.12.1 SERVICES RELATING TO A SPECIFIC PATIENT 46
- 2.12.1.1 Response to symptoms
- 2.12.1.2 Self Care Products including the supply of Schedule 0, Schedule 1 and Schedule 2 medicines
- 2.12.1.3 Follow up
- 2.13 MINIMUM STANDARDS FOR SCREENING AND MONITORING SERVICES IN PHARMACIES**
- 2.13.1 MINIMUM STANDARDS ON PROMOTION OF PUBLIC HEALTH
- 2.13.1.1 Physical facilities
- 2.13.1.2 Documentation and record keeping
- 2.13.1.3 Professional and ethical aspects
- 2.13.2 MINIMUM STANDARDS REGARDING TESTING

- 2.13.2.1 Minimum standards regarding test materials and instruments
- 2.13.2.2 Minimum standards regarding the taking of samples
- 2.13.3 MINIMUM STANDARDS FOR BLOOD PRESSURE MONITORING SERVICES
  - 2.13.3.1 Equipment
  - 2.13.3.2 Procedure and interpretation of results
  - 2.13.3.3 Documentation and record keeping
- 2.13.4 MINIMUM STANDARDS FOR THE PERFORMANCE OF PEAK FLOW TESTS
  - 2.13.4.1 Equipment
  - 2.13.4.2 Procedure and interpretation of results
  - 2.13.4.3 Documentation and record keeping
- 2.13.5 MINIMUM STANDARDS FOR THE PERFORMANCE OF HIV TESTS
  - 2.13.5.1 Physical facilities and equipment
  - 2.13.5.2 Collecting of samples
  - 2.13.5.3 Informed consent
  - 2.13.5.4 Counselling
  - 2.13.5.5 Interpretation of results
  - 2.13.5.6 Collecting and sending blood samples to a laboratory
  - 2.13.5.7 Documentation and record keeping
  - 2.13.5.8 Ethical Aspects
  - 2.13.5.9 Training
  - 2.13.5.10 Advertising the service
- 2.14 MINIMUM STANDARDS FOR IMMUNISATION SERVICES**
  - 2.14.1 PHYSICAL FACILITIES AND EQUIPMENT
  - 2.14.2 PROCEDURE
  - 2.14.3 DOCUMENTATION AND RECORD KEEPING
  - 2.14.4 ETHICAL ASPECTS
  - 2.14.5 TRAINING
- 2.15 MINIMUM STANDARDS FOR REPRODUCTIVE HEALTH SERVICES**
  - 2.15.1 PHYSICAL FACILITIES AND EQUIPMENT
  - 2.15.2 PROCEDURE
  - 2.15.3 DOCUMENTATION AND RECORD KEEPING

2.15.4 LEGAL AND ETHICAL ASPECTS

2.15.5 TRAINING

**2.16 MINIMUM STANDARDS FOR OTHER HEALTH CARE SERVICES**

2.16.1 RESIDENTIAL AND NURSING HOMES

2.16.2 SMOKING CESSATION

2.16.3 NUTRITION ADVICE

2.16.4 BABY AND CHILD HEALTH

**2.17 MINIMUM STANDARDS FOR ASEPTIC DISPENSING SERVICE**

2.17.1 INTRAVENOUS ADDITIVE SERVICE

2.17.2 TOTAL PARENTERAL NUTRITION (TPN) PREPARATION SERVICE

2.17.3 CYTOTOXIC PREPARATION AND RECONSTITUTION SERVICE

**2.18 COMPOUNDING**

**2.19 PRE-PACKING**

2.19.1 MINIMUM STANDARDS FOR PRE-PACKING

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

**2.21 MINIMUM STANDARDS FOR THERAPEUTIC MEDICINE MONITORING SERVICE**

**2.22 MINIMUM STANDARDS FOR THE PROVISION OF COMPLEMENTARY MEDICINE**

**2.23 MINIMUM STANDARDS FOR ANIMAL HEALTH CARE SERVICES**

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

2.24.1 FACILITIES

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

2.24.3 RESPONSIBILITIES

**2.25 REVIEW OF PATIENTS OVERALL MEDICATION REQUIREMENTS**

2.25.1 PATIENT INFORMATION / DATABASE

2.25.2 ASSESSMENT



- 2.25.3 DEVELOPMENT OF A CARE PLAN (TAKING APPROPRIATE ACTIONS)
- 2.25.4 FOLLOW-UP EVALUATION

### **CHAPTER 3**

#### **PROFESSIONAL STANDARDS FOR PHARMACY HUMAN RESOURCE**

##### MINIMUM STANDARDS FOR HUMAN RESOURCES IN PHARMACY

#### **3.1 SCOPE OF PRACTICE OF PHARMACY PERSONNEL**

#### **3.2 RECOMMENDED STANDARDS REGARDING STAFF SELECTION, APPRAISAL AND TRAINING**

- 3.2.1 STAFF SELECTION
- 3.2.2 STAFF APPRAISAL AND DEVELOPMENT
- 3.2.3 STAFF TRAINING

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

##### **3.3.1 PHARMACIST INTERNS / PRE-REGISTRATION EXPERIENCE**

- 3.3.1.1 Objectives of the internship
- 3.3.1.2 Prerequisites for training

##### **3.3.2 PHARMACISTS ASSISTANTS**

- 3.3.2.1 Prerequisites for training

#### **3.4 MINIMUM STANDARDS ON PHARMACEUTICAL HUMAN RESOURCE PHARMACEUTICAL PERSONNEL**

##### **3.4.1 STANDARDS FOR CONTINUING PROFESSIONAL DEVELOPMENT OF PHARMACEUTICAL PERSONNEL**

- 3.4.1.1 Competency
- 3.4.1.2 Self-assessment (self-audit)
- 3.4.1.3 Legislative changes
- 3.4.1.4 New services
- 3.4.1.5 Other health care professionals

#### **3.5 PROFESSIONAL INDEMNITY**

- 3.6            MINIMUM STANDARDS FOR “LOCUM” / RELIEF PHARMACISTS**
  
- 3.7            MINIMUM STANDARDS FOR THE MANAGEMENT OF HUMAN RESOURCES IN WHOLESALE PHARMACIES**
  
- 3.7.1        GENERAL
- 3.7.2        PHARMACY SUPPORT PERSONNEL
- 3.7.3        RESPONSIBLE PHARMACIST
  
- 3.7.3.1      Duties and responsibilities of the responsible pharmacist
  
- 3.7.4        TRAINING
- 3.7.5        HYGIENE

## **CHAPTER 4**

### **PROFESSIONAL STANDARDS FOR PHARMACY MANAGEMENT**

#### MINIMUM STANDARDS FOR MANAGEMENT OF THE PHARMACY / PHARMACEUTICAL SERVICE

- 4.1            INTRODUCTION**
  
- 4.2            MINIMUM STANDARDS FOR PHARMACY ADMINISTRATION AND MANAGEMENT**
  
- 4.2.1        PHARMACY MANAGEMENT
  
- 4.2.1.1      Pharmacy Planning
  
- 4.2.2        QUALITY STANDARDS FOR PHARMACY
  
- 4.2.2.1      Quality Management
- 4.2.2.2      Pharmacy Effectiveness
  
- 4.2.3        ETHICS AND PROFESSIONAL STANDARDS
  
- 4.2.3.1      Inter-professional relationships
- 4.2.3.2      Closure of Pharmacies
- 4.2.3.3      Standard Operating Procedures
  
- 4.2.3.3.1    Community Pharmacy
- 4.2.3.3.2    Institutional Pharmacy
- 4.2.3.3.3    Wholesale Pharmacy

4.2.3.3.4 Primary health facility

### **4.3 MINIMUM STANDARDS FOR QUALITY MANAGEMENT IN THE INSTITUTIONAL PHARMACY**

4.3.1 MANAGEMENT

4.3.2 PHARMACY AND THERAPEUTICS COMMITTEES

4.3.3 ADVERSE REACTION REPORTING

4.3.4 MANAGING FORMULARIES, CLINICAL GUIDELINES AND TREATMENT PROTOCOLS

4.3.5 MINIMUM STANDARDS FOR VISITS BY PHARMACEUTICAL REPRESENTATIVES

4.3.6 MINIMUM STANDARDS FOR CONTINUOUS SUPPLY OF MEDICINES

## **ANNEXURES**

### **ANNEXURE A SCOPE OF PRACTICE OF PHARMACY PERSONNEL**

## **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 patients 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) Effective systems 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 and surname 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.  
[R 1.2.1(d) subs by BN 50 in G. 38511.]
- (e) The pharmacist(s) and pharmacy support personnel on duty must wear a name tag or badge indicating his / her name, surname and registered designation (e.g. responsible pharmacist, specialist, etc.) for the purposes of identification of such person by the public. This may be combined into a single badge or two separate badges.  
[R 1.2.1(e) subs by BN 50 in G. 38511.]
- (f) 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) ...

[R 1.2.2(b) rep by BN 35 in G. 35095.]

### **1.2.2.1 A PHARMACY IN ANOTHER BUSINESS**

- (a) The pharmacy premises must be clearly identified and demarcated from the premises of any other business or practice.
- (b) The demarcation must be permanent, solid and closed-off at all times, which demarcation may be *inter alia*, brick and mortar, aluminium, steel, glass, dry wall or wood partition.
- (c) The demarcation must be from floor to the ceiling height and must enclose all areas attached to the pharmacy, viz; the waiting area, the clinic, the semi-private area and the private area.
- (d) The pharmacy must have a single point of entry and a single point of exit in compliance with the Occupational Health and Safety Act, 85 of 1993 (OHSA).
- (e) In order to comply with the requirement of accessibility to pharmaceutical services, a pharmacist must have an unfettered 24-hour access to the pharmacy.

[R 1.2.2.1 ins by BN 35 in G. 35095.]

### **1.2.2.2 ANOTHER BUSINESS OR PRACTICE IN A PHARMACY**

The following criteria will be applied by Council in considering applications for another business or practice in a pharmacy. The opening and operation of another business in a pharmacy must be such that—

- (a) the other business has obtained approval from their statutory council or registration authority (if applicable) and submit same with the application.
- (b) the other business does not pose any conflicting interest either ethically or professionally to the practice of pharmacy such as—

- (i) added security risk to the keeping and supply of medicines;
  - (ii) added risk to the patients;
  - (iii) compromises the quality, efficacy and safety of the medicine.
- (c) the premises of the other business must be clearly identified and demarcated from the pharmacy premises—
  - (i) the demarcation must be permanent, solid and closed-off at all times, which demarcation may be *inter alia*, brick and mortar, aluminium, steel, glass, dry wall or wood partition;
  - (ii) The demarcation must be from floor to the ceiling height and must enclose all areas attached to the pharmacy, viz; the waiting area, the clinic, the semi-private area and the private area.

[R 1.2.2.2 ins by BN 35 in G. 35095.]

### **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.
- (f) 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.
- (f) 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 90 cm 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 five editions of Martindale.  
[R 1.2.11.5(a) subs by BN 35 in G. 35095.]
- (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.
- (f) 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) semi-private area at each point where dispensing of medicine to the patient or the patient's agent / caregiver occurs.
- (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(s) at each point where dispensing of medicine to the patient or the patient's agent / caregiver occurs, there must in addition be access to another separate private room / area where communication can take place between a pharmacist and a patient or the patient's agent / caregiver in private.

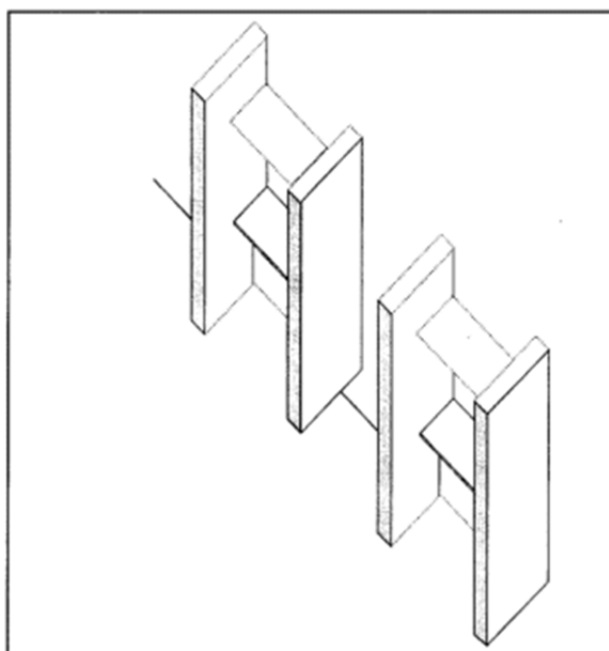
Standards for the different types of areas, including the equipment required, are provided below.

[R 1.2.13.1 subs by BN 83 in G. 31378.]

#### **1.2.13.2 Semi-private area(s)**

This area(s) is for the provision of information and / or advice that may occur in an area visible to other patients.

- (a) The area(s) could be of a modular “bank teller” type, where a counter is utilised, offering the patient or his / her agent / caregiver 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 or his / her agent / caregiver 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(s), 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**

[R 1.2.13.2 subs by BN 83 in G. 31378.]

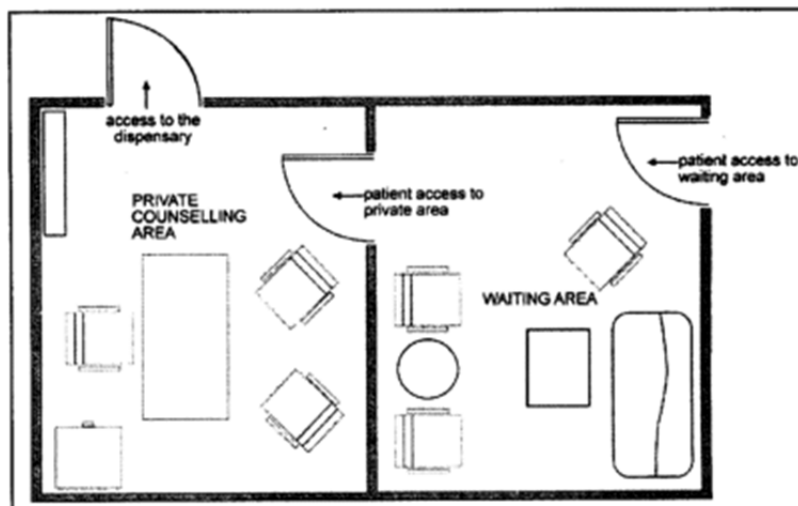
**1.2.13.3 Separate private area**

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, 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 and / or his / her agent / caregiver on medicines, and other related issues.

[R 1.2.13.3(a) subs by BN 83 in G. 31378.]

- (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 adequate. 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**

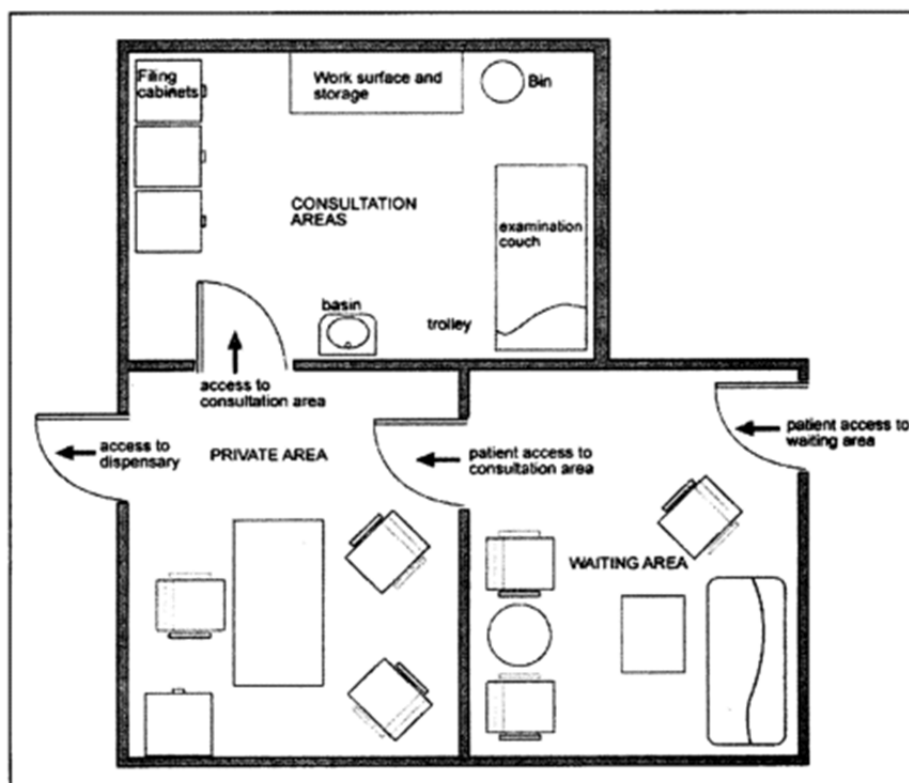
[R 1.2.13.3(c) subs by BN 83 in G. 31378.]

**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 7.5 square meters).  
[R 1.2.13.4.1(b) subs by BN 83 in G. 31378.]
- (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.
- (f) A toilet in the vicinity of the consultation area is strongly recommended.
- (g) A comfortable waiting area for patients situated, if possible, near the consultation area is a necessity.
- (h) Procedures must be in place to ensure that medicines and working areas are not contaminated by infected materials and / or instruments.

#### **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;
- (f) a peak flow meter;
- (g) a "Road to Health Card" and additional copies for supply to patients;
- (h) tongue depressors;
- (i) equipment used for first aid, e.g. plaster, gauze, cotton wool, sterile wound dressings, scissors;
- (j) disposable rubber gloves;
- (k) oxygen with a flow meter;
- (l) a clinical thermometer;
- (m) alcohol swabs of 70% alcohol solution or surgical spirits;
- (n) a magnifying glass;
- (o) tissues;
- (p) towels or paper towels;
- (q) disinfectants (especially disinfectants recommended for control of the AIDS virus e.g. 2% glutaraldehyde, 1% 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.

#### **1.2.14 PHARMACY TRANSACTIONS**

For a pharmacy that is within another business, the following transactions shall take place within the pharmacy only—

- (a) The prescription shall be handed over or delivered to a designated pharmacy staff or submitted to the pharmacy directly, e.g. by electronic transmission, postal / courier delivery or deposited in a locked prescription receiving box which is only accessible to the pharmacist (as per GPP rules).
- (b) the dispensing process (phase 1,2, and 3).
- (c) the recording of medicines and scheduled substances, which includes the recording of schedule 1 and 2 medicines in terms of Regulation 11 of the General Regulations to the Medicines and Related Substance Act 101 of 1965.
- (d) the payment for all medicine and scheduled substances.

[R 1.2.14 ins by BN 35 in G. 35095.]

### **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, repackaging, 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 numbers) 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 assistants (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.
- (f) 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.
- (f) 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.
- (f) 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) EDL / STG.
- (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 subdistrict 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.
- (f) 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 be stored 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.

## **1.9 MINIMUM STANDARDS RELATING TO AUTOMATED DISPENSING UNITS FOR THE PURPOSE OF DISPENSING MEDICINES AND MEDICAL DEVICES**

### **1.9.1 Introduction**

Automated dispensing units (ADUs) are mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, picking, packaging, labelling, and / or giving out medicines and medical devices. They are also called automated dispensing cabinets (ADCs), automated dispensing devices (ADDs), automated dispensing machines (ADMs), automated pharmacy systems (APS), or unit-based cabinets (UBC).

Council recognises that ADUs are technology advancements that can improve speed and accuracy of medicine delivery. ADUs can assist pharmacists and licensed dispensers with phase 2 of dispensing, freeing them to focus more on patient care. The role of ADUs in the dispensing process makes it necessary for Council to exercise its ethical and legal commitment to the community by regulating ADUs in order to ensure safe delivery of pharmaceutical services.

### **1.9.2 Purpose**

The purpose of this standard is to regulate the use of ADUs in community pharmacies, institutional pharmacies, dispensaries in primary health care clinics and medicine rooms of licensed dispensers. Minimum standards specifically relating to ADUs are thus intended to guide pharmacists and licensed dispensers on the use of ADUs. Where ADUs are utilised, all relevant legislation is applicable.

### **1.9.3 General considerations**

- (a) ADUs may be installed in a pharmacy or dispensary in a primary health care clinic or medicine rooms of licensed dispensers for the purpose of assisting with phase 2 of the dispensing process in accordance with the applicable legislation.
- (b) The installation and the location of the ADU must be such that medicines and medical devices are not accessed and / or received directly by the patient or his or her caregiver or agent.
- (c) The Responsible Pharmacist wishing to install the ADU must apply to Council and pay the applicable fees prior to installation and operation of an ADU.
- (d) The ADU may be installed in the primary healthcare clinic dispensary that complies with the minimum standards provided in Rule 1.6 of the GPP document.
- (e) The ADU may be installed in the medicine room of a licensed dispenser that complies with the minimum standards provided in Rule 1.7 of the GPP document.
- (f) The Responsible Pharmacist or a licensed dispenser utilising the ADU must have a contingency plan to ensure continuous supply of medicines and medical devices in an event of power or system failure.
- (g) A pharmacy that operates an ADU must still comply to all relevant standards and legislation.

### **1.9.4 Dispensing of medicines using a ADU**

- (a) Phase 1 and Phase 3 of dispensing must be done by the pharmacist, pharmacy support personnel or licensed dispenser, within their scope of practice.
- (b) A pharmacist, pharmacy support personnel or licensed dispenser may only operate one ADU at a time and thereby dispense one prescription at a time.

- (c) The pharmacist or licensed dispenser must be accessible to respond to inquiries or requests pertaining to all medicines and medical devices dispensed from an ADU.
- (d) All prescription dispensed from ADU must be signed in person by the pharmacist or licensed dispenser.
- (e) All medicines and medical devices stored in the ADU must be packaged and labelled in accordance with the applicable legislation when dispensed to the patient.

#### **1.9.5 The stocking and management of the ADU**

The filling and or stocking of all medicines and medical devices into the ADU must be done by the pharmacist, pharmacist intern, and relevant pharmacy support personnel under the supervision of the pharmacist or licensed dispenser.

#### **1.9.6 The responsibilities of a responsible pharmacist of a pharmacy approved to operate an ADU**

In addition to complying with the requirements of Regulation 28 of the Regulations relating to the practice of pharmacy, the responsible pharmacist must—

- (a) ensure that access to the medicines and medical devices in the ADU comply with the applicable legislation.
- (b) ensure that only registered persons handle medicines and medical devices in the ADU.
- (c) ensure that the ADU is filled / stocked accurately and in accordance with established, written policies and procedures.
- (d) ensure that in the process of picking, re-packaging and packing, cross-contamination is avoided at all times.
- (e) ensure that the ADU is tested prior to initial use in accordance with the manufactures' specifications to ensure that the ADU is operating properly.
- (f) ensure that the ADU is tested on a periodic basis in accordance with the manufactures' specifications to ensure that the ADU is operating properly.
- (g) assign, discontinue, or change access control of persons to the ADU in line with such persons scope of practice.

#### **1.9.7 Security, location, connectivity and features of an ADU**

- (a) The ADU must have adequate security systems and procedures, evidenced by written policies and procedures, to—
  - (i) prevent unauthorised access;
  - (ii) comply with legislation; and
  - (iii) prevent the illegal use or disclosure of protected health information (confidentiality).
- (b) The ADU must have a procedure and physical mechanism for securing and accounting for medicines and medical devices removed from and subsequently returned to the ADU, all in accordance with the applicable legislation.
- (c) The ADU must have a procedure and physical mechanism for securing and accounting for damaged or expired medicines and medical devices in accordance with the applicable legislation.

#### **1.9.8 Record keeping**

- (a) A record of medicines and medical devices filled and or stocked into the ADU must be maintained and must include identification of the registered persons filling / stocking and checking for accuracy.
- (b) Records must be maintained and must be readily available to Council. Over and above the requirements of Regulations 11 and 30, such records, must include but are not limited to—
  - (i) Identification of the persons accessing the ADU for purposes stock management;
  - (ii) identification of persons accessing the ADU for purposes of dispensing;
  - (iii) name, strength, dosage form, and quantity of the medicine and / or medical devices;
  - (iv) name of the patient for whom the medicine and / or medical devices were dispensed; and
  - (v) such additional information as the responsible pharmacist may deem necessary.
- (c) All transactions involving medicines and medical devices stored in the ADU must be recorded electronically.



- (d) All aspects of handling specified Schedule 5 and Schedule 6 medicines must meet the requirements of all applicable legislation.

### **1.9.9 Information to be submitted in support of an application for the installation of the ADU in a pharmacy**

Documentation that must be submitted with the application for review by Council must include but is not limited to—

- (a) manufacturer's name and model of the ADU including type of equipment and serial numbers.
- (b) a professionally drawn floor plan and site plans of the pharmacy premises indicating the location of the ADU.
- (c) name and address of the pharmacy where the ADU is to be installed.
- (d) description of how the ADU is used in the dispensing process.

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## **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.
- (f) that patients receive stock that has been suitably stored and has an expiry date that allows sufficient time for usage by the patient before the expiry date.

### **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.
- (f) 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 storekeeping 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.
- (f) 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 MINIMUM STANDARDS FOR THE PROCUREMENT, STORAGE AND DISTRIBUTION OF THERMOLABILE PHARMACEUTICAL PRODUCTS**

### **2.3.5.1 Introduction**

Thermolabile pharmaceutical products are defined as all products which require constant cold storage at product specific temperatures below room temperature. This also includes vaccines which are normally stored between 2°C and not exceeding 8°C. "Cold chain products" bears a corresponding meaning.

Storage, supply and distribution forms part of the supply chain management of thermolabile pharmaceutical products. All pharmacists are responsible for the effective, efficient and safe handling, storage and distribution of such products. These standards set out appropriate steps for meeting this responsibility.

Handling and storage of thermolabile pharmaceutical products must be in accordance with procedures, which must be established and designed to prevent contamination, deterioration of

the goods, and damage to packs and / or confusion of products. Particular care must be given to maintaining the integrity of ingredients and seals on packs. Attention must be paid to instructions from the manufacturer relating to handling or storage of the goods. Distribution systems chosen to deliver thermolabile pharmaceutical products from the manufacturer / importer to the end user must take into account basic operational parameters, including timeliness and accountability.

Importers must take all reasonable measures to ensure that thermolabile pharmaceutical products are not mishandled or exposed to adverse storage conditions at ports of entry.

Storage, supply and distribution of thermolabile pharmaceutical products must be in accordance with the provisions of the Medicines and Related Substances Control Act, 101 of 1965 and the manufacturer's specification.

#### **2.3.5.2 Procurement**

Procurement of thermolabile pharmaceutical products must be performed in terms of the Minimum standards for procurement, storage and distribution as detailed in Rule 2.3 of the *Rules pertaining to good pharmacy practice*.

#### **2.3.5.3 Storage area**

Storage areas may include *inter alia* **cold rooms, refrigerators and freezer**. Thermolabile pharmaceutical products require controlled temperature storage and therefore must be identified on receipt and be stored in accordance with written instructions. Temperatures must be monitored and recorded twice daily. Records must be reviewed regularly. Controlled temperature storage areas must be equipped with temperature recorders. Control must be adequate to maintain all parts of the area within the specified temperature range. This control is essential in maintaining the quality of thermolabile pharmaceutical products and in helping to protect the end user from substandard or ineffective thermolabile pharmaceutical products as a result of inadequate control—

- (a) Thermolabile pharmaceutical products must be stored in a storage area, refrigerator or cold room, in a temperature regulated environment as per the information on the manufacturer's product label indicating which temperature must be maintained at all times.
- (b) The storage area must be large enough to allow for orderly arrangement of products, to permit air circulation especially between shelving and for proper product rotation. If it is filled to capacity, the effect on temperature distribution must be investigated.

- (c) The storage area must be kept clean. Internal air temperature distribution must be mapped on installation of the storage area while empty and thereafter fully stocked. This must be done annually under conditions of normal use. Thermolabile pharmaceutical products must not be stored in areas shown by temperature mapping to present a risk (e.g. in the airflow from the refrigeration unit).
- (d) All storage areas, such as refrigerators or cold rooms must be properly maintained in order to maintain the factory standards for such storage areas. Proof of maintenance must be provided.
- (e) Condensation from chillers must not be collected inside the storage area, and no condensation from chillers may collect or drip onto the products.
- (f) A suitable number of temperature recording instruments that complies with or meets WHO specifications, being at least a logging device, must be installed to record temperatures and to provide temperature and profiles as per the temperature mapping of the storage area. Monitors that complies with or meets WHO specifications, must be adequate to monitor and record temperature ranges in all parts of the area within the specified temperature range.
- (g) Temperatures must be monitored and recorded at least twice daily, with a minimum of seven hour interval and the records from such monitoring must be reviewed daily.
- (h) Large commercial refrigerators and walk-in cold rooms must be monitored with an electronic temperature-recording device that measures load temperature in one or more location, depending on the size of the unit.
- (i) In the monitoring of large commercial refrigerators and walk-in cold rooms, portable data-loggers that can be downloaded onto a computer may be used instead of a fixed device.
- (j) The refrigerator, cold room or freezer must be connected to a standby generator or other emergency power system to ensure uninterrupted power supply in the event of power failure.
- (k) The refrigerator, cold room or freezer must be connected to an alarm system and / or warning system in the event of a power failure or if the storage area temperature limits are exceeded.
- (l) Any recording devices / instruments must be calibrated annually against a certificated standard.

- (m) The refrigerator, cold room or freezer must be clearly designated and appropriately signed to store exclusively thermolabile pharmaceutical products.
- (n) Within a community or institutional pharmacy the storage area must be inside the pharmacy and must be easily accessible to the pharmacist and pharmacy support personnel and other authorised healthcare professionals.
- (o) Within a health facility (other than a pharmacy), any storage area for thermolabile pharmaceutical products must be easily accessible to the authorised healthcare professionals.

#### **2.3.5.4 Distribution**

A distribution system must have in place—

- (a) a comprehensive quality system.
- (b) a process for continual quality improvement.
- (c) an ambient and cold chain distribution strategy.
- (d) a risk assessment programme.

Thermolabile pharmaceutical products must be transported by appropriately specialised means in such a way that they are secure and are not subjected to unacceptable degrees of heat / cold.

- (a) Packaging system of thermolabile pharmaceutical products, for purposes of distribution must be quality assured to ensure that it occurs within the cold room environment, fulfils the manufacturers' specifications requirements, is thermally designed and validated, and is related to Temperature Profile(s) / Logistic history.
- (b) There must be clear, visible labelling on the packaging with instructions regarding storage conditions, special precautions and warnings for the shipment.

#### **2.3.5.5 Transportation**

- (a) Transportation of thermolabile pharmaceutical products must be in such a way that it is secure and the temperature is maintained to product specifications.
- (b) Mode(s) of transportation must be approved for transporting thermolabile pharmaceutical products. Examples include refrigerator trucks, cars, ships, and containers. Thermolabile

pharmaceutical products shall be transported in any mode(s) of transportation which is permanently enclosed and sealed. No open vehicles shall be permitted for purposes of transporting thermolabile pharmaceutical products.

- (c) In the event of the mode(s) of transport not being specific for the transportation of thermolabile pharmaceutical products, the specialised packaging like validated cooler bag packaging must be used.
- (d) For purposes of transportation, the route must be planned and assessed and / or validated to ensure that delays and / or exposure to extreme temperatures are correctly assessed. Transportation between South Africa and other neighbouring countries and within South Africa, due to large geographical areas, must be treated as unique in terms of the range of temperatures that the thermolabile pharmaceutical products may experience.
- (e) The transport must be clean and free from all forms of contamination, *inter alia* rats, vermin, birds, fungi, and mites.
- (f) During transportation thermolabile pharmaceutical products must not be packaged with non-pharmaceutical items or containerised with any other goods (for example food and beverages which may also require refrigeration transportation), which could result in contamination.
- (g) The transport must have a sufficient capacity to allow for orderly storage of thermolabile pharmaceutical products during transportation.
- (h) Temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards that complies with or meets WHO specifications must monitor the temperature of the loaded area of the transportation throughout the trip, and the validated cooler box packaging must have at least a temperature monitoring device that complies or meets with WHO specifications.
- (i) Personnel transporting thermolabile pharmaceutical products must be appropriately trained, in terms of an approved unit standard for cold chain management and shall provide the suitable documentation as proof, for this function and they must ensure that the correct procedures are followed to maintain the cold chain within the manufacturer's specification.
- (j) At any stage of transportation, a delivery document must show evidence that the transport requirements, *inter alia* temperature control have been met.



- (k) Damage to containers or any other event or problem which occurs during transit must be reported to and recorded by the Responsible Pharmacist of the distributing pharmacy. Upon arrival the person responsible for the transportation of the thermolabile pharmaceutical products must inform receiving personnel, pharmacists, or other authorised healthcare professionals, that the package includes thermolabile pharmaceutical products and that they require immediate attention.

#### **2.3.5.6 Receiving**

Thermolabile pharmaceutical products must be identified on receipt and be stored in accordance with written instructions for purposes of stock management within the shortest possible time from offloading.

- (a) The receiving area must protect deliveries from bad weather during the unloading of thermolabile pharmaceutical products.
- (b) The receiving area must be separated from the storage area.
- (c) Upon arrival of thermolabile pharmaceutical products, the receiving personnel must do spot checks and inspect the delivery vehicle to ensure product integrity with regards to the following—
  - (i) product security;
  - (ii) that the product has not been tampered with and that there are no damaged containers;
  - (iii) that products were protected from weather;
  - (iv) and that there is no risk for contamination of products.
- (d) The delivery document must be reviewed for evidence that transportation requirements, *inter alia* temperature control, have been met.
- (e) Check temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards to ensure the temperature history of the transport and the temperature history of the thermolabile pharmaceutical product being transported were maintained within in limits.
- (f) If any discrepancies are identified, they must all be documented. In addition the supplier must be notified immediately and the thermolabile pharmaceutical products must be identified and segregated.

- (g) A Standard Operating Procedure for receiving of thermolabile pharmaceutical products must be used to ensure these products are within manufacturer specific temperature range during the receiving process.
- (h) Quality assessment sampling requiring laboratory testing is required for the received thermolabile pharmaceutical products within a manufacturing pharmacy before they are taken to the main store facility.
- (i) Quality assessment sampling requiring observation for damaged products is required for the received thermolabile pharmaceutical products within a wholesale, community or institutional pharmacy before they are taken to the main store facility.
- (j) Delivery documents must be signed off on temperature data and condition of other control devices used.
- (k) The thermolabile pharmaceutical products must be removed from the transportation container or cooler bag prior to storage in the main store area to prevent temperature deviation.

#### **2.3.5.7 Documentation**

- (a) Documentation is critical. Each step of the supply chain must follow established protocols in order to maintain proper records.
- (b) Customs delays may occur due to inaccurate or incomplete customs documentation, therefore guidelines for creating a commercial invoice must be followed to ensure the proper verbiage, number of copies, and other details.
- (c) Each time the process does not conform to the procedure, the event must be properly documented, investigated and corrected so that the deviations do not occur on future transportation.

#### **2.3.5.8 Personnel**

- (a) All persons involved in the procurement, storage and distribution of thermolabile pharmaceutical products must have the education, training, experience or combination of these elements that will allow them to effectively discharge this responsibility and be capable of meeting these requirements. This training must be documented.

- (b) Procedures and conditions of work for employees and other persons having access to thermolabile pharmaceutical products must be designed and managed to minimise the possibility of such pharmaceutical products being in possession of unauthorised persons.
- (c) All persons involved in the procurement, storage and distribution of thermolabile pharmaceutical products must have the ability / skill appropriate to their responsibility, for ensuring that thermolabile pharmaceutical products are handled, stored and distributed in accordance with the required minimum standards.
- (d) There must be an adequate number of competent persons involved in all stages of the distribution of thermolabile pharmaceutical products in order to ensure that the quality of these products is maintained.
- (e) Persons involved in the procurement, storage and distribution of thermolabile pharmaceutical products must be supplied with appropriate personal protective equipment and with specialised protective garments suitable for the activities that they perform.
- (f) Material safety data sheets must be accessible to any staff member that requires the information. A Spillage Handling Standard Operating Procedure must be available, in accordance with national environment management act (1978) and other related prescripts.
- (g) Appropriate procedures relating to personal hygiene and sanitation, relevant to the activities to be carried out, must be established and observed. Such procedures must cover *inter alia* health, hygiene and clothing of personnel.

#### **2.3.5.9 Disruption in the procurement, storage and distribution of thermolabile pharmaceutical products (cold chain)**

When there is a disruption in the storage and or distribution of thermolabile pharmaceutical products or a disruption is reasonably suspected—

- (a) In the event that there is disruption in the cold chain, the designated responsible person must be informed and appropriate steps taken to manage the situation.
- (b) Actions must comply with manufacturer's documented advice, where possible and where available.
- (c) An incident report and root cause analysis investigation must be completed to ensure lessons are learned to prevent reoccurrence.

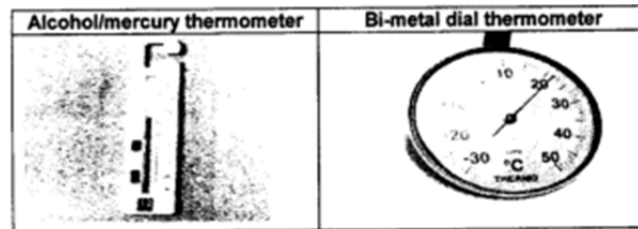
- (d) Pharmacies and authorised healthcare professionals must have business continuity plans for storing thermolabile pharmaceutical products in the event of refrigerator breakdown, loss of electricity supply, defrosting or other disruptions to the cold chain, which must be implemented immediately to prevent loss.
- (e) Refrigerator temperature must be recorded by noting the current reading and recording the maximum and minimum temperatures.
- (f) If the temperature of the storage area has deviated from the product specific temperature requirement, stock must be moved to an alternative cold storage area.
- (g) In the event of moving stock, the stock so moved must be segregated by packing separately and marked, indicating "Batch Number(s) involved in a potential incident - **do not use until authorised**" and dated to make sure the implicated stock can be identified and kept separate.
- (h) Where immediate removal is not possible, the storage area must be kept closed to maximise temperature control.
- (i) Monitoring of the temperature must be maintained on at least an hourly basis and recorded up until the point of restoration to working order of the storage area or removal and transfer to another cold store.
- (j) Check for evidence of exposure of the thermolabile pharmaceutical products for deviations in temperature and establish how long the products have been stored outside of the specified temperature requirements.
- (k) Refer to the manufacturer for advice on stability as a result of temperature deviation and report the occurrence on an incident report form.
- (l) Where necessary record and quarantine the thermolabile pharmaceutical product for destruction in line with the minimum standards for destruction and disposal of medicines and scheduled substances.
- (m) If advised that the products are safe for use then mark as **"Use first"** and date, such products must then be used before any other stock of the same product.

[R 2.3.5 subs by BN 50 in G. 38511.]

#### 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

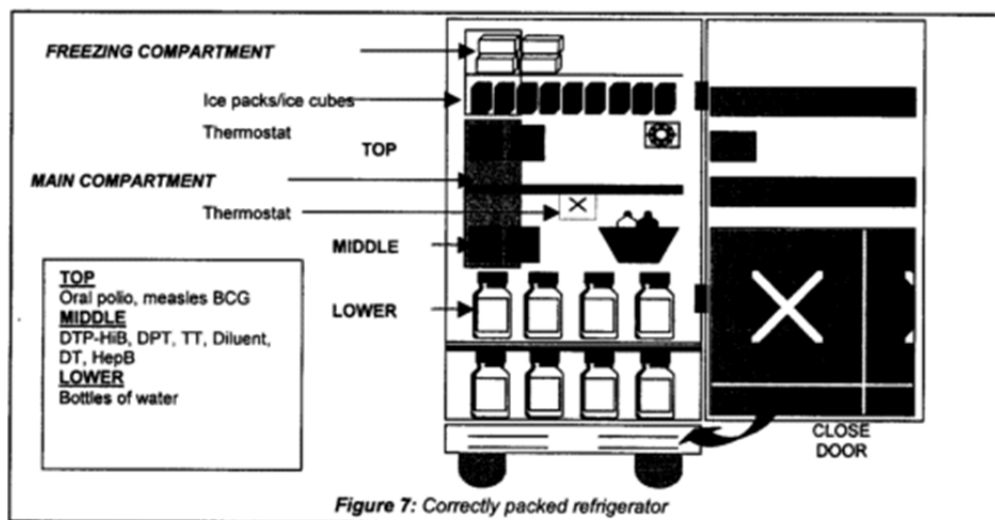


- (d) If the power is off for any length of time, the refrigerator should not be opened until the power supply is restored.
- (e) The refrigerator must be cleaned and defrosted at least once a month.
- (f) The cold chain must be maintained when the refrigerator is cleaned. Cooler boxes should be used 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 10 mm 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**

1. *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.
2. *Choose a test sample:* Take a vial of vaccine from the batch that you suspect has been frozen. This is the test sample.
3. *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.
4. *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**

<b>When should a child be immunised?</b>		
<b>Age of Child</b>	<b>Which Vaccine?</b>	<b>How and where is it given?</b>
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 / re-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 five 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.
- (f) 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
- (f) prescription reference number.

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

### **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.

#### **2.7.1.3.2.1.1 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.
- (f) 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.
- (f) 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).

#### **2.7.3.11 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 MINIMUM STANDARDS SPECIFICALLY RELATING TO THE COLLECTION AND THE DELIVERY OF MEDICINES TO PATIENTS FROM A COMMUNITY OR INSTITUTIONAL PHARMACY**

### **2.7.5.1 Purpose**

The purpose of this standard is to regulate activities relating to the collection by and the delivery of medicines to patients from a community or institutional pharmacy.

### **2.7.5.2 General considerations**

- (a) All efforts must be made to enable access to counselling of the patient by a pharmacist relevant to their healthcare needs;
- (b) When a person other than a pharmacist delivers medicines to a patient or a patient's caregiver, the pharmacist must furnish written instructions, that shall include the patient's details and information regarding the correct use of medicine, and a patient information leaflet (where applicable);
- (c) All medicines should, whenever possible, be delivered to patients at an agreed time or date; and
- (d) In the absence of an adult (i.e. a person above 14 years old as defined by the Medicines Act) or another person entitled by law to receive the medicine, it must be retained and stored under appropriate conditions until delivery can be effected or be returned to the pharmacy.

### **2.7.5.3 Collection of medicines from the pharmacy**

Definition: **Agent:** a person nominated, either formally or informally, by the patient.

**Caregiver:** a person who has accepted responsibility for looking after a patient.



The caregiver or agent may not practice the scope of practice of a pharmacist.

- (a) A patient's agent or caregiver may collect medicines and accept information pertaining to a particular patient provided that the pharmacist is satisfied that patient safety, confidentiality and medicine quality is maintained and the patient has provided written consent;
- (b) The patient's caregiver may only collect medicines for a patient or patients who are under their direct care, a patient's agent may only collect medicines for a patient or patients who have given written consent for such collection, and in the case of multiple patients the pharmacist must satisfy themselves that the patient's agent or caregiver is the appropriate person to give the medicines to.

#### **2.7.5.4 Transportation for the delivery of medicines**

- (a) Transportation of medicines must be in such a way that it is secure and limits access to medicines by persons allowed to have access to medicine in law only, prevents any contamination and ensures integrity to the manufacturers product specifications;
- (b) The vehicle should allow orderly storage to ensure safety, quality and efficacy of pharmaceutical products during transportation;
- (c) Where relevant and to the extent that it is applicable, cold chain management must be observed, and delivery must prove compliance with the minimum standards for thermolabile pharmaceutical products;
- (d) Personnel transporting pharmaceutical products must be appropriately trained and shall provide the suitable documentation as proof, for this function and they must ensure that the correct procedures are followed to maintain the cold chain within the manufacturer's specification;
- (e) At any stage of transportation, a delivery document must show evidence that the transport requirements, inter alia temperature control have been met;
- (f) Damage to containers or any other event or problem which occurs during transit must be reported to and recorded by the responsible pharmacist of the pharmacy from which the pharmaceutical products were sent;
- (g) Upon arrival the person responsible for the transportation of the pharmaceutical products must inform the patient or patient's caregiver, that the package contains pharmaceutical products and provide information about specific storage requirements (as applicable); and

- (h) Proof of delivery (signed by the patient or the patient's caregiver) must be presented to the pharmacy to ensure that the medicines have been received.

[R 2.7.5 of Annex A subs by GeN 431 in G. 40892.]

## **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.

**[Editor Note:** Numbering as per original *Gazette*.]

- (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 12 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.

- (f) 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 EDL / STG.
- (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.
- (f) 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.
- (f) 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.
- (f) 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.
- (f) 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.
- (f) There is a natural variation in the peak expiration flow rate with values in the morning generally lower than those taken in the evening. Determination should be done two or three times a day. On each occasion three determinations 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 re-evaluated annually to provide for the growth of children and possible changes in the disease of the patient.
- (h) On its own, peak flow determinations are not adequate to make a diagnosis. A diagnosis of asthma and other 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
- (f) 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.
- (f) 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**

- (a) 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, psycho-social implications, work, etc.
- (i) the personal and practical implications of performing the test.
- (j) assessment of personal risk of HIV infection.
- (k) safer sex and strategies to reduce risk.
- (l) possible reactions to negative and positive test 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.
- (f) 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 three 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, lifestyle or an underlying disease state;
- (e) administering immunisation agents;
- (f) 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 containers).
- (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 resident 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.
- (f) 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 participate 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.

- (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—

**[Editor Note:** Numbering as per original *Gazette*.]

- (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.

**[Editor Note:** Numbering as per original *Gazette*.]

## **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.
- (f) 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 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**

Any person registered with the South African Pharmacy Council who performs one or more of the functions relating to the scope of practice of the category in which he / she is registered must be covered by his / her own indemnity insurance.

[R 3.5 subs by BN 83 in G. 31378.]

### **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.
- (f) 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.

[Editor Note: Numbering as per original *Gazette*.]

- (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.
- (f) 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;
- (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 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;
- (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) 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 24-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.
- (f) 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 12 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, repackaging, supplying or selling of any medicine or scheduled substance or the supervision thereof; and
- (e) the application for the registration of a medicine in accordance with the Medicines Act.

**1.5.2 The scope of practice of a pharmacist is as follows—**

- (a) the acts specially pertaining to the profession of a pharmacist as prescribed in (1.5.1) above;
- (b) the formulation of any medicine for the purposes of registration as a medicine;
- (c) the distribution of any medicine or scheduled substance;
- (d) the re-packaging of medicines;
- (e) the initiation and conducting of pharmaceutical research and development; and

- (f) the promotion of public health.

## **2. AUTHORITY, DUTIES AND RESPONSIBILITIES OF A RESPONSIBLE PHARMACIST**

In terms of the Pharmacy Act, every pharmacy must, except in such circumstances and subject to such conditions as 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
- (f) in addition to the general responsibilities also—
  - (i) ensure that unauthorised persons could not by lawful means obtain access to medicines or scheduled substances or the pharmacy premises outside of normal trading hours;
  - (ii) establish policies and procedures for the employees of the pharmacy with regard to the acts performed and services provided in the pharmacy;
  - (v) ensure the safe and effective storage and keeping of medicine or scheduled substances in the pharmacy under his or her direct personal supervision; and



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

[Editor Note: Numbering as per original Gazette.]

## **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 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 pharmacy, the responsible pharmacist may be absent only if—
  - (i) ...  
[R 2.1.1.2(a)(i) of Annex A rep by BN 50 in G. 38511.]
  - (ii) Schedule 1 to 6 substances are locked away in an area of which the key must be in the personal possession of the responsible pharmacist;  
[R 2.1.1.2(a)(ii) of Annex A subs by BN 50 in G. 38511.]

- (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.

#### **MINIMUM STANDARDS FOR CHOLESTEROL MONITORING SERVICE**

Accuracy and precision of blood cholesterol measurement, which are critical for the classification and referral of screening participants, depend on appropriate quality control and staff training. As these services are professional services, any publicity should comply with the Code of Conduct and Minimum Standards for screening and monitoring services. Before undertaking testing, pharmacists should ensure they are adequately covered by insurance in respect of themselves, their staff and the patients who are being tested.

The following standards must be applied when a cholesterol monitoring service is established in a community pharmacy.

### **Physical facilities**

- (a) When taking samples, the performance of screening tests must be done in a private consultation area in the pharmacy.
- (b) The consultation area must comply with the requirements as described in 1.2.13 of the GPP manual.

### **Equipment**

- (a) Equipment must be accurate, reliable, simple to use, easily cleaned and easily maintained.
- (b) To ensure ongoing accuracy and precision of determinations, a suitable quality control system is used, must be implemented and applied on a regular basis.
- (c) A reliable method of testing should be used.
- (d) Equipment must be maintained in good order to ensure that performance is not impaired.

### **Procedure for carrying out the test**

- (a) The service should be fully explained to the patient before any readings are taken.
- (b) Written consent must be sought and obtained before any test is carried out.
- (c) All procedures and arrangements should be in accordance with the requirements of the National Health Laboratory for clinical laboratories.
- (d) The pharmacist should wash his / her hands and then put on new, clean non-sterile examination gloves.
- (e) The site of puncture for sample extraction from the patient's finger should be wiped clean using a sterile alcohol swab.
- (f) Allow time for the alcohol to evaporate, otherwise this might interfere with the sample.
- (g) Care should be exercised when taking the sample.
- (h) Set finger-pricking device at a suitable depth for thickness of skin to puncture.

- (i) Place the finger-pricking device on the cleaned puncture site and press activating button.
- (j) Time should be allowed for a large enough droplet of blood to develop. The pharmacist must inform the patient that care must be taken to ensure that the blood does not spill or drop.
- (k) The patient's droplet sample should be guided to the sample plate and the droplet placed on the blood stick.
- (l) The sample area should be saturated with the blood to ensure an accurate reading.
- (m) Record the Total Cholesterol and where possible the HDL reading immediately.
- (n) Where results are not within the desirable range, in addition to providing counselling and advising medical consultation where appropriate, pharmacists should provide suitable printed information leaflets where these are available.
- (o) Wipe and clean equipment with alcohol swabs. Dispose of waste from the procedures in front of patient - they can therefore be assured that the cleaning happens after each patient and can witness the procedure in order to achieve confidence in the service.

### **Interpretation of results**

- (a) The result of the test should be provided in writing on a standard form. Where the results are not within a desired range, the patient's consent must be sought for this information to be sent to his / her GP. If a patient does not give permission for the pharmacist to contact his / her GP, he / she must be advised to seek medical advice, and must be supplied with the results in writing.
- (b) The form should be dated and signed by the pharmacist, with the name and address of the client provided.
- (c) At all stages, before and during and after the test, the patient should be kept fully informed about the process and implications of the test and be given opportunities to ask questions.
- (d) A single elevated cholesterol measurement does not establish the diagnosis of high blood cholesterol; two or more cholesterol measurements are needed before the diagnosis of high blood cholesterol.
- (e) Pharmacists are advised to be careful not to make any diagnostic decisions when undertaking cholesterol testing.
- (f) The patient's medical practitioner has the clinical responsibility for the diagnosis and subsequent clinical responsibility for the treatment of the patient.

## **Documentation and record keeping**

- (a) The pharmacist must retain a written record of the result of the test, together with the following information—
- the type of test;
  - batch number of the test material;
  - advice or referral given to the patient,
- for at least three years.
- (b) Such records must be stored safely to preserve confidentiality.

## **Confidentiality**

The pharmacist must keep all information provided by the patient and the result of the test, confidential and only disclose information with the consent of the patient.

## **Waste Disposal**

- (a) Dressings, swabs and other contaminated wastes from treatment areas should be placed in a suitable clinical waste storage bag or bin with a suitable plastic liner at the point of generation.
- (b) Liner bags should be removed at least daily or when three-quarters full. They should be securely fastened with adhesive plastic tape before removal and deposited in a clinical waste storage bag - which should also be securely fastened. The waste should then be sent for incineration.
- (c) Syringes, needles and cartridges should be discarded intact and placed in a suitable 'sharps container', which when full should be sealed and placed into a chemical waste bag for storage prior to removal and disposal by incineration.

## **Counter infection measures**

All procedures and arrangements should be in accordance with the requirements of the National Health Laboratories for clinical laboratories. The main counter-infection measures, where applicable, should include—

- (a) Preventing puncture wounds, cuts and abrasions in the presence of blood and body fluids, and protecting existing wounds, skin lesions, conjunctivae and mucosal surfaces (aseptic hand washing

techniques, use of an appropriate antiseptic etc., gloves, spillage procedures and cleaning procedures).

- (b) Applying simple protective measures designed to avoid; contamination of the person or clothing and using good basic hygienic practices, including regular hand washing.
- (c) Controlling surface contamination by blood by ensuring containment and disinfection.
- (d) Avoiding the use of sharps where possible but where their use is essential, exercising particular care in handling and disposal.
- (e) Disposing of clinical waste in accordance with Standard Operating Procedures.  
[Minimum Standards for Cholesterol Monitoring Service ins to Annex A by BN 132 in G. 28350.]

#### **MINIMUM STANDARDS FOR CONTROL OF SCHEDULE 6 MEDICINES OR SUBSTANCES**

Control of Schedule 6 medicines or substances are of such nature that only persons authorised in terms of the Medicine Act have access to these substances.

- (a) Schedule 6 medicines or substances must be stored in designated places under lock and key at all times.
- (b) The key must be in personal possession of an authorised person responsible for the control of Schedule 6 medicines or substances.
- (c) A register of schedule 6 medicines or substances must be kept and shall be balanced so as to show clearly the quantity of every schedule 6 medicine or substance remaining in stock as on the last day of March, June, September and December of each year and such balancing shall be completed within 14 days following each said dates.
- (d) A pharmacist's assistant shall not handle any Schedule 6 medicine or substance except for the purpose of dispensing under the direct personal supervision of pharmacist.

[Minimum Standards for Control of Schedule 6 Medicines or Substances ins to Annex A by BN 132 in G. 28350 (corrected by BN 3 in G. 28439).]

#### **MINIMUM STANDARDS FOR EMERGENCY POSTCOITAL CONTRACEPTION (EPC)**

##### **INTRODUCTION**

Emergency post-coital contraception (EPC) is often referred to as the 'morning after pill'. Emergency contraceptive pills are birth control pills used in high doses, taken within 72 hours of unprotected sex. The

EPC will not be effective if the woman is pregnant already, although it is not considered to be harmful to the foetus.

EPC can alter the timing and type of bleeding of the next menstrual period. Bleeding may start a little early or a little late, but if it is more than five days late then pregnancy is a possibility and further referral is necessary. EPC is not as effective as conventional methods of contraception and is not recommended for regular use.

Emergency contraception should not be used in patients with a history of blood clots. Women with diabetes, liver disease, heart disease, kidney disease, or high blood pressure require special consideration.

#### **BEFORE TESTING (PHARMACIST MUST CONSIDER THE FOLLOWING BEFORE SUPPLYING EPC)**

(a) The following information must be obtained from the patient prior to the supply of EPC to the patient (in addition to that required in the course of dispensing a prescription)—

- certainty that the patient does not want to become pregnant;
- date of patient's last menstrual period to rule out established pregnancy;
- the time that has elapsed since unprotected intercourse occurred (less than 72 hours is more likely to prevent pregnancy);
- whether the patient has been a victim of sexual assault.

(b) To assess how likely it is that the woman might be pregnant, the following questions could be asked—

- Is your period late? How late?
- Was your last period lighter or shorter than normal?
- Was your last period unusual in any other way?
- At any time before this occasion and since your last period, have you had unprotected sexual intercourse?

If the woman answers 'yes' to any of these questions, then a referral, or a pregnancy test, should be recommended.

Supply of EPC could, however, be considered for a woman who, in addition to this current incident of unprotected sexual intercourse, has had within her current cycle previous incidents of unprotected intercourse since pregnancy may not have resulted from these, but could now.

## **Emergency Contraception Regimens**

- (a) Emergency contraception regimens consist of two doses of oral contraceptive tablets.
- (b) The first dose is administered within 72 hours of unprotected intercourse. The second dose is taken 12 hours later. Studies support the administration of the first dose within 72 hours after unprotected intercourse.
- (c) Dose: The number of tablets taken depends on the product used.
- (d) The timing of the first dose of medication is critical. The regimen becomes completely ineffective by day six or seven when implantation usually occurs.
- (e) The sooner after unprotected intercourse the tablets are taken, the more effective they will be.
- (f) Generally a total of 0.10 or 0.12 mg ethinylestradiol and 0.5 or 0.6 mg levonorgestrel are taken with each dose. Examples of regimens include—
  - 2 tablets of Ovral® each tablet contains 250 ug d-norgestrel / 500 ug ethinylestradiol
  - 2 tablets E-gen-c® each tablet contains levonorgestrel 0.25 mg ethinylestradiol 0.05 mg
  - Norlevo® which contains 2 X levonorgestrel 0,75 mg per tablet

## **Use of EPC when breastfeeding**

Small amounts of levonorgestrel may appear in breast milk. While not considered harmful, to reduce the amount that the baby might ingest, the woman can be advised either to express milk immediately before taking the EPC or to delay taking the medicine until immediately after feeding the baby. This approach must be weighed against the need to minimise delays in treatment.

## **Professional and ethical responsibility of pharmacists in the provision of EPC**

Pharmacists must ensure that the following standards are observed in the supply of EPC as an over-the-counter-medicine in a pharmacy—

- (a) As with all medicines, the pharmacist who supplies EPC must have sufficient knowledge of the product to enable him / her to make an informed decision when requests for EPC are made.
- (b) A pharmacist must deal with the request personally and decide whether to supply the product or refer the patient to another appropriate healthcare professional.



- (c) Pharmacists must ensure that all necessary advice and information is provided to enable the patient to assess whether to use the product suggested / supplied.
- (d) Requests for EPC should be handled sensitively with due regard being given to the customer's right to privacy.
- (e) Only in exceptional circumstances should pharmacists supply the product to a person other than the patient.
- (f) Pharmacists should, whenever possible, take reasonable measures to inform patients of regular methods of contraception, disease prevention and sources of help.
- (g) To help reduce patient stress and anxiety, it is crucial that pharmacists remain supportive and refrain from making judgemental comments or indicating disapproval by means of body language or facial expressions while discussing EPC.
- (h) Supportive pharmacist attitudes, including respect for population diversity and patient beliefs, will also improve compliance and promote effective patient-pharmacist communication if follow-up is needed.
- (i) Pharmacists must bear in mind that patients seeking EPC may be under stress after unprotected intercourse for many reasons which may include—
  - fear of becoming pregnant;
  - embarrassment at failing to use contraceptives effectively;
  - general embarrassment about sexual issues;
  - lack of knowledge about EPC;
  - rape and / or sexual abuse trauma;
  - concern about auto-immune deficiency syndrome (AIDS) and sexually transmitted infections (STIs);
  - worry about missing the narrow window of opportunity for EPC; or
  - a combination of these factors.
- (j) Pharmacists who do not wish to provide EPC treatment for personal reasons should maintain objectivity and remain professional when dealing with patients. In this case, patients must be referred to an alternate source of EPC.

- (k) If the patient questions the pharmacist as to why he or she will not be providing the product or service personally, the pharmacist should answer in a manner that does not make the patient feel uncomfortable.
- (l) Alternate sources for EPC might include referral to one or more pre-arranged options such as—
- another pharmacist in the same pharmacy;
  - another pharmacy in the vicinity;
  - a medical practitioner;
  - a nearby hospital, community health centre, primary health care clinic or reproductive health clinic.

### **Confidentiality**

It is important that all pharmacy staff, including pharmacists, pharmacist interns, pharmacist's assistants and any staff who may be the first contact for the patient be informed of the EPC service available at the pharmacy. Adequate training of personnel in the pharmacy is advocated in the handling of patients seeking these services—

- (a) All staff must show sensitivity and ensure confidentiality.
- (b) The test should be conducted in a private counselling area.
- (c) In the testing and counselling—
- use non-specific language to refer to sensitive terms (e.g. use “the incident” or the “situation” rather than saying “unprotected intercourse” or “sex”);
  - use a written form to collect key information about the patient's situation.

### **PATIENT COUNSELLING**

#### **General principles**

- (a) Through the course of counselling, it may become evident that a referral is needed to a medical practitioner, reproductive health clinic etc.
- (b) If the EPC product comes with a pregnancy test, it is meant to be used to rule out a pregnancy that may have occurred since her last menstrual period.

- (c) The pharmacist should refer to the patient information leaflet and ensure that she understands how to use the pregnancy test correctly.
- (d) Women must be counselled to take the first dose of EPC as soon as it is convenient, keeping in mind the timing of the second dose. For example, rather than encouraging the patient to take the first dose at 16h00 (with the second dose at 04h00), it might be better to suggest that she takes the first dose at 19h00.
- (e) The pharmacist must explain that emergency contraception does not protect against or treat sexually transmitted infections (STIs). If the patient thinks she may have contracted a STI, she will need to see a medical practitioner immediately.
- (f) The pharmacist must remind the patient that EPC is not 100% effective and will not terminate an established pregnancy. If her period does not commence within three weeks, she should consider having a pregnancy test.
- (g) The patient should be advised that her period will probably come on time but may be a few days earlier or later than normal.
- (h) The pharmacist must emphasise that emergency contraception is for emergency use only and that it is less effective than other means of birth control if used repeatedly.
- (i) The patient must be reminded to begin using ongoing contraception as soon as she resumes intercourse. She may be at high risk of pregnancy following EPC use if ovulation is delayed. If her regular method of contraception failed, the patient must be counselled on an effective method to use if necessary.
- (j) The patient must be supplied with a patient information leaflet containing instructions, as well as the pharmacy phone number. She must be encouraged to call if she has any further questions.

### **Continued contraception**

- (a) Emergency contraceptives are meant solely for emergency use and are not as effective as other birth control methods for ongoing contraception. Pharmacists should encourage patients to talk to a medical practitioner or nurse about using an ongoing contraceptive method to prevent pregnancy in the future.
- (b) If the patient does not have a regular health care provider, the pharmacist can offer referrals to local providers.

- (c) Women should be told that EPC will not provide continued protection against pregnancy for the remainder of the menstrual cycle, and be advised about other contraceptive measures - including recommending referral where appropriate.
- (d) A woman seeking EPC because she has missed one or more oral contraceptive pills should be advised to continue taking her pills as normal. In addition she should be advised to use a barrier method of contraception for the next seven days.

### **Referral**

The woman should be advised to see her doctor or reproductive health clinic for a pregnancy test if her next period is more than five days late or is unusual in any way or, for those taking an oral contraceptive, if there is no bleed in the pill-free interval.

### **Repeated use of emergency contraception**

- (a) Although experience has shown that very few women request emergency contraception repeatedly, mainly because of the unpleasant side effects some women experience while using them, patients should be asked if they have used emergency contraception before, and should be counselled accordingly.
- (b) Because EPC is less effective at preventing pregnancy than typical use of regular contraceptive methods, a patient presenting repeatedly for emergency contraception should be provided with treatment but informed of the high cumulative failure rate with repeated use, and provided with referrals for ongoing care.

### **HIV and Sexually Transmitted Infections (STIs)**

- (a) Patients must understand that EPC does not protect against STIs, including HIV / AIDS and that use of a condom is necessary to protect against these infections.
- (b) Patients may be very concerned about possible infection, especially in cases of rape. Counselling on this topic is essential, with referral for diagnosis and treatment provided when needed.
- (c) Medical referral may be necessary to screen for infections. For this purpose, patients should be advised to schedule a follow-up appointment with a medical practitioner or reproductive health or sexual health clinic after taking the EPC.
- (d) If appropriate, the pharmacist should provide information (e.g. leaflets) on sexual health and STIs.

### **Alcohol / drugs**

In some cases the patient may not remember whether penetrative sex took place or not. In such cases, it is best to assume that intercourse occurred and provide emergency contraceptives.

### **Dealing with children and parents**

Parents often have inaccurate information about their child's contraceptive use. Parents may react with anger if they find oral contraceptives, condoms; or a product for emergency contraception in the child's personal belongings because these indicate a level of sexual activity of which they were not aware.

They may also feel displaced because the child did not first discuss the matter with them. Sometimes the provider (e.g. pharmacist, nurse) becomes the primary target of the parent's feelings.

(a) In such cases pharmacists must first be able to address the parent's immediate concerns and provide accurate information about contraceptives, and then address their questions. In talking with parents, pharmacists should keep the following objectives in mind—

- Be direct, honest and professional;
- Tell parents that you understand their concern;
- Inform parents that minors can consent to contraceptive and reproductive health services and it is the pharmacist's obligation to provide them.

(b) If the pharmacist becomes aware that a child (any one under the age of 16) has been physically harmed, sexually abused or sexually exploited by a parent or other person, the pharmacist must report these circumstances to the appropriate local / provincial authority.

[Minimum Standards for Emergency Post-coital Contraception (EPC) ins to Annex A by BN 132 in G. 28350.]

## **MINIMUM STANDARDS FOR GLUCOSE MONITORING**

### **Definition**

Blood glucose monitoring is the measurement of glucose in the blood that can be done at any time on a portable machine. It can be used as a self-test for the diabetic.

### **Alternative names**

Glucose monitoring;

Random glucose;

Glucose - random;

Serum glucose – random.

### **Why the test is performed**

- (a) This test is used as a screening test for blood glucose levels.
- (b) It may be used screen for diabetes.
- (c) The test allows the diabetic to carefully monitor blood glucose levels to assure that they are within the normal range.
- (d) It may be used to monitor control in patients who have diabetes and to detect uncontrolled diabetic patients.
- (e) The individual can then respond quickly to high or low blood sugar-levels with appropriate intervention.

**The following standards must be considered when a glucose monitoring service is established in a community pharmacy—**

### **Physical facilities—**

- (a) The taking of samples for the performance of screening tests must be done in a private consultation area in the pharmacy.
- (b) The consultation area must comply with the requirements described in 1.2.13 of the GPP manual.

### **Equipment**

The following aspects must be considered in glucose monitoring tests—

- (a) Equipment must be accurate, reliable, simple to use, easily cleaned and easily maintained.
- (b) Accuracy and precision of blood glucose measurements, which are critical for the classification and referral of screening participants, depends on appropriate quality control and staff training.

To ensure ongoing accuracy and precision of determinations, a suitable quality control system is used, must be implemented and applied on a regular basis—

- (c) The use of calibration and control solutions by the pharmacist shall assure accuracy of results.
- (d) The user should know whether the instrument is calibrated to whole blood or plasma glucose.

- (e) Equipment must be maintained in good order to ensure that performance is not impaired.

### **Performance of the test**

- (a) The service should be fully explained to the patient before any readings are taken.
- (b) Written consent from the patient must be sought and obtained before any test is carried out.
- (c) It is important to have all test items within reach before starting the test.
- (d) All procedures and arrangements should be in accordance with the requirements of the National Health Laboratory for clinical laboratories.
- (e) The pharmacist should wash his / her hands and then put on non-sterile examination gloves.
- (f) The site of puncture for sample extraction from the patient's finger should be wiped clean using a sterile alcohol swab.
- (g) Allow time for the alcohol to evaporate, otherwise this might interfere with the sample.
- (h) Care should be exercised when taking the sample and correct procedure must be followed or the results will not be accurate.
- (i) Set finger-pricking device at a suitable depth for thickness of skin to puncture.
- (j) Place the finger-pricking device on clean sample area and press activating button.
- (k) Time should be allowed for a large enough droplet of blood to develop. The operator must inform the patient that care must be taken to ensure that the blood does not spill or drop.
- (l) The patient's blood droplet should be guided to a reagent strip, which uses a chemical substance to react to the amount of glucose in the blood.
- (m) When using enzyme impregnated strips for glucose measurement it is imperative that the strips are properly stored in the screw cap airtight container provided until use, to ensure for maximum shelf life.
- (n) The reagent strip should be saturated with the blood to ensure an accurate reading.
- (o) The meter then reads the strip and displays the results as a number on a digital display.
- (p) Newer monitors can use blood from other areas of the body besides the fingers, reducing discomfort.

- (q) Record the glucose reading immediately.
- (r) Patients must be provided with the results in a written form. Where the results are not within a desired range, the patient's consent must be sought for this information to be sent to his / her. If a patient does not give permission for the pharmacist to contact his / her GP, he / she must be advised to seek medical advice, and must be supplied with the results in writing.
- (s) Where results are not within the desirable range, in addition to providing counselling and advising medical consultation where appropriate, pharmacist should provide suitable printed information leaflets where these are available.
- (t) Before undertaking testing, pharmacists should ensure they are adequately covered by insurance in respect of themselves, their staff and the patients who are being tested.
- (u) Dispose of waste from the procedures in front of patient who can therefore be assured that the cleaning happens after each patient and can witness the procedure in order to achieve confidence in the service.

### **Interpretation of results**

- (a) The result of the test should be provided in writing on a standard form.
- (b) The form should be dated and indicate the name and address of the client.
- (c) At all stages, before and during and after the test, the patient should be kept fully informed about the process and implications of the test and be provided with the opportunity to ask questions.
- (d) A single elevated glucose measurement, does not establish the diagnosis of high blood glucose, two or more glucose measurements are needed before the diagnosis of high blood glucose.
- (e) Pharmacists may not make any diagnostic decisions when undertaking glucose testing.
- (f) Pharmacists must take into account any food that the patient may have eaten prior to the test, when interpreting the results.
- (g) The medical practitioner has the clinical responsibility for the diagnosis and subsequent clinical responsibility for the treatment of the patient.

### **Documentation and record keeping**



- (a) The pharmacist must retain a written record of the result of the test, together with information and consent form provided by the client and the type of test and batch number of the test materials, for at least three years. Such records must be stored safely to preserve confidentiality.

### **Confidentiality**

- (a) The pharmacist must keep all information provided by the patient and the result of the test confidential and only disclose information with the consent of the patient.

[Minimum Standards for Glucose Monitoring ins to Annex A by BN 132 in G. 28350.]

## **MINIMUM STANDARD FOR PREGNANCY TESTING SERVICE**

The following standards must be considered when a service offering performance of pregnancy tests is established in a community pharmacy—

### **Physical facilities—**

- (a) The performance of pregnancy tests must take place in a private consultation area in the pharmacy.
- (b) A clean toilet facility attached to the pharmacy is a necessity for the production of a urine sample.
- (c) The consultation area must comply with the requirements described in section 1.2.13 of the GPP manual.
- (d) A reliable method of testing must be used.

### **Procedure, interpretation and provision of results**

The following aspects must be considered in pregnancy testing—

- (a) The procedure must be explained to the patient, her permission obtained and the patient made to feel at ease.
- (b) A signed and dated confirmation of the request for the test should be obtained.
- (c) The form on which confirmation is obtained should state the limits of accuracy of the test.
- (d) All questions, relating to the test, must be asked by the pharmacist and the answers recorded in writing.
- (e) A Standard Operating Procedure, to be available in the pharmacy for inspection, must be devised and followed to ensure that no confusion occurs between samples.

- (f) Care must be taken to prevent contamination, which can result from the handling of samples of urine.
- (g) Persons carrying out tests should wash their hands before leaving the consultation area.
- (h) Any cuts and grazes on hands or on exposed parts of the body must be covered with waterproof dressings.
- (i) The result of the test must be provided in writing on a standard form.
- (j) The form must be dated, signed by the pharmacist, and bear the name and address of the client.
- (k) The result should be given as positive or negative with an explanation of such terms and the limits of accuracy of the test, (refer earlier comment) e.g.: "The specimen provided has been tested for urinary gonadotrophin and has been found to be: Positive / Negative. A positive result indicates a probable pregnancy".
- (l) At the request of the client, a copy of the form should be sent to her medical practitioner.
- (m) Notwithstanding the result of the test, the client should be strongly advised to consult her medical practitioner or reproductive health service.

### **Documentation and record keeping**

The pharmacist must retain a written record of the result of the test, together with information and consent form provided by the client and the type of test and batch number of the test materials, for at least three years. Such records must be stored safely to preserve confidentiality.

### **Confidentiality**

The pharmacist must keep all information provided by the patient and the result of the test confidential and only disclose information with the consent of the patient.

[Minimum Standards for Pregnancy Testing Service ins to Annex A by BN 132 in G. 28350.]

### **PRODUCTS WHICH MAY NOT BE SOLD IN A PHARMACY**

The following may not be sold in the pharmacy—

- (a) Arms and ammunition;
- (b) Fireworks;

(c) Tobacco, snuff, cigarettes and tobacco related products;

(d) Liquor, except when meant for medicinal purposes; and

(e) Gambling services and / or products.

[Products which may not be sold in a Pharmacy ins to Annex A by BN 132 in G. 28350; para (e) subs by BN 35 in G. 35095.]

### **MINIMUM STANDARD FOR URINE ANALYSIS**

Urine analysis can be used to detect and measure the level of a variety of substances in the urine, including leucocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketones, bilirubin and glucose. These tests use a thin strip of plastic (dipstick) impregnated with chemicals that react with substances in the urine and change colour. For confirmation, the test may need to be repeated with more sophisticated and accurate laboratory analysis of the urine, in which case the patient should be referred to a medical practitioner.

#### **Physical facilities**

(a) A clean toilet facility attached to the pharmacy is essential.

(b) Screening tests must be performed in a private consultation area in the pharmacy.

(c) The consultation area must comply with the requirements as described in 1.2.13 of the GPP manual.

#### **Equipment**

Urine sample must be collected in a suitable clean container, which should be supplied, to the patient.

#### **Procedure for carrying out the test**

The following aspects must be considered in urine testing—

(a) The procedure must be explained to the patient, her / his permission obtained and the patient made to feel at ease.

(b) A signed and dated confirmation of the request for the test must be obtained.

(c) The form on which confirmation is obtained should state the limits of accuracy of the test.

(d) All questions that the patient or the patient's caregiver may have, relating to the test, must be answered by the pharmacist and the answers recorded in writing.

- (e) A Standard Operating Procedure, to be available in the pharmacy for inspection, must be devised and followed to ensure that no confusion occurs between samples.

### **Obtaining a Clean-Catch Urine Sample**

The following information and procedure for obtaining a clean-catch urine sample must be explained to the patient or the patient's caregiver—

- (a) The procedure is quite simple; there is usually no fluid or food restriction before the test.
- (b) The head of a man's penis or the opening of a woman's urethra is cleansed, usually with a small pad that contains an antiseptic substance.
- (c) The first few drops of urine are allowed to flow into the toilet, washing out the urethra.
- (d) Patient must collect the mid-stream urine in a sterile container.
- (e) The last few drops of urine are allowed to flow into the toilet.

### **Storage and testing of samples**

- (a) Contamination of testing material and samples must be prevented.
- (b) Urine samples must be stored at room temperature and tested in less than four hours after collection.
- (c) Urine must not be exposed to direct sunlight as this may result in the oxidation of bilirubin and urobilinogen.
- (d) The testing areas of reagent strips must not be touched by hand or come into contact with the working surfaces or other materials.
- (d) Expiry dates of material must be checked before use.
- (e) Remove one strip at a time and replace the lid immediately.
- (f) Strips must be checked for any discolouration or darkening of material which could be an indication of deterioration of the reagent strips.
- (f) Dip the test strip into fresh urine for approximately two seconds.
- (g) Drain excess urine on the rim of the container in which the urine was collected. Remove excess urine by briefly blotting the side of the strip on absorbent tissue.

- (h) After 30-60 seconds (60-120 seconds in the case of the leucocytes test patch), compare the test strip with the colour scale or the colour grades on the label.
- (i) NB: Colourations which appear only along the edges of the test patches, or develop after more than two minutes, do not have any diagnostic significance.
- (j) Persons carrying out tests should wash their hands before leaving the consultation area.
- (k) Any cuts and grazes on hands or on exposed parts of the body must be covered with waterproof dressings.

### **Interpretation of results**

- (a) The result of the test should be provided to the patient or his / her caregiver in writing on a standard form, which includes the date and the name and address of the patient, and which is signed by the pharmacist.
- (b) Where the results are not within the desired range, the patient's consent must be sought for this information to be sent to his / her medical practitioner. "If a patient does not give permission for the pharmacist to contact his / her GP, he / she must be advised to seek medical advice, and must be supplied with the results in writing.
- (c) Abnormal findings indicate certain problems e.g.

**Protein:** Protein in the urine (proteinuria) can usually be detected quickly by using a dipstick. Protein may appear constantly or only intermittently in the urine, depending on the cause. Proteinuria is usually a sign of kidney disorders. Proteinuria may be benign or pathological.

### **Abnormal protein values may be indicative of**

#### Benign proteinuria

- postural
- excessive exercise
- high or low temperature
- during pregnancy

#### Pathological proteinuria

#### External

- colic
- liver cirrhosis
- plasmacytoma
- cardiac insufficiency

#### Renal

- pyelonephritis
- glomerulonephritis

**Glucose:** Glucose in the urine (glucosuria) can be detected accurately by dipstick. The most common cause of glucose in the urine is diabetes mellitus.

#### **Abnormal glucose values may be indicative of**

- Renal Glycosuria
- Diabetes Mellitus
- Renal glycosuria during pregnancy
- Excessive consumption of carbohydrates

**Ketones:** Ketones in the urine (ketonuria) can be detected by dipstick. Ketones are formed when the body breaks down fats, rather than glucose are used to produce energy. Ketones are harmful to the body if allowed to accumulate.

#### **Abnormal ketones values may be indicative of**

- Diabetic ketoacidosis
- Insulin overdose
- Insufficient food intake
- Nausea and vomiting
- Starvation
- Strict dieting
- Severe stress
- Severe fever due to infection

**Blood:** Blood in the urine (haematuria) is detectable by dipstick and confirmed by microscopic examination of the urine, and other laboratory tests. Sometimes there is enough blood in the urine to be visible, making the urine appear red or brown. The patient must be referred to a medical practitioner when blood cells or haemoglobin are detected in urine, as it is of pathological significance.

#### **Abnormal blood / haemoglobin values may be indicative of**

Haematuria (blood in urine)

- kidney and bladder calculi
- damage to kidney or urinary tract

Haemoglobinuria (haemoglobin in urine)

- breakdown of red blood cells
- poisoning

Myoglobinuria

- myocardial infarct
- muscle damage

**Nitrites:** Nitrites in the urine (nitrituria) are also detectable by dipstick. High nitrite levels indicate urinary tract infection.

**Abnormal nitrite values may be indicative of**

Bacterial infection

- E Coli
- Salmonella
- Citrobacter
- Proteus
- klebsiella

**Leukocyte Esterase:** Leukocyte esterase (an enzyme found in certain white blood cells) in the urine can be detected by dipstick. Leukocyte esterase is a sign of inflammation, which is most commonly caused by a urinary tract infection.

**Abnormal leukocytes values may be indicative of**

- kidney infection
- cystitis
- urethritis
- contamination
- vaginal secretion

**pH levels in urine:** The acidity or alkalinity of urine is measured by dipstick. Certain foods and metabolic disorders may change the acidity of urine.

### **Abnormal pH values may be indicative of**

Persistent alkaline urine (pH 7-8)

- suggests urinary tract infection
- vegetarian diet
- alkalosis
- pyloric stenosis / obstruction
- vomiting
- alkalizing drugs

Persistent acid urine (pH 5-7)

- gout
- fever
- phenacetin intake
- predisposition to uric acid calculi (kidney stones)

**Concentration:** The concentration of urine (also called the osmolality or specific gravity) may be important in diagnosing abnormal kidney function. The kidneys lose their capacity to concentrate urine at an early stage of a disorder that leads to kidney failure. In one special test, a person drinks no water or other fluids for 12 to 14 hours; in another, a person receives an injection of antidiuretic hormone. Afterward, urine concentration is measured. Normally, either test should make the urine highly concentrated. However, in certain kidney disorders (such as nephrogenic diabetes insipidus), the urine cannot be concentrated even though other kidney functions are normal.

### **Abnormal specific gravity values may be indicative of**

Reduced specific gravity

- diabetes insipidus
- certain renal diseases
- excess fluid intake
- diabetes mellitus

Raised specific gravity

- dehydration
- adrenal insufficiency
- nephrosis
- congestive cardiac-failure



- liver disease
- Constant specific gravity
- chronic renal disorder

**UROBILINOGEN:** When abnormal values of urobilinogen are found during a urine test, further investigation is required to ascertain patient's health status. In the intestines bacteria form urobilinogen from bilirubin. This is then absorbed and passes to the liver and urine.

**Abnormal urobilinogen values may be indicative of**

Increased values—

- overburdening of the liver
- excessive RBC breakdown
- increased urobilinogen production
- re-absorption - a large hematoma
- restricted liver function
- hepatic infection
- poisoning
- liver cirrhosis
- Low values
- failure of bile production
- obstruction of bile passage

**BILIRUBIN:** Bilirubin levels in urine is a result of haemoglobin breakdown. In the liver, bilirubin is conjugated to an acid to make conjugated bilirubin. Unconjugated bilirubin is water soluble and can therefore be excreted in urine.

**Abnormal bilirubin values may be indicative of—**

Pre-hepatic condition

- anaemias,
- excessive breakdown of RBC,

Hepatic condition

- hepatitis,
- cirrhosis,
- obstruction of biliary duct,
- toxic liver damage

Post-hepatic condition

- biliary tree obstruction

### **Documentation and record keeping**

- (a) The pharmacist must retain a written record of the result of the test, together with information provided by the patient, the type of test used and the batch number of the test material, for at least one year.
- (b) Such records must be stored safely to preserve confidentiality.

### **Confidentiality**

The pharmacist must keep all information provided by the patient and the result of the test, confidential and only disclose information with the consent of the patient.

[Minimum Standard for Urine Analysis ins to Annex A by BN 132 in G. 28350.]

## **MINIMUM STANDARDS RELATING TO THE APPROVAL OF TUTORS AND PREMISES FOR TRAINING OF PHARMACIST INTERNS AND PHARMACIST'S ASSISTANTS**

### **Criteria for approval of tutors of pharmacist interns**

Council applies the following criteria in the approval of tutors and premises for the training of pharmacist interns—

- (a) In terms of the Pharmacy Act, an internship can only be undertaken at a pharmacy or institution approved by Council.
- (b) The prospective tutor must have had at least three years' experience as a pharmacist.
- (c) This requirement may be relaxed in circumstances where the prospective tutor or organisation submits an acceptable motivation. In such cases the prospective tutor must have at least two years' experience (pharmaceutical community service included).
- (d) The prospective tutor must convince the Registrar that he / she is abreast of professional knowledge in order to maintain a high standard of competence relative to his / her activity.
- (e) A pharmacist with a suspended sentence may not act as a tutor.
- (f) The prospective tutor must demonstrate that sufficient activities relating to the scope of practice of pharmacists are performed in the pharmacy, in order to ensure sufficient exposure of the intern to the practice of the profession.

- (g) The approved tutor must practise full-time at the premises where the internship will take place.
- (h) Pharmacists who practise part-time in a pharmacy (e.g. % positions) cannot act as tutors of pharmacist interns.
- (i) If the approved tutor is going to be absent from a pharmacy / institution for more than four weeks, the training of the intern must be delegated to another pharmacist for the period of absence of the tutor. The approved tutor remains responsible for the training of the pharmacist intern, even though delegation has taken place.

### **Criteria for the approval of pharmacies**

The following are considered in the evaluation of an application for approval of a pharmacy for purposes of training—

- (a) Whether sufficient activities relating to the scope of practice of pharmacists are performed in the pharmacy, in order to ensure sufficient exposure of the intern to the profession.
- (b) Compliance with the requirements of good pharmacy practice—
  - (i) The presence of a private or semi-private counselling area where one of the key functions of the pharmacist, namely the provision of advice on the safe and correct use of medicines, can be carried out;
  - (ii) Evidence of controlled access of the public to scheduled medicines (including Schedule 2 medicines), and compliance with the legal requirements for record-keeping;
  - (iii) The availability of sufficient literature sources and / or electronic access to such information;
  - (iv) The availability of appropriate apparatus and equipment;
  - (v) Sufficient space in the dispensing area for safe dispensing; and
  - (vi) The general appearance of the pharmacy.
- (c) In the event of the pharmacy moving to new premises or changing ownership, the approval of the tutor(s) and pharmacy lapses.
- (d) The tutor(s) involved must re-apply for approval as a tutor and for the approval of the pharmacy for training purposes.

### **Internship programme in hospital complexes (Public sector hospital complexes)**

Interns may be allowed to rotate in hospital complexes (i.e. where hospitals have been grouped together in health care complexes and / or provide health care services in collaboration with community health care centres or primary health care clinics) under the following conditions—

- (a) There must be at least one approved tutor to be responsible for the effective practical training of the pharmacist intern concerned.
- (b) Facilities (hospital pharmacies) where the intern will be rotating must be approved and recorded by Council and each facility must have a pharmacist to supervise the internship.
- (c) The facility (hospital pharmacy) where such rotation would take place for purposes of practical training, the period(s) that such services would be provided, as well as the name of the pharmacist under whose supervision the intern would work, must be clearly indicated / described in the contract to be approved by Council before the internship commences.
- (d) The rotation must be for purposes of practical training only.
- (e) Community Service Pharmacists may be used to supervise training of an intern where rotation takes place.
- (f) (refer section on 'Delegation of training by an approved tutor').

An approved tutor may not delegate his supervisory responsibilities to the Community Service Pharmacist.

[Minimum Standards Relating to the Approval of Tutors and Premises for Training of Pharmacist Interns and Pharmacist's Assistants ins to Annex A by BN 132 in G. 28350.]

### **MINIMUM STANDARD FOR A DRIVE-THROUGH FACILITY IN A PHARMACY**

**“Drive-through”** facility means any combination of structural, mechanical, electronic or other elements located within and without the dispensary department of a licensed pharmacy. This facility enables the personnel of the pharmacy to provide pharmaceutical services to a patient who drives a vehicle to the pharmacy, without the personnel of the pharmacy leaving the dispensary department or the patient leaving his / her vehicle.

The term includes, a window or other opening in the exterior wall of a prescription department of a licensed pharmacy. This can be stand alone or in conjunction with one or more mechanical, electronic or other devices.

### **FEATURES OF A PHARMACY WITH A DRIVE-THROUGH FACILITY**

A pharmacy with a drive-through facility must be established in place that allows direct access to and from a public road—

- (a) A pharmacy with a drive-through facility must have a roadway around the pharmacy to allow for an unimpaired flow of traffic.
- (b) A pharmacy with a drive-through facility must be housed in a building specifically designed for the purpose. It must devote a considerable amount of its ground space for a circular road around the building, which cannot be used for anything else.
- (c) A pharmacy with a drive-through facility must be equipped with weatherproof porticos which will enable a pharmacist to hand the medicine directly to the patient and to do the counselling on a face-to-face basis.
- (d) A pharmacy with a drive-through facility must be equipped with two porticos—
  - (i) One portico will be used to receive the prescription and all of the legal and professional information required; and
  - (ii) a second portico will be used for the supply of the medicine and the relevant counselling.

### **Minimum requirements**

The pharmacy requiring to provide services through the drive-through facility shall apply to the Council for approval, then submit plans, showing the remodelled dispensary to comply with minimum requirements for a drive-through facility. A drive-through facility must—

- (a) Be constructed and maintained in a manner that secures the premises, i.e. the pharmacy, from unlawful or unauthorised access.
- (b) Be readily accessible to the personnel of the pharmacy, those authorised to be in the dispensary department.
- (c) Provide two-way visual and auditory communication between the personnel of the pharmacy and the patient receiving pharmaceutical services.
- (d) Be equipped with a computer terminal that is part of the pharmacy's computerised system for recording information concerning prescriptions. The terminal must be so located within the dispensary department, to ensure that when personnel of the pharmacy provide pharmaceutical services to a patient by means of the drive-through facility, they can use the computer terminal without, losing visual or auditory communication with the patient.

- (e) Be equipped in order to allow the pharmacist, or intern pharmacist under the supervision of a pharmacist, to provide a patient receiving pharmaceutical services with counselling without losing visual or auditory communication with the patient.
- (f) If the patient is not sitting in the driver's seat, but alongside or in one of the rear seats, it is essential that the pharmacist has access into the portico, via a door from the pharmacy so that the medicine can be handed directly to the patient and that the counselling is on a direct pharmacist-to-patient basis (face-to face basis).

A pharmacy shall not provide pharmaceutical services by, means of a drive-through facility, which does not include a window, or other opening, in the exterior wall of the pharmacy.

[Minimum Standard for a Drive-Through Facility in a Pharmacy ins to Annex A by BN 12 in G. 28593.]

### **MINIMUM STANDARDS REGARDING DESTRUCTION AND DISPOSAL OF MEDICINES**

[Minimum Standards Regarding Destruction and Disposal of Medicines ins to Annex A by BN 83 in G. 33898 and withdrawn by BN 104 in G. 34330.]

### **MINIMUM STANDARDS REGARDING MAINTENANCE AND DISPOSAL OF CONFIDENTIAL INFORMATION RELATING TO PATIENTS**

#### **INTRODUCTION**

In terms of the National Health Act 61 of 2003 all information concerning patients, including information relating to his / her health status, treatment or stay in a health establishment is confidential.

Patient information is generally held under legal and ethical obligations of confidentiality. Information provided in confidence must not be used or disclosed in a form that might identify a patient without his or her consent. The exception to the above is contained in the rules relating to code of conduct for pharmacists and other persons registered in terms of the Pharmacy Act, 53 of 1974.

1. Confidential information is defined as information accessed or maintained by the pharmacy, which contains personally identifiable information that could be used to identify the patient. This information may relate to but is not limited to—
  - (a) the patient's name, address, telephone number, identity number and / or any other identifying number;
  - (b) the name, address and details of a prescriber; and
  - (c) medicines (i.e. prescription and / or non-prescription medicines) or medical devices, prescribed, dispensed, sold and / or supplied to the patient including information such as therapeutic effect,

diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions.

2. Confidential documents relating to patient information refers to personally identifiable data about an individual patient and such data is not generally considered to be public knowledge. Confidential documents relating to patient information includes but is not limited to the following documents—
  - (a) Labels
  - (b) Prescriptions
  - (c) Prescription records and registers
  - (c) Patient medication records
  - (d) Patient medical records
  - (e) Records relating to screening tests performed

## **PURPOSE**

3. The purpose of this standard is to ensure patient's records are maintained and disposed of in confidential manner.

## **GENERAL CONSIDERATIONS**

4. In order to protect personal information from improper disclosure and potential misuse, the responsible pharmacist of the pharmacy must take the necessary action to prevent the acquisition and misuse of personal information relating to patients.
5. The responsible pharmacist must ensure that there are policies and procedures in place in the pharmacy to protect documents relating to patient information from any unauthorised disclosure and use, whether or not it results from disposal. At a minimum, this means restricting access to documents relating to patient information to staff whose responsibilities do not require them to have this information i.e. persons who are not registered with council.

## **Maintenance of the patient's records**

6. Any information stored about a patient must be pertinent, accurate and up-to-date.
7. To maintain the integrity and confidentiality of patient information contained in records and prescriptions for medicine, any system or computer utilised must have adequate security including

system safeguards' designed to prevent and detect unauthorised access, modification, or manipulation of patient records and prescriptions.

### **Computer records**

8. All computer records in the pharmacy must be secure. Any system used must be capable of restricting access. Suitable passwords, Personal Identification Number (PIN) or other restricted access systems must be in place.
9. PIN numbers or passwords should be changed at regular intervals (for example if a member of staff terminates employment at the pharmacy). The level of access that various members of the pharmacy team have to a patient's records should be appropriate to their duties. For example, a member of staff who is responsible only for ordering stock will not need access to patient medication records.
10. Computers must be situated so that data cannot be seen intentionally, or by accident, by those who are not authorised to have access to it.
11. Access to the database must be restricted at all times. In particular, it is important to ensure proper control over computer media such as flash sticks, compact disks, backup copies that may contain copies of medication records that are also maintained in paper files.
12. The responsible pharmacist must ensure that third parties such as software vendors, manufacturers, medical schemes and managed healthcare companies do not have access to the database without their authorisation. Disclosure of any patient's information must be within the legal and ethical obligations of confidentiality.
13. The responsible pharmacist must ensure that information given to software vendors and manufacturers concerning medicine usage does not contain personally identifiable data about an individual patient. Information given to software vendors and manufacturers must be anonymised i.e. the identity of the individual who is the subject of that information cannot be traced back to him / her or ascertained from the information.

### **Disposal of the patient's records**

14. Disposal of patient records is defined as the day-to-day discarding of duplicate, extra or obsolete reports, which contain personally identifiable information that could be used to identify the patient. The records include but are not limited to items such as labels, prescriptions, prescription records and registers, patient medication records, patient medical records and records relating to screening tests performed.
15. Destruction of patient records is defined as the systematic permanent disposal of patient's records that have been maintained for the prescribed retention period. The purpose of disposal or destruction is to



permanently remove records from active use, with no possibility of reconstructing the information contained in them, while maintaining the confidentiality of the information they may contain.

16. Disposal of any materials containing or including patient- specific or confidential information must be conducted in such a manner as to preserve patient confidentiality. Disposing may involve shredding documentation, or alternatively placing it in confidential waste or deleting the information by way of a permanent marker.
17. The following steps must be followed prior to disposing of confidential documents—
  - (a) Shred the entire record.
  - (b) Erase the personal information contained in the record.
  - (c) Modify the record to make personal information contained in it unreadable.
  - (d) Take action to ensure that no unauthorised person will have access to the personal information contained in the record from the time it is disposed of until the time it is ultimately destroyed.

[Minimum Standards regarding Maintenance and Disposal of Confidential Information Relating to Patients  
ins to Annex A by BN 83 in G. 31378.]

**INFORMATION RELATING TO COMPLIANCE WITH GOOD PHARMACY PRACTICE TO BE SUBMITTED  
IN SUPPORT OF AN APPLICATION FOR A LICENCE FOR A PHARMACY PREMISES TO BE ISSUED IN  
TERMS OF THE REGULATIONS RELATING TO THE OWNERSHIP AND LICENSING OF PHARMACIES  
PUBLISHED IN TERMS OF THE PHARMACY ACT 53 OF 1974 AS AMENDED**

The following information must be submitted to Council as proof of compliance with Good Pharmacy Practice for purposes of recommendations made by Council to the National Department of Health for the issuing of a licence by the Director-General for a premises wherein or from which the business of a pharmacy shall be carried out in terms of the Pharmacy Act 53 of 1974 as amended:

**SUPPORTING DOCUMENTATION**

	CRITERIA	Yes	No
1.	A letter of appointment for the responsible pharmacist; NB: No pharmacist maybe the responsible pharmacist for more than one pharmacy;		
2.	A letter of acceptance of the above appointment;		
3.	Copy of the site plan of the building indicating the location, of the pharmacy premises in relation to adjoining or surrounding businesses and access to and from the premises;		
4.	Copy of the professionally drawn floor plan indicating the actual layout of the pharmacy premises drawn to scale with exact measurements;		

5.	Signed affidavit regarding eligibility, ownership and compliance with standards (must be signed by sole proprietor, all partners of the partnership, all members of the Close Corporation, all shareholders of a Private Company and all Directors of a Public Company;		
6.	In case of a Close Corporation the latest CK2 as approved);		
7.	In case of a company a copy of the Certificate of Incorporation (Change of name if applicable) and the latest CM29;		
8.	If applicable, schedules from the auditors certifying the names of the directors and shareholders;		
9.	A bank guaranteed cheque or proof of payment of the licence application fee made payable to the SAPC.		

## FLOOR PLAN

The following information must be clearly indicated in the submitted copy of the professionally drawn floor plan indicating the actual layout of the pharmacy premises drawn to scale with exact measurements:

	CRITERIA	Yes	No
1.	The size of the premises;		
2.	The size of the dispensary;		
3.	All entrances and exits of the pharmacy;		
4.	All entrances to the enclosed areas in the pharmacy e.g. admin office, manager's office, dispensary, kitchen, private area and consultation area;		
5.	A separate facility for washing hands;		
6.	A separate facility for compounding of extemporaneous preparations and cleaning of equipment;		
7.	Sufficient and adequate lighting;		
8.	A suitable waiting area;		
9.	A fridge for heat sensitive pharmaceuticals and vaccines;		
10.	A suitable separate private room for private consultation of patients;		
11.	A suitable consultation area for the provision of screening and monitoring tests, where applicable;		
12.	All Scheduled medicines to be stored / displayed inaccessible to the public;		
13.	A dispensing counter for prescriptions and pharmacist initiated prescriptions (OTC), with a suitable semi private area for each point where dispensing of medicine to the patient or the patient's agent / caregiver occurs; the dimensions of the dispensing counter and semi private area are to be indicated on the floor plan and are to comply with the following requirements—		
	(i) Height of partitioning of the semi private area from floor -1800 mm;		
	(ii) Dispensing point: 900 mm deep by 1000 m wide;		

	(iii)	400 mm from edge of the counter;		
<b>NB:</b> If a counter for pharmacist initiated prescriptions (OTC) is separate from the prescription counter, the above criteria apply to both counters.				

### Trading Title

The following criteria will be applied by Council in considering applications for the use of a title, trading title, name, description, brand name or logo (referred to as the “name”) used with respect to a community or an institutional pharmacy situated in a private or a public health facility in terms of Section 35A(c) of the Pharmacy Act 53 of 1974. Council shall regard the use of following names as unacceptable:

	CRITERIA	Yes	No
1.	The use of the same or a similar name, including a name that sounds similar but is spelt differently, as that of another pharmacy if such pharmacies do not have the same owner;		
2.	Any name which is likely to be considered offensive;		
3.	A name that is calculated to suggest that the pharmacy in question is superior to another pharmacy or pharmacies;		
4.	A name which creates the impression that medicines are being sold at discounted prices;		
5.	A name which may be misleading to the public;		
6.	A name that is not associated with or does not belong to the pharmacy concerned;		
7.	A name that is calculated to suggest that the professional skills or ability or facilities for the rendering and supply of services which form part of the scope of practice of a pharmacist are superior or better than those of other pharmacies or pharmacists;		
8.	A name that is calculated to suggest that a pharmacy is associated with, belongs to or is in any way connected with a body corporate, firm or business, when not owned or part owned by that body corporate, firm or business;		
9.	Any name which is in contravention to the Pharmacy Act 53 of 1974.		

### GENERAL

The application must be signed and sworn in the presence of a Commissioner of Oaths.

[Information Relating to Compliance with Good Pharmacy Practice to be submitted in support of an application for a licence for a pharmacy premises to be issued in terms of the Regulations Relating to the Ownership and Licensing of Pharmacies published in terms of the Pharmacy Act 53 of 1974 as amended added to Annexure A by BN 83 in G. 31378]

### MINIMUM STANDARDS REGARDING DESTRUCTION AND DISPOSAL OF MEDICINES

[Minimum Standards regarding Destruction and Disposal of Medicines ins to Annex A by BN 83 in G. 33898; withdrawn by BN 104 in G. 34330.]

## **MINIMUM STANDARDS REGARDING DESTRUCTION AND DISPOSAL OF MEDICINES AND SCHEDULED SUBSTANCES**

### **1. INTRODUCTION**

The destruction of medicines and scheduled substances may only take place in accordance with the Medicines and Related Substances Act (Act 101 of 1965) and other applicable legislation.

Regulation 27 of the General Regulations published under the Medicines and Related Substances Act (Act 101 of 1965) states that no medicines and scheduled substances may be disposed of into municipal sewerage systems and that the destruction or disposal of medicine and scheduled substances must be conducted in such a manner as to ensure that they are not retrievable.

In addition, pharmacists should not dispose of medicines and scheduled substances in refuse that may be destined for landfill or municipal refuse sites.

### **2. PURPOSE**

The purpose of this standard is to ensure that the disposal and destruction of medicines and scheduled substances within pharmacies is undertaken safely and in accordance with the requirements of Regulation 27 of the General Regulations of the Medicines and Related Substances Act, 101 of 1965, relevant waste legislation and with due regard to minimising the risk of such an activity causing harm to the environment or harm to health.

### **3. GENERAL CONSIDERATIONS**

Some of the elements in this standard are not statutory requirements but are good practice which pharmacists would be expected to follow whenever practicable.

- 3.1 All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste. The person responsible for the destruction may be requested to prove that the method of destruction is in accordance with such regulations.
- 3.2 All medicines and scheduled substances (including medicines and scheduled substances returned by patients) must be destroyed in such a manner that does not allow recovery or retrieval.
- 3.3 In respect of schedules 5, 6, 7 and 8, a person authorised by the Director General: Health must provide a certificate of destruction and in the case of an officer of the South African Police

Services (SAPS); a case number must be provided. These references must be kept with the relevant record or register for a period of five years.

3.4 All quantities destroyed must be recorded in the relevant record or register on the date of destruction and signed by the person responsible for the destruction, indicating the reference to the destruction certificate or case number as the case may be.

3.5 The destruction must be properly documented—

- (a) All quantities destroyed must be recorded and in the case of specified schedule 5 (where applicable) and schedule 6 medicines and scheduled substances, the quantities of medicines and scheduled substances to be destroyed must be indicated in the relevant register and signed by the witnesses required in the procedure;
- (b) Destruction certificates (where applicable) and the letter of authorisation by the person duly authorised by the Director General: Health must be referenced in, or attached to the relevant specified schedule 5 and schedule 6 register and retained for the same period of time as the register itself. (five years).

3.6 The following details should be recorded—

- (a) name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances;
- (b) date of expiry of the medicines and scheduled substances;
- (c) in the event of the information detailed in Rule 3.6 (a) and (b) not being available, the weight of the medicines and scheduled substances;
- (d) the name, position and signature of the person and the witness destroying the medicines and scheduled substances;
- (e) the reason for the destruction; and
- (f) the date of destruction.

#### **4. LEGISLATIVE REQUIREMENTS**

4.1 If a contractor is not used, a medicine containing Schedule 1, 2, 3, and 4 substances may only be destroyed in the presence of a pharmacist or an authorised person in charge of a place where medicines and scheduled substances are kept. Such pharmacist or authorised person shall certify such destruction.

- 4.2 For medicines and scheduled substances containing a Schedule 5 and 6, 7 or 8, the Responsible Pharmacist of the institution / facility where the medicines and scheduled substances are kept, should first obtain approval for destruction from a person duly authorised by the Director General: Health.

The request should be made on the institution / facility letterhead stating the following details—

- (a) name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances;
- (b) the date of expiry of the medicines and scheduled substances.

- 4.3 The medicines and scheduled substances in Rule 4.2 may only be destroyed in the presence of an inspector, an officer of the South African Police Service or any other person authorised by the Director General. Such person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register.

- 4.4 Notwithstanding Rule 4.2, the Medicines Control Council may authorise in writing the destruction of specified schedule 5 and 6 substances by a manufacturer of such substances in the absence of an inspector.

## **5. MINIMUM REQUIREMENTS FOR THE DESTRUCTION OF MEDICINES AND SCHEDULED SUBSTANCES**

A medicine and scheduled substance may be destroyed as follows—

- 5.1 Destruction by a contractor who specialises in waste disposal regarding the disposal of chemical or medicinal waste.
- 5.2 If a contractor is not used, at least one pharmacist and one member of the pharmacy support personnel must witness the removal and the destruction of the correct quantities of the medicines and scheduled substances authorised for destruction, regardless of the where the destruction will take place.
- 5.3 In the case of where a contractor is used, at least one pharmacist and one member of the pharmacy support personnel must witness the removal of the medicines and scheduled substances authorised for destruction.

- 5.4 The contractor must appoint, as required from time to time, a pharmacist in charge to ensure that the medicines and scheduled substances are destroyed or disposed in such a manner that precludes their recovery.
- 5.5 The contractor must issue a Certificate of Destruction, which must include at least the following—
- (a) name of the person / contractor / company who has issued the Certificate of Destruction;
  - (b) the details of the pharmacist responsible for the destruction;
  - (c) the date of destruction of the medicines and scheduled substances;
  - (d) a list of the medicines and scheduled substances to be destroyed.

## **6. MINIMUM REQUIREMENTS FOR THE DISPOSAL OF MEDICINES AND SCHEDULED SUBSTANCES**

Medicines and scheduled substances destined for destruction should be separated into six types and labelled accordingly—

- (a) Solid dosage form;
- (b) Creams, ointments and powders;
- (c) Ampoules and liquids (contained in glass);
- (d) Aerosols;
- (e) Radioactive drugs;
- (f) Cytostatic and cytotoxic medicines and scheduled substances.

## **7. DEFINITIONS**

- (a) Disposal in terms of these Rules shall mean the removal of medicines and scheduled substances destined for destruction without the intention of retrieval, in compliance with existing legislation.
- (b) Destruction in terms of these Rules shall mean rendering the medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to health.

## **MINIMUM STANDARD RELATING TO THE SUPERVISION OF PHARMACY SUPPORT PERSONNEL**

### **1 Definitions**

**“Pharmacy Support Personnel”** means the various categories of support personnel as prescribed and registered as such in terms of the Pharmacy Act. These include Pharmacist's Assistants (learner basic, basic, learner post basic and post basic), Pharmacy Technicians, Pharmacy Technical Assistants and Pharmacy General Assistants.

### **2 Introduction**

Pharmacy support personnel form an integral part of the system in the delivery of pharmaceutical services. The functions performed by a pharmacist can be categorised as either product orientated or patient orientated. In efforts to improve service delivery and develop the concept of comprehensive pharmaceutical care, it is essential that the pharmacist as far as possible devolves responsibility and functions related to product supply to appropriate pharmacy support personnel, within their scope of practice, thus allowing pharmacists more time for patient orientated activities. It is the responsibility of the pharmacist to supervise the pharmacy support personnel with regard to the control, purchase, sale, manufacturing, pre-packaging, dispensing and supply of medicines.

### **3 Purpose**

The purpose of this standard is to give guidance to pharmacists and pharmacy support personnel on how to manage the supervision. The standard will further expand on the independent role of a pharmacy technician based at a primary health care clinic.

### **4 General considerations applicable to all sectors**

- 4.1 Pharmacy support personnel may practise in any category of pharmacy i.e. manufacturing, wholesale, community, institutional pharmacy, in either the public or private sector or public sector primary health care clinic in either the public or the private sector provided that they are competent to practise and are appropriately registered with Council to practise in that sector.
- 4.2 All pharmacy support personnel are responsible for their own safe and efficient practice and are bound by the applicable legislation, the Rules relating to good pharmacy practice, the Rules relating to acts or omissions for which the council may take disciplinary action, the Code of Conduct for persons registered with the Council, as well as guidelines published in terms of the legislation.



- 4.3 Clear and detailed job descriptions must be in place describing the role and responsibilities of all pharmacy support personnel.
- 4.4 A pharmacy technician or a pharmacist's assistant (post basic) may have direct interaction with patients and health care professionals.
- 4.5 A pharmacy technician or a pharmacist's assistant (post basic) may not dispense prescriptions containing Schedule 5 and 6 medicines except in the case of a pharmacy technician or a pharmacist's assistant (post basic) working under the indirect supervision of a pharmacist in a primary health care clinic. The pharmacy technician or a pharmacist's assistant (post basic) may, however, issue Schedule 5 medicines on prescriptions which have been prepared and are in a patient ready pack e.g. in the case of down-referrals. He / she may also perform Phase 2 of the dispensing process for prescriptions containing Schedule 5 medicines.
- 4.6 A pharmacy technician or a pharmacist's assistant (post basic) may not receive verbal instructions e.g. a telephonic prescription from an authorised prescriber for a new prescription for a patient.
- 4.7 A pharmacist may supervise a maximum of 3 pharmacy support personnel, inclusive of qualified personnel and those who are undergoing training. A pharmacist may supervise a combination of pharmacy support personnel with different role types.

## **5 Supervision of pharmacy support personnel in community and institutional pharmacy**

A pharmacy, as defined in the Pharmacy Act, 53 of 1974, must be conducted under the continuous personal supervision of a pharmacist. A pharmacist must be physically present in the pharmacy. Therefore pharmacy support personnel may only work in a pharmacy under the supervision of a pharmacist who is physically present in the pharmacy.

The pharmacist involved in the supervision of pharmacy support personnel in a pharmacy must ensure that he / she is at all times available to supervise the activities taking place in the pharmacy. The pharmacist must perform random checks of all activities taking place in the pharmacy. The following approach must be used in the dispensing of prescriptions where pharmacy technicians or pharmacist's assistants: post- basic are involved—

- 5.1 All prescriptions coming into a pharmacy must be triaged by a pharmacist.
- 5.2 Prescriptions which contain medicines which fall into Schedules 1 and 2 may be dispensed by a pharmacy technician or a pharmacist's assistant (post basic) under the direct personal supervision of a pharmacist (Phases 1, 2 and 3 of the dispensing process).

- 5.3 Any prescription which contains medicines which fall into Schedule 3 and higher must be evaluated and interpreted by a pharmacist (Phase 1 of the dispensing process).
- 5.4 After a prescription has been evaluated by a pharmacist, the pharmacist must indicate that this function has been performed by him / her e.g. by initialling on the prescription.
- 5.5 Data capturing may be done by a pharmacy technician or a pharmacist's assistant (post basic) with authorisation by a pharmacist.
- 5.6 The preparation of all prescriptions may be done by the pharmacy technician or the pharmacist's assistant (post basic) (Phase 2). The pharmacy technician or the pharmacist's assistant (post basic) must indicate that he / she prepared the prescription.
- 5.7 All calculations relating to the patient's dosage or the volume of liquids to be supplied must be validated by a pharmacist before dispensing takes place.
- 5.8 The pharmacist must decide which patients require counselling by a pharmacist e.g. patients with complicated regimens, the first time supply of chronic medicine, patients with comorbidities, patients with adherence problems etc. (Phase 3 of the dispensing process).
- 5.9 A pharmacy technician or a pharmacist's assistant (post basic) may explain the benefits of generic substitution to a patient as required in terms of Section 22F of the Medicines and Related Substances Act 101 of 1965. A pharmacist must, however, be involved in the final substitution decision as to which medicine should be dispensed for the patient in cases where such a choice must be made.
- 5.10 In the case of prescriptions containing Schedule 5 and 6 medicines the pharmacist must be involved in the dispensing process.

## **6 Supervision of pharmacy support personnel in manufacturing and wholesale pharmacy**

The pharmacist involved in the supervision of pharmacy support personnel in a manufacturing or wholesale pharmacy must ensure that he / she is at all times available to directly supervise the activities taking place in a pharmacy. The pharmacist must randomly check all activities taking place in a pharmacy. The following approach must be used—

- 6.1 A manufacturing or a wholesale pharmacy must be conducted under the supervision of a pharmacist who is physically present in the pharmacy.
- 6.2 The pharmacist must be involved at all critical stages in the manufacturing, packaging and distribution process. Pharmacist involvement is needed but is not limited to the control of scheduled substances, the conducting of independent dispensing checks, the conducting of mix

checks, line clearance and product release onto the market. Pharmacists must also be responsible for dealing with product complaints and product recalls.

6.3 Pharmacy support personnel may be involved in the performance of 'non-critical' functions so that pharmacists can focus on the 'critical' functions required to produce products in line with the Good Manufacturing Practice (GMP) guidelines.

6.4 These 'non-critical' functions must be identified and formally agreed upon by the responsible pharmacist of the manufacturing or wholesale pharmacy and the pharmacists responsible for each area of the pharmacy and then suitably documented and measured.

## **7 Supervisory support at a primary health care clinic**

A pharmacy technician or a pharmacist's assistant (post basic) may work under indirect supervision in a dispensary in a primary health care clinic. Supervisory support must be provided by a pharmacist who is not necessarily physically present at all times in the primary health care clinic.

When working in a primary health care clinic with supervisory support of a pharmacist, the pharmacy technician or the pharmacist's assistant (post basic) may dispense prescriptions which contain medicines as contained in the Primary Health Care Essential Medicines List and which are prescribed in accordance with the Standard Treatment Guidelines. In addition he / she may dispense prescriptions which are in accordance with such other protocols which may be approved by the Pharmacy and Therapeutics Committee of the province, municipal or other competent authority under which the primary health care clinic falls provided that such protocols are publicly available.

A pharmacist may only provide supervisory support to a pharmacy technician or a pharmacist's assistant (post basic) working in the dispensary in a primary health care clinic which falls under the jurisdiction of the same competent authority e.g. district or metropolitan council by whom he / she is employed. In cases where a pharmacist has been seconded from one authority to another he / she may support pharmacy technicians or pharmacist's assistants: post-basic working in primary health care clinics falling under the jurisdiction of the authority to whom he / she has been seconded.

The pharmacist involved in providing supervisory support to a pharmacy technician(s) or a pharmacist assistant(s) post-basic working in the dispensary in a primary health care clinic must ensure that he / she is at all times available to provide the necessary support either telephonically or by physically visiting the clinic to support activities taking place in the clinic.

7.1 The pharmacist who undertakes supervisory support of pharmacy technicians or pharmacist's assistants post-basic whilst not physically present in the dispensary in a primary health care

clinic must visit the pharmacy technician(s) or pharmacist's assistant(s): post-basic at the primary health care clinic at least once a month. Visits must be documented.

- 7.2 No indirect supervision of a pharmacy technician(s) or a pharmacist's assistant(s) post-basic may take place outside the boundaries of the district authority or metropolitan council where the pharmacist providing supervisory support is employed.
- 7.3 The pharmacist providing supervisory support must ensure that written and up-dated protocols and Standard Operating Procedures are available describing clearly the responsibility of the pharmacy technician or the pharmacist's assistant (post basic).
- 7.4 The pharmacy technician or the pharmacist's assistant (post basic) must report to the facility manager (line function), and the pharmacist who provides supervisory support to the pharmacy technician or the pharmacist's assistant (post basic), will provide professional supervision of the pharmacy technician or the pharmacist's assistant.
- 7.5 The pharmacist providing supervisory support must be available at all times when the clinic is open either telephonically by means of a land line or cellular phone or by electronic means.
- 7.6 In the case of patients with co-morbidities, consultation with a pharmacist should take place when a prescription is dispensed. Such consultation could take place telephonically or electronically.
- 7.7 In-service training must be provided to update the pharmacy technician or the pharmacist's assistant (post basic) about developments relevant to his / her practice.
- 7.8 Clearly documented referral to primary health care clinic procedure shall be in place at primary health care clinics where the prescription is prepared at a pharmacy and sent to a primary health care clinic or other site for collection, (e.g. a community pharmacy).
- 7.9 A mechanism of monitoring and evaluating the pharmaceutical service provided at the primary health care clinic must be in place.

[Minimum Standard relating to the Supervision of Pharmacy Support Personnel ins to Annex A by BN 271 in G. 37193.]