National
Pharmacy
Council
Rwanda

GOOD PHARMACY PRACTICE IN RWANDA

Kigali, August 2021

National Pharmacy Council
Rwanda

FOREWORD

The health of the public is fundamental to the happiness and welfare of all people. Barriers to good health include poor access to quality pharmaceutical products, lack of access to trained health professionals and care, inadequate health workforce, unaffordable cost of care and poor standards of education for health-care professionals.

The mission of the National Pharmacy Council ("Council") is serving the public interest and in terms of its statutory obligation, is to ensure compliance with the principles of morality, integrity and dedication essential to the practice of the pharmacy profession and ensure that all its members comply with their professional requirements and the laws and regulations governing pharmacists. The vital element in this mission is the commitment of the pharmacy professionals 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.

As health-care professionals, pharmacists possess a unique and complex body of knowledge and skills which they apply on behalf of other members of the community to optimize health outcomes from pharmaceutical products and health technologies. This commitment to act in the service of others carries with it an obligation to do so in accordance with expected behaviors as set down in code of ethics for pharmacy profession. In addition, the increasingly complex and diverse nature of pharmacists' roles in the health-care system and public health demands a continuous maintenance of the competence of pharmacists as health-care professionals who have up-to-date skills and expertise.

The scope of practice, generally, refers to the boundaries within which a health professional may practice. While pharmacists remain committed to assisting patients with access and information related to their medications, pharmacists today are providing a broad spectrum of services, within their scope of practice, including but not limited to conducting health and wellness promotion, managing chronic diseases and performing medication management, administering immunizations, and working in and partnering with hospitals and health systems to improve health and wellness resulting in reduction of hospital readmissions.

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Enabling pharmacists to practice at the top of their education and training, and be better integrated into the patient's health care team, will improve health outcomes and greatly benefit specific populations, especially those with chronic diseases such as diabetes and cardiovascular diseases.

In order to achieve its mission, National Pharmacy council has conceived this document as a new paradigm for pharmacy practice in Rwanda. The education and training of pharmacists and pharmacy technicians in Rwanda must equip them for the roles they have to undertake in practice and be in line with the 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 pharmaceutical products and health technologies, a reasonable introduction to disease states and the relevant elements of the social and behavioral sciences. At all stages, the development and improvement of communication skills should be given due emphasis.

All practicing pharmacists and pharmacy technicians are obliged to ensure that the service they provide is of quality and complies with Good Pharmacy Practice.

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DEFINITION OF KEY TERMS

In this document, the following terms shall mean:

Controlled pharmaceutical products: pharmaceutical products considered narcotics, vaccines, antibiotics, antiretrovirals, antituberculosis and antimalarial drugs and other drugs which have high potentiality to cause severe adverse drug reactions or to be misused through self-medication.

Council: the National Pharmacy Council

Dispensing: 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 and the provision of information and instructions by a pharmacist to ensure the safe and effective use of medicine by the patient.

Institutional pharmacy: physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed and pharmacy primary care is provided.

Over the Counter Product: any pharmaceutical product included in the list of non-prescription pharmaceutical products as set out by the competent authority.

Pharmaceutical Care: Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: cure of a disease; elimination or reduction of a patient's symptomatology; treating or slowing of a disease process; or preventing a disease or symptomatology.

Pharmaceutical products: any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored,

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cleaning hospitals, and equipment and farm houses. This includes drug, pharmaceutical products and health technologies, medications and pharmaceuticals.

Pharmacovigilance: is the science and activities dealing with the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem of drugs.

Adverse drug reactions: Any response to drug, which is noxious & unintended which occurs at doses normally used for treatment, prophylaxis, diagnosis, or modification of physiological function.

Pharmacist: any person holding a second cycle university degree in pharmacy who is registered.

Pharmacist intern: a person enrolled or a graduate of a pharmacy school who is serving a period of time of practical experience under the supervision of a pharmacist as defined in the rules of the council.

Pharmacy professional: any person who is either a pharmacist or a pharmacy technician.

Pharmacy Technician: any person holding a first cycle university degree in pharmacy who is registered.

Prescription: a written direction by an authorized prescriber intended for a pharmacist in connection with the preparation, treatment and dispensing of a pharmaceutical product.

Responsible Pharmacist: a person given the full responsibility of managing a retail pharmacy, a wholesale pharmacy or a pharmaceutical plant.

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1 INTRODUCTION

This document provides an overview of the current context and scope of pharmacy practice, the range of professional services offered by pharmacists, and the supporting role of pharmacy technicians. It has been developed to provide a link between credentialing and scope of practice, it also describes how credentials commonly held by pharmacists correlate with their professional scope of practice. Intended readers of this good pharmacy practice include members of the pharmacy profession and other health professions, students, healthcare administrators, members of academia, regulators, insurers, and the general public.

The mission of the pharmacy profession is to improve public health through ensuring safe, effective, and appropriate use of medications. Contemporary pharmacy practice reflects an evolving paradigm from one in which the pharmacist primarily supervises medication distribution and counsels patients, to a more expanded and team-based clinical role providing patient centered medication therapy management, health improvement, and disease prevention services.

By describing the full range of professional services currently provided, this document seeks to clarify the contribution of pharmacists to healthcare delivery and the resulting benefits to society. The vision for pharmacy profession in Rwanda is to have Pharmacists being the healthcare professionals responsible for providing patient care that ensures optimal medication therapy outcomes.

Optimal medication therapy implies that the use of pharmaceutical products and health technologies occurs within a system that assures the highest likelihood of achieving desired clinical, humanistic, and economic outcomes. Pharmacists will benefit society and be essential to the provision of effective health care by ensuring that: (a) medication therapy management is readily available to all patients; (b) desired patient outcomes are more frequently achieved; (c) overuse, underuse, and misuse of medications are minimized; (d) medication-related public health goals are more effectively achieved; (e) cost effectiveness of medication therapy is optimized.

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The majority of pharmacists in Rwanda practice in community pharmacies, hospitals and supply chain institutions. Other practice areas or roles include the pharmaceutical industry, academia, research, policy making, regulatory agencies, professional bodies (council included) and insurance companies. The council recognizes that pharmacy technicians are a critical part of the pharmacy workforce supporting pharmacists to manage the medication use process. With the emerging technology, pharmacists are required to play a more proactive and expanded role in patient care.

Regardless of practice setting, professional pharmacy services and activities emphasize communication, education, and information exchange with patients and their caregivers, prescribers, and other healthcare professionals. The management of medication use by pharmacists provides patient-centered medication therapy and is integrated with the additional responsibilities of medication distribution, supervision of pharmacy technicians, adaptation of new pharmaceutical technologies, efficient management of systems and resources, as well as integration of information systems and applications, all in a rapidly changing healthcare environment.

This broad scope of professional practice and the complexity of activities within each of these individual practices require a pharmacy workforce with diverse knowledge and skills, competently trained, and adequately credentialed. This workforce must demonstrate professional judgment, ethics, attitudes, and values.

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2 THE UNDERLYING PHILOSOPHY

Pharmacy as a dynamic, information-driven, patient-oriented profession, through its infrastructure, competence and skills, is committed to fulfill the health care needs of Rwanda and its people by being the following but not limited to:

a. Custodian of Pharmaceutical products and health technologies ;
b. Formulator, manufacturer, distributor and controller of safe, effective and quality medicines;
c. Adviser on the safe, rational and appropriate use of medicines;
d. Provider of accessible essential clinical services including essential screening and referral services;
e. Provider of accessible health care information;
f. Provider of suitable pharmaceutical care by taking responsibility for the therapeutic outcome and being actively involved in the design, implementation and monitoring of effective pharmaceutical services;
g. Committed to competency and professionalism;
h. Assessor of applications for registration of medicines in accordance with the law;
i. Formulator of any medicine for the purposes of registration as a medicine;
j. Distributor of any medicine or scheduled substance;
k. Able to do repackaging of pharmaceutical products and health technologies;
l. Able to initiate and conduct pharmaceutical research and development.
m. Committed to co-operate with other members of the health care team in the interest of the patient; and
n. Committed to ensure cost-effective pharmaceutical services.

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3 THE SCOPE OF PHARMACY PRACTICE

The scope of pharmacy practice describes the procedures, actions, and processes that a pharmacy professional is authorized to undertake in keeping with the terms of their professional license to practice. The table 1 describes **Pharmacy services and related competencies.**

3.1 Scope of Pharmacist

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

1. 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:
   a. Assessment of a patient's medicine-related needs (the indication, dose, safety and effectiveness) for therapy;
   b. Dispensing of any pharmaceutical products and technologies on the prescription of a person authorized to prescribe medicines and medical device;
   c. Providing information and advice to any person with regard to the use of pharmaceutical products and technologies;
   d. Determining patient compliance with the therapy and follow-up to ensure that the patient's medicine-related needs are met;
2. The provision of legally accepted pharmacist-initiated therapy;
3. The compounding, manipulation, preparation or packaging of pharmaceutical products and technologies or the supervision thereof;
4. The manufacturing of pharmaceutical products and technologies or the supervision thereof;
5. Purchasing, acquiring, importing, keeping, using, releasing, storing, packaging, re-packaging, supplying or distributing any pharmaceutical products and technologies or the supervision thereof;

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6. The application for registration of pharmaceutical products and technologies in accordance with the applicable law in Rwanda;
7. The formulation of any pharmaceutical product and technology for the purposes of registration as a medicine in Rwanda;
8. Quality assurance of pharmaceutical products and technologies;
9. The initiation and conduct of pharmaceutical research and development:
   a. Development of new pharmaceutical products
   b. Development and deployment of innovations and technologies pertaining to the pharmacist's expertise
   c. Testing and offer expert advice regarding new inventions i.e., innovations, technologies and clinical trials
10. Pharmacy and related policies formulation and enforcement;
11. Participation in pre-service and in-service training/education activities
12. Provision information to patients/clients and other health professionals

3.2 Scope of Pharmacy Technician

A Pharmacy technician registered and licensed with the Council may perform the following services/acts under the direct supervision of a pharmacist:

- ✓ The dispensing of pharmaceutical products and technologies;
- ✓ assist in the compounding, manipulation or preparation of non-sterile or sterile pharmaceutical products and technologies according to a formula and Standard Operating Procedures approved by the responsible pharmacist;
- ✓ The re-packaging of medicine;
- ✓ The distribution and control of pharmaceutical products and technologies;
- ✓ The ordering of pharmaceutical products and technologies;
- ✓ The selection, manipulation or compounding of the pharmaceutical products and technologies, the labelling and supply of the medicine in an appropriate container following the interpretation and evaluation of the prescription by a pharmacist;

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- ✓ The provision of instructions regarding the correct use of medicine supplied;
- ✓ The provision of information to individuals in order to promote health.

3.3 Scope of Pharmacist Intern

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 supervision of a pharmacist.

Table 1: Pharmacy services and competences

Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Obtain patient consent, where required	Yes	Yes
Protect patient confidentiality	Yes	Yes
Respect diversity	Yes	Yes
Accept responsibility and accountability for actions	Yes	Yes
Accept written prescriptions or refill requests	Yes	Yes
Receiving repeat prescriptions from health-care providers	Yes	Yes
Receive verbal prescriptions from prescribers	Yes	Yes
Receive verbal prescriptions from prescribers for narcotics, controlled drugs, benzodiazepines or targeted substances	Yes	No
Input patient, third-party insurance, and prescription information into electronic devices	Yes	Yes

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Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Prioritize prescription processing with the assistance of information software	Yes	Yes
Identify potential interactions, therapeutic duplications and incompatibilities within patient profiles	Yes	Yes
Confirm that the pharmacist has had the opportunity to review the prescription and patient profile or health record	N/A	Yes
Refer therapeutic issues and questions to the pharmacist	N/A	Yes
Select the product(s) needed	Yes	Yes
Ensure integrity and stability of product(s) including expiry dates, color, odor, etc.	Yes	Yes
Take the medication from the shelf to the despensing area	Yes	Yes
Calculate, convert, and document the result of dosage calculations	Yes	Yes
Perform compounding calculations	Yes	Yes
Verify calculations with the pharmacist	N/A	Yes
Count, measure, weigh and / or pour medications	Yes	Yes
Reconstitute medications	Yes	Yes
Adhere to clean, or where required, aseptic techniques	Yes	Yes
Verify accuracy and appropriateness of ingredients and quantities, including weights and volumes	Yes	Yes
Verify the accuracy and completeness of a pharmaceutical product prepared for release	Yes	Yes

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Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Select type of prescription container	Yes	Yes
Label container, including relevant auxiliary labels	Yes	Yes
Pre-package pharmaceuticals including replenishment of stock bottles	Yes	Yes
Prepare non-sterile compounds	Yes	Yes
Prepare sterile compounds (including IVs, TPNs)	Yes	Yes
Handle and prepare hazardous products appropriately	Yes	Yes
Prepare bulk manufactured products	Yes	Yes
Fill unit dose carts from a fill list	Yes	Yes
Check filled unit dose carts	Yes	Yes
Check and restock emergency	Yes	Yes
Prepare boxes, cardiac arrest kits, nursing unit cupboards and carts and night cupboard supplies from an approved list	Yes	Yes
Confirm that the pharmaceutical product has been checked and signed off by a pharmacist	N/A	Yes
Provide appropriate patient information materials as specified by the pharmacist confirm that the patient or patient's representative has received or has been offered counselling by the pharmacist	N/A	Yes
Assist the patient to make informed decisions regarding the selection and use of drug administration devices, monitoring devices and health aids	Yes	Yes

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Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Comply with legislation, policies and standards applicable to pharmacy practice	Yes	Yes
Follow procedures for the proper storage, handling, preparation, distribution, removal, and disposal of drugs	Yes	Yes
Ensure the cleanliness, functionality, and integrity of compounding, packaging, dispensing and storage equipment	Yes	Yes
Perform routine equipment maintenance	Yes	Yes
Store and transport pharmaceutical products appropriately	Yes	Yes
Manage inventory	Yes	Yes
Question, report and assist in the resolution of potential and actual unsafe, illegal, unethical, or unprofessional actions or situations	Yes	Yes
Use appropriate pharmacy reference material	Yes	Yes
Direct patients to the location of non-prescription medications	Yes	Yes
Act as a role model and mentor to new staff and students	Yes	Yes
Collect and verify accuracy of patient demographics and known allergies	Yes	Yes
Transferring and receiving prescriptions from other pharmacists or pharmacy technicians	Yes	Yes
Checking pharmaceutical products prepared by a pharmacy technician or unregulated pharmacy personnel	Yes	N/A

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Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Perform quality assurance audits/checks on distribution functions and activities	Yes	Yes
Initiate billing, verify, and assist in the adjudication for payment	Yes	Yes
Provide copies of prescriptions on patients' request	Yes	Yes
Assist patients and health care team members in understanding the scope, limitations and exceptions to third-party insurance coverage including coordination of benefits	Yes	Yes
Dispensing electronic prescriptions	Yes	Yes
Take medication history	Yes	Yes
Medication reconciliation	Yes	No
Document drug distribution processes and outcomes i.e., medication errors, missing medicines, etc.	Yes	No
Prepare reports and documents	Yes	Yes
Use non-integrated health information systems	Yes	Yes
Use integrated health information systems	Yes	Yes
Manage workflow	Yes	Yes
Being accountable to patients	Yes	Yes
Inter-professional collaboration	Yes	Yes
Managing Product recalls	Yes	No
Certifying written drug orders	Yes	Yes

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Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Chronic Disease Management	Yes	No
Collaborative Primary Health Care Teams	Yes	Yes
Ensure Continuity of Care	Yes	Yes
Distribution, dispensing, and administration of drug products with appropriate patient advice	Yes	No
Documentation and communication of information and decisions	Yes	No
Ensure appropriate prescribing for explicit objectives	Yes	No
Ensure safe, accessible and cost- effective Pharmaceutical products and health technologies are available	Yes	Yes
Contribute to the implementation and maintenance of safe and effective systems of drug supply and distribution	Yes	Yes
Health promotion and disease prevention requiring clinical knowledge	Yes	Yes
Identify and resolve drug-related problems	Yes	No
Recognize and respond to unusual patterns of drug distribution (including diversion, misuse, and fluctuations in utilization)	Yes	Yes
Administration of drugs by injection and other routes	Yes	No

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Pharmacy Services and Competencies	Pharmacist	Pharmacy Technician (Supervised by a pharmacist)
Non-prescription drug selection and education	Yes	No
Pharmaceutical products and health technologies assessment for compliance packaging	Yes	No
Medication adherence programs requiring clinical knowledge	Yes	Yes
Medication reviews	Yes	No
Minor ailment management	Yes	No
Participation of patients in their own care	Yes	No
Understand, participate in, and promote patient safety initiatives	Yes	Yes
Pharmaceutical care / medication management	Yes	No
Prescriptive Authority	Yes	No
Therapeutic Drug Monitoring (detection and resolution of drug- related problems)	Yes	No
Timely recognition of drug indication and other signs and symptoms related to drug use, along with accurate identification of underlying disease	Yes	No
Document and report adverse drug reactions/events through official channels.	Yes	Yes

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4 FUNCTIONS OF PHARMACISTS

With the development of specific and potent synthetic drugs, the emphasis of the pharmacist's responsibility has moved substantially towards the utilization of scientific knowledge in the proper use of modern pharmaceutical products and health technologies, and the protection of the public against dangers that are inherent in their use.

Pharmacists are employed in regulatory control and drug management, community pharmacy, hospital pharmacy, pharmaceutical industry, academic activities, training of other health care workers, and research. In all these fields, the aim is to ensure optimum drug therapy, by contributing to the preparation, supply and control of pharmaceutical products and health technologies but also providing information and advice to prescribers or users of pharmaceutical products and health technologies.

4.1 Regulatory Control and Drug Management

4.1.1 Health policy and drug policy

Pharmacists in administration participate in formulating health and drug policies, particularly those on the selection, procurement and distribution of drugs. They serve as sources of information for other health professionals and the public, and participate in the preparation of pharmacopoeias and other official documents.

4.1.2 Pharmaceutical Supply Management

Pharmacists are responsible for pharmaceutical products management, which include the selection of essential drugs, the quantification, the procurement, storage and distribution of drugs and their rational use, as well as the design and use of information systems. They also collect and collate data required by national agencies. They are also involved in pharmaceutical products disposal.

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4.1.3 Educational Policy

Pharmacists cooperate with educators in establishing and implementing policies with regard to training programmes and continuing professional development.

4.1.4 Regulation and enforcement

Pharmacists are involved in approval, registration and quality control of drugs, cosmetics and medical devices. They are also involved in control of distribution of drugs through licit and illicit channels and in inspections of the manufacture, importation, distribution, and sale of drugs.

4.1.5 Professional regulation

Pharmacists are engaged in establishing criteria for registration of pharmacists and licensing requirements, register pharmacies and pharmacists. They also monitor professional conduct of registered pharmacists.

4.1.6 International agencies

Pharmacists are employed in international bodies such as World Health Organization, Interpol International Pharmaceutical Federation, etc. to perform a variety of administrative functions.

4.2 Community Pharmacy

Pharmacists in community pharmacies supply Pharmaceutical products and health technologies in accordance with a prescription and over the counter Pharmaceutical products and health technologies. Their professional activities cover also counselling of patients at the time of dispensing of prescription and non-prescription Pharmaceutical products and health technologies, drug information to other health professionals, patients and general public and participation in health promotion

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programmes. Pharmacists should undertake also the task of ensuring the quality of products they supply.

The main activities of community pharmacists include:

- ✓ Process prescriptions
- ✓ Care of patients
- ✓ Administer immunizations, and Family Planning methods in accordance with Laws and Regulations of Rwanda.
- ✓ Monitoring of drug utilization
- ✓ Extemporaneous preparation and small-scale manufacture of pharmaceutical products
- ✓ Dispense and advise on food supplements responding to symptoms of minor ailments
- ✓ Informing other health professionals and the public
- ✓ Health promotion
- ✓ Orient and refer patients appropriately
- ✓ Manage the supply chains of pharmaceutical products and technologies.

4.3 Hospital Pharmacy/institutional pharmacy

In addition to activities done in community pharmacy, the following are activities done by hospital institutional pharmacist:

- ✓ Promote the rational prescribing and use of drugs,
- ✓ Influence selection of drugs and drug regimens, monitor patient compliance and therapeutic response to drugs and recognize and report adverse drug reactions,
- ✓ Monitor patterns of drug usage and thus recommend changes accordingly,
- ✓ Influence the preparation and composition of drug formulary,
- ✓ Educate other health professionals about rational use of drugs,
- ✓ Participate in research studies,
- ✓ Control manufacture and procurement of drugs,
- ✓ Plan and implement clinical trials,
- ✓ Participate in supervision and outreach,

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- ✓ Develop and implement quality assurance systems.

4.4 Industrial Pharmacy

Pharmacists in pharmaceutical industry perform the following duties:

- ✓ Participate in research, drug discovery and drug development
- ✓ Oversee the production of pharmaceutical products
- ✓ Establish and monitor an integrated approach to quality control and quality assurance
- ✓ Compile and share information on pharmaceutical products and health technologies
- ✓ Prepare information required for patent and authorization submissions
- ✓ Facilitate collaboration between companies, health professionals and governments in relation to clinical trials and surveillance,
- ✓ Make contribution to proper marketing practices,
- ✓ Promote an ethical approach within management policies.

4.5 Academia

Academic pharmacists engage in education, pharmaceutical practice, research and community outreach.

4.6 Training of other health professionals

Training provided by pharmacists include efforts to optimize drug therapy, by promoting the rational use and storage of drugs and methods of reducing drug abuse, and is directed to medical and other prescribers or suppliers of drugs including community health workers.

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5 STANDARDS FOR GOOD PHARMACY PRACTICE

Standards are an important part in the measurement of quality of service to the consumer. All practicing pharmacy professionals are obliged to ensure that the service they provide to every patient is of appropriate quality. Good pharmacy practice is a means of clarifying and meeting that obligation.

The requirements for good pharmacy practice include:

a. A licensed pharmacist must put the welfare of the patient and of the public in general at the forefront.
b. The pharmacist must provide appropriate information and advice to the patient, ensuring the proper use of pharmaceutical products and technologies and monitoring thereof.
c. Licensed pharmacists must adhere to Good Manufacturing Practice to ensure the safety, quality and efficacy of medicine where applicable.
d. An integral part of the pharmacist's contribution to health care is the promotion of rational use of pharmaceutical products and technologies.
e. The objective of each element of the pharmaceutical care is clearly defined, relevant to the individual and effectively communicated to and accepted by all those involved.

In satisfying these requirements:

a. The ongoing relationship with other health professionals should be seen as a therapeutic alliance involving mutual trust and confidence in all matters relating to pharmacotherapeutics;
b. The relationship with other pharmacy professionals should be as colleagues, each seeking to improve pharmaceutical services, rather than as competitors;
c. There must be input by the pharmacist regarding decisions on medicine use policy at all levels;

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d. The relationship with those involved in paying for pharmaceutical services should also be one of mutual trust, involving appropriate professional discretion from the pharmacy professionals;
e. 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 pharmaceutical establishment;
f. The pharmacy professional needs independent, comprehensive, objective and current information about therapeutics and pharmaceutical products and technologies in use;
g. The philosophy underlying practice must be professionally rather than commercially orientated;
h. Pharmacy professionals in each field of practice must accept personal responsibility for the self-assessment and maintenance of competence throughout their involvement in the profession;
i. Good pharmacy practice as published by the Council must be adhered to by all pharmacy professionals practicing in Rwanda;
j. And 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.

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5.1 MINIMUM STANDARDS FOR PROCUREMENT, STORAGE AND DISTRIBUTION

5.1.1 Responsibility for procurement

The pharmaceutical aspects of the purchase of all pharmaceutical products and technologies must be the responsibility of a pharmacist. Written policies for the procurement, storage and distribution of pharmaceutical products and technologies must be available in the pharmaceutical establishment. Written policies must assist in ensuring:

- ✓ product traceability;
- ✓ that the procurement and distribution process is fully documented;
- ✓ effective batch recall of pharmaceutical products and health technologies when necessary;
- ✓ that optimal storage conditions are monitored (including during transport);
- ✓ the safety of pharmaceutical products and health technologies;
- ✓ that patients receive products that have been suitably stored and has an expiry date that allows sufficient time for product use.

5.1.2 Sources of supply

- ✓ The licensed pharmacist has a professional responsibility to exercise control over all pharmaceutical products and technologies, which are purchased or supplied.
- ✓ A purchasing policy must be in place to ensure the safety of pharmaceutical products and technologies.
- ✓ A licensed pharmacist must not purchase, dispense or supply any pharmaceutical product and technology if s/he has any reason to doubt its safety, quality or efficacy.
- ✓ Procurement should be supported by quality assurance to avoid falsified, counterfeit, unlicensed or substandard pharmaceutical products and health technologies.
- ✓ The licensed pharmacist must know and select right suppliers by applying various quality parameters and procurement procedures in place;

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- ✓ 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.

5.1.3 Safe systems of work

A licensed 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 pharmaceutical establishment. In adhering to this principle, the following must be taken into consideration:

- ✓ Safe systems of work must be established and maintained by a licensed pharmacist to eliminate, as much as possible, errors in any component of the pharmaceutical service.
- ✓ Secure storage for pharmaceutical products and technologies must be provided in all premises and approved store-keeping procedures and adequate stock control systems must be maintained.
- ✓ A policy for the storage, dispensing and administration of pharmaceutical products and technologies in pharmaceutical establishments must be defined and updated regularly.
- ✓ A licensed pharmacist must establish systems, and be responsible, for the professional element of the procurement of all pharmaceutical products and technologies purchased through the pharmaceutical service.
- ✓ Within a multidisciplinary system, a pharmacist is responsible for providing advice as required on the procurement of pharmaceutical products and technologies.

5.1.4 Medical gases

The procurement, storage and distribution of medical gases must comply with the requirements, which include but not be limited to the following:

- ✓ 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.

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- ✓ Cylinders and other containers of medical gases must be stored in accordance with the current guidelines issued by the manufacturers of the gas.
- ✓ Each patient, and appropriate members of the patient's family or caregiver, must receive full and proper instruction from a pharmacist or a suitably trained person in the safe care and handling of the cylinders and associated equipment.
- ✓ To facilitate recalls of faulty medical gases giving sets, the name, type, serial number and location of each regulator must be recorded and held in the pharmacy.
- ✓ 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.

5.1.5 Thermolabile pharmaceutical products

Thermolabile pharmaceutical products are defined as all products which require constant cold storage at product specific temperatures below room temperature.

Storage, supply and distribution form 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.

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Storage, supply and distribution of thermolabile pharmaceutical products must be in accordance with the provisions of the applicable laws and regulations and the manufacturer's specification.

Procurement of thermolabile pharmaceutical products

Procurement of thermolabile pharmaceutical products must be performed in terms of the Minimum standards for procurement, storage and distribution.

Storage area of thermolabile pharmaceutical products

Storage areas may include cold rooms, refrigerators and freezers. 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.
- ✓ 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.
- ✓ There must be an alternative source of power to avoid power cuts which may affect the quality of thermolabile pharmaceutical products.

Distribution of thermolabile pharmaceutical products

A distribution system must have in place:

- ✓ a comprehensive quality assurance system;
- ✓ a process for continuous quality improvement;
- ✓ an ambient and cold chain distribution strategy;
- ✓ a risk assessment programme.

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Transportation of thermolabile pharmaceutical products

Transportation of thermolabile pharmaceutical products must be in such a way that it is secure and the temperature is maintained to product specifications. 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.

In the event of the mode(s) of transport not being specific for the transportation of thermolabile pharmaceutical products, the specialized packaging like validated cooler bag packaging must be used. 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.

The transport must be clean and free from all forms of contamination, inter alia rats, vermin, birds, fungi, and mites.

During transportation, thermolabile pharmaceutical products must not be packaged with non-pharmaceutical items or containerized with any other goods (for example food and beverages which may also require refrigeration transportation), which could result in cross contamination.

The transport must have a sufficient capacity to allow for orderly storage of thermolabile pharmaceutical products during transportation. Temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards that comply with or meet 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.

Personnel transporting thermolabile pharmaceutical products must be appropriately trained for cold chain management and shall provide the suitable documentation as proof for this function and they

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must ensure that the correct procedures are followed to maintain the cold chain within the manufacturer's specification. At any stage of transportation, a delivery document must show evidence that the transport requirements, inter alia temperature control, have been met.

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 pharmaceutical establishment. Upon arrival the person responsible for the transportation of the thermolabile pharmaceutical products must inform receiving personnel, pharmacists, or other authorized health professionals, that the package includes thermolabile pharmaceutical products and that they require immediate attention.

Receipt of thermolabile pharmaceutical products

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.

- ✓ The receiving area must protect deliveries from bad weather during the unloading of thermolabile pharmaceutical products.
- ✓ 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:
    a. product security,
    b. that the product has not been tampered with and that there are no damaged containers,
    c. that products were protected from weather,
    d. that there is no risk for contamination of products.
    e. The delivery document must be reviewed for evidence that transportation requirements, inter alia temperature control, have been met.
    f. 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

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history of the thermolabile pharmaceutical product being transported were maintained within in limits.

g. 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.

h. Quality assessment sampling requiring laboratory testing is required for the received thermolabile pharmaceutical products within a manufacturing pharmaceutical establishment 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.

Documentation of thermolabile pharmaceutical products

Documentation is critical. Each step of the supply chain must follow established protocols in order to maintain proper records. Customs delays may occur due to inaccurate or incomplete custom documentation, therefore guidelines for creating a commercial invoice must be followed to ensure the proper verbiage, number of copies, and other details. 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.

Personnel of thermolabile pharmaceutical products

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

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allow them to effectively discharge this responsibility and be capable of meeting these requirements. This training must be documented.

Procedures and conditions of work for employees and other persons having access to thermolabile pharmaceutical products must be designed and managed to minimize the possibility of such pharmaceutical products being in possession of unauthorized persons.

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:

- ✓ 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.
- ✓ Actions must comply with manufacturer's documented advice, where possible and where available.
- ✓ An incident report and root cause analysis investigation must be completed to ensure lessons are learned to prevent reoccurrence.
- ✓ Pharmacists and authorized health 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.
- ✓ Refrigerator temperature must be recorded by noting the current reading and recording the maximum and minimum temperatures.
- ✓ 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.
- ✓ 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 authorized' and dated to make sure the implicated stock can be identified and kept separate.

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- ✓ Where immediate removal is not possible, the storage area must be kept closed to maximize temperature control.
- ✓ 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.
- ✓ 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.
- ✓ Refer to the manufacturer for advice on stability as a result of temperature deviation and report the occurrence on an incident report form.
- ✓ Where necessary record and quarantine the thermolabile pharmaceutical product for destruction in line with the minimum standards for destruction and disposal of pharmaceutical products and technologies.
- ✓ 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.

5.2 Minimum Standards for hazardous products

These standards apply to any health setting that use, store, or handle any quantity of hazardous materials. Hazardous materials are defined as materials that represent a risk to human health, property, or the environment due to their physical or chemical characteristics.

They include explosives; compressed gases, including toxic or flammable gases; flammable liquids; flammable solids; oxidizing substances; toxic materials; radioactive material; and corrosive substances.

When a hazardous material is no longer usable for its original purpose and is intended for disposal, but still has hazardous properties, it is considered a hazardous waste.

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5.2.1 General Hazardous Material Management

The overall objective of hazardous material management is to avoid or, when avoidance is not feasible, minimize uncontrolled releases of hazardous materials or accidents (including explosion and fire) during their production, handling, storage and use.

Health facilities which manufacture, handle, use, or store hazardous materials should establish management programs that are commensurate with the potential risks they present.

It is in the responsibility of the pharmacist:

- ✓ To identify of the types and amounts of hazardous materials present in the setting.
- ✓ To record the information on the identified hazardous, the information includes: name and description (e.g., composition of a mixture) of the hazardous product, classification (e.g., code, class or division), quantity of hazardous product and characteristics.

5.2.2 Hazardous Materials Transfer

Uncontrolled releases of hazardous materials may result from small cumulative events, or from more significant equipment failure associated with events such as manual or mechanical transfer between storage systems or process equipment. Recommended practices to prevent hazardous material releases from processes include:

- ✓ Use of dedicated fittings, pipes, and hoses specific to materials in tanks and maintaining procedures to prevent addition of hazardous materials to incorrect tanks;
- ✓ Use of transfer equipment that is compatible and suitable for the characteristics of the materials transferred and designed to ensure safe transfer;
- ✓ Regular inspection, maintenance and repair of fittings, pipes and hoses;
- ✓ Provision of secondary containment, drip trays or other overflow and drip containment measures, for hazardous materials containers at connection points or other possible overflow points.

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5.2.3 Reaction

Fire, reactive, flammable and explosive products should be managed to avoid uncontrolled reactions or conditions resulting in fire or explosion.

Recommended prevention practices include:

- ✓ Storage of incompatible materials (acids, bases, flammables, oxidizers, reactive chemicals) in separate areas, and with containment facilities separating material storage areas;
- ✓ Provision of material-specific storage for extremely hazardous or reactive materials;
- ✓ Use of flame arresting devices on vents from flammable storage containers;
- ✓ Provision of grounding and lightning protection for tank farms, transfer stations, and other equipment that handles flammable materials;
- ✓ Selection of materials of construction compatible with products stored for all parts of storage and delivery systems, and avoiding reuse of tanks for different products without checking material compatibility;
- ✓ Storage of hazardous materials in an area of the facility separated from the main production works. Where proximity is unavoidable, physical separation should be provided using structures designed to prevent fire, explosion, spill, and other emergency situations from affecting facility operations;
- ✓ Prohibition of all sources of ignition from areas near flammable storage tanks;

5.2.4 Emergency Preparedness and Response

When handling hazardous materials, procedures and practices should be developed allowing for quick and efficient responses to accidents that could result in human injury or damage to the environment.

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5.2.5 Production

Standard operating procedures (SOPs) must be available for all operating procedures and should be regularly reviewed and kept up to date for all manufacturing operations. All entries on batch records should be initiated by the operator and independently checked by another operator or supervisor.

5.2.6 Labelling

All products should be clearly identified by labels, which must remain permanently attached to the containers under all storage conditions. An area of the container should be left uncovered to allow inspection of the contents. If the final container is not suitable for labelling, the label should appear on its package. Information on batch coding must be provided to the national and/or regional authorities.

The labels of radiopharmaceuticals must comply with the relevant national regulations and international agreements. For registered radiopharmaceuticals, the competent authority should approve the labels.

The label on the container should show: the name of the drug product and/or the product identification code; the name of the radionuclide; the name of the manufacturer or the company and/or the person responsible for placing the drug on the market;

The label on the package should state: the qualitative and quantitative composition; the radioactive isotopes and the amount of radioactivity at the time of dispatch; the route of administration; the expiry date; any special storage conditions.

5.3 MINIMUM STANDARDS SPECIFIC TO INSTITUTIONAL PHARMACIES

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

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5.3.1 Selection of pharmaceuticals

A Drug and Therapeutics Committee (DTC) must be in place for the selection of Pharmaceuticals and the promotion of rational drug use. 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 medicines. This system includes a formulary of approved pharmaceutical substances as well as a policy and procedures for the approval and provision of medicines not included in the formulary as required.

The DTC must be responsible for the formulary. Pharmaceutical usage review programmes must be developed to ensure maximum patient benefit on the most cost-effective basis.

5.3.2 Procurement and storage

- ✓ The pharmaceutical storage area(s) must be under control of the responsible pharmacist. Delivery of Pharmaceutical products and health technologies 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 pharmaceutical products and technologies and their onward passage to the pharmacy.
- ✓ Stock control of pharmaceutical products and technologies must be the responsibility of a pharmacist.
- ✓ The pharmacist should be responsible for quantification and ensure that procurement process meet standards of procurement of pharmaceutical products.
- ✓ There must be written procedures, which must be updated regularly, covering all activities.

The responsible pharmacist must establish and maintain adequate records of purchases for inventory control and satisfaction of legal and audit requirements.

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The responsible pharmacist is accountable for:

- ✓ The selection of pharmaceutical products and technologies with due regard to quality and registration status, in co-operation with the DTC;
- ✓ Adherence to central contract or purchasing agreements (as applicable);
- ✓ The maintenance of up-to-date price records to ensure that the most favorable prices are obtained (as applicable);
- ✓ Establishing and maintaining adequate records of purchases for inventory control and satisfaction of legal and audit requirements;
- ✓ The establishment and maintenance of a system for reporting errors and withdrawing defective products;
- ✓ All purchase orders must be on official documents carrying a unique order number.
- ✓ The responsible pharmacist must ensure that all areas where pharmaceutical products and technologies are stored are of acceptable standard.
- ✓ The responsible pharmacist must ensure that all pharmaceutical products and technologies storage areas are inspected regularly (at least monthly) to at least ensure that:
  - pharmaceutical products and technologies are stored and handled in accordance with the pharmaceutical manufacturer's requirements;
  - no expired or obsolete pharmaceutical products and technologies are stored;
  - pharmaceutical products and technologies requiring special environmental conditions are stored properly;
  - stock levels are adequate to ensure the continuous supply and accessibility of medicines at all times, including the availability of essential drugs;
  - inflammable substances are stored separately and in an appropriate manner;
  - disinfectants and preparations for external use are stored separately from Pharmaceutical products and health technologies for internal use;
  - hazardous Pharmaceutical products and health technologies are pre-packed only in accordance with the provisions of the applicable laws and regulations;

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- the expired stock is separated and kept in secure place before disposal.

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:

- ✓ Establishing minimum and maximum stock/re-order levels;
- ✓ Stock control accounting for pharmaceutical products, received into and removed from stock;
- ✓ Identification and proper disposal of expired, deteriorated, recalled or obsolete pharmaceutical products and the timely return of items for credit;
- ✓ Recording of orders, usage as well as financial data for analysis, interpretation and planning.

5.3.3 Distribution of pharmaceuticals to wards, departments, theatres, clinics and other outlets

Distribution of pharmaceutical products and technologies within a hospital/institution must take place under the direction and control of a pharmacist and must be in accordance with applicable laws and regulations. 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. 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.

Written Standards Operating Procedures must be provided on how supplies of pharmaceutical products and technologies are to be obtained from the pharmacy together with an indication of nurses' responsibilities for signing approved requisition documents. 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. A record must be kept according to institutional record keeping policy.

Procedures must be established to ensure that adequate control of issues is maintained and that regular review of stock ranges are carried out to minimize wastage and overstocking. Regular stock checking

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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.

5.4 Minimum Standards for the Dispensing of Pharmaceutical Products and Technologies on the Prescription of an Authorized Prescriber

5.4.1 Dispensing procedures

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

The dispensing process is divided into three phases, namely:

- ✓ Phase 1: Reception, interpretation and assessment 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 supervision of a pharmacist. Phases 2 and 3 may be performed by a pharmacy technician under the direct supervision of a pharmacist.

In terms of the scope of practice of a pharmacy technician, s/he 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. S/he may also provide instructions regarding the correct use of 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 authorized person.

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Phase 1: Reception, interpretation and assessment of the prescription

Receipt of the prescription and confirmation of the integrity of the communication. Adequate procedures must exist for:

- ✓ identifying the patient, the prescriber and the entity responsible for payment (as applicable);
- ✓ ensuring the legality/authenticity of the prescription;
- ✓ 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 according to internal institutional policy;
- ✓ helping the patient to resolve the problem when the prescription cannot be dispensed;
- ✓ interpreting the type of treatment and the prescriber's intentions;
- ✓ identifying the medicine, and checking the pharmaceutical form, strength, appropriate dosage, presentation, method of administration and duration of treatment;
- ✓ informing the patient of the benefits and implications of the substitution for a branded medicine of an interchangeable multi-source medicine.

Assessment of the prescription to ensure the optimal use of medicine. Each prescription must be professionally assessed by a pharmacist with respect to:

- ✓ Therapeutic aspects (Pharmaceutical and Pharmacological) i.e., the safety of the medicine; possible contra-indications; drug/drug interactions; drug/disease interactions; treatment duplications;
- ✓ Appropriateness for the individual and the indication for which the medication is prescribed;
- ✓ Social, legal and economic aspects;
- ✓ 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.
- ✓ For the assessment of a prescription the following information sources can be used:

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- questions put to the patient or caregiver;
- questions put to the prescriber where doubts arise or further information is required;
- pharmacopoeias, formularies, technical books, electronic sources, professional journals, compendia of pharmaceutical legislation and medicine supply agreements with the health services;
- And outside information from drug information centers, competent authorities and pharmaceutical manufacturers.

Phase 2: Preparation and labelling of the prescribed medicine

Selecting or preparing the medicine includes the following activities:

- ✓ Patient-ready packs/pre-packed pharmaceutical products and health technologies are correctly selected;
- ✓ Preparation of extemporaneous preparations: Where applicable, the pharmacy must have adequate facilities for preparation of extemporaneous preparations of individual prescriptions.
- ✓ Counting must be done on a clean counting tray and the final dosage form placed in a suitable container.
- ✓ 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.
- ✓ All dispensing procedures, whether performed by a pharmacist, pharmacist intern or pharmacy technician must be carefully checked for accuracy and completeness.
- ✓ Signing the prescription: Accountability must be accepted by the pharmacist who signs and stamps 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.

Labelling of dispensed products must be clear, legible and indelible. Lettering must as far as possible be mechanically printed. The label should contain at least the following information and any other information as stated by applicable laws and regulations:

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- ✓ the proprietary name, generic name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
- ✓ the name of the person for whom treatment is intended;
- ✓ the directions in regard to the manner in which such medicine should be used (Dosage, dosing interval and route of administration);
- ✓ the name and registration number of the pharmacist and institution address;
- ✓ The date of dispensing;
- ✓ Reference number;
- ✓ Expiry date and Batch number;
- ✓ And the pharmacy's stamp

The following information must be recorded with regard to the supply of pharmaceutical product and technology without a prescription: the name of the person to whom it was intended; its name and quantity; and the name of the pharmacist, pharmacist intern or pharmacy technician who dispensed it.

A prescription book or other permanent record in respect of pharmaceutical products and technologies must be kept at all premises where prescribed pharmaceutical products and technologies are dispensed and must contain the following details:

- ✓ the name of the pharmaceutical products and technologies;
- ✓ the date on which the prescription was dispensed;
- ✓ the dosage form and quantity of the pharmaceutical products and technologies;
- ✓ the name and address of the patient,
- ✓ the name and address of the authorized prescriber
- ✓ prescription reference number.

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Phase 3: Provision of information and instructions to the patient to ensure the safe and effective use of pharmaceutical products and technologies.

Advising a patient or the patient's agent/caregiver (physical presence is preferred) must be carried out by a licensed pharmacist. A patient information leaflet, containing the information should be available at the point of dispensing. Information must be structured to meet the needs of individual patients. 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. Information provided to patients regarding their pharmaceutical products and technologies use must always be done with professional judgement and the prescriber should be contacted when necessary.

5.4.2 Monitoring patient outcomes

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

5.4.3 Supervision of dispensing and supply

Dispensing must be done by or under the supervision of a pharmacist in accordance with applicable legislation in Rwanda. In a pharmacy with only one pharmacist present, this pharmacist must be able to supervise activities in the Pharmaceutical products and health technologies supply area (as applicable) at the same time as supervising dispensing. A pharmacist responsible for supervising the dispensing or supply of any pharmaceutical products and technologies in a pharmacy bears the associated legal and professional responsibility.

Every prescription dispensed in a pharmacy must be seen by a pharmacist and judgement made by him/her as to what action is necessary. The pharmacist must exercise judgement to ensure fulfilment

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of professional duties to the patients in the best possible way. The pharmacist must thus be able to delegate to pharmacy technician tasks that s/he is confident can be undertaken by a pharmacy technician and fall within her/his scope of practice. The pharmacist must be available in the pharmacy to intervene, provide advice and check the dispensing of any prescription under his/her supervision. Systems must be developed to ensure that the distribution of pharmaceutical products and technologies is reliable and secure to the point of delivery.

5.4.4 Safety in dispensing procedures

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.

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. The prescription must be endorsed according to any action taken e.g., telephonic confirmation of an unusual dosage, etc.

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

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. All containers intended for pharmaceutical products and technologies must be protected and kept free from contamination. All solid dose oral preparations must be dispensed in a re-closable container or in unit packaging of strip or blister type unless:

- ✓ the original pack is such as to make this inadvisable;

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- ✓ the patient is elderly or handicapped and will have difficulty in opening the re-closable container; or
- ✓ a specific request is made that the product shall not be dispensed in a re-closable container.
- ✓ advice must be given to keep all pharmaceutical products and health technologies out of the reach of children.

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

A pharmacist must use his/her professional knowledge/judgement in relation to reuse of pharmaceutical products and health technologies as follows:

- ✓ Pharmaceutical products and health technologies brought in by patient remain the patient's own property. Under no circumstances may they be used by anyone else.
- ✓ All expired pharmaceutical products and technologies must be destroyed in accordance with the disposal policy.
- ✓ The continued use of patients' own pharmaceutical products and health technologies while in hospital may be necessary in special circumstances. Appropriate safeguards are required.

No information may be divulged about the affairs of any person obtained in the course of dispensing a prescription except to a person authorized to have access to such information and acting within his/her lawful jurisdiction.

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

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High standards of personal cleanliness must be observed in dispensing. Direct contact between the dispensed product and the operator's hands must be avoided. 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. No personnel may smoke or prepare or consume food in any area where pharmaceutical products and technologies are dispensed or supplied.

Expired pharmaceutical products and technologies must not be dispensed or supplied to the public. Particular care must be taken with prescriptions for several months' treatment. Ideally, prescriptions should be for a maximum of twenty-eight (28) days' treatment but, where a quantity covering a longer period is dispensed, the pharmacist must ensure that the product will be within its shelf life at the end of that period. A record of the expiry dates of all pharmaceutical products and technologies procured by the pharmacy must be kept.

Pharmacists or registered nurses in charge of units must return excessive and short-dated stock to the pharmacy timely. The items which have expired must be recorded and priced. The destruction of expired pharmaceutical products and technologies must only take place in accordance with the laws and regulations in Rwanda.

Adverse drug reactions must be reported in accordance with laws and regulations of Rwanda.

A pharmacist shall 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 pharmaceutical products and technologies of an interchangeable multi-source medicine; and dispense an interchangeable multi-source pharmaceutical products and technologies instead of the medicine prescribed by licensed health professionals.

If a pharmacist is forbidden to substitute for a branded pharmaceutical products and technologies of an interchangeable multi-source medicine, that fact shall be noted by the pharmacist on the prescription. When an interchangeable multi-source pharmaceutical products and technologies is

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dispensed by a pharmacist, s/he 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.

A pharmacist shall not dispense an interchangeable multi-source pharmaceutical products and technologies:

- ✓ if the person prescribing the pharmaceutical products and technologies has written on the prescription the words 'NO SUBSTITUTION' next to the item prescribed;
- ✓ if the retail price of the interchangeable multi-source pharmaceutical products and technologies is higher than that of the prescribed pharmaceutical products and technologies;
- ✓ where the product has been declared not substitutable.

5.5 Minimum Standards for Patient Information and Advice

Patient information is of vital importance in the proper use of pharmaceutical products and health technologies. Lack of information and misunderstanding contribute to the failure of the therapy, thus wasting resources and adding to the costs of care. Patient information must respect patient autonomy, improve health and enhance the outcome of medical treatment by:

- ✓ empowering patients to make informed decisions about their medical treatments and take responsibility for their own health care;
- ✓ improving communication between patients and health care providers; and
- ✓ aiding and encouraging effective use of pharmaceutical products and technologies.

Pharmacists must give advice and information to patients on how to use pharmaceutical products and health technologies safely and effectively to maximize therapeutic outcomes.

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.

Pharmacists must assess and, where appropriate, comment on promotional materials for pharmaceutical products and technologies.

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Upon receipt of a prescription, or a request for dispensing of pharmaceutical products and technologies 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 optimize the pharmaceutical products and technologies prescribed. Care must be taken to assess the wishes of the prescriber and the information and counselling needs of individual patients. Written information must be used to supplement verbal communication as appropriate.

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. Confidentiality of the patient must be respected. 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.

5.6 Minimum Standards for Record Keeping Procedures

5.6.1 Patient medication records

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.

Patient medication records must be developed, preferably using computer technology. Patient medication records must respect the patient's privacy. The following information must be captured in a patient medication record:

- ✓ the full name of the patient;
- ✓ the address and telephone number of the patient;
- ✓ the patient's date of birth;
- ✓ the patient's gender;
- ✓ current weight of the patient;
- ✓ the name of the prescriber and date of consultation;

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- ✓ a list of all pharmaceutical products and health technologies obtained (prescription as well as non-prescription) by the patient at the point of supply during the twelve-month period immediately preceding the date of dispensing;
- ✓ the number allocated to each prescription dispensed and the date thereof;
- ✓ any known allergies and idiosyncrasies or adverse reactions of the patient towards pharmaceutical products and technologies;
- ✓ family history of the patient where applicable;
- ✓ the presence of other factors, e.g., smoking;
- ✓ medical history of the patient;
- ✓ the identity of any other pharmaceutical products and technologies currently being used by the patient, and any related information indicated by care providers.

5.6.2 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:

- ✓ The pharmacist must record all professional actions that might require confirmation in the future.
- ✓ Up-to-date records of prescriptions must be kept as discussed above.
- ✓ Any warning or precaution issued by professional institutions or authorized officials regarding pharmaceutical products and health technologies, or pharmaceutical legislation must be recorded and complied with immediately.

5.7 Minimum Standards for Clinical Pharmaceutical Services in Institutional Pharmacies

Clinical pharmacy is concerned with the application of pharmaceutical expertise to help maximize drug efficacy and minimize drug toxicity in individual patients. Clinical pharmacy can be separated into two components. The first is the overall management of pharmaceutical products and

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technologies 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.

5.7.1 Ward pharmacy services

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

Clinical pharmacists must utilize their knowledge and skills of pharmaceutical sciences and product awareness to promote safety, efficacy and economy in the use of pharmaceutical products and health technologies. Clinical pharmacists must offer advice to other health care providers on appropriate medication to ensure that pharmaceutical products and health technologies are used correctly and in the appropriate therapeutic context. The clinical pharmacist must co-operate with other health care providers in determining the minimum number of ward rounds to be attended to ensure that the clinical pharmacist has a full appreciation of the clinical context in which advice on the use of pharmaceutical products and health technologies is given.

Clinical pharmacists should participate in specialist care teams. Close involvement with decisions on therapy will bring the pharmacist closer to the patient and provide opportunities for advising patients on self-administration of pharmaceutical products and health technologies. Where a local formulary is in operation, the clinical 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. Clinical pharmacists must provide a patient counselling service where the need arises.

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.

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5.7.2 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 potential risk factors for medication-related problems. Through prescription monitoring, the pharmacist must identify problems or opportunities for optimizing treatment.

A multi-disciplinary approach must be followed regarding the monitoring of prescriptions. The prime objective of this service is to safeguard the patient and ensure the optimal use of medicines. Potential problems must be communicated to the prescriber and resolved preferably before the medicine is dispensed or the first dose is administered. 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.

Potential medicine-related problems must be discussed with the health care providers 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 pharmaceutical products and health technologies prescribed. The occurrence of any problems relating to the use of pharmaceutical products and health technologies 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.

Prescriptions must be evaluated for the following reference materials:

- ✓ legality, legibility and completeness;
- ✓ relative efficacy of the medicine for the clinical indication;
- ✓ duplication of pharmacologically similar drugs;
- ✓ potential adverse reactions to pharmaceutical products and health technologies, including allergies;
- ✓ possible drug/disease incompatibilities;
- ✓ significant drug/drug interactions;

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- ✓ correct dosage, route, dosage interval and duration of treatment;
- ✓ appropriate dosage form and route of administration;
- ✓ problems relating to intravenous administration, including potential incompatibilities, medicine stability, volume of intravenous fluid for medicine administration and rate of administration;
- ✓ compliance with any applicable formulary/treatment guidelines,

Patients and their medicine therapy must be monitored for the following:

- ✓ The manifestation of adverse reactions or drug toxicity. The pharmacist should attempt to detect these adverse effects at an early stage. Any recognized reaction or adverse effect whether possibly or definitely drug-related, must be investigated and reported;
- ✓ Possible altered kinetics of drug absorption, distribution, metabolism or excretion which may affect therapy. This may include the interpretation of pharmacokinetic laboratory data and utilization 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;
- ✓ the appropriate duration of therapy;
- ✓ administration errors and omissions;
- ✓ drug/laboratory test interference;
- ✓ drug/food interactions;
- ✓ drug/drug interactions;
- ✓ Additional medication which may be needed for optimum response or prevention of adverse effects; and the patient's response to therapy to determine if it is adequate or excessive in relation to the desired therapeutic endpoint.
- ✓ Patients with special problems likely to affect therapeutic efficacy of pharmaceutical products and health technologies, will require more intensive monitoring, according to the following criteria: patients whose age, weight, clinical state or condition may affect drug absorption or

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disposition, alter dosage requirements or predispose the patient to adverse reactions or drug toxicity; patients taking pharmaceutical products and health technologies known to have a high risk of toxicity and a narrow therapeutic index; patients taking pharmaceutical products and health technologies which may interact; patients taking an investigational medicine; patients whose therapy is changed frequently; and patients receiving intravenous therapy.

- ✓ Monitoring schedules must be set at a frequency suitable for the patient mix and prescribing practice.
- ✓ All pharmacists monitoring prescriptions must be able to provide appropriate information on request using local or other information sources.

5.7.3 Provision of drug information and advice

The purpose of this service is to ensure that appropriate advice is available timely to meet the requirements of health care professionals. The advice could range from the rational choice of pharmaceutical products and health technologies within a particular class of drugs in order to support formulary review, to the selection of an appropriate dosage regimen for an individual patient.

Drug information within the hospital must be maintained and developed in conjunction with other established drug information centers. This service must take cognizance of the specific needs of the hospital personnel and patients.

5.8 Minimum Standards for Pharmacist-Initiated Therapy

When called upon by a member of the public to advice on symptoms, the request must be dealt with by a pharmacist or another member of staff in the pharmacy who is appropriately registered and licensed with relevant professional council. 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:

- ✓ 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

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the condition has persisted, any action that has already been taken, and which pharmaceutical products and health technologies the person concerned is already using.

- ✓ 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.
- ✓ In the case of a minor self-limiting health problem, appropriate advice must be given and a medicine recommended only when necessary.
- ✓ 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.

For the Self-Care products, including the supply of "over the counter" pharmaceutical products and health technologies; the pharmacist must utilize experience to select pharmaceutical products and health technologies taking into account their quality, efficacy and safety. If a medicine is supplied, the pharmacist should do his/her best to ensure that the patient or caregiver has no doubts as to:

- ✓ the name (generic/trade) and physical description of the medicine;
- ✓ intended use of the medicine and expected action;
- ✓ route, dosage form, dosage and timing of administration;
- ✓ any special directions or precautions for the preparation or administration of doses;
- ✓ duration of treatment;
- ✓ any relevant drug/drug, drug/food, drug/alcohol interactions;
- ✓ common severe side or adverse effects or interactions and therapeutic contra-indications that may be encountered, including their avoidance, and the action required if they occur;
- ✓ techniques for self-monitoring of medicine therapy;
- ✓ storage conditions; and
- ✓ action to be taken in the event of a dose not taken or in the event of an overdose.
- ✓ The supply of all medicines must be indicated in the patient's profile.
- ✓ For each type of health problem that can be treated within the framework of self-care, protocols for the action of pharmacy technicians and members of staff who are not registered with relevant professionals must be established.

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- ✓ The protocol must define when referral to a pharmacist is necessary.

The pharmacist should assess the outcome of the therapy with the patient's cooperation. The pharmacist must advise the patient to consult a doctor if the symptoms persist beyond a stated time.

5.9 Minimum Standards for Screening and Testing Services in Pharmacies

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.

Protocols which specify records to be kept must be established 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.

There must be effective communication with the patient's doctor and other relevant health care professionals. Pharmacists and members of staff involved must have sufficient training to enable them to give appropriate and sound advice.

The purpose of the service, for example that it is a screening and/or monitoring service, should be clearly emphasized. Pharmacists are entitled to inform the public of the availability of screening and monitoring tests. Pharmacists may supply screening and monitoring tests to the public to perform at home.

5.10 Minimum Standards for Immunization Services

Although the pharmacist's involvement in immunization services varies with each practice setting, the pharmacist can be actively involved in the following activities:

- ✓ Educating the public and other health care professionals about immunization;
- ✓ Advocating for pediatric immunization;
- ✓ Screening patients who are at risk of preventable infectious diseases by occupation, life- style or an underlying disease state;

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- ✓ Administering immunization agents;
- ✓ Recording immunization data; and using the immunization database to generate reminder letters for booster doses.

5.11 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. Contraceptives may be supplied in accordance with the provisions of the applicable laws and regulations in Rwanda. Reproductive health counselling must be done in a private designated area in the pharmacy. The consultation area must comply with the requirements in place.

5.11.1 Minimum Standards for Emergency Contraception

Emergency contraception is often referred to as the 'morning after pill'.

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

- ✓ Pharmacist must have sufficient knowledge of the product to enable him/her to make an informed decision;
- ✓ Pharmacist must deal with the request personally and decide whether to supply the product or refer the patient to another appropriate healthcare professional;
- ✓ Pharmacists must ensure that all necessary advice and information is provided;
- ✓ Requests for emergency contraception should be handled sensitively with due regard being given to the customer's right to privacy;
- ✓ Only in exceptional circumstances should pharmacists supply the product to a person other than the patient;
- ✓ Pharmacists should, whenever possible, take reasonable measures to inform patients of regular methods of contraception, disease prevention and sources of help;
- ✓ Pharmacists should help reduce patient stress and anxiety,

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- ✓ Refer the client/patient to an alternate source of emergency contraception if the Pharmacists do not wish to provide emergency contraception treatment for personal reasons;
- ✓ The pharmacist should answer in a manner that does not make the patient feel uncomfortable;
- ✓ The information received should be kept confidential in accordance with code of ethics for pharmacy profession and other laws and regulations.

5.12 Minimum Standards for Other Health Care Services

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

- ✓ The pharmacist must have written information on how to stop/reduce smoking;
- ✓ 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;
- ✓ All anti-smoking products must be sold with an invitation to come back and report progress.
- ✓ Supporting information must be readily available;
- ✓ Counselling sessions to stop smoking must be available from the pharmacist by appointment or a suitable system must exist for referral;
- ✓ Smoking must not be permitted in the pharmacy.

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:

- ✓ Pharmacists must provide advice regarding vitamin and mineral supplementation for patients with nutritional deficiencies;
- ✓ Where applicable, pharmacists must explain to patients the benefits of high fiber diets.
- ✓ Pharmacists must be informed on the signs and symptoms of anorexia;

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- ✓ Pharmacists must be informed on nutrition advice to be given during pregnancy, e.g., the supplementary folic acid intake;
- ✓ Requests for weight reduction advice and products must be met in a structured manner;
- ✓ A policy must exist to ensure that weight reduction advice is not given to those who do not require it;
- ✓ A weight reduction guide must be available in the pharmacy and be provided to appropriate patients;
- ✓ Those who need to lose weight must be given advice on healthy eating and exercise;
- ✓ Slimming mixtures and unhealthy slimming pharmaceutical products and health technologies /techniques must not be promoted in the pharmacy;
- ✓ The following patients should not be advised to go on very low-calorie diets: patients who are underweight; patients who are pregnant; diabetic patients; and children;
- ✓ Specialist groups for whom nutritional advice is of particular importance can be identified and counselled appropriately. Examples of such patient groups are: patients with diabetes, hypertensive patients, patients requiring lipid advice, elderly patients, stoma patients, terminally ill patients, and pregnant women;
- ✓ All symptoms that show prolonged change of bowel habit in customers over 50 years must be referred to a medical practitioner.

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

- ✓ Pharmacists and pharmacy support personnel must be informed regarding childhood problems and on the importance of early referral;
- ✓ All symptoms in young babies under one year must be referred to the pharmacist for advice;
- ✓ The pharmacist must keep up to-date regarding the latest guidelines on child safety,
- ✓ The pharmacist must know the symptoms of common childhood illnesses;
- ✓ The pharmacist must provide advice regarding sugar intake and dental care;

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- ✓ All parasitic worm preparations must be sold with advice on hygiene and treating all family members;
- ✓ Pharmacists must know the principles of vitamin supplementation for infants;
- ✓ Pharmacists must actively promote immunization programmes;
- ✓ 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:
    - o the pharmacy should stock a range of accessories and equipment to facilitate breastfeeding,
    - o the pharmacist and pharmacy support personnel must actively encourage mothers to continue breastfeeding when appropriate,
    - o the pharmacist must refer mothers experiencing difficulty with breastfeeding for specialist professional help, t
    - o he pharmacist must give advice on the use of pharmaceutical products and health technologies in association with breastfeeding.

5.13 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:

- ✓ 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.
- ✓ A safe system of work must be applied throughout preparation and there must be safeguards to ensure that the final product is stable and safe throughout its shelf life.
- ✓ Only staff trained in pharmaceutical aseptic technique must provide this service, provided that it falls within their scope of practice.

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- ✓ 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.
- ✓ Procedures must be established to ensure that principles of Good Manufacturing Practice are applied to the aseptic dispensing service.
- ✓ 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.
- ✓ Accurate records must be kept for each product prepared, including label details. These must include: Patient's name (hospital number) and ward; name, form and strength of medicine; recommendations for use; appropriate warnings; and batch number, expiry date, date and time of preparation.
- ✓ 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.

5.13.1 Intravenous additive service

If any intravenous additive service is provided, the following standards are applicable:

- ✓ Standard policies and procedures must be established for IV preparation and administration.
- ✓ 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.
- ✓ Only staff trained in the pharmaceutical aseptic technique must handle such solutions, provided that it falls within their scope of practice.
- ✓ Procedures must be introduced to ensure that dosage calculations are correct and that the addition will not result in any chemical or physical incompatibility.
- ✓ 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.

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- ✓ Policies and procedures must be established for the addition of pharmaceutical products and health technologies to intravenous fluids and their administration. The pharmacy must have access to adequate information sources concerning the intravenous administration of pharmaceutical products and health technologies and related compatibilities and stabilities.
- ✓ Accurate records must be kept of each admixture including label details. In addition to the requirements for labelling, the following information must be included on the label: patient's name, (hospital number) and ward; name and amount of additive(s); name, strength and quantity of the primary IV solution; batch number, expiry date and date and time of preparation; method of IV administration (continuous or intermittent). If intermittent, the interval of administration must be stated; and rate of administration.
- ✓ All admixtures must be inspected for particulate matter before they are supplied for administration.
- ✓ 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.
- ✓ The pharmacy must provide an efficient system for distribution of ready-prepared admixture solutions.
- ✓ The pharmacist should, where possible, ensure that intravenous additives are used appropriately.

5.13.2 Total parenteral nutrition (TPN) preparation service

If a total parenteral nutrition preparation service is provided, the following standards are applicable:

- ✓ 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.
- ✓ 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.

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- ✓ Accurate batch control records must be kept for all TPN solutions issued for administration to patients.
- ✓ There must be a uniform standard for labelling TPN solutions. In addition to the requirements for labelling, the following information must be included on the label: identification of the product; the patient's name and ward; the name and amount of each constituent; storage conditions; the total volume; the time and date of preparation; the rate of administration; the batch control number; statements to the effect that the solution remains sterile if unopened and that the bag must be used for the named patient only; the expiry date of the solution; and that additives are prohibited.

5.13.3 Cytotoxic preparation and reconstitution service

Cytotoxic pharmaceutical products and health technologies have a potential for being mutagenic, teratogenic and carcinogenic. It is prudent that a very reasonable precaution should be taken by staff handling cytotoxic pharmaceutical products and health technologies to ensure that absorption does not occur, especially as no adequate means of monitoring or measuring inadvertent absorption have been devised.

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. Procedures must be established to ensure that the hazards associated with the handling, preparation and administration of cytotoxic agents are kept to a minimum by ensuring that: the correct technique is used; staff are properly trained and aware of the various hazards; appropriate protective clothing is provided and used; correct action is taken following any accidental spillage or contamination of the person; and suitable equipment for waste is provided to minimize the risk of contamination.

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. A nominated pharmacist must ensure that cytotoxic drug handling policies are regularly revised. The responsible person must ensure that facilities are suitable for the

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type of preparation. Equipment must be designed to minimize 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.

The preparation and reconstitution of cytotoxic pharmaceutical products and health technologies 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 pharmaceutical products and health technologies 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 centralized basis within e.g., an oncology unit. Horizontal laminar flow cabinets must not be used.

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 standardized procedures so that individual constituents are readily traceable.

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 pharmaceutical products and health technologies. Strict aseptic technique must be employed throughout for injectable preparations.

Protective clothing must include the following: gloves that are of material appropriate to the product being handled; safety spectacles with side pieces or locally approved alternatives; a single use plastic apron (specially designed coats, with long sleeves and cuffs are preferable); and a single use surgical mask.

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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.

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: the name and strength of the medicine; the total quantity of the medicine; the name of the patient; the date of preparation; the expiry date; and the batch number of the preparation.

Any special recommendations from the manufacturer must be observed. 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. The working area used for the preparation or reconstitution of cytotoxic pharmaceutical products and health technologies must be thoroughly cleaned immediately after use.

All excess medicine, equipment and protective clothing used in the preparation must be disposed of and dealt with according to local procedures.

Procedures for administration of cytotoxic pharmaceutical products and health technologies 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 pharmaceutical products and health technologies. All procedures must be designed to ensure that all products achieve the required standard of quality.

All personnel must receive special training in working with cytotoxic pharmaceutical products and health technologies and be monitored regularly to ensure compliance with all procedures. Personnel working in a cytotoxic reconstitution service must be rotated regularly.

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A permanent register of all employees who routinely handle cytotoxic pharmaceutical products and health technologies must be maintained. 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 medicines.

5.14 Minimum Standards for Compounding

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.

All the necessary requirements must be provided, including: appropriately trained personnel; adequate premises and space; suitable equipment and services; suitable materials, containers and labels; approved procedures (including cleaning procedures); and suitable storage and transport.

Procedures must be written in instructional form and be applicable to the facilities provided. Compounding may be done by registered and licensed pharmacy technicians who are competent to perform the procedures concerned. 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. A system must be in place to recall any batch or product, should it be necessary.

High standards of personal cleanliness must be observed by all those concerned with the compounding process. Hand-washing facilities must be conveniently available to the personnel involved.

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.

Equipment used for compounding must be designed and maintained in such a way as to: be suitable for its intended use; facilitate thorough cleaning when necessary; minimize any contamination of drugs and their containers; and minimize the risk of confusion or the omission of a processing step such as filtration or sterilization.

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Equipment and utensils must be thoroughly cleaned and, if necessary, sterilized and maintained in accordance with specific written directions. Before the commencement of any compounding, a check must be made to ensure that all apparatus and equipment to be used have been cleaned/sterilized.

5.15 Minimum Standards for Pre-Packing

Pre-packing entails the repacking of pharmaceutical products and health technologies from bulk packs into smaller packs suitable for patient use and must be performed in terms of the provisions of the laws and regulations. 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.

Where tablets are pre-packed they must be manually counted, weighed, or electronically counted. Measuring by volume is not permitted. Pre-packing must take place only under the required conditions of temperature and humidity. 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.

To comply with the above requirements, the following minimum standards must be complied with in the packaging of pharmaceutical products and health technologies in patient-ready packs:

- ✓ 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.
- ✓ 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.
- ✓ All equipment must be kept clean and before each production run checked for efficiency and accuracy.
- ✓ Electronic tablet counters must preferably be fitted with dust covers and extractor fans.
- ✓ The personnel operating the equipment must be competent to do so and appropriately registered and licensed with professional councils.

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- ✓ The personnel must be adequately protected from possible exposure to health hazards (e.g., oncolytic, penicillin, etc.)
- ✓ A master pre-packing document must be compiled for each product to be packed, specifying the following: the name of the product; a description of its pharmaceutical form and strength; the pack size expressed as quantity of product in the final container; a complete list of packaging materials required; and the method of packaging as well as the speed of the turntable and vibrator where applicable. A batch number must be assigned to each batch of medicine packed.
- ✓ 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: the name of the product; the strength and dosage form of the product; the name of the manufacturer; the expiry date; the manufacturer's batch number; the assigned packaging batch number; the date of packaging; the allocated expiry date; and a sample of the label and plastic bag used.
- ✓ 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 materials.
- ✓ 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.
- ✓ The following information must appear on all labels/plastic bags: the delegated packaging batch number and/or packaging date as required; the approved name of the substances where applicable; the strength; the quantity or volume of medicine; the expiry date; the name and address of the packaging institution; and any necessary additional information, e.g., storage conditions, warnings, etc.
- ✓ Space on the label must be provided for: the directions for use; the name and reference number of the patient; and the name and address of the hospital.
- ✓ Containers and packaging material must conform to the following requirements: protecting the product from light and moisture; preventing contamination of the product, including possible microbial contamination; and prevention of product deterioration.

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5.16 Minimum Standards for Therapeutic Drug Monitoring Service

A therapeutic drug monitoring (TDM) 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 blood concentrations of a medicine in specific conditions coupled with the interpretation of the results obtained. If a TDM service is provided the following standards are applicable:

- ✓ 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 samples are collected and analyzed by suitably trained people observing health and safety procedures.
- ✓ Pharmacists must be involved in the interpretation of results from TDM.
- ✓ Policies and procedures must include: guidance on the types of medicine for which TDM has been shown to be of value and those pharmaceutical products and health technologies where blood level measurements are unnecessary; indications for TDM; detailed guidelines on the application of TDM to all the pharmaceutical products and health technologies for which the service is available; and guidelines on sampling.
- ✓ A pharmacokinetic profile form/reporting sheet, must be designed and agreed upon by the Drugs and Therapeutics Committee. Explanatory notes must be provided on the use of these forms.
- ✓ Results from TDM 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.
- ✓ Quality assurance procedures must be introduced to ensure that results are accurate, consistent and reproducible. This should involve participation in rational quality control schemes if these are available.

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1. Minimum Standards for the Provision of Complementary Medicine

Where complementary pharmaceutical products and health technologies are offered for sale, staff involved must be trained in the use thereof. The pharmacy must stock only those complementary pharmaceutical products and health technologies, which are judged by the pharmacist to be effective and appropriate for the treatment of stated conditions.

The client must be given appropriate information about the use and effectiveness of complementary medicine sold to them. The client must be informed of possible adverse reactions as well as drug/drug and drug/food interactions.

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.

5.17 Minimum Standards for 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 made by another health care professional, in order to maximize therapeutic outcomes. A review of the patient's overall medication requirements involves analyzing 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.

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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 patient with a new prescription; patients on chronic therapy, depending on the disease, the pharmaceutical products and health technologies prescribed, and the patient's needs; situations where a medicine therapy problem is identified and/or a potential medicine-related problem is anticipated to occur in the future; 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 but also a pharmacy technician 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:

- ✓ 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;
- ✓ the development of a care plan (care planning, interventions) by the pharmacist and patient/caretaker in consultation with the prescriber, in accordance with goals of medicine therapy and appropriate interventions; and
- ✓ A follow-up evaluation to determine the actual patient outcomes that have resulted from the care provided.

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