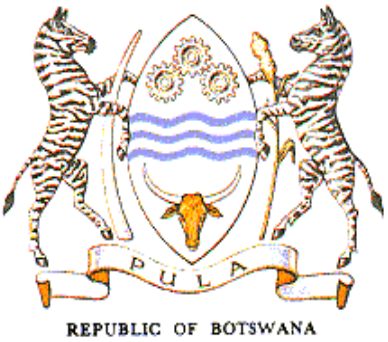

PHARMACY PRACTICE STANDARDS 2002

PHARMACEUTICAL SERVICES DIVISION

MINISTRY OF HEALTH

BOTSWANA

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1 FOREWORD

These Pharmacy Practice Standards shall guide pharmacists and pharmacy technicians in their professional duties to ensure the maintenance of Good Pharmacy Practice as stipulated in the Botswana National Drug Policy. The Implementation of these standards shall be in line with the provisions of the Health Professions Act, Drug and Related Substances Act and other relevant statutory instruments regulating pharmacy practice in Botswana.

The Pharmaceutical Society of Botswana, Botswana Pharmacy Association and other professional groups representing pharmacists and pharmacy technicians are required to ensure that all their registered members adhere to the highest standards of professional conduct as stipulated in the Code of Ethics in these standards. All pharmacists and pharmacy technicians must practice within legal requirements and uphold professional integrity.

In these Standards of Pharmacy Practice the Internship is structured into a twelve month programme with a minimum attachment of six months in a hospital pharmacy/ retail pharmacy to optimise the acquisition of pharmaceutical care competencies under the direct supervision of registered pharmacist preceptors. The remaining six months can be completed in any of the core pharmacy practice disciplines under the professional supervision of registered pharmacists that are involved in Continuing Professional Development Programmes recognized by the Health Professions Council.

The Ministry of Health shall provide the necessary resources to facilitate the implementation of Pharmacy Practice Standards. I look forward to the immediate and continuous implementation of these standards by all pharmacists and pharmacy technicians registered by the Health Professions Council in Botswana.

Finally I would like to thank the Head of Technical Support Services, Chief Pharmacist, Heads of Pharmaceutical Units in the Ministry of Health; Pharmaceutical Society of Botswana and other stakeholders in the pharmaceutical sector for their valuable contributions.

Dr. P.N. Mazonde

Director of Health Services

2 INTRODUCTION

Pharmacy is a patient oriented, information driven and dynamic profession with varied spheres of practice. The aim of the pharmacy practice standards is to promote excellence in the practice of pharmacy for the benefit of the population through the implementation of Good Pharmacy Practice in drug manufacturing, quality assurance, distribution, patient care services and human resource development.

3 SCOPE OF THESE STANDARDS

The Pharmacy Practice Standards specify the general requirements in the different areas of pharmacy practice and the professional responsibilities of the pharmacist in those areas.
The standards cover the following areas of pharmacy practice:

1) Community Pharmacy
2) Hospital Pharmacy
3) Industrial Pharmacy
4) Drug Distribution
5) Quality Control
6) Drug Regulation

4 SCOPE OF PRACTICE OF PHARMACISTS

In order to fulfill the health care needs of Botswana, pharmacists are expected to perform the following broad functions:

1) Manage all pharmaceutical services;
2) Manufacture and compound drugs;
3) Distribute pharmaceuticals;
4) Dispense and ensure rational use of drugs;
5) Provide pharmacist initiated therapy;
6) Provide drug information and education;
7) Promote public health;
8) Promote communication;
9) Research and development.

5 ROLE OF PHARMACY TECHNICIANS

Pharmacy Technicians are qualified health workers with a national diploma in pharmaceutical technology from a tertiary learning institution which is recognized by the Botswana Health Professions Council. Pharmacy Technicians play an important role in the provision of pharmaceutical services in Botswana. They shall practice pharmacy under the professional guidance and supervision of a pharmacist. Consequently their practice shall be implicitly bound by these standards.

Pharmacy technicians shall perform the following functions under *the professional supervision* of a pharmacist:

1) **Dispense pharmaceuticals and promote rational drug use;**
2) **Drug procurement, stock control, storage and distribution;**
3) **Quality assurance and quality control activities;**
4) **Drug regulation;**
5) **Compound pharmaceutical preparations;**
6) **Promote public health;**
7) **Promote safe disposal of pharmaceutical waste;**
8) **Conduct research.**

6 GOOD PHARMACY PRACTICE REQUIREMENTS

Good Pharmacy Practice requires that:

1) **A pharmacist's first concern must be the welfare of the patient in all settings.**
2) **The core of the pharmacy activity is the supply of drugs and other health care products, appropriate information and advice to the patient, and monitoring the effects of their use.**
3) **That an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and appropriate drug use**
4) **That the objective of each element of pharmacy service is relevant to the individual, is clearly defined and is effectively communicated to all those involved**
5) **That pharmacist's adhere to Good Manufacturing Practice, Good Distribution and Dispensing Practices to ensure the safety, quality and efficacy of drugs.**

In satisfying these requirements:

1) **Professional factors shall be the main philosophy underlying practice, although it is accepted that economic factors are important.**
2) **There must be pharmacist input to decisions on drug use.**
3) **The on going relationship with other health professionals shall be seen as a therapeutic partnership involving mutual trust and confidence in all matters relating to pharmaco-therapeutics.**
4) **The relation with other pharmacists shall be as colleagues, each seeking to improve pharmacy services, rather than as competitors.**
5) **In practice organizations and group practices, pharmacy managers shall accept a share of responsibility for the definition, evaluation, and improvement of quality**
6) **The pharmacist shall be aware of the essential medical and pharmaceutical information about each patient.**
7) **The pharmacist shall have access to independent, comprehensive, objective and current information about therapeutics and drug use**
8) **Pharmacists in each field of practice shall accept personal responsibility for maintenance and assessment of competence throughout their professional working lives**
9) **Educational programs for entry to the profession shall appropriately address contemporary and foreseeable future changes in the practice of pharmacy**
10) **National standards for good pharmacy practice shall be adhered to by practitioners.**

7 CODE OF ETHICS

The Code of Ethics is intended to set the standard of professional conduct for all pharmacists and "persons lawfully conducting a community pharmacy business". It shall be regarded as governing the conduct of all pharmacists both within and outside the practice of pharmacy.

In the case of persons lawfully conducting a community pharmacy business, the Code of Ethics shall be regarded as extending to the department or departments in which the preparation, dispensing, sale or supply of medicinal products is carried on or where surgical appliances or allied products of a kind commonly associated with pharmacy are sold or supplied.

Not all matters that should be subject to a standard of professional conduct are included in the Code; the matters mentioned are those upon which it is thought that guidance may be needed.

1) **A pharmacist prime concern in the performance of his/ her duties must be for the welfare of both the patient and other members of the public.**

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

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

4) **A pharmacist must respect the confidentiality of information acquired in the course of professional practice relating to patients and their families. Such information must not be disclosed to anyone without the consent of the patient or appropriate guardian, except where it is in the best interest of the patient and or the public to do so.**

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

6) **A pharmacist must neither agree to practice under any condition of service that compromise professional independence or judgment nor impose such conditions on other pharmacists.**

7) **A pharmacist should, in the public interest, provide information about the availability of professional services. Such publicity must not claim or imply any superiority over the professional service provided by other pharmacists or pharmacies must be dignified and not bring the profession into disrepute.**

8) **A pharmacist offering services directly to the public must do so in premises that reflects the professional character of pharmacy.**

9) **A pharmacist must at all times endeavour to cooperate with professional colleagues and members of other health professions so that patients and the public may benefit.**

7.1 Explanatory notes on the Code of Ethics

The following notes are intended to explain the Code of Ethics, but are not intended to be exhaustive since new circumstances arise which will be held to be professional misconduct.

7.1.1 WELFARE OF THE PATIENT

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

Guidance on interpretation and application of the principle:

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

7.1.2 HONOUR AND DIGNITY OF THE PROFESSION

A pharmacist must uphold the honour and dignity of the profession and not engage in any activity that may bring the profession into disrepute.

Guidance on interpretation and application of the principle;

1) **A pharmacist must have due regard for the reasonably accepted standards of behaviour both within and outside his professional practice.**

2) **Any breach of the law, whether or not directly related to a pharmacist's professional practice, may bring the profession into disrepute and be considered to be misconduct.**

3) **A pharmacist must not use or permit the use of his/her qualifications or his/her position as a pharmacist to mislead or defraud.**

4) **While a pharmacist is encouraged to make reference to a doctorate, he/she must not deliberately use a doctorate degree in such a way as to lead the public to believe that the pharmacist is a medical practitioner.**

7.1.3 STANDARD OF PROFESSIONAL CONDUCT

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

Guidance on interpretation and application of the principle:

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

1) **be a law-abiding citizen;**

2) **refrain from purporting to be a medical practitioner or any category of supplementary health service personnel unless so registered;**

3) **co-operate to ensure safety and order in the provision of health care in his/her work situation;**

4) **within the range of his/her professional ability, safeguard the physical and mental well-being, the personal rights and the dignity of the person receiving care;**

5) **protect the good name of the pharmacy profession;**

6) **observe the rules of professional confidentiality;**

7) **remain professionally competent and abreast of the latest developments in the health area in which he/she functions in accordance with his/her scope of practice;**

8) **Observe the provisions of the Botswana Health Professions Act and the Drugs and Regulated Substance Act and the regulations made there under.**

7.1.4 CONFIDENTIALITY

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

unless the interest of the patient or the public requires such disclosure.

Guidance on interpretation and application of the principle:

1) **A pharmacist must restrict access to information that may be retained through memory or held in records which may be manual, mechanically or electronically maintained, relating to a patient and/or the patient's family to those who, in the pharmacist's judgement, need that information in the public interest.**

2) **A pharmacist must ensure that anyone who has access to information relating to a patient and the patient's family:**

   i) **Is aware of the need to respect its confidential nature;**

   ii) **Does not disclose such information without reference to and only with the consent of the patient;**

   iii) **If a pharmacist judges it necessary to disclose information relating to a patient and the patient's family the content shall be limited to the minimum necessary for the specific purpose involved.**

7.1.4.1 Guidelines regarding circumstances when information might need to be disclosed

1) **Where the information is to be shared with others who participate in, or assume responsibility for, the care or treatment of the patient, and would be unable to provide that care or treatment without that information.**

2) **Where disclosure of the information is to a person or body that is empowered by statute to require such a disclosure; for example to a presiding officer of a court.**

3) **Where necessary for the purpose of a medical research project which a recognized ethics committee has approved.**

4) **Rarely, where disclosure is justifiable on grounds of public interest; for example, to assist in the prevention, detection of or prosecution for serious crime or where disclosure could prevent a serious risk to public health.**

5) **Where necessary to prevent serious injury or damage to the health of a third party.**

6) **In the last two exceptions listed above, it will be necessary to assess the risk and seriousness of the potential consequence of failure to disclose as against the rights of the patient to confidentiality.**

7) **If the condition of the patient precludes the seeking of his/her consent, for example, through unconsciousness, mental handicap, psychiatric illness, dementia or brain injury, the assessment of the best interests of the patient shall take into account any known wishes of the patient, the patient's next of kin, any other relative or anyone with powers of attorney.**

8) **Where the patient is a child, the pharmacist must decide whether to release information to a parent or guardian without the consent of the child but in the child's best interests. Much will depend on the maturity of the child concerned and his/her relationship with his/her parent or guardian.**

9) **When undertaking contraceptive advice, efforts shall be made to establish whether the girl is less than 16 years of age. If this is the case, the pharmacist shall strongly urge her to seek advice from her general practitioner, parent or similar responsible adult. In deciding whether to provide contraceptive advice, regard should be paid to the maturity of the girl and the consequences of unprotected intercourse taking place.**

10) **Where necessary, any disclosure and its extent shall be recorded on the patient's record.**

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

7.1.5 PROFESSIONAL DEVELOPMENT

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

Guidance on interpretation and application of the principle;

1) **A pharmacist must keep abreast of changes in pharmacy practice.**

2) A pharmacist must remain up-to-date in the law relating to pharmacy and the knowledge and technology applicable to pharmacy.

3) A pharmacist must maintain competence and effectiveness as a practitioner.

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

It encompasses a range of activities including:

1) continuing education;

2) professional audit;

3) participation in non-pharmacy related but relevant formal post-graduate education;

4) performance appraisal, identification and documentation of personal development targets;

5) research, including practice research and the achievement of higher degrees by research;

6) active involvement with professional organizations;

7) Provision of training, preceptorship or mentoring.

7.1.6 PROFESSIONAL INDEPENDENCE

A pharmacist must neither agree to practice under any conditions which compromise professional independence or judgement nor impose such conditions on other pharmacists.

Guidance on interpretation and application of the principle:

1) Pharmacists should not agree to practice under terms that interfere with or impair the proper exercise of professional judgment and skill, that cause deterioration of the quality of professional services, or that require consent to unethical conduct.

2) Any obstruction of a pharmacist in personal control of a community pharmacy business by anyone in managerial control of

the business which results in failure to maintain a proper standard of conduct within that business shall be regarded as a failure on the part of the owner of the business to observe a proper standard as well as on the part of the pharmacist.

7.1.7 INFORMATION REGARDING PROFESSIONAL SERVICES

A pharmacist shall in the public interest, provide information about the availability of professional services. Such publicity must not claim or imply any superiority over the professional service provided by other pharmacists or pharmacies must be dignified and not bring the profession into disrepute.

Guidance on interpretation and application of the principle;

1) **A pharmacist may make information about himself/herself or his/her practice available which may reasonably be regarded as being necessary or is in the public interest for the public to be informed about.**

2) **Information announcements, advertisements or any other form of publicity should not be of a character that could reasonably be regarded as likely to bring the profession into disrepute. Publicity for professional services must be discreet and dignified so as to impress upon the public that drugs are not ordinary articles of commerce and that pharmacists are professional people providing, in addition to the supply of drugs, skilled and informed advice on pharmaceutical matters and health care.**

3) **Publicity must be factual, accurate and must not abuse the trust, or exploit the lack of knowledge of a consumer/patient.**

4) **In order to avoid an invidious distinction between pharmacists or pharmacies there should be no criticism of the services of other pharmacist or pharmacies and there should be no claim of superiority over any other pharmacist or pharmacy either expressed or implied.**

5) **Publicity by bodies representing pharmacists and/or pharmacies and seeking to promote the profession as a whole should be encouraged.**

7.1.8 PROFESSIONAL APPEARANCE AND NATURE OF PHARMACY

A pharmacist offering services directly to the public must do so in premises that reflects the professional character of the pharmacy.

Guidance on interpretation and application of the principle;

1) **Even when environmental and / or safety standards are satisfactory, the external and internal appearance of a community pharmacy premises or hospital pharmacies should not only give clear indication that professional services are available within, but also inspire confidence in the nature of health care that can be expected.**

2) **Inside the community pharmacy premises, no matter to what extent commercial activities may be conducted, the public should be able to recognise clearly that part of the premises in which professional services are provided.**

7.1.9 COOPERATION WITH OTHER HEALTH PROFESSIONALS

A pharmacist must at all times endeavour to cooperate with professional colleagues and members of other health professions so that patients and the public may benefit.

Guidance on interpretation and application of the principle;

1) **Close cooperation between pharmacists and medical practitioners is to be welcomed; however a pharmacist should not have an undesirable business association with a medical practitioner. There is no objection to a pharmacist being employed by a medical practitioner providing a dispensing service.**

2) **A pharmacist should not recommend a medical practitioner or medical practice unless so requested by a member of the public seeking medical advice.**

Guidelines for the general requirements in the different areas of pharmacy practice and the professional responsibilities of the pharmacist in those areas are covered under specific areas of pharmacy practice in the chapters that follow.

8 DRUG REGULATION PHARMACY PRACTICE STANDARDS

8.1 SCOPE

A national medicines regulatory authority shall ensure that all medicines and related substances are subjected to appropriate pre-marketing evaluation, marketing authorisation and post-marketing monitoring to establish compliance with required standards of quality, safety and efficacy.

The functions of a medicines regulatory authority shall be guided by an appropriate and up to date legislation, regulations, guidelines and procedures. This enhances accountability, establishes transparency and cultivates productivity.

8.2 ORGANISATION

1) **There shall be a Medicine Regulatory Board appointed by the Minister of Health. The Board shall appoint the following committees:**

   i) **A medicine and related substances registration committee of the Board and may delegate some or all of its functions or duties in connection with assessment of medicines and related substances with regard to quality, safety and efficacy;**

   ii) **A licensing committee of the Board and may delegate some or all of its functions or duties in connection with licensing of premises, persons and outlets of medicines and related substances;**

   iii) **Any other committees or sub-committees of the Board, and may delegate to such committees or sub-committees any of its functions or duties, subject to such conditions as it may specify.**

2) **The medicines regulatory authority shall be a body corporate, with perpetual succession and a common seal, and capable, in its corporate name of -**

   i) **Suing and being sued;**

   ii) **Purchasing or otherwise acquiring, holding, managing, charging and disposing of property, movable or immovable;**

   iii) **Entering into contracts, and doing or performing all such other things as may be necessary and as may lawfully be done or**

performed by a body corporate, for the proper performance of its functions and undertaking of its duties.

3) **The authority shall ensure efficiency and credibility in the execution of medicine regulatory functions to meet the needs of the national medicines policy towards ensuring the availability of medicines of acceptable safety, efficacy and quality.**

4) **The authority shall comprise the board and the technical staff to fulfil its mandate.**

8.2.1 MEDICINES CONTROL

1) **This is an enforcement arm of the authority. It is responsible for ensuring that the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell such medicines comply with defined codes of practice and statutory requirements;**

2) **The responsible person shall be a pharmacist.**

3) **The duties shall include:**

   i) **Collecting samples of medicines and related substances to ascertain that they are not substandard.**

   ii) **Ensuring that medicines and related substances are imported, manufactured, exported, stored, sold and distributed by duly authorised persons;**

   iii) **Inspection and licensing of all domestic manufacturing premises, testing facilities, importing agents, wholesalers, distributors, clinics, hospital pharmacies, retail pharmacies, dispensaries and other outlets where medicines and related substances are sold or supplied;**

   iv) **Monitor conditions for storage, distribution and sale of medicines;**

   v) **Regulate of the distribution, prescription and dispensing of medicines;**

   vi) **Ensure that all medicines are manufactured according to good manufacturing and good laboratory principles;**

   vii) **Ensure that all clinical trials involving medicines are carried out according to good clinical practice requirements;**

viii) Enforce standards as may be applicable.

ix) Monitoring and review the implementation of the legislation;

x) Monitor and regulate the importation/exportation and handling of medicinal Habit Forming Drugs (HFD);

xi) Maintain statistics on the medicinal and illicit consumption of HFD's;

xii) Monitor and regulate the advertising of medicines and related substances to the general public.

8.2.2 MINIMUM REQUIREMENTS FOR APPLICATION FOR APPROVAL TO OPERATE A PHARMACEUTICAL BUSINESS

These requirements shall be communicated to the prospective applicant at the time of enquiring on any pharmaceutical operation and referred to when receiving applications for licensing.

8.2.2.1 SUBMISSION REQUIREMENTS FOR APPLICATION FOR APPROVAL TO OPERATE A PHARMACEUTICAL BUSINESS

For the purpose of approval for licensing to import/export, manufacture, distribute and sell drugs in Botswana as a pharmaceutical manufacturer, pharmaceutical wholesaler, community pharmacy, pharmaceutical agency or a pharmaceutical representative, the following items shall be submitted to the Drugs Regulatory Authority for:

1) Pharmaceutical Wholesalers and Community Pharmacies:

   i) Form MH 2050 Form 3 completed in triplicate;

   ii) A covering letter summarising the business prospects;

   iii) Registration certificate of the pharmacist from Botswana Medical Council;

   iv) At least two references and a brief C.V. of the pharmacist;

   v) A declaration letter for continuous personal supervision of a pharmacist;

   vi) A sketch/plan of the premises;

   vii) A brief note on other intended employees;

   viii) Information on other related businesses;

   ix) A copy of the payment receipt from Central Medical Stores Revenue Collector.

2) Pharmaceutical Agencies and Representatives:

   i) Form MH 2050 Form 3;

   ii) A covering letter summarising the business prospects;

iii) A brief note on intended employees (if any);

iv) Letters of agreement and appointment from companies intended to be represented;

v) List of drugs intended to be handled;

vi) Information on other related businesses;

vii) Copy of payment receipt from Central Medical Stores Revenue Collector.

3) Pharmaceutical Manufacturers:

i) Form MH 2050 Form 3 completed in triplicate;

ii) A covering letter summarising the business prospects;

iii) An organisational structure of the company;

iv) Information about pharmacists at key operations like Production and Quality Assurance;

a) Registration certificates from Botswana Medical Council;

b) At least two references and a brief C.V. for each pharmacist;

c) Job descriptions.

v) e)A declaration letter for continuous personal supervision of a pharmacist;

vi) A brief note on other intended employees;

vii) g)A list of products to be handled;

viii) h)A list of equipment to be used in warehouse, production and quality control;

ix) A sketch/plan of the premises;

x) Information on other related businesses;

xi) A copy of the payment receipt from Central Medical Stores Revenue Collector.

8.2.2.2 MINIMUM (PRE-LICENSING) REQUIREMENTS FOR A PHARMACY

These requirements shall be communicated to applicant prior to the first inspection and issuance of Approval for Licensing.

8.2.2.2.1 Premises

1) The premises of a pharmacy shall be separated from rooms intended for private use.

2) The premises shall be well built, dry, well lit, and ventilated and of sufficient dimensions to allow the goods in stock, especially medicaments to be kept in a clearly visible and appropriate manner.

3) The area of the section to be used as dispensary department shall not be less than 6 square metres for one pharmacist working there in, with additional 2 square metres for each additional pharmacist.

4) Sufficient space should be provided in the dispensary to ensure an efficient flow of work and effective communication and supervision. The height of the premises shall be at least 2.5 metres.

5) The floor of the pharmacy shall be tiled or coated to be rendered smooth and washable.

6) The walls shall be plastered or tiled or oil painted so as to maintain smooth and washable surfaces devoid of holes, cracks and crevices.

7) A pharmacy shall be supplied with ample supply of good quality water.

8) A barrier to prevent the admission of the public shall separate the dispensing area. The door leading into the dispensing area shall be lockable to render the dispensary inaccessible in the absence of a pharmacist.

9) The dispensary shelves should be designed such that they discourage members of the public from reading the labels of prescription drugs.

10) A sink with adequate supply of hot and cold running water shall be provided within the dispensing area for washing hands, utensils, apparatus, etc.

11) Some space for confidential counselling shall be provided.

12) Segregated areas designated for eating and smoking, if so desired.

8.2.2.2.2 Personnel

a) The pharmacy shall be operated under the continuous personal supervision of a registered pharmacist who shall also function as the manager.

b) Well-trained and medically fit shop assistants shall be employed.

8.2.2.2.3 Furniture and apparatus

1) The furniture and apparatus of a pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment.

2) A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with smooth washable and impervious material like stainless steel, laminated material, plastic, melamine, Formica etc.

3) A pharmacy shall be provided with a lockable tamper-proof cupboard for the storage of habit forming drugs and shall be clearly marked with the words "Habit forming Drugs" or "Narcotics" or "Dangerous Drugs" in red letters on a white background.

4) A pharmacy shall be provided with the following minimum apparatus and equipment.

   i) A suitable number of tablets and capsules counters and spatulas to avoid contamination of medicines when dispensing.

   ii) A suitable range of graduate glass measuring cylinders beakers, pipettes and any suitable glassware necessary for the proper carrying out of the dispensing duties of a pharmacist.

iii) A refrigerator unit capable of storing products within a selected temperature ranges e.g. 2-8 °C. The efficiency of this refrigerator should be regularly checked.

iv) A suitable range of containers for the dispensing of tablets capsules creams, ointments, and liquids.

v) A suitable range of labels for the above mentioned containers.

vi) A balance with a comprehensive range of mass pieces.

vii) A suitable range of mortars and pestles of both glass and earth-ware material.

viii) A suitable means of sterilisation of medicines if in-house preparation of sterile products is to be carried out.

8.2.2.2.4 Reference material

1) A pharmacy shall be provided with the following minimum reference books:

   i) The latest edition of Martindale (The Extra Pharmacopoeia);

   ii) The latest addition of MIMS or any other compendium;

   iii) A medical dictionary;

   iv) A pharmaceutical dictionary;

   v) A recent edition of a comprehensive text book on pharmacology;

   vi) Any latest text book on dispensing practice;

   vii) A copy of the Drugs and Related Substance Act and Regulations.

8.2.2.2.5 Security and Fire Protection

1) The pharmacy shall be equipped with an effective and appropriate security system and a suitable fire protection system.

8.2.2.3 OPERATION REQUIREMENTS FOR RETAIL PHARMACY PRACTICE

These shall be discussed at time of issuing of the Approval for Licensing.

1) License of premises shall be displayed at all times in the premises.

2) Registration certificate of pharmacist shall be displayed at all times in the dispensary.

3) The name of the pharmacist in-charge shall be printed alongside the name of the pharmacy at the main entrance of the pharmacy.

4) The pharmacy shall be operated under the continuous personal supervision of the pharmacist in charge. When it is compulsory that the pharmacist be absent from the pharmacy e.g. when sick then the following options may be adopted:

i) An assistant approved by Drugs Regulatory Unit may remain in charge for a period not exceeding one (1) working day or ten (10) hours whichever is appropriate. The dispensary shall remain closed and locked during this period;

ii) The services of a duly registered locum pharmacist may be engaged for a period approved by the Drugs Regulatory Unit;

iii) The pharmacy may be closed until the services of a registered pharmacist are obtained.

5) The Drugs Regulatory Unit shall be informed in writing of any change, resignation or dismissal of the pharmacist in-charge or additional employment of other pharmacists in the pharmacy.

6) A job description for the pharmacist shall be drawn up.

7) Good personal hygiene instructions and procedures shall be written and displayed in the pharmacy.

8) Smoking, eating and chewing should not be allowed in the dispensary area, and a kitchen may be designated for such practices.

9) "No Smoking", and "No Eating" signs shall be conspicuously displayed in the pharmacy and the dispensary.

10) All employees shall be medically examined prior to employment and medical examination shall be conducted at least once a year there after. Records of the medical exams shall be kept.

11) All employees shall be trained in the safe handling of medicines and personal hygiene to the extent to which their services may dictate. The pharmacist shall engage in a suitable continuous education programme offered by any recognised institution. Records of such training whether in-service or verbal or formal or other shall be kept.

12) Cleaning procedures and schedules for cleaning of floors, shelves, toilets should be drawn up and displayed.

13) Drugs shall be segregated from all other materials.

14) A refrigerator for storage of thermo-labile materials shall be installed in the pharmacy, and shall not be used for any foodstuff.

15) Schedule 1A and 1B drugs shall be kept under lock and key and all registers and records of ordering and dispensing of these shall be maintained and be made available for inspection. Schedule 1A and 1B drugs shall be dispensed only on a written prescription, a record of the transaction entered into a Habit Forming Drugs Register and a prescription record book, and a copy of the prescription retained.

16) Schedule 1C drugs shall be dispensed only on a written prescription, a record of the transaction entered into a prescription record book, and a copy of the prescription retained in the pharmacy.

17) A prescription record book shall be kept for all prescription drugs. Copies of prescriptions shall be kept in the pharmacy.

18) All pharmacy only drugs shall never be sold without the knowledge of the pharmacist, his approved assistant or the locum pharmacist.

19) Prescription (Schedules 1 and 2) drugs shall be segregated from Pharmacy Only (Schedule 3) drugs, which in turn shall be segregated from General Sale over-the-counter (Schedule 4) drugs.

20) There shall be a written procedure for checking and destroying or returning of expired drugs.

21) All expired drugs shall be segregated from other stocks and kept in a place labelled "Expired Drugs".

22) All different sections in the pharmacy shall be clearly labelled.

23) Adequate compounding equipment should be purchased when in-house compounding is to be carried out, and substances prepared in-house shall be kept for a period not exceeding 7 days unless stability for that period can be substantiated.

24) A detailed record of compounding including date of preparation, batch number(s) of ingredients, and expiration date shall be kept in the pharmacy.

25) Prescriptions should be dispensed in suitable containers labelled in accordance with the Drugs and Related Substances Act requirements.

26) Pharmacy Only (Schedule 3) drugs and Prescription (Schedule 2) drugs should NOT be sold to any person under the age of sixteen (16), without a prescription: Provided that:

    i) When accompanied by a guardian (a parent, an appointee of a parent or any adult of at least ten years age difference to the minor) a prescription may not be necessary for Schedule 3 drugs; and

    ii) If the pharmacist recommends the Schedule 3 drug and a record of what transpired is kept a prescription may not be necessary for Schedule 3 drugs.

27) Only registered drugs or listed drugs (List of Drugs Allowed into Botswana) shall be kept in the pharmacy.

8.2.2.4 MINIMUM (PRE-LICENSING) REQUIREMENTS FOR A PHARMACEUTICAL WHOLESALER

These shall be communicated to applicant prior to the 1st inspection and issuance of Approval for Licensing.

1) The managing director of the intended wholesaler shall be a pharmacist registered with the Botswana Medical Council. An application for wholesale licensing shall be made only when there are intentions of running the business under continuous personal supervision of a Registered Pharmacist.

2) The premises intended to be used for the wholesale business shall be located such that contamination of commodities from the exterior is avoided.

3) Premises shall be constructed and maintained to protect against weather, ground seepage and entrance and harbouring of vermin, birds, pests and pets.

4) There shall be a receiving area and a dispatch area both protected from the weather.

5) Premises shall be clean tidy and in a good state of repair.

6) The premises shall be of an area of NOT less than 50 square meters and shall be separate from offices and rooms of private use.

7) There shall be a cloakroom separate from the warehouse areas.

8) Toilet facilities shall be appropriately located, designed and equipped with adequate hand washing facilities.

9) The premises in which medicinal products are stored shall be made secure with access restricted to authorised personnel only.

10) Floors shall be made of a washable and durable finish, which can withstand movement of heavy loads.

11) Walls shall be made with a washable finish e.g. oil paint.

12) There shall be no open drain channels within or close to the premises.

13) Covered dustbins shall be provided at suitable positions for collection of waste material to be removed later to dedicated collection points.

14) A space for storage of cleaning materials shall be provided for.

15) Fire warning, escape and extinguishing facilities shall be provided in the building.

16) A fridge freezer for the storage of thermo-labile material shall be provided.

17) Segregated storage shall be provided for expired, damaged, recalled and returned goods.

18) Segregated storage shall be provided for flammable and volatile materials.

19) Some kind of Temperature/humidity control and monitoring shall be provided.

20) Thermometers shall be mounted at various points on the wall and shelves to summarily record the temperature in the premises and refrigerators.

21) A temperature monitoring record shall be maintained indicating temperature recorded in the morning (opening time) and afternoon temperature (at about 14:00 hours).

8.2.2.5 OPERATION REQUIREMENTS FOR A PHARMACEUTICAL WHOLESALER

These shall be discussed at time of issuing of the Approval for Licensing).

A pharmaceutical wholesaler Approval for Licensing is issued on the following conditions. In the event that any of these conditions is neglected, the Approval may be suspended or cancelled.

1) The Approval for Licensing is issued based on the organisational structure, which gives the pharmacist the necessary autonomy. Any modification to the structure should be communicated to the Drugs Regulatory Unit prior to being effected.

    i) In the eventuality that a pharmacist resigns dies or leaves a post for whatever reason, such a change should be reported to the Drugs Regulatory immediately. All pharmaceutical operations shall cease immediately until a suitable and approved

replacement or a locum tenens has been employed. A similar approach shall be taken in the case of pharmaceutical representatives.

2) The license of the business shall be displayed at all times in the premises.

3) The business shall be conducted under the continuous personal supervision of a registered pharmacist with an up to date registration (Blue Card). A copy of the original certificate shall be displayed in the premises.

4) Copies of all relevant licenses and certificates shall be displayed. All originals shall be made available to inspectors immediately when requested. The supervising pharmacist's name and qualifications shall be displayed conspicuously over the main entrance.

5) A deputy (pharmacist) in the absence of the supervising pharmacist (e.g. locum pharmacist) shall be appointed and his particulars submitted to D.R.U. for approval.

6) The company shall be in possession of an up to date compendium of laws and regulation related to the practice of pharmacy (The Medical Dental and Pharmacy Act and the Drugs and Related Substance Act 1992).

7) The company shall also be in possession of some references, minimum requirement being:

   i) The latest edition of Martindale -The Extra Pharmacopoeia;

   ii) The latest addition of MIMS/MDR;

   iii) A medical dictionary;

   iv) A pharmaceutical dictionary;

   v) A recent edition of a comprehensive text book on pharmacology;

   vi) Any latest text book on pharmaceutics.

8) The company shall purchase stocks only from approved suppliers and shall devise a system of tracing products back to the supplier/manufacturer.

9) The following Standard Operating Procedures and/or work instructions concerning the various types of operations within the business shall be written, dated, signed by an authorised person, endorsed or approved by the management and displayed in appropriate positions about the premises:

   i) Good personal hygiene;

   ii) Cleaning of premises (floors, shelves, etc.);

   iii) Receipt, storage, packaging and dispatch of goods;

   iv) Goods requiring special handling (e.g. thermo-labile);

   v) Returned, rejected and expired drugs;

   vi) Product complaints;

   vii) g) Recalled medicines;

   viii) h) Elimination of pest, insects, rodents and others.

10) Written instructions shall be provided for receiving goods, e.g.:

    i) deliveries examined for integrity of containers, spoilage and possible contamination;

    ii) inventory updates;

    iii) Careful handling of cartons.

11) There shall be written procedures and work instructions assigning responsibility for sanitation and describing cleaning schedules, methods, equipment, materials to be used and facilities to be cleaned in sufficient detail.

12) There shall be a written procedure for detecting expired stocks.

13) All personnel shall undergo medical examinations prior to employment and any person with a communicable disease shall not be allowed to handle drugs. NO PERSON SHALL BE REQUESTED TO TAKE AN HIV TEST. Personnel who handle drugs shall undergo periodic health checks.

14) All personnel shall practise good personal hygiene. Instructions on good personal hygiene shall be given to all employees at the time of employment.

15) Smoking, eating, drinking and chewing shall not be allowed in the storage areas.

16) Personnel handling drugs shall be suitably dressed in clean uniform.

17) Only authorised personnel shall be allowed to enter the storage areas.

18) Clean and well ventilated toilets with hand-washing facilities, soap and towels shall be provided.

19) The storage areas and toilets shall be cleaned every day. The shelves shall be cleaned at least every two months or more frequently depending on the environment.

20) Waste material shall not be allowed to accumulate. Waste bins with cover shall be provided.

21) The premises shall be sufficiently large in order to keep the stocks in an orderly, neat and tidy condition.

22) The premises shall be constructed, serviced and maintained so as to protect the stored materials, from all potentially harmful influences, such as rain, exposure to sun, dust and odour, entry of animals, vermin insects and pests.

23) The storage areas shall be sufficiently large to allow for physical segregation of stocks.

24) Special and segregated areas shall be available for storage of flammable and explosive substance, highly toxic substances, narcotics and other dangerous drugs.

25) Segregated storage shall be provided for expired, damaged, recalled and returned goods.

26) 26 Toilet facilities shall never be used for storing stock.

27) The fire warning, and extinguishing facilities, the temperature and humidity control equipment, as well as the refrigerator, freezer and cold storage shall be checked regularly to ensure continuous good operation and specific temperature maintenance. An alternative to be used in case of fridge failure shall be kept ready.

28) The receiving area shall be adequate for control and clearing of arrived goods.

29) The receiving clerk shall be provided with a list and handling instructions for materials requiring special storage.

30) Written instructions shall be available which specify the procedures to be adopted in warehouse areas. They shall describe adequately the storage procedures and define the flow of materials and information through the organisation.

31) All drugs shall be stored according to the manufacturers' recommended storage conditions.

32) Special attention shall be paid to drugs requiring special storage conditions e.g. vaccines and other drugs requiring cold storage for cold chain maintenance.

33) Goods shall be placed above the floor level either on shelves or pallets.

34) All returned goods shall be placed in quarantine and returned to other stocks only after the approval of a pharmacist following a satisfactory quality re-evaluation.

35) All the drugs in stock shall be registered.

36) Procedures to recall drugs shall be established to facilitate the recall of a batch from the distribution chain.

37) An effective system to control stock rotation shall be devised e.g. first to expire first out principle and all stocks shall be checked regularly in order to preclude issue of outdated drugs.

38) Expired drugs shall be removed from the shelf and stored at designated areas awaiting destruction by incineration or other suitable method (in conjunction with Environmental Health Officers) or returned to the supplier.

39) No expired drugs shall be found on the shelves together with stocks for sale unless evidence of a granted extension of shelf life, following satisfactory results of re-analysis is produced. The shelf-life extension shall be approved by the D.R.U.

40) Procedures shall be written regarding the handling of product complaints and these procedures shall be distributed to all personnel likely to receive product complaints, e.g. representatives, receptionists, order clerks, etc.

41) Transportation of drugs shall only be carried out in vehicles designed to retain product integrity. Only quantities to be delivered are to be carried at any one time. Door to door sale or hawking of drugs is strictly prohibited.

42) The vehicle shall be adequately equipped with proper storage facilities, with special consideration for the maintenance of the cold chain.

43) Only drugs registered or listed in accordance with the Drugs and Related Substances Act 1992 shall be kept in stock.

44) Drugs shall be distributed to appropriate licence holders/only.

45) A system for ensuring that medicines are sold only to duly licensed persons shall be devised.

46) A register shall be kept for schedules 1A, 1B and 1C drugs.

47) Import and export permits shall be obtained from D.R.U for all controlled substances and estimates on these submitted to Drugs Regulatory Authority.

48) Records of all purchases, customs clearances, invoices, sales and any other relevant records shall be kept for at least 5 years.

8.2.2.6 AGENCY LICENSE HOLDER - REGULATION GUIDELINES

These shall be discussed at time of issuing of the Approval for Licensing.

The Agency license holder shall:

1) Import, export or distribute drugs not classified as habit-forming drugs listed under Schedules 1A, 1B or 1C, or any other controlled substance for which an import or export authorisation from the Ministry of Health is required. Imported drugs shall be registered in Botswana or shall appear in the List of Drugs Allowed into Botswana.

2) NOT keep stocks of any drugs or related substances.

3) Only act on behalf of a manufacturer or wholesaler or retailer or practitioner while in possession of an order issued and signed by a pharmacist, medical practitioner or dentist indicating thereon the name and quantity of the substance in trade. In the case of Schedule 4 drugs, the agent shall be in possession of an order authorised by the management of a business licensed under the Liquor and Trade Act.

4) Retain a record of such an order for a period of at least two years.

5) Submit letters of appointment from the suppliers and prospective buyers.

6) Submit a list of drugs to be imported, exported or distributed in the following format (strictly!):

   i) Name of Drug;

   ii) Name of Active ingredient in I.N.N.

   iii) Strength (e.g. mg, mg/ml or g, etc.);

   iv) Dosage Form (i.e. tablet, ointment, elixir);

   v) Name and Origin of Manufacturer.

8.2.3 DRUG REGISTRATION

a) This section shall be under the supervision of a pharmacist. It shall be responsible for ensuring that all medicines and related substances manufactured in, imported into or exported from Botswana are registered and conform to established criteria of quality, safety and efficacy

b) The duties among others shall include:

i) Assessing the drug registration application to ensure that it meets the Drugs and Related Substances Act and the guidelines.

ii) Timely grant, renew, suspend or cancel authorisations for medicines and related substances after due assessment for conformity to relevant legislation and guidelines whether locally manufactured or imported and whether intended for local use or export.

iii) **Ensuring that the advertising of medicines and related substances is in accordance with product information approved by the Board**.

8.2.4 PHARMACOVIGILANCE

a) The section shall be under the supervision of a pharmacist.

b) The responsibilities shall be to;

i) Establish procedures for Adverse Drug Reactions reporting, assessment and maintenance of information for appropriate action to be taken.

ii) Monitor compliance of marketing authorisation with respect to pharmaco-vigilance guidelines.

iii) Make arrangements for the monitoring and reporting of adverse reactions to medicines and related substances.

8.3 APPOINTMENTS

a) The Minister shall, appoint a person, suitably qualified technically and scientifically, to be the Managing Director of the authority, who shall be the chief executive officer of the authority;

b) The Managing Director of the authority shall be a registered pharmacist with requisite medicines regulatory experience;

c) The Managing Director of the authority shall be the secretary of the Board;

d) The Managing Director of the Authority shall be charged with the administration and organisation of the authority, the control and management of the personnel, and the responsibility of accounting for all financial transactions of the authority;

e) The Minister shall appoint a suitably qualified person to be the Deputy Managing Director of the authority, who shall perform such functions and carry out such duties as the Managing Director may assign to him, and who shall, in the absence for any reason of the Managing Director, act as Managing Director;

f) The Board shall, after consultation with the Managing Director, appoint such members and staff of the authority with requisite scientific and technical knowledge, as it deems necessary for the proper performance of the functions, and the carrying out of the duties, of the authority.

8.4 TRAINING

a) There shall be a training plan to address the training needs of the authority.

b) The staff of the authority shall be given the necessary training to undertake their responsibilities and perform their duties efficiently and effectively.

8.5 PROFESSIONAL PRACTICE

a) Professionals working for the authority shall be guided by relevant statutes and codes of practice governing the practice of the individual professions, including but not limited to the following:

b) Pharmacists shall:

i) Direct the evaluation of medicines registration applications;

ii) Direct the inspection of pharmaceutical operations;

iii) Authorise guidelines and procedures;

iv) Provide professional interpretation, analysis and advice;

v) Develop and review guidelines, legislation and procedures;

vi) Develop and supervise the implementation of a quality system;

vii) Participate in continuing education programmes that further the practice of each profession.

8.6 QUALITY SYSTEM

a) The authority shall establish, implement and maintain a quality system commensurate to the scope of its activities to ensure transparency, efficiency and effectiveness.

b) The quality system shall be documented in a quality manual;

c) There shall be periodic quality audits to determine the extent of implementation of all quality instruments outlined in the manual;

d) External accreditation shall be relentlessly pursued.

8.7 TRANSPARENCY

a) The Drug Regulatory Authority shall operate on a policy that maximises transparency in all regulatory activities.

b) There shall be a system to make public all policies, guidelines, procedures and others whether or not contained in the quality manual to address but not limited to the following:

i) Medicine registration and exemption;

ii) Application evaluation;

iii) Licensing and registration of pharmaceutical operations;

iv) Handling and administration of HFD's;

v) Handling of complaints;

vi) Handling of samples;

vii) Handling of payments of fees;

viii) Handling of adverse medicine reaction reports;

ix) Conducting inspections;

x) Documentation and record keeping;

xi) Licensing of premises.

c) Medicines regulatory decisions and other information relating to the quality, safety and efficacy of medicines shall be made accessible to the general public.

8.8 EFFICIENCY AND EFFECTIVENESS

a) The authority shall develop and implement a corporate strategy.

b) The drug registration and pharmaceutical operation's licensing systems shall be computerised.

c) Where permissible within the legislation, the authority shall out-source some of its services.

d) Where applicable a computerised filing system for records and documents shall be established and maintained to expedite retrieval.

e) The authority shall adopt as minimum requirements the guidelines issued and modified by the World Health Organisation on manufacturing, distribution, donations, advertising, laboratory, storage, stability, conduct of clinical trials, and other guidelines on medicines or medicinal products or active pharmaceutical ingredients except where it otherwise specified.

8.9 INFRASTRUCTURE

a) The authority shall be equipped with adequate facilities and infrastructure for the proper functioning of medicines regulatory activities including:

i) Availability and access to appropriate transportation systems;

ii) Availability and access to appropriate communication services;

iii) Availability and access to adequate and appropriate literature and information sources relating to medicines and regulatory activities;

iv) Availability of appropriate information management system and technologies.

b) The premises housing the authority shall be designed and constructed to ensure adequate space, security and safety for documents and drug samples.

c) The authority shall implement an information technology policy that minimises manual record keeping and submission in order to maximise the utilisation of both human and infrastructure resources.

9 STANDARDS OF GOOD HOSPITAL PHARMACY PRACTICE

Good Hospital Pharmacy Practice aims at ensuring that drugs of acceptable safety, efficacy, quality and cost are always available to the people who need them and that these drugs are used rationally to facilitate therapeutic success.

9.1 THE UNDERLYING PHILOSOPHY

Hospital Pharmacy Practice shall be under the direct leadership of a pharmacist.

Pharmacists provide pharmaceutical care by taking responsibility for the therapeutic outcome of therapy and by being actively involved in the design, implementation and monitoring of clinical pharmacy services.

9.1.1 GOALS OF A HOSPITAL PHARMACEUTICAL SERVICE

1) To advance rational, patient-orientated evidence based pharmacy practice.

2) To promote pharmacists as integral members of the health care team in order to allow for full utilization of their clinical and pharmaco-therapy functions.

3) To serve as a primary advocate for advancing professional practice, increasing the cost-effectiveness of pharmaceutical services, and improving the quality of patient care.

4) To advocate the pharmacist's value to patients in ensuring that appropriate clinical services and medicine-use control process are applied to their benefit.

5) To promote good health by fostering the optimal and responsible use of medicines, and to encourage healthy lifestyles either by educating and counselling, including prevention of improper or uncontrolled use of medicines.

6) **To provide professional guidance on minimum staffing levels for various institutions to ensure sufficient availability and retention of competent in the profession.**

7) **To provide guidance in the formulation of continuing education programmes for pharmaceutical personnel.**

9.2 DISPENSING AND MANUFACTURING EQUIPMENT

9.2.1 DISPENSING EQUIPMENT

1) There must be adequate, suitable equipment in the dispensary. Each item must be clean, in good repair and of suitable material. Below is a minimum list that shall be extended according to the requirements of the dispensary.

   i) A suitable means of counting tables and capsules. The equipments must be cleaned regularly so that cross contamination between products is avoided.

   ii) An accurate dispensing balance with proof of periodic maintenance and calibration. The calibration of certified equipment shall be determined by the frequency of use.

   iii) A range of graduated, stamped glass measures.

   iv) A refrigerator with a maximum/minimum thermometer and capable of storing products at temperatures between 2 °C and 8 °C. The refrigerator must be cleaned, defrosted and checked periodically to ensure efficient running.

   v) Dispensing labels. Additional warning labels must be available, unless those warnings are printed on the dispensing labels. Where a computer application is relied on for warnings/interactions, this shall be the latest version available.

   vi) Suitable equipment for extemporaneous drug preparation.

   vii) Suitable means for sterilisation of medicinal products if prepared on the premises.

   viii) Suitable refuse receptacles with closable lids.

   ix) Appropriate equipment for individualised in- patient dispensing.

9.2.2 MANUFACTURING EQUIPMENT

Where manufacturing is done equipment must conform to Good Manufacturing Requirements. Manufacturing equipment shall be designed, located and maintained to suit its intended purpose, and also designed so that it can be easily and thoroughly cleaned. Repairs and maintenance operations shall not present any hazard to the quality of the products.

9.2.2.1 CYTOTOXIC RECONSTITUTION EQUIPMENT

1) Vertical laminar flow cabinets regularly maintained that provide safety must be used when cytotoxics are reconstituted or handled. Equipment shall be designed and regularly maintained to minimize the risk of contamination of the product as well as the operator.

2) Appropriate material shall be used for disposable plastic apron, disposable gloves and disposable surgical masks. Gloves must be of material appropriate to the product being handled.

3) Approved safety spectacles with side-pieces shall be used during the reconstitution of cytotoxics.

9.2.2.2 THERAPEUTIC DRUG MONITORING EQUIPMENT

Blood Drug Level Analyser shall be used to monitor blood drug levels for drugs in a hospital pharmacy where clinical pharmacy services are provided.

9.2.2.3 COMPUTER SYSTEMS

All hospital pharmacies shall be computerized to facilitate among others inventory management, dispensing, labelling, patient medication monitoring, access to laboratory data and adverse drug monitoring databases.

9.3 REFERENCES

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

1) Martindale or its equivalent

2) MIMS, MDR,

3) Botswana National Formulary

4) Current Comprehensive Pharmacology Textbook

5) Dispensing Pharmacy Reference Book

6) Botswana Laws and Regulations pertaining to Pharmaceuticals which are regularly updated.

7) Good Pharmacy Practice manual with the appropriate annexure.

8) Internet/Electronic databases.

9.4 ORGANISATION AND PERSONNEL

The pharmaceutical management structure shall meet the service and organizational needs of the health facility. The pharmacists heading the different pharmaceutical units shall have relevant experience and expertise. The following shall constitute minimal requirements for the efficient and effective management of a hospital pharmacy:

1) An operations manual governing all functions shall be developed, implemented and periodically revised to align it with recent pharmacy practice standards.

2) Lines of authority and areas of responsibility shall be clear and must be within labour legislation.

3) A manual with standard operating procedures governing all pharmacy functions must be prepared and revised in accordance with changing circumstances and needs. All pharmacy

personnel shall be familiar with the contents of such a manual and must practice in accordance with standards set in the manual.

4) Cost-effective and service orientated work schedules, systems and procedures which most effectively utilize pharmacy personnel and resources shall be instituted and subjected to regular re-evaluation and in this way establish an acceptable standard of practice.

5) Policies and procedures shall be developed for the provision of a pharmacy service on a twenty four hour basis. Management of drugs and dispensing of medicines by persons other than pharmacists and pharmacy technicians shall be reduced to the absolute minimum and must be fully controlled by the pharmacy.

6) The pharmacy shall be represented in all Hospital Management Committees including drug-related committees.

7) Regular staff meetings of pharmacists shall be held periodically.

8) The hospital pharmacy shall establish its own professional quality assurance committee.

9.4.1 PERSONNEL

1) A Pharmacist managing the hospital pharmacy shall be responsible for specifications as to quality, quantity and source of supply of all drugs and pharmaceutical preparations used in the diagnosis and treatment of patients within the Health Facility.

2) A Pharmacist In-charge with clearly defined authority shall be operationally accountable to the Hospital Superintendent/Manager for the provision of the pharmaceutical service.

3) The pharmacist managing the hospital pharmacy shall be responsible for:

   i) Budgeting for the provision of a pharmaceutical service;

   ii) Preparing Management Reports;

   iii) Developing, implementing and reviewing a comprehensive Human Resource Management strategy to attract, develop and retain the best pharmaceutical officers in hospital pharmacy practice.

   iv) Implementation of a Performance Management System to ensure efficient and effective service-delivery.

4) The Pharmacist In-charge of a Hospital Pharmacy shall be responsible developing and implementing an in-service staff development programme for pharmaceutical staff.

5) Pharmaceutical officers shall be encouraged to undertake research relevant to hospital pharmacy practice.

9.5 PHARMACY/DRUG AND THERAPEUTICS COMMITTEE

1) The pharmacist shall be a member of the Drugs and Therapeutics Committee.

2) The Pharmacist shall be responsible for formulary development, drug information and rational drug use.

9.6 MEDICINES UTILISATION REVIEW

The Pharmacist shall be responsible for conducting regular Medicines Utilization Reviews/Pharmaco-economics reviews that must cover the analysis and evaluation of management information on prescribing practices with a view to promoting cost- effective use of medicines.

9.7 CLINICAL TRIALS

1) **The Pharmacist shall play a leading role in all clinical trials concerned with medicinal products.**

2) **The Pharmacist must be part of the investigating team to advise on the pharmacokinetic profile, Good Manufacturing Practice and disposal of clinical trial material.**

9.8 PATIENT COUNSELLING SERVICE

The Pharmacist shall counsel the patients/clients on intended use of drug, outcome of treatment, side effects, cautions, dosing, interactions, storage, monitoring and safe use of drugs and medical devices.

9.9 DRUG INFORMATION SERVICE

1) **The Pharmacist shall ensure that drug information provided is authentic, accurate and shall establish a system for recording this information.**

2) **The Pharmacist providing a drug information service shall be responsible for among others:**

   i) **Evaluating and analysing drug and therapeutic information contained in current literature;**

   ii) **Developing a system of classification and organisation to enable rapid retrieval of this information;**

   iii) **Monitoring and reporting on adverse drug reactions;**

   iv) **Conducting research and continuing education activities**

   v) **Coordinating medicines utilization reviews.**

9.10 PHARMACEUTICAL SERVICE IN PRIMARY HEALTH CARE

Pharmacists shall be involved in Primary Health Care to promote high quality Pharmaceutical Care, access to essential drugs, rational drug use, healthy life styles and discouraging substances abuse.

9.10.1 HEALTH EDUCATION

1) **Pharmacists shall provide timely, effective and appropriate health education to the public on correct use of pharmaceuticals and other related health issues.**

2) **The Pharmacist shall take responsibility for ensuring that the information provided is in line with current health policy.**

9.11 THERAPEUTIC DRUG MONITORING SERVICE

1) **The clinical pharmacist shall identify appropriate equipment for Therapeutic Drug Monitoring.**

2) **The clinical pharmacist must draw blood samples and after analysis of test results must counsel and advise as necessary.**

3) **Policies and Procedures shall include:**

   i) **Guidance on the type of medicines selected for therapeutic drug monitoring;**

   ii) **Indications for therapeutic drug monitoring**

   iii) **Detailed guidance on the application of therapeutic drug monitoring to all the medicines for which the service is available in the hospital.**

   iv) **Guidance on sampling.**

9.12 CLINICAL PHARMACY SERVICES

1) **Clinical pharmacy is pharmacy practice that is patient orientated. It is an organised and directed pharmacy practice that centres on development and application of knowledge and skills to ensure rational therapy.**

2) **Clinical Pharmacists shall participate in specialist care teams and shall:**

i) Contribute to the choice of regimen, particularly when more than one condition is being treated.

ii) Provide the Clinician with evaluated information on pharmaceutical and therapeutic aspects of the use of medicines as well as changing awareness of the toxic profile of medicines.

iii) Decide on which dosage form or formulation of the active principle shall be used once the clinician has selected the appropriate treatment.

iv) Provide therapeutic drug monitoring service.

v) Order and interpret the relevant blood therapeutic level tests and assays for drugs in other body fluids.

3) Clinical Pharmacists shall undertake ward rounds to:

i) Assess and counsel patients

ii) Obtain medication histories

iii) Promote safe and effective use of medicines

iv) Optimize therapy and improve patient compliance

v) Monitor therapy changes and assist to design and implement a program for the identification, recording and reporting of adverse drug reactions.

9.13 PRESCRIPTION MONITORING SERVICE

1) Pharmacists shall ensure that prescriptions shall be evaluated for the following:

i) Legality, legibility and completeness;

ii) Relative efficacy of the medicine for the clinical indication;

iii) Duplication of pharmacologically similar drugs;

iv) Potential drug interactions and adverse reactions

v) Possible drug/disease incompatibilities;

vi) Correct dosage, dosage interval and duration of treatment;

vii) Appropriate dosage form and route of administration;

viii) Problems relating to intravenous administration, including potential incompatibilities, medicine stability, volume of intravenous fluid for medicine administration and rate of administration.

2) The Pharmacist shall monitor patients and their medicine therapy for:

i) Routine monitoring

ii) The appropriate duration of therapy;

iii) Administration errors and omissions;

iv) Drug Interaction

v) Additional medication which may be needed for optimum response or prevention of adverse effects

vi) The patient's response to therapy to determine if it is adequate or excessive in relation to the desired therapeutic endpoint;

3) The following special risk group shall need intensive monitoring by the clinical pharmacist:

a) Patients who are aged and have organ failure;

b) Patients whose age, clinical state or condition may affect drug absorption or disposition, alter dosage requirements or predispose to adverse reactions or drug toxicity;

c) Patients taking a number of medicines concurrently;

d) Patients taking medicines known to have a high risk of toxicity and a narrow therapeutic index;

e) Patients taking medicines which may interact;

f) Patients taking an investigational drug;

g) Patients whose therapy is changed frequently.

9.14 PARENTERAL NUTRITION (TPN) SERVICE

1) The preparation of Total Parenteral Nutrition Products shall be done under licensed premises and all the processes shall be carried out under the direct control of a pharmacist.

2) **The pharmacist shall design a quality assurance programme that is in line with Good Manufacturing Practices and other relevant regulations.**

9.15 CYTOTOXIC RECONSTITUTION SERVICE

1) **The Pharmacist shall develop and implement Standard Operating Procedures for the preparation, handling and safe disposal of cytotoxic medicines.**

2) **The Pharmacist shall ensure that the Standard Operating Procedures are in line with Good manufacturing Practices.**

9.16 ASEPTIC DISPENSING SERVICE

1) **Aseptic techniques shall be carried out under the direct supervision of a pharmacist and shall be in line with Good Manufacturing Practices.**

2) **The Pharmacists shall take responsibility for ensuring that all personnel working in the aseptic area receive adequate training in aseptic techniques.**

9.16.1 INTRAVENOUS ADDITIVE SERVICE

1) **The Pharmacist shall develop and implement Standard Operating Procedures and work instructions for an Intravenous Additive Service.**

2) **The Pharmacist shall establish procedures to ensure that safe systems of work apply through out the admixture and there shall be safeguards to ensure that the solution is stable and safe throughout administration to the patient.**

9.17 STANDARDS FOR DRUG MANAGEMENT

1) **The Pharmacist shall develop and implement Standard Operating Procedures to ensure adherence to Good Drug Management Principles.**

2) **These shall include:**

   i) **Procurement and Quality Assurance;**

   ii) **Receipt and Inspection;**

   iii) **Storage and Inventory Management;**

iv) Distribution and Financial Management;

v) Safe waste disposal.

10 DRUG QUALITY CONTROL LABORATORY STANDARDS

1) The Quality Control Pharmacist shall be responsible for the sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been proven satisfactory.

2) The quality control pharmacist shall be involved in all decisions which concern the quality of the product.

3) A Drug Quality Control Laboratory Pharmacist shall be responsible for ensuring that drugs produced, imported, exported, distributed and used in Botswana meet the acceptable standards of quality through analysis and quality monitoring.

4) A Drug Quality Control Laboratory Pharmacist must ensure that the analytical results provided from the Drug Quality Control Laboratory, must be relied upon to describe accurately the properties of the drug samples he assesses and the information derived from these analyses can serve as an adequate basis for any administrative and legal requirement.

5) The Drug Quality Control Pharmacist shall develop and implement a quality surveillance system to ensure product safety, efficacy and quality.

6) Personnel working in the laboratory must have a high degree of technical competence, critical ability and professional integrity.

10.1 0RGANIZATION

1) The laboratory shall be designed to carry out authorized tests for drugs and related medical products using the appropriate advanced technology, which is in line with the current practice.

2) The minimum requirement of the laboratory shall be to perform qualitative and quantitative analysis on drugs, which includes drug identity and purity, assays for content and strength based on chemical, instrumental and microbiological techniques and various performance tests for dosage forms.

3) The tests shall cover drug tests according to internationally recognized pharmacopoeias (standard reference texts).

4) The laboratory shall be an entity that can be held legally responsible.

5) The responsibilities of key personnel who perform other activities other than testing and/or calibration in the laboratory shall be well defined in order to identify potential conflicts of interest.

6) The laboratory shall have managerial and technical personnel with the authority and resources required to perform their duties.

7) Policies and procedures shall be in place to ensure clients' information, confidentiality and proprietary rights including procedures for protecting electronic storage and transmission of results.

8) Policies and procedures shall be in place to avoid any involvement in any activities that would diminish competence, judgment, impartiality or operational integrity in the laboratory.

9) An organizational structure shall be available to define the laboratory's activities and the relationships between the head of the laboratory, quality manager, management, technical operations and support services.

10) The responsibility and authority of all personnel who work in the laboratory shall be clearly defined.

11) Current job descriptions for all personnel shall be maintained.

12) There shall be adequate supervision of testing staff, including trainees, by competent personnel who are familiar with laboratory methods and procedures, purpose of each test and assessment of the test results.

13) There shall be a technical manager who will have overall responsibility for the technical operation of the laboratory.

14) The laboratory shall have all its policies and procedures documented in accordance with the international standard in line with the current General Requirements for the Competence of Testing and Calibration Laboratories to enable it to become accredited.

10.2 PERSONNEL

1) The Head of the Drug Quality Control Laboratory shall be a registered pharmacist with relevant post graduate experience and expertise in pharmaceutical analysis.

2) Analysts shall be graduates in pharmacy, pharmaceutical sciences, analytical chemistry, microbiology or other relevant subjects.

3) Technical staff shall hold diplomas in pharmacy, laboratory technology, microbiology or other relevant subjects.

4) There shall be sufficient personnel to support the volume of activity handled by the Drug Quality Control Laboratory.

10.3 TRAINING

1) Laboratory personnel shall be given the necessary training to perform their assigned duties and responsibilities adequately.

2) A training programme shall be documented and continuous training shall be conducted on Good Laboratory Practice and to keep abreast with advances in analytical methods and instrumentation.

3) Training of technicians shall be provided at the institutions recognised by the Botswana Health Professionals Council.

10.4 PROFESSIONAL PHARMACY PRACTICE

Pharmacists' responsibilities shall be described under the relevant regulation(s) governing the practice of pharmacy and shall include, but not be limited to:

1) Providing professional advice and promoting Good Laboratory Practice.

2) Establishing and issuing procedures, authorizing changes to processes, specifications, procedures, test methods and investigating failure and complaints.

3) Periodically revising all procedures in accordance with the quality system.

4) Performing and supervising the testing of all drugs and related medical products and packaging materials in the drug quality control laboratory

5) Approving or rejecting drugs and related medical products and packaging materials if they do not meet the required specifications.

6) Establishing, participating and ensuring conformity to the laboratory's quality policy/system, quality assurance, quality control.

7) Participation in continued education programmes which further the professional practice of pharmacy.

8) Participation in validation processes/procedures.

10.5 QUALITY SYSTEM

1) The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The policies, systems, programmes, procedures and instructions shall be documented to assure the quality of the test results.

2) The laboratory shall have a Quality Manager, who shall have a defined responsibility and authority to ensure that the quality system is implemented and followed at all times. The Quality Manager shall approve all quality documents. The Quality Manager should have direct access to the highest level of management where decisions are made on laboratory policy and resources.

3) The quality systems policies and objectives shall be documented in a quality manual. The quality policy will define the purpose and objectives of the laboratory and outline the ways in which these objectives would be achieved. The quality policy statement shall be issued under the authority of the head of the laboratory.

4) The policy statement shall also include:

   i) The laboratory's commitment to good professional pharmacy practice.

   ii) A requirement that all personnel working in the laboratory should familiarize themselves with the quality documentation and implement the policies and procedures in their work.

5) The quality manual shall include supporting and technical procedures.

6) The roles and responsibilities of the quality manager, technical and management and support staff shall be defined in the quality manual.

10.6 QUALITY AUDITS

1) Internal audits shall be conducted periodically to determine whether quality activities and related results comply with the planned activities and, whether these activities are implemented effectively and are suitable to achieve the organizational objectives.

2) Competent personnel of the organization shall carry out internal audits in an independent and detailed manner. External audits shall be engaged when the need arises.

3) Information on internal audits shall be documented as a report detailing observations / facts made during the audit.

4) If audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test, calibration results and non conformities, corrective action shall be taken by the laboratory and clients shall be notified in writing should the investigations show that the laboratory's results have been affected.

5) The area of activity audited, the audit findings and corrective actions that arise from the findings shall be recorded.

6) Follow up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

10.7 MANAGEMENT REVIEWS

Laboratory Management shall periodically review the quality system, audit reports, testing and calibration activities to ensure continued improvement and effectiveness. Any findings from the review shall be recorded and action taken accordingly.

10.8 NON CONFORMANCES

Written and documented policies and procedures shall be established and implemented for any non-conformances in testing, calibration activities and the quality system. Where there is any doubt about the compliance of the laboratory's operation, the corrective action procedures shall be followed.

10.9 CORRECTIVE ACTION

There shall be a procedure to identify the cause of the problem and the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent its occurrence by monitoring the results to ensure that the corrective action has been effective.

10.10 PREVENTIVE ACTION

The procedure for preventive action shall be developed, implemented and monitored to prevent potential sources of non-conforming work in the laboratory.

10.11 PREMISES

10.11.1 REGISTRATION AND LICENSING

The Drug Quality Control Laboratory shall be registered and comply with the relevant acts.

10.11.2 DESIGN

1) The laboratory shall be designed and constructed to suit the operations to be carried out. Sufficient space shall be given to facilitate effective cleaning and maintenance in order to avoid cross-contamination, any build up of dust or dirt and any adverse effect on the quality of products / results.

2) The laboratory shall be constructed of fire-resistant material and the layout and connecting corridors should be determined not only by working efficiently but also by safety considerations, particularly in areas where inflammable liquids or compressed gases are used or stored.

3) The laboratory shall be provided with rooms equipped for its specific purpose. All rooms shall be provided with storage cabinets for reagents, glassware and samples, wall shelving and working space. Separate rooms shall be available to protect sensitive instruments from vibration, electrical interference, adverse environmental conditions, etc.

4) The laboratory facility for sampling, testing and calibration shall be such as to facilitate correct performance of the tests and calibrations. Environmental conditions and sound and vibration levels shall be monitored, controlled and recorded.

5) All laboratory rooms shall be supplied with suitable utilities for intended purposes.

6) Access to and use of areas affecting the quality of the tests shall be controlled.

7) A well designed fume cupboard shall be provided to remove and treat gaseous emissions.

8) Proper air handling system shall be provided.

9) Toilet facilities shall be available and must be kept clean and in order. Toilets must not open directly into the laboratory or be able to contaminate the laboratory.

10.11.3 HYGIENE

1) The laboratory shall have an area where glassware and equipment can be washed with a source of hot and cold tap water.

2) Toilet areas shall not be used for storage.

10.11.4 SAFETY IN THE LABORATORY

1) Safety standards shall be properly maintained in the laboratory. Specific and general safety instructions shall be documented and made available to each member of staff.

2) Smoking, eating and drinking shall be prohibited in the laboratory.

3) All laws pertaining to safety shall be followed.

4) Procedures shall be in place for the safe disposal of unwanted corrosive or dangerous products.

10.11.5 SECURITY

Appropriate security measures and systems shall be in place in the laboratory. The laboratory shall be lockable and must exclude unauthorized entry.

10.12 EQUIPMENT

1) All items of sampling, measurement and test equipment shall be furnished in the laboratory to achieve the correct performance of tests and calibrations. The equipment with software shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and calibrations concerned.

2) The minimum required equipment in the laboratory shall be of the appropriate technology in line with current practice and shall cover approved drug tests in internationally recognized reference texts.

3) Authorized personnel shall operate equipment in the laboratory. Current and appropriate standard operating procedures and manuals for all equipment shall be availed and be readily accessible to laboratory personnel.

4) Equipment shall be properly and regularly maintained and kept clean.

5) Procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning shall be available.

6) Any damaged or defective equipment shall be clearly marked and isolated in the laboratory to prevent usage until it has been repaired or disposed of.

7) Any adjustments on test and calibration equipment, hardware and software inclusive, shall be safeguarded to prevent invalid test and calibration results.

8) Records shall be maintained for each equipment and shall include at least the following:-

   i) The identity of the item of equipment and its software.

   ii) The manufacturer's name, type, identification and serial number or other unique identification.

   iii) Checks that indicate that the equipment complies with the specification.

   iv) The current location, where appropriate.

   v) The manufacturer's instructions, if available or reference to their location.

   vi) Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and the due date of the next calibration.

   vii) The maintenance plan, where appropriate and maintenance carried out to date.

   viii) Any damage, malfunction, modification or repair to the equipment.

10.13 DOCUMENTATION

1) The laboratory shall establish and maintain procedures to control all documentation for the laboratory.

2) All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorised personnel prior to use. All the documents should be listed in a master list or equivalent.

3) Documents shall be reviewed regularly and kept up to date. A system shall be put in place to avoid the use of outdated / obsolete documents. Retained obsolete documents for legal or knowledge preservation must be suitably marked.

4) Authorized editions of appropriate document shall be readily available at all locations where their operations are essential.

5) Documents shall be uniquely identified and shall include the following information:

   i) Title and date of issue, revision identification page numbering (total number of pages inclusive)

   ii) Issuing authority and signature of authorizing person(s).

6) Any changes to documents shall be reviewed and approved by the same authorized personnel who reviewed the documents.

7) Documents shall not be handwritten except where documents require the entry of data, these entries shall be clearly marked, legible initialled and dated. These revised documents shall be formally re-issued and made available as soon as practicable.

8) Documents shall be computerized and the detailed procedures relating to the system in use shall be available. Only authorised persons shall have access to enter or modify document information in the computer. Records of changes and deletions shall be detailed. Computerized documents shall be protected by back up.

10.14 TESTING

10.14.1 SAMPLING

1) The laboratory shall have a sampling plan and procedures for sampling at the location where sampling is undertaken. Appointed competent person(s) shall perform sampling.

2) Should a client require deviations, additions or exclusions from the documented sampling procedure, records shall be documented and communicated to appropriate staff.

3) A standard test request form, shall accompany each sample submitted to the laboratory. An inspection of the sample should be performed to ensure that the product label conforms to the information contained in the test form. Any discrepancies found shall be recorded immediately on the test request form.

4) Samples not accompanied with the test request form shall not be inspected until relevant documentation has been received. In emergencies a request for analysis verbally may be accepted pending the receipt of written confirmation.

5) A sample register must be established which may be in the form of a record book, card file or a computer to enter all incoming samples and accompanying documents. An appointed competent person shall be responsible for the sample registry and must have wide experience in analysis, supervise their delivery and keep a constant check on progress of analyses and dispatch of completed reports.

6) The sample register shall include:-

   i) Name of client that submitted the sample.

   ii) Registration number which is affixed to the sample for identification in such a way as not to obliterate other markings or inscriptions.

   iii) Separate registration numbers assigned for different batches of the same drug or different dosage forms.

   iv) A description of the product including its composition, brand name, dosage form, strength, manufacturer, batch number and expiry date.

   v) Size of the consignment.

   vi) Source of the material.

7) There shall be a sampling procedure, which includes:

   i) The method of sampling

   ii) Equipment to be used.

   iii) Amount of sample to be taken.

   iv) Instructions for any required sub-division of the sample

   v) The type and condition of the sample container to be used.

   vi) The identification of containers sampled.

vii) Any special precautions to be observed, especially with regard to the sampling of sterile or noxious materials.

viii) The storage condition.

ix) Instructions for cleaning and storage of sampling equipment.

8) The sample size shall be large enough to carry out tests as specified in the monographs of internationally recognized pharmacopoeias even when a number of replicate tests are required.

i) A retention sample originating from the same consignment as the analytical sample shall always be kept in the laboratory, where possible in the original container, for use if the test results of the analysis are disputed.

ii) Labels shall be put on the remaining analytical sample and retention sample to indicate the date at which they may be discarded. These samples shall be stored in an appropriate storage room.

iii) A procedure shall be in place to specify the storage period for conforming and non-conforming samples.

10.14.2 TEST METHODS

1) The laboratory shall use current and recognised international, regional or national standards to perform tests, which are within its scope.

2) The laboratory shall use validated test methods which meet the needs of the client and which are appropriate for the tests it undertakes.

3) The introduction of laboratory developed methods and non-standard methods shall be assigned to a qualified analyst equipped with adequate resources.

4) Laboratory developed methods, non-standard methods and standard methods used outside their intended scope (non-pharmacopoeia methods) shall be validated periodically to meet the needs of the laboratory. A file of non-pharmacopoeia quality specifications for drugs tested to specifications established either by the manufacturer or by the laboratory itself shall be maintained.

10.14.3 TEST REPORT

1) The test results shall be reported accurately and clearly, in accordance with the specifications laid down in the test methods. The test results shall be reported in a prescribed test report / analytical test report. The test report shall include:

i) A title (e.g., Quality Control Report, Test Report).

ii) Name and address of the laboratory.

iii) Name and address of the client.

iv) Identification of the test report such as a serial number.

v) Identification of the method used.

vi) Date of receipt of sample /test item.

vii) Reference to the sampling plan and procedures used.

viii) Description of the sample.

ix) Test results.

x) Interpretation of the results and final conclusion.

xi) Name and signature of the analyst.

xii) Name(s), function(s) and signature(s) of person(s) authorizing the test report.

xiii) Name of sampler;

xiv) Batch size and batch number;

xv) Name of manufacturer and date of manufacture;

xvi) Expiry date, sample size and name of sample.

2) The interpretation and approval of test results shall be done by a Pharmacist.

3) If the test report contains test results performed by subcontracted laboratories they shall be clearly identified and documented. Any calibration that has been subcontracted by another laboratory shall also be documented, by the laboratory performing the work, and a calibration certificate shall be issued.

4) Amendments to the test report shall be documented and referred to the original report when a new report is made.

10.14.4 REAGENTS

1) All reagents including solvents used in tests shall be of appropriate quality.

2) Appropriate safety regulations shall be drawn up and rigorously implemented wherever toxic or flammable reagents are stored and used. Those subject to poison regulations or to controls applied to narcotic and psychotropic substances shall be clearly marked as "POISON" and stored separately from other reagents in locked cabinets. A register of these substances must be maintained.

3) Reagents made up in the laboratory shall be prepared according to written procedures and, when applicable, to published pharmacopoeia or other standards.

4) Labels on laboratory reagents and volumetric solutions shall clearly specify the following:

i) Name of the preparation

ii) The manufacturer

iii) Date of preparation

iv) The concentration

v) Standardization factor

vi) Expiry date

vii) Storage condition

viii) Name and signature of person who prepared it.

5) Responsibility for making reagents in the laboratory shall be assigned to competent personnel.

10.14.5 REFERENCE MATERIAL/STANDARDS

1) All reference materials shall be entered into a register.

2) The register shall contain details not only of official reference substances and reference preparations but also secondary reference materials and non-official materials prepared in the laboratory as working standards. Each entry shall be assigned a number and should give a precise description of the material, its source, the date of receipt, the batch number, the intended use of the material (e.g., infrared reference material, impurity reference material for thin layer chromatography, etc), expiry date, the place in the laboratory where it is stored and any special storage conditions.

3) A file must be kept and maintained containing information on the properties of each reference material. In the case for working standards prepared in the laboratory, information should include the results of all tests and checks used to establish the standard and the initials and signature of the responsible analyst.

4) The assigned number/identification number on the reference material shall be clearly marked on it and a new identification number must be marked on each new batch of material as soon as it is delivered or prepared. All reference materials shall be inspected at regular intervals to ensure that they do not deteriorate and are stored correctly.

5) There shall be written and documented procedures on handling and storage of reference materials.

10.14.6 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

1) Quality control procedures for monitoring the validity of tests and any calibration performed shall be put in place in the laboratory.

2) Results shall be recorded and reviewed.

3) These shall include:

   i) Participation in inter-laboratory trials/proficiency testing programmes.

   ii) Regular use of certified materials and/or internal quality control using secondary reference materials.

   iii) Replicate tests or calibrations using the same or different methods.

4) Retesting or recalibrating retained items.

10.14.7 SUBCONTRACTING OF TESTS AND CALIBRATION

1) Any subcontracted work shall be placed with a competent subcontractor.

2) If work is subcontracted the laboratory shall advise the client of the arrangement in writing and when appropriate, get the approval of the client in writing.

3) The laboratory shall be responsible to the client for the subcontractor work, except where the client specifies which subcontractor to be used.

4) The laboratory shall maintain a register of all the subcontractor laboratories that it uses for drug and related medical products testing.

10.15 SERVICE TO THE CLIENT

The laboratory shall provide reasonable access to relevant areas of the laboratory for the witnessing of tests performed for the client.

10.16 CONTRACT REVIEW

1) The laboratory shall establish and maintain procedures for the review of requests and contracts. These procedures will lay down the requirement between the laboratory and client which include:-

   i) method used for testing

   ii) resources used

   iii) cost

   iv) duration to meet the clients' requirement

   v) Capable/competent personnel.

2) Any differences between the request and contract shall be settled before any work commences. The contract shall be acceptable both to the laboratory and client.

3) Changes to the contract shall be maintained and recorded.

4) The review shall cover any work that is subcontracted by the laboratory.

5) Should the contract be amended after work has commenced, the same contract review process shall be repeated and the client shall be informed.

10.17 PURCHASING SERVICES AND SUPPLIES

1) There shall be written and documented policies and procedures in place for the selection and purchasing of services and supplies in the laboratory. Procedures shall exist for the purchase, receipt and storage of equipment, reagents, standards and consumable material relevant for the tests and calibration.

2) The laboratory shall ensure that purchased items are not used until they have been inspected and should comply with specified requirements. Records of actions taken to check compliance shall be maintained.

3) All purchasing shall be done on an official purchasing document.

4) The laboratory shall evaluate suppliers of critical consumables, supplies and services, which affect the quality of testing and calibration. Evaluation records shall be maintained as well as a list o approved suppliers.

10.18 COMPLAINTS

The laboratory shall have a policy and procedure for the resolution of complaints. Records shall be maintained, and of the investigations and corrective action taken by the laboratory.

10.19 RECORDS

1) Recordkeeping procedures shall be established and maintained for identification, compiling, indexing, filing, storage, maintenance, disposal and access of quality and technical records in the laboratory.

2) If records are stored electronically/by computer there shall be a procedure to protect them.

11 PHARMACY PRACTICE STANDARDS FOR INDUSTRIAL PHARMACY

The aim of these standards is to ensure that all pharmaceutical-manufacturing organizations maintain good manufacturing practice and good pharmacy practice.

11.1 OBJECTIVES

The objectives of Industrial Pharmacy Standards are:

1) to ensure that products are consistently manufactured and controlled in order to assure their quality, safety and efficacy in accordance with their market authorization and any other regulations relevant to the production and control of drugs and related substances.

2) to ensure that premises and equipment are adequately designed, constructed, laid-out and maintained to allow easy and logical flow of work, and suit operations to be carried out.

3) To ensure that personnel trained and qualified personnel are employed to control manufacturing operations and carry out their duties in accordance with accepted standards of pharmacy practice as stated herein.

11.2 STANDARD ORGANISATION AND PERSONNEL

1) Each pharmaceutical manufacturer shall have sufficient personnel at all levels with relevant qualification(s), experience and expertise.

2) The duties and responsibilities of personnel in positions of responsibility shall be clearly stated in written job descriptions. Such personnel shall have adequate authority to carry out their responsibilities and duties. There shall be no gaps or overlaps in the responsibilities of those personnel concerned with the application of good manufacturing practice. The responsibilities placed on any one individual shall not be so extensive as to present any risk to quality.

3) All personnel shall be made aware of the principles of good manufacturing practice (GMP) that affect them and receive initial and continuing GMP training including instructions in hygiene relevant to their needs.

4) There shall be a quality assurance unit, which is independent of production, whose responsibility and authority shall be to approve or reject all components, raw materials, in-process materials, packaging materials and finished products as well as authority to inspect all production records, to ensure compliance with standard operating procedures. The quality unit shall participate in the issuing of procedures, authorizing changes to processes, specification, procedures and test methods and investigating failure and complaints.

5) e) An organizational chart by function shall be available showing interdepartmental relationships as well as relationships to the management.

11.3 PERSONNEL AND LICENSING

As stipulated in the Drugs and Related Substances Act the holder of authorization to manufacture pharmaceutical products shall employ at least a registered pharmacist who shall control the manufacturing of drugs and in addition, as a requirement of GMP, another who shall be head of Quality Control. These pharmacists shall have the relevant experience and/or expertise in their field, be registered with the Botswana Health Professions Council and shall have, in sufficient numbers, auxiliary technical supportive personnel as well as others necessary to perform non-professional functions.

11.3.1 QUALIFICATIONS

1) Each person engaged in the manufacture, processing, packaging or storage of drugs shall have the education, training and experience to enable that person to perform the assigned functions. Qualified persons shall include pharmacist who shall be registered with the Botswana Health Professions Council.

2) Training shall be in the particular operations that the employee performs and in general and specific GMP and written procedures as they relate to the employee functions.

11.3.2 TRAINING

1) All Production, Quality Control and other personnel shall be given the necessary training to perform their assigned duties and responsibilities adequately. All those whose duties take them into the manufacturing area(s) and the control laboratories (including the technical, maintenance and cleaning personnel), or whose activities could affect the quality of the product, shall be trained in principles of GMP. Newly recruited personnel shall receive training in theory and practice, relevant to their tasks, of GMP and continuing training shall also be given, the practical effectiveness of which must be periodically assessed.

2) Training programmes approved by the Head of Production or Quality Control as appropriate shall be available and training records kept.

3) Personnel working in areas where contamination is a hazard shall be given specific training.

4) The concept of Quality Assurance and all the measures capable of improving its understanding and implementation shall be fully discussed during training sessions.

5) The holder of authorization to manufacture pharmaceutical products shall support the continued professional development of its registered pharmacists and shall provide / support such programmes. The holder of authorization to manufacture pharmaceutical products shall participate in programmes that further the professional practice of pharmacy and these may

include internships, preceptor-ships, or other professional development activities designed to provide insight into the unique practice of industrial pharmacy.

11.3.3 KEY PERSONNEL

Key personnel include the Head of Production and the Head of Quality Control, who must be independent from each other. The two key personnel must be registered pharmacist with relevant experience and/or expertise, of equal level of authority, neither of whom shall be responsible to the other but have the responsibility for achieving the requisite quality. The head of Quality Control must be able to carry out his/her defined functions impartially. Both heads of Quality Control and Production must be full-time employees of the firm or must be permanently and continuously at the disposal of the firm to carry out their responsibilities.

11.4 PROFESSIONAL PHARMACY PRACTICE

1) Pharmacists' responsibilities shall, in addition to those described under the relevant regulation(s) governing the practice of pharmacy be:

i) to perform and supervise the manufacture, processing, packaging and storage of starting materials and finished products in accordance with GMP;

ii) to establish adequate and continued GMP and personal hygiene training for all employees;

iii) to establish and issue procedures, authorize changes to processes, specifications, procedures, test methods, and investigate failure and complaints;

iv) to periodically review all procedures in accordance with system of quality assurance and GMP, including hygiene, sanitation, training etc.

v) to perform and supervise the testing of all components, starting materials, in-process materials, packaging materials, and finished products.

vi) to approve or reject all components, starting materials, in-process materials, packaging materials, and finished products;

vii) to ensure conformity to the firm's quality policy/system (quality assurance, quality control, GMP etc);

viii) to provide professional advice to senior management and ensure that the firm complies with all relevant regulations;

ix) To participate in continued professional development programmes and programmes that take further the professional practice of pharmacy.

2) Good Manufacturing Practice specifically requires that the holder of authorization to manufacture pharmaceutical products shall have at least two key personnel (heads of Production and Quality Control), who shall be registered pharmacists with relevant experience whose responsibilities are elucidated below.

11.4.1 HEAD OF PRODUCTION

The general responsibilities of the head of Production are as follows:

1) to ensure that products are produced and stored according to the appropriate documentation, master manufacturing formula, master manufacturing instructions and specifications in order to consistently obtain the required quality;

2) to approve the instructions relating to production operations and to ensure their strict implementation;

3) to ensure that production records are evaluated and signed by an authorized person before they are sent to the Quality Control Department;

4) to check the maintenance of the department, premises and equipment and ensure that these facilities are kept in a good state of operation;

5) to ensure that appropriate validations are done;

6) to ensure that the initial and continuing training of his department personnel is carried out and adapted according to need;

7) to efficiently and effectively manage the production department and ensure that responsibilities which have a bearing on quality and shall be jointly exercised with the head of Quality Control are effectively carried out.

11.4.2 HEAD OF QUALITY CONTROL

The responsibilities of head of Quality Control shall, but not exclusively, be:

1) to verify and implement all quality control procedures;

2) to approve or reject, independent of production and as he/she sees fit, starting materials, packaging materials, and intermediate, bulk, in-process and finished products;

3) to evaluate batch records;

4) to ensure that all necessary testing is carried out;

5) to ensure that materials are not released for use, nor products released for sale or supply until their quality has been judged satisfactorily;

6) to approve specifications, sampling instructions, test methods and other Quality Control procedures;

7) to approve and monitor any contract analysis;

8) to check the maintenance of the department, premises and equipment and ensure that the facilities are kept in good state of operation;

9) to ensure that appropriate validations are done;

10) to ensure that the required initial and continuing training of the department personnel is carried out and adapted according to need;

11) To effectively and efficiently manage the Quality Control department and ensure that responsibilities which should be jointly exercised with the head of Production are effectively carried out.

11.4.2.1 Jointly exercised responsibilities relating to quality

The heads of the Quality Control and Production Departments have some shared or jointly exercised responsibilities relating to quality. These include:

1) the authorization of written procedures and other documents including amendments;

2) the monitoring and control of the manufacturing environment;

3) plant hygiene and sanitation;

4) process and equipment validation;

5) training;

6) the approval and monitoring of suppliers of materials;

7) the designation and monitoring of storage areas and conditions for materials and products;

8) the retention of records;

9) the monitoring of compliance with GMP requirements;

10) the inspection, investigation and taking of samples in order to monitor factors which may affect product quality;

11) The approval and monitoring of contract manufacturers.

Some of the responsibilities of the head of Production and the head of Quality Control may be delegated to other qualified persons. A Quality Assurance Manager who oversees all the quality assurance arrangements may be appointed. The person responsible for Quality Control may report to the Quality Assurance Manager and share some of his/her responsibilities.

11.5 QUALITY SYSTEM AND QUALITY ASSURANCE

1) The holder of a pharmaceutical products' manufacturing authorization must manufacture products so as to ensure that they are consistently manufactured and controlled in order to assure their quality, safety, efficacy in accordance with their market authorization and any other regulations relevant to the production and control of drugs and related substances.

2) Each holder of a manufacturing authorization shall have a Quality Control Department, which shall be independent from other departments, and under the authority of a pharmacist with appropriate experience or expertise. Adequate resources must be made available to ensure that all the Quality Control functions are effectively and reliably carried out.

11.5.1 GOOD QUALITY CONTROL LABORATORY PRACTICE

1) Quality Control laboratories shall be separated from production areas. Furthermore, laboratories for the control of biological, microbiological and radioactive substances shall be separated from each other.

2) Quality Control laboratories shall be designed to suit the operations to be carried out in them, with sufficient space provided to avoid mix-ups and cross-contamination. There shall be adequate suitable space for the storage of samples and records.

3) Separate rooms are necessary to protect sensitive instruments from vibration, electrical interference, humidity etc.

11.5.2 SAMPLING

1) Sampling shall be done in accordance with appropriate written procedures which describe the method of sampling, equipment to be used, amount of sample to be taken, instructions for any subdivision of the sample, type and condition of sample container to be used, identification of containers sampled, special precautions to be observed, storage conditions, and instructions for the cleaning and storage of sampling equipment.

2) Reference samples shall be representative of the batch of materials or products from which they have been taken and be of a size sufficient to permit at least a full examination. For finished product, reference samples shall be kept till one year after the expiry date.

11.5.3 TESTING

Analytical methods shall be validated. All testing operations shall be carried out according to the approved methods. The results obtained shall be recorded and checked to ensure that they are consistent with all other information and calculations critically examined.

11.5.4 REAGENTS / STANDARDS

Special attention shall be given to laboratory reagents, volumetric glassware and solutions, reference standards and culture media. These shall be prepared in accordance with written procedures.

11.5.5 VALIDATION AND CALIBRATION

11.5.6 AUDITS

Audits on all systems, procedures and operations shall be regularly conducted in order to monitor compliance with and the effectiveness of GMP and Quality Assurance principles in the various operations and to allow for improvement and corrective measures where required. They shall follow pre-arranged programme, be detailed and carried out by competent and qualified persons from the company. Audits reports shall be made and corrective measures agreed upon, recorded and followed up.

11.6 HYGIENE AND PERSONAL HEALTH

1) Detailed hygiene programmes shall be established and adapted to the different needs within the factory. They shall include procedures relating to the health, hygiene practices and clothing of personnel. They shall be promoted by management and widely discussed during training sessions.

2) All personnel shall receive medical examination upon recruitment and thereafter annually. Direct contact shall be avoided between the operator's hands and the exposed product. Protective garments / clothing shall be appropriate to the operations to be carried out.

3) Only authorized personnel shall enter into those areas of the building and facilities designated as limited access areas.

11.7 PREMISES AND EQUIPMENT

11.7.1 PREMISES

1) Premises and equipment must be located, designed, constructed and maintained to suit operations to be carried out. Their layout and design must permit logical flow, effective cleaning and maintenance, minimization of the risk of errors and cross-contamination, build up of dust or dirt and, in general, anything else that would have an adverse effect on the quality of the products. The adequacy of working and in-process space shall permit the orderly and logical positioning of equipment and materials to minimize the risk of confusion between different medicinal products and / or their components, to avoid cross-contamination and to minimize the risk of omission or wrong application of any of the manufacturing or control steps in order not to compromise the quality and safety of the product in any manner.

2) The premises shall be situated in an environment which, when considered together with measures to protect the manufacture, presents minimal risk of causing contamination of materials or products. The interior surfaces (walls, floors and ceilings) shall be smooth, free from cracks and open joints, and shall not shed particulate matter and permit easy and effective cleaning and if necessary disinfection.

3) Premises shall be designed and equipped so as to afford maximum protection against entry of insects, animals (particularly rodents) and / or birds. A pest control programme must be in place at all times. It must be maintained in good order with repairs being carried out in such a way that they do not present a hazard to the quality of the products.

4) Lighting, temperature, humidity and ventilation shall be, appropriate for the processes taking place in any particular area and such that they do not adversely affect, directly or indirectly, either the products during manufacture and storage or the accurate functioning of the equipment.

5) In order to minimize the risk of cross-contamination, dedicated and self-contained facilities must be available for the production of particular products, such as highly sensitizing materials (penicillins), biologicals, certain hormones, cytotoxics, certain highly active drugs and non-medicinal products. The manufacture of poisons (e.g. pesticides, herbicides etc) shall not be allowed in premises used for the manufacture of medicinal products.

6) Storage areas shall be designed or adapted and segregated to ensure good storage conditions and allow orderly storage of the various categories of materials and product e.g. starting and packaging materials, intermediate, bulk and finished products, products in quarantine, release, rejected, returned or recalled.

7) Receiving and dispatch bays shall protect materials and products from the weather. Highly active materials or products and printed materials shall be stored in designated safe and secure areas.

8) Rest and refreshment rooms shall be separate from other areas. Facilities for changing clothes, washing and toilet purposes shall be easily accessible and appropriate for the number of users. Toilets shall not directly communicate with the production and storage areas.

11.7.2 EQUIPMENT

1) Manufacturing equipment shall be designed, located and maintained to suit its intended purpose, and also designed so that it can be easily and thoroughly cleaned. Repairs and maintenance operations shall not present any hazard to the quality of the products. There shall be written procedures for cleaning and equipment stored in a clean and dry condition.

2) Production equipment shall not present any hazard to the products. The parts of the production equipment that come into contact with the product must not be reactive, additive or absorptive to such an extent that it will affect the quality of the product.

3) Balances and measuring equipment of an appropriate range and precision shall be available for production and control operations. These shall be calibrated and checked at defined intervals by appropriate methods and records of such tests maintained.

4) Where products are manufactured using multi-purpose equipment(s), such practice may be acceptable provided the equipment can be adequately cleaned according to validated written procedures. Products that leave residues that cannot be easily removed shall be produced in dedicated equipment. An equipment cleaning and use log system or a system that can be used to determine prior use, identify previous lot / batch number and that the equipment was cleaned shall be put in place and conformity documented.

5) Defective equipment must be removed from the production and quality control areas or at least be clearly labelled as defective.

11.8 DOCUMENTATION

1) Good documentation is an essential part of the quality assurance system. Clearly written documentation prevents errors due to spoken communication and permits tracing of batch history, specifications, manufacturing formulae and instructions, procedures and other records.

2) Documents shall have unambiguous content, designed, prepared, approve and signed by appropriate and authorized persons, reviewed and updated, and distributed with care.

3) Any alteration made to an entry on a document shall be signed and dated; the alteration shall permit the reading of the original information and, where appropriate, the reason for such an entry.

4) Batch records shall be made or completed at the time each action is taken and in such a way that all significant activities are traceable and shall be retained for at least one year after expiry of the finished product. Original data such as laboratory notebooks and other relevant data shall be retained for the same period.

5) Data may be recorded by electronic data processing systems, photographic or other reliable means, but detailed procedures relating to systems in use shall be available and the accuracy of these records shall be checked. Only authorized persons shall be able to enter or modify data and there shall be records of changes and deletions made. Any amendment shall be

formerly authorized and signed and in the case of permanent amendment, the amended document shall be replaced at the earliest opportunity by a newly prepared and appropriately authorized document. An out-dated or superseded document shall be removed from active use and a copy retained for reference.

11.8.1 MASTER SPECIFICATION

1) Specifications for starting and packaging materials: these may include; material description, sampling and testing procedures or reference to procedures, quantitative and qualitative requirements and limits, storage conditions and maximum storage before re-examination.

2) Specifications for intermediate and bulk products: these may include, as is appropriate, similar specifications as for starting materials and finished goods.

3) Specification for finished products: these may include designated name of product, pharmaceutical form and package details, sampling and testing procedures or reference to procedures, quantitative and qualitative requirements and limits, storage conditions, special handling precautions and shelf-life.

4) Manufacturing Formula, Processing Instructions and Packaging Instruction: formally authorized manufacturing formula, processing instructions and packaging instruction shall exist for each product and batch size to be manufactured. These are often combined in one document.

5) Batch Processing Records: Batch processing Record shall be kept for each batch processed. It shall be based on the relevant parts of the currently approved Manufacturing Formula, Processing Instructions and Packaging Instructions. The record shall carry the number of the batch being manufactured.

11.8.2 PROCEDURES AND RECORDS

1) There shall be authorized written procedures and records for each delivery of starting and primary and printed packaging material, sampling, testing, release and rejection as well as distribution of finished products.

2) There shall also be authorized written procedures and associated records of action taken or conclusions reached for; validation, equipment assembly and calibration, maintenance, cleaning and sanitation, personnel matters including training, clothing, hygiene, environmental monitoring, pest control, complaints, recalls, returns and other major items of manufacturing and test equipment.

3) Logbooks shall be kept for major or critical equipment, recording any validations, calibrations, maintenance, cleaning or repair operations, including the date and identity of the people who carried out these operations.

11.9 PRODUCTION

1) Production operations must follow clearly defined procedures; they must comply with the principles of GMP in order to obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorizations.

2) The following standards shall apply to production operations:

   i) The pharmacist(s) shall ensure that production is performed and supervised by competent people and in accordance with GMP.

ii) All handling of materials and products and distribution shall be done in accordance with written procedures or instructions and where necessary recorded.

iii) Incoming materials, intermediate and bulk products, and finished products shall be physically or administratively quarantined immediately after receipt or processing until they are released for use or distribution.

iv) All materials and products shall be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation.

v) Operations on different products shall not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or contamination.

vi) At every stage of processing, products and materials shall be protected from microbial and other contamination.

vii) At all times during processing, all materials, bulk containers, major items of equipment and where appropriate rooms used shall be labelled or otherwise identified with an indication of the product or material being processed; its strength, batch number and where applicable the stage of production.

viii) Any deviation from instructions or procedures shall be avoided. If a deviation occurs, the quality assurance department shall when appropriate approve the deviation in writing.

ix) Contamination of starting materials or of a product by another material or product shall be avoided by appropriate technical or organizational measures. This risk of accidental cross contamination arises from the uncontrolled release of dust, gases, vapours, sprays or organism from materials and products in process, from residues on equipment and from operators' clothing.

x) Measures to prevent cross-contamination and their effectiveness shall be checked periodically according to set procedures.

11.9.1 VALIDATION

1) There shall be a validation master plan. Validation studies should reinforce GMP and be conducted in accordance with defined procedures. Results and conclusions shall be recorded.

2) When any new manufacturing formula or method of preparation is adopted or significant amendments to the manufacturing process including change in equipment or materials, which may affect product quality, steps shall be taken to demonstrate its suitability for routine processing.

3) Processes or procedures shall undergo periodic critical re-validation to ensure that they remain capable of achieving the intended results.

11.9.2 15.20.3 STARTING MATERIALS

1) Starting materials shall only be purchased from approved suppliers named in the relevant specification and where possible, directly from the producer.

2) Starting materials in the storage area shall be appropriately labelled.

3) There shall be appropriate procedures or measures to assure the identity of the contents of each container of starting material.

4) Only starting materials which have been released by the Quality Assurance Department and which are within their shelf-life shall be used.

5) Starting materials shall only be dispensed by designated persons, following a written procedure.

11.9.3 PROCESSING OPERATIONS

1) Before any processing operation is started, steps must be taken to ensure that the work area and equipment are clean and free from any starting materials, products and residues or documents not required for the current operation.

2) Any necessary in-process controls and environmental controls shall be carried out and recorded.

11.9.4 PACKAGING MATERIALS

1) Particular attention shall be paid to printed materials. They shall be stored in adequately secure conditions such as to exclude unauthorized access and mix-ups.

2) Packaging materials and labels shall only be issued for use, following an approved and documented procedure, by authorized personnel.

11.9.5 PACKAGING OPERATIONS

1) Particular attention shall be given to minimizing the risk of cross contamination, mix-ups or substitutions. Different products shall not be packaged in close proximity unless there is physical segregation.

2) Steps shall be taken to ensure that the work area, packaging lines, printing machines and other equipment are clean and free from any products, materials or documents not required for the current operation.

3) The line clearance shall be performed according to an appropriate checklist.

4) On-line control of the product during packaging shall include at least the checking of general appearance of the packages, whether packages are complete, whether the correct products and packaging materials are used, correctness of any over-printing, and correct functioning of line monitors.

5) Upon completion of a packaging operation, any unused batch-coded packaging materials shall be accounted for and then destroyed.

11.9.6 FINISHED PRODUCTS

1) Finished products shall be held under quarantine until their final release under appropriate storage conditions.

2) After release, finished products shall be stored as usable stock under appropriate storage conditions.

11.10 REJECTED, RECOVERED AND RETURNED MATERIALS

1) Rejected materials and products shall be clearly marked as such and stored separately in restricted areas. They should either be returned to the supplier or where appropriate, reprocessed (only if the quality of the final product will not be affected) or destroyed. Whatever action is taken shall be approved and recorded by authorized personnel.

2) The need for additional testing of any finished product, which has been reprocessed, or into which a recovered product has been incorporated shall be considered by the Quality Assurance Department.

3) Products returned from the market and which have left the control of the manufacturer shall be destroyed unless without doubt their quality is satisfactory; they may be considered for re-sale, re-labeled or recovered in a subsequent batch and only after they have been critically assessed by the Quality Assurance Department in accordance with a written procedure. Any action take shall be appropriately recorded.

11.11 COMPLAINTS AND PRODUCT RECALL

1) All complaints and other information concerning potentially defective products must be reviewed carefully according to written procedures. In order to provide for all contingencies, a system shall be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.

2) A person shall be designated responsible for handling the complaints and deciding the measures to be taken together with sufficient supporting staff to assist him. If this person is not the Qualified Person, the latter shall be made aware of any complaint, investigation or recall.

3) There shall be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint, investigation or recall.

4) All decisions and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records. Complaints records shall be reviewed regularly for any indication of specific or recurring problems requiring attention possibly the recall of marketed products.

5) The person responsible for Quality Assurance shall be normally be involved in the study of problems related to product complaints and/recalls.

6) The Competent Health Authorities including the Drug Regulatory Authority shall be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, or any other serious quality problems with a product.

11.12 CONTRACT MANUFACTURING AND ANALYSIS

Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings, which could result in a product or work of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor, which clearly establishes the duties of each party.

12 STANDARDS FOR INTERNSHIP PROGRAMME FOR PHARMACY GRADUATES AND REGISTRATION OF PHARMACISTS, PHARMACIST INTERNS AND PHARMACY TECHNICIANS

12.1 INTRODUCTION

1) The internship year/period is regarded as a period during which the pharmacy graduate should acquire a mature and responsible attitude towards the practice of pharmacy in relation to the general public and other health professions. At the end of the internship period the intern should have experienced exposure to the practice of pharmacy and achieved the status of a competent professional.

2) The notes and guidelines that follow are for the guidance of the intern, preceptor and any other pharmacist concerned with the supervision of interns during the internship period. These guidelines are designed to assist the preceptor in a structured manner in the training, education and evaluation of the intern.

3) The preceptor is reminded that the intention of the guidelines is not only to impart technical skills but to also reinforce awareness that the graduate is to become a member of a profession and to develop within the intern a professional attitude and a sense of responsibility.

12.2 AIMS AND OBJECTIVES

1) The primary aims of the programme are to reinforce among pharmacy graduates awareness that they are to become members of a profession and to develop further within them a professional attitude and a sense of responsibility.

2) The internship programme is therefore of great importance and the above aims can only be achieved if the following objectives are achieved:

   i) to give the intern pharmacist the practical experience of applying the knowledge acquired during undergraduate course;

   ii) to give the intern the opportunity to gain practical experience and make sound therapeutic decisions based on an understanding of the disease conditions, appropriate treatment, pharmacological properties of drugs, contraindications, dosage, side effects and drug interactions;

   iii) to give the intern the opportunity to gain practical experience in the provision of advice to patients and other health professions on the proper use of medicines, including potential interactions with other medications or any other substances and instructions on the action to be taken when symptoms are described by patients i.e. advice to consult a doctor or the sale of an appropriate medicine or neither;

   iv) to give opportunity to the intern to apply the principles of pharmaceutical care;

   v) to give the intern an understanding of the application in practice of the laws relating to the profession of pharmacy and ethical principles;

   vi) to give the intern a comprehensive knowledge of the requirements for good dispensing practice based on experience and a demonstrated capability;

vii) to give the intern opportunity to develop the techniques of good personal communication with members of the public, health professions, government officials, and other bodies;

viii) to give the intern an understanding of the administrative structures of the Botswana Health Services;

ix) to give the intern an understanding and experience in the ordering, storage, stock control of medicines (drug management);

x) to give the intern a knowledge of the major features of practice in the different aspects of pharmacy;

xi) to give the intern experience in the recording and pricing of prescriptions;

xii) to give the intern experience in the sale, distribution, manufacture and compounding of pharmaceuticals;

xiii) to give the intern experience in the application of management techniques to hospital pharmaceutical services, community pharmacy, distribution / wholesale services manufacturing operations, and regulatory affairs;

xiv) to give the intern experience of principles and practice of good manufacturing practice and good laboratory practice;

xv) to give the intern a working knowledge of the various reference books and other sources of information dealing with pharmaceutical legislation, the actions and uses of drugs and medicines and the supply of surgical appliances;

xvi) to give the intern experience in the provision of lectures or seminars or tutorials and as a demonstrator in practicals including an appreciation of assessment procedures and the direction of students projects;

xvii) to give the intern opportunity to perform research;

xviii) to facilitate the development of a desirable approach and attitude towards the profession of pharmacy.

12.3 INTERNSHIP PRECEPTORS

1) A pharmacist can only be an internship preceptor after at least four years practice as a registered pharmacist in Botswana in the aspect of pharmacy with which the particular establishment is concerned.

2) The internship preceptor must be an active member of good standing within the pharmaceutical community and must have contributed positively to the profession and /or have attended recognized continued education programmes including a seminar for internship preceptors.

3) The internship preceptor shall be engaged full-time in premises, which has been designated as training institution for interns.

4) The Registrar may, upon application and recommendation of the registration board, give authority, which shall be renewed every two years, to any suitably qualifying pharmacist to be an internship preceptor.

12.3.1 ROLE OF THE INTERNSHIP PRECEPTOR

The most important role of the internship preceptor is to provide a role model for the graduate pharmacist in all aspects of practice with emphasis on the values and attributes of a pharmacist. The preceptor is a mentor for the intern.

12.3.2 RESPONSIBILITIES OF THE PRECEPTOR

1) The Internship Preceptor shall:

   i) observe the requirements of all legislation, regulations and the ethical rules of the profession;

   ii) educate and train the intern in an appropriate manner so as to impart specific attitude and value system expected of a registered pharmacist in Botswana;

   iii) provide all required equipment, materials, programmes, access to information systems and literature necessary;

   iv) attend continued professional development courses;

   v) be available to the intern in order to assist with the day-to-day tasks and to provide guidance in the development of an independent and responsible decision maker;

   vi) To conduct evaluations and assessments of the intern at intervals as may be stipulated by the Botswana Health Professions Council.

12.4 APPROVAL OF ESTABLISHMENTS

1) The relevant regulatory authority and the Botswana Health Professions Council must give approval of establishments in which internship experience is gained.

2) In every establishment, facilities shall be available for the graduate to keep up-to-date with recent developments in medicines, therapeutics and in legislation relating to medicines.

3) Approval of establishment for the purpose of registration can only be considered if adequate reference resources are available in current editions and there is adequate pharmaceutical activity to give the intern enough experience.

4) The internship preceptor must apply to the Botswana Health Professions Council and state clearly how aspects of the common core functions of pharmacy will be covered and time period. The preceptor must make an undertaking, to the Botswana Health Professions Council, that all common core functions will be covered.

5) The internship preceptor must only be responsible for one intern except in large organizations where the preceptor's responsibilities may be devolved to other equally qualified and registered pharmacists.

12.5 INTERN PHARMACIST

1) An intern pharmacist is any person who has successfully completed a pharmacy graduate course from an institution recognized by the Botswana Health Professions Council, who has at least been awarded a Bachelor of Pharmacy degree or a Bachelor of Science degree in pharmacy or an equivalent degree, and is not registered to practice as a pharmacist in Botswana.

2) Such a person may be a new graduate, a pharmacist who the Botswana Health Professions Council may have recommended that he / she undergoes an internship programme.

3) Such a person must have applied to the Registrar to be registered as an intern and furnished him with the relevant documents as stipulated in the relevant form(s).

12.6 INTERNSHIP PROGRAMME

12.6.1 DURATION

1) The internship programme for a pharmacy graduate not registered in Botswana shall be full time and continuous for a period of 12months (2112hrs), 6months (1056hours) of which must be spent either in hospital or community pharmacy. All internship credit hours shall be earned in Botswana.

2) For a pharmacist seeking registration in Botswana who is registered in any one of the Commonwealth countries a 3 months internship must be undertaken to acclimatize to the conditions of pharmacy practice in Botswana.

3) For pharmacist registered in non Commonwealth countries a 6 months internship must be undertaken to acclimatize to the conditions of pharmacy practice in Botswana and to take cognizance of the fact that in some of these countries no internship is required prior to registration.

4) All externally registered pharmacists shall be required to successfully sit for an examination set by Pharmacy Council or Pharmacy Committee set by the Botswana Health Professions Council.

5) At the end of the internship programme the intern shall be required to have competence in the following functions as determined by the scope of pharmaceutical practice:

   i) manage all the branches of pharmacy such as hospital, retail, industry, distribution, regulation and academia;

   ii) manufacture and compound medicines;

   iii) distribute medicines (e.g. wholesaling);

   iv) dispense medicines and counsel patients / provide adequate information on safe use of medicines;

   v) provide pharmacist-initiated care (pharmaceutical care);

   vi) provide drug information and education;

   vii) Conduct research.

12.6.2 INDUSTRIAL PHARMACY INTERNSHIP

The main objective of the industrial internship training is to provide knowledge and experience of Quality Assurance in the development, manufacture and control of pharmaceuticals and hence to provide experience of:

1) the responsibilities of the Qualified Person;

2) the principles of good manufacturing practice and good laboratory practice;

3) formulation and manufacture of pharmaceutical products;

4) quality control of non-sterile and sterile products;

5) the basic regulatory requirements as it applies to industry e.g. for product license application/applications for registration of product;

6) the provision of medical information;

7) All other relevant core functions of a pharmacist as stated in the aims and objectives of the internship programme.

12.6.3 COMMUNITY PHARMACY INTERNSHIP

The main objective of the internship training shall be to provide knowledge and experience in the philosophy of pharmaceutical care and to create the awareness of the need for the pharmacist to carry full responsibility for the outcome of therapy and hence to provide experience of:

i) management and accounting as applied to the establishment concerned;

ii) Good Pharmacy Practice (patient welfare, quality of medicines, rational cost effective dispensing and prescribing, effective communications etc);

iii) over the counter prescribing and pharmacist initiated therapy in response to patients descriptions of symptoms and giving advice to patients;

iv) dispensing;

v) the regulatory/legislative requirements as they apply to community pharmacy;

vi) all other relevant core functions of a pharmacist as stated in the aims and objectives of the internship programme;

vii) Research and development.

12.6.4 HOSPITAL PHARMACY INTERNSHIP

1) The main objective of the internship training is to provide knowledge, experience and awareness that the pharmacist is part of the health care team in which she/he contributes to the therapy of in-patients whilst carrying the responsibility for the outcome of therapy for discharged patients and out-patients and hence to provide where appropriate, experience of:

i) Dispensing;

ii) clinical pharmacy;

iii) research;

iv) management;

v) manufacturing;

vi) legislation;

vii) patient education and counselling;

viii) All other relevant core functions of a pharmacist as stated in the aims and objectives of internship programme.

12.7 ASSESMENT

1) The assessment of the pharmacy intern's performance shall take place in accordance with schedules set forth by the Botswana Health Professions Council and informally on a day-to-day basis.

2) The assessment shall be systematic and regular.

3) Assessment shall be based on forms and guidelines, which the Botswana Health Professions Council shall issue and the results of the assessment shall be submitted to the Botswana Health Professions Council at stipulated intervals.

12.8 COMPLETION OF INTERNSHIP

Upon successful completion of the internship experience and successful passing of the Internship (Board examinations) examination the pharmacist intern may apply for registration as a pharmacist with the Botswana Health Professions Council.

12.9 REGISTRATION AS PHARMACIST

12.9.1 APPLICATION FOR REGISTRATION

1) Any person who has successfully completed a pharmacy graduate course from an institution recognized by the Botswana Health Professions Council, who has at least been awarded a Bachelor of Pharmacy degree or a Bachelor of Science degree in pharmacy or an equivalent degree, and has successfully completed the prescribed internship programme or internship time period, may apply to be registered as pharmacist in Botswana.

2) The applicant shall furnish to the Registrar the following certified copies:

   i) identity document;

   ii) curriculum vitae;

   iii) pharmacy degree or equivalent university (tertiary institution) certificate;

   iv) university (tertiary institution) transcripts or a detailed marked certificate;

   v) letter of good standing from a statutory professional pharmacy body which the applicant is a member where applicable;

   vi) current certificate of registration with a statutory professional pharmacy body;

   vii) letter of offer of employment if non-citizen;

   viii) Letter of declaration that the applicant has satisfactorily undergone an internship programme as prescribed by the Botswana Health Professions Council.

3) Any person who has satisfactorily complied with the above and has successfully undergone Board Examinations shall be registered as a pharmacist in Botswana.

12.10 REGISTRATION AS PHARMACY TECHNICIAN

12.10.1 APPLICATION FOR REGISTRATION

1) Any person who holds a diploma of the Institute of Health Sciences of Botswana granted in respect of Pharmacy Technology / Pharmacy may apply to be registered as a pharmacy technician in Botswana.

2) Any person who holds an equivalent diploma to that of the Institute of Health Sciences of Botswana granted in respect of Pharmacy Technology / Pharmacy may apply to be registered as a pharmacy technician in Botswana.

3) The applicant shall furnish to the Registrar the following certified copies:

   i) identity document;

   ii) curriculum vitae;

   iii) pharmacy / pharmacy technology diploma or equivalent tertiary institution certificate;

   iv) tertiary institution transcripts;

   v) letter of good standing from a statutory professional pharmacy body which the applicant is a member, where applicable;

   vi) current certificate of registration with a statutory professional pharmacy body;

   vii) letter of offer of employment if non-citizen;

   viii) Letter of declaration that the applicant has satisfactorily undergone a prescribed practical and clinical attachment as prescribed by the Botswana Health Professions Council.

4) Any person who has satisfactorily complied with the above and has successfully undergone Board Examinations shall be registered as a pharmacy technician in Botswana.

12.11 GUIDELINES FOR PRECEPTORS AND INTERNS

12.11.1 INITIAL DISCUSSIONS WITH THE PHARMACIST INTERN

Initial discussions between the preceptor and the intern shall take place to establish the intern's previous experience, specific interests, known weaknesses and strengths.

The structure, timetable, the contents of the internship programme and methods of assessment shall be discussed and outlined to the intern. The impact of the outcome of the assessment shall candidly be discussed with the intern since this will affect the intern's ability to register as a pharmacist.

It is important that the preceptor is adequately prepared for this discussion, since this may influence the intern's perception, enthusiasm and confidence throughout the internship period.

12.11.2 2 ORIENTATION

A period of about two weeks, or any such period that would be deemed suitable depending on the institution, shall be devoted to orientation to enable the intern to adjust to the new work environment. The intern shall be introduced to all members of staff, as appropriate, given a supervised tour of the department, institution by the preceptor.

Work related issues such as; type of work performed in different areas, organizational structure of the institution, responsibilities of the intern versus other staff members, should be explained.

The intern shall be made aware of:

- Work hours, wages, time and method of payment, and leave entitlement;
- Expected conduct, punctuality, confidentiality and acceptable levels of competency;
- Dress code and general appearance;
- Contractual obligations (absenteeism etc);
- General arrangements (ancillary areas – refreshments, canteens etc).

12.11.3 SPECIFIC TASKS OF THE INTERN

The specific tasks of the intern must be explained fully with emphasis on the area of practice. Areas of practice, which do not have their guidelines contained within these guidelines, should use their guidelines together with these guidelines.

12.11.4 INTERNSHIP PROGRAMME GUIDELINES

A suggested training programme for the intern is contained in the relevant section of this manual for community, hospital and industry, other areas of pharmacy practice may use their own programmes as long these have been approved by the Botswana Health Professions Council. Institutions may also use their own specific training programmes that should cover, as a minimum, items contained in the stipulated programmes.

12.11.5 SPLITTING OF INTERNSHIP PROGRAMME

The internship may be split between any of the following for as long as at least 6 months is spent in either community or hospital pharmacy practice: industry, hospital, community, academia, wholesale/distribution, essential drugs programme and regulatory authority.

12.11.6 ASSESSMENT

The assessment of the intern must take place on a systematic and regular basis and should involve positive reinforcement of appropriate performance and constructive criticism on performance that could be improved.

The preceptor should assess the performance of the intern on a day-to-day basis and not necessarily record but should correct, adjust or reinforce execution of daily duties and activities.

The Internship Appraisal Form should be completed in the presence of the intern and all issues discussed before it is sent to the Botswana Health Professions Council. Areas that need improvement should be noted and more emphasis put on them.

12.11.7 TIMETABLE

ASSESSMENT STAGE	**COUNCIL REQUIREMENT**
First Report (13 weeks)	Submission to Council within one month
Second Report (26 weeks)	Submission to Council within one month
Third Report (36 weeks)	Submission to Council within one month
Final Report (52 weeks)	Submission to Council within one month

12.11.8 COMMON CORE AREAS OF THE INTERNSHIP PROGRAMME

In addition to specific guidelines for each area of pharmacy practice (e.g. hospital, industry, community etc), the common core guideline provides guidelines for common core areas to be covered during the internship programme by all interns. This guideline is an aid to be used by the preceptor to plan the internship experience for the intern. All items must be introduced and discussed with the intern to ensure full understanding of expectations and responsibilities.

The preceptor must tick to indicate areas covered and when covered during the internship programme.

12.11.8.1 Dispensing Services

1) A comprehensive knowledge of an efficient, courteous and accurate dispensing service based on appropriate practical dispensing experience and the intern must demonstrate proficiency/capability. Knowledge and appropriate practical experience of dispensing shall include:

	WEEKS			
	13	26	39	52
Receipt, authentication and evaluation of prescriptions				
Dispensing of ethical preparations				
Dispensing of extemporaneous preparations				
Supervision of pharmacy assistants and technicians				

2) Provide advice to patients and other health professionals on the rational and proper use of medicines including dosage and administration, potential drug interactions and interactions with other substances (food, alcohol etc).

	WEEKS			
	13	26	39	52
Queries arising from evaluation of prescriptions				
Verbal advice to patients on how to take medicines				
Cautionary / warning labels				
Basic communication techniques associated with the above				

3) Instruction on provision of advice to patients and action to be taken when patients seek professional advice and present/describe symptoms (pharmacy consultation), i.e. referral to a medical doctor, pharmacy initiated therapy or neither.

	WEEKS			
	13	26	39	52
Basic communication techniques associated with the above				

4) Provision of advice and information to medical doctors and other health professionals on matters arising from prescriptions, possible adverse reactions, interactions, contra-indications, dosage regimens etc. Areas to be covered should include:

	WEEKS			
	13	26	39	52
Provision of advice relating to prescriptions, medicinal products, drug dosage, adverse reactions, incompatibilities, interactions etc				
The use of information sources in connection with the above				
Maintenance of information files				
Experience of personal communication with patients, the public, doctors, dentists, nurses and other health professionals				

12.11.8.2 Information Sources

1) A working knowledge of the various reference books and other information sources dealing with pharmaceutical and relevant legislation, actions and uses of drugs and surgical appliances.

	WEEKS			
	13	26	39	52
Drugs and Related Substances Act and Regulations				
Botswana Health Professions Act and Regulations				
The Martindale				
British Pharmacopoeia				
British National Formulary				
Monthly Index of Medical Specialties (MIMS)				
Reference books on surgical appliances and requisites				
Journals and other relevant information sources				
Electronic information sources				

12.11.8.3 Legislation

1) An understanding of the application the laws relating to the pharmacy profession which shall include but not limited to a knowledge of the main provisions/section of the Drugs and Related Substances Act and the Botswana Health Professions Act such as:

	WEEKS			
	13	26	39	52
Control over Drugs				
Habit Forming Drugs				
Drugs and Related Substances Act Regulations				
Botswana Health Professions Council, Committees and Boards				
Registration and licensing of practitioners				
Enquiries and disciplinary proceedings for practitioners				
Matters of Professional Conduct and Ethics				
Botswana Health Professions Act Regulations				

12.11.8.4 Drug Management

1) An understanding of and experience in Drug Management (ordering, storage and stock control)

	WEEKS			
	13	26	39	52
Ordering systems and methods				
Storage requirements (rotation, security, temperature, humidity, cold-chain, expiry dating etc)				
Stock control methods (maximum / minimum levels, consumption rates / turn-over intervals, shelf-life etc)				

12.11.8.5 Communication Techniques

Development of communication techniques in dealing with members of the public, health professionals and officials of other bodies/institutions

12.11.8.5.1 Communication with Health professionals

	WEEKS			
	13	26	39	52

Prescription in accuracies (e.g. dosage)				
Drug interaction, adverse reactions and contraindications				
General drug information				

12.11.8.5.2 Communication with Patients

	WEEKS			
	13	26	39	52
Queries arising when prescription is presented to the patient				
Advice on how to take medicines				
Cautionary warning labels				

12.11.8.5.3 16.12.5.3 Communication with other officials

	WEEKS			
	13	26	39	52
Administration staff				
Medical representatives				
Others (Regulatory officials, Police, Customs and Excise etc)				

12.11.8.6 Management and Accounting

1) An understanding of the main / basic principles of accounting and management (awareness of these in the place of employment)

	WEEKS			
	13	26	39	52
Management structure				
Accounting procedure				

12.11.8.7 National Health Policies

1) An understanding and knowledge of the main health policies and relevant organizational structures of the Ministry of Health.

2) A knowledge of the major features of practice in the different aspects of pharmacy (different specialist areas)

	WEEKS			
	13	26	39	52
Ministry of Health's organizational structure (TSS, PHC, DHS etc)				
National Drug Policy				
Pharmacy Practice Standards				
Specialist area				
Specialist area				
Specialist area				

12.11.8.8 Basic First Aid

An introduction to basic first aid.

	WEEKS			
	13	26	39	52
Principles of first aid				

Resuscitation				
Haemorrhage				
Any other major principles of first aid				

12.11.9 PROGRAMME FOR INTERNS IN COMMUNITY PHARMACY

1) This guideline provides a basic programme to be followed when giving the pharmacy graduate (intern) experience in community pharmacy. It is an aid to be used by the preceptor to plan the internship experience for the intern. All items must be introduced and discussed with the intern to ensure full understanding of expectations and responsibilities.

2) The preceptor must tick to indicate areas covered and when covered during the internship programme.

12.11.9.1 Dispensing Services

1) An in-depth knowledge and appropriate practical experience of the Dispensing Service

	WEEKS			
	13	26	39	52
Recording of prescriptions				
Authenticity of prescriptions				
Introduction to medical aid system				
Levy procedures				
Endorsement procedure				
Sorting and submission of prescriptions to medical aids				
Computer systems (editing and entering information, merging patient information, back-up procedures etc)				
Emergency supply				
Recording pharmacist initiated prescriptions				
Recording and retention procedures for patient records				
Review checking procedures and handing out of prescriptions				
Interpretation of prescriptions				
Review of patient history				
Accurately dispense prescriptions				
Labelling of medicines				
Handing out and storage of dispensed medicines				
Extemporaneous preparations and dispensing thereof				
Dispensing and recording of Habit Forming Drugs				
Prescription registers				
Habit Forming Drugs Register				
Storage and importation of Habit Forming Drugs				
Other legal responsibilities for dispensing				
Drug recall procedures				
Disposal of unwanted medications				
Role of Pharmacy Technicians				
Role of non – pharmaceutical staff				
Misuse of prescription drugs (or potential thereof)				
Mismanagement of patients (or potential thereof)				
Checking of and dealing with dated stocks				

12.11.9.2 Sale of Medicines

	WEEKS			
	13	26	39	52
Advice including sale of medicine (Pharmacist initiated therapy)				
Advice without sale of medicine				

Referral to medical practitioner				

12.11.9.3 Communication

	WEEKS			
	13	26	39	52
Discussion of prescription problems with prescriber				
Handing out prescriptions and counselling patients on safe and effective use of medicines				
Counselling for metered dose aerosols, humidifiers and nebulisers				
Dealing with unusual dose or strength (how to discuss, etc)				
Guidelines to convey problems to prescribers				
Counselling techniques				
Dealing with special groups (elderly, children, pregnant mother-to-be, etc)				
Communication with health professionals				
Explaining use of different surgical requisites/appliances (dressings, colostomy care products, etc)				
Use of diabetic monitoring devices				
Use of cough and cold products (to prevent incorrect use and misuse)				
Family planning/contraception/condom use (AIDS), etc				
Counselling for obese patients (dieting)				
Counselling for the chronically ill patients				

12.11.9.4 Pharmacist Initiated Therapy

	WEEKS			
	13	26	39	52
Analgesics (Schedule 3)				
Antihistamines (S3)				
Topical nasal decongestants				
Laxatives				
Vitamins				
Cough preparations				
Antacids				
Eye/ear/nose preparations				
Skin infections – bacterial, fungal and viral				
Treatment of bites and common rashes				
Acne, seborrhoea and dandruff				
Sunscreens				
External analgesics, burns				
Dental hygiene				
Cold and flu preparations				
Use of diabetic monitoring devices, urine test strips and syringes				
Baby formula and baby products				
Anthelmintics (Sch3)				
Nappy rash				
Contact lens products				
Foot care				
Review of over the counter drugs used by special groups (e.g. the elderly, pregnant mother-to-be etc)				
Sports supplements including vitamins				
Scabies				

12.11.9.5 Pharmaco-therapy

	WEEKS			
	13	26	39	52

Oral contraceptives				
Beta – Blockers and other antihypertensives				
Calcium channel blockers, ACE inhibitors and related drugs				
Antibiotics and sulphonamides				
Analgesics and NSAID				
Drugs used to treat respiratory problems, asthma and emphysema				
Hormone replacements, osteoporosis				
Anti-malarials, antivirals and other anti-infectives				
Cardiac glycosides, antiarrythmics, anticoagulants				
ENT drugs				
Drugs used to treat GI ulcers and reflux oesophagitis				
Diuretics				
Oral/topical antifungals, topical steroids				
Treatment of allergy, psoriasis, acne etc				
Analgesics (narcotic / non-narcotic)				
Drugs used to treat angina and ischaemic heart disease				
Lipid lowering agents				
Diagnostic agents and tests e.g. glucose monitoring				
Psychotropic drugs				
Steroidal drugs (hormone replacement, anabolic steroids)				
Commonly prescribed drugs in paediatrics and neonatology				
Antiemetics, anaesthetics				
Tonics, food supplements, enzymes				
Immunology, vaccines etc				

12.11.9.6 16.12.10.6 Drug and general information service

	WEEKS			
	13	26	39	52
Familiarization with and use of required information sources				
Accessing information from manufacturers				
Preparation of written patient information				
Literature review				
Preparation of written information to other health professionals				
Information search and report writing				
Preparation of information charts for patients on oral steroids and other patient groups (e.g. asthmatics)				

12.11.9.7 Management

	WEEKS			
	13	26	39	52
Stock control systems (e.g. point of sale)				
Stock rotation and ordering procedures				
Control of suppliers accounts (packing slips, invoices, statements etc)				
Control and cash accounting				
Supervision and control of staff				
Pricing policies and systems				
Planning and conducting staff training				
Security arrangements				
Shop lay-out				
Good customer services, handling and minimizing complaints				
Basic human resources management				
Marketing methods				
Planning, budgeting and control				
Basic financial accounting, banking, insurance and taxation issues				
Staff motivation				

Stock – taking				
Point of sale systems				

12.11.9.8 Legislation

1) Experience of the application of laws relating to Pharmacy, community pharmacy and retail business

	WEEKS			
	13	26	39	52
Drugs and Related Substances Act and Regulations: Registration of drugs Drugs Advisory Board Export, import and distribution of drugs Classification, dispensing and prescription of drugs Retailing of drugs Inspection of premises Habit Forming Drugs (import / export control, records, registers, prescriptions, storage etc) Regulations Application for licenses				
Trade and Liquor Act: Licensing of retail business Health Inspections (health and safety)				
Botswana Health Professions Act and Regulations: Establishment of council Objectives, duties and function of council Committees and professional boards Registration of practitioners, registers Disciplinary proceedings Offences and penalties Regulations				

12.11.10 PROGRAMME FOR INTERNS IN HOSPITAL PHARMACY

This guideline provides a basic programme to be followed when giving the pharmacy graduate (intern) experience in hospital pharmacy. It is an aid to be used by the preceptor to plan the internship experience for the intern. All items must be introduced and discussed with the intern to ensure full understanding of expectations and responsibilities.

The preceptor must tick to indicate areas covered and when covered during the internship programme.

12.11.10.1 Dispensing Service

1) An in-depth knowledge and appropriate practical experience of the Dispensing Service (Out-patients)

	WEEKS			
	13	26	39	52
Recording of prescriptions				
Authenticity of prescriptions				
Introduction to medical aid system				
Levy procedures				
Endorsement procedure				
Sorting and submission of prescriptions to medical aids (claims etc)				
Computer systems (editing and entering information, merging patient information, back-up procedures etc)				

Emergency supply				
Recording and retention procedures for patient records				
Review checking procedures and handing out of prescriptions				
Interpretation of prescriptions				
Review of patient history				
Accurately dispense prescriptions				
Labelling of medicines				
Handing out and storage of dispensed medicines				
Extemporaneous preparations and dispensing thereof				
Dispensing and recording of Habit Forming Drugs				
Duration of supply limitations				
Habit Forming Drugs Register				
Storage and importation of Habit Forming Drugs				
Other legal responsibilities for dispensing				
Drug recall procedures				
Disposal of unwanted medications				
Role of Pharmacy Technicians				
Role of non – pharmaceutical staff				
Misuse of prescription drugs (or potential thereof)				
Mismanagement of patients (or potential thereof)				
Checking of and dealing with dated stocks				

12.11.10.2 Communication

	WEEKS			
	13	26	39	52
Discussion of prescription problems with prescriber				
Handing out prescriptions and counselling patients on safe and effective use of medicines				
Counselling for metered dose aerosol, humidifiers and nebulisers				
Guidelines to convey problems to prescribers				
Counselling techniques				
Dealing with special groups (elderly, children, pregnant mother-to-be, chronically ill etc)				
Communication with health professionals, drug information				
Explaining use of different surgical requisites / appliances (dressings, colostomy care products etc)				
Use of diabetic monitoring devices				
Family planning / contraception / condom use (AIDS) etc				

12.11.10.3 Clinical Pharmacy

	WEEKS			
	13	26	39	52
Format and use of prescription charts / cards				
Reading, interpretation and dispensing of prescriptions				
Reading and interpretation of patients records (lab, clinical etc)				
Doctor – clinical pharmacist – nurse interactions				
Therapeutic drug monitoring				
Pharmacokinetics, therapeutics				
Medical information and literature review				
Presentations/Lectures to other health professionals				
Therapeutic committees				
Rational Drug Use				
Patient counselling and consultation				
Adverse drug reaction monitoring				

12.11.10.4 Drug Distribution

	WEEKS			
4.1) **Wards and Departments:**	13	26	39	52
Wards and department stock list systems				
Requisitions				
Top – up systems				
Measures for the control of drugs on wards and departments				
Ward drugs boxes – safety and security				
Ward emergency trays/boxes				
4.2) **Habit Forming Drugs**				
Requisitions				
Supply of				
Records – Pharmacy (Registers etc)				
Storage				
4.3) **Returns policy**				
From wards				
Patient's own drugs on admission				
Out-patients				
Habit Forming Drugs				
4.4) **Documentation**				
Pharmaceutical responsibility and checking procedures (SOPs)				
Locally restricted drugs ("special orders"/specialist drugs etc)				
Ward/Department drug checks (level, condition, expiry, validity)				

12.11.10.5 Emergency Procedures

	WEEKS			
	13	26	39	52
On-call systems				
Out of hours drug cupboard				
Emergency kits (poisons / antidotes, cardiac arrest, etc)				
Major incident kit				
Records, stock checks and replenishment				
Tablet and capsule identification				
Reference books				

12.11.10.6 Medical Gases

	WEEKS			
	13	26	39	52
Pharmacy responsibilities				
Ordering, storage and supply				

12.11.10.7 Good Manufacturing and Good Laboratory Practices

1) Principles and practice of good manufacturing practice and good laboratory practice (Knowledge and where appropriate, experience in procedures using these principles)

	WEEKS			
	13	26	39	52
7.1) **Personnel and training** Key responsibilities ---------- Organisation and staff---------- Training and supervision---------- Personal hygiene----------				

	WEEKS			
	13	26	39	52
7.2) **Premises** Design---------- Construction---------- Maintenance----------				
7.3) **Raw materials** Testing---------- Storage---------- Issue---------- In-process control---------- Release----------				
7.4) **Equipment** Design---------- Suitability and Selection---------- Cleaning and maintenance----------				
7.5) **Documentation** Specification---------- Sampling---------- Master formulae---------- Records---------- Standard Operating Procedures---------- Plant maintenance----------				
7.6) **Manufacturing process** Materials---------- Methods---------- Packaging---------- Labelling---------- Storage---------- Distribution/transportation----------				
7.7) **Validation** ---------- 7.8) **Complaints/product recall procedures**---------- 7.9) **Sampling procedures**---------- 7.10) **Environmental monitoring**---------- 7.11) **Clean room standards**---------- 7.12) **Safety regulations**----------				

12.11.10.8 Research

	WEEKS			
	13	26	39	52
Information research and report writing				
Literature review				
Drug Utilization Studies				
Clinical experience (presentation)				
Clinical pharmacokinetics (presentation)				

12.11.10.9 Management

	WEEKS			
	13	26	39	52
Stock control systems (e.g. point of sale)				
Stock rotation and ordering procedures				
Control of suppliers accounts (packing slips, invoices, statements etc)				
Supervision and control of staff				
Planning and conducting staff training				
Security arrangements				

Hospital pharmacy lay-out (OPD, inpatients, production and other designated areas)				
Good customer services, handling and minimizing complaints				
Planning, budgeting and control				
Staff motivation				
Stock – taking				

12.11.11PROGRAMME FOR INTERNS IN INDUSTRY

This guideline provides a basic programme to be followed when giving the pharmacy graduate (intern) experience in industry. It is an aid to be used by the preceptor to plan the internship experience for the intern. All items must be introduced and discussed with the intern to ensure full understanding of expectations and responsibilities.

The preceptor must tick to indicate areas covered and when covered during the internship programme.

12.11.11.1 Legislation

1) An in-depth knowledge and appropriate practical experience of the applicability of the Drug and Related Substances Act to Pharmaceutical Industry

	WEEKS			
	13	26	39	52
Licenses for manufacture of drugs				
Licenses for wholesaling				
Registration of drugs				
Inspection of premises				
Classification, dispensing an prescription of drugs				
Export, import and distribution of drugs				
Advertising of drugs				
Habit Forming Drugs				
Regulations, approval for manufacture of drugs, records to be kept				
Packaging, labelling and package inserts / leaflets				
Quality Assurance – concept				
Quality Control				
Guide to Good Manufacturing Practice (WHO, EU, Orange Guide)				
Guide to Good Laboratory Practice (WHO, EU)				

12.11.11.2 Qualified Person (s)

1) Responsibilities and role of the "Qualified Person" (Key personnel – Head of Production and Head of Quality Control)

	WEEKS			
	13	26	39	52
Knowledge of premises, manufacturing and QC equipment and conditions of use				
Knowledge of qualifications, competence and level of responsibility of staff				
Confirmation that premises, equipment and personnel are adequate to provide medicines suitable for marketing (authorization of process etc)				
Supervision of GMP (raw materials, manufacture, containers, storage, dispatch etc)				
Accessing relevant information				

12.11.11.3 Good Manufacturing and Good Laboratory Practices

1) Practical experience of the principles and practice of Good Manufacturing and Good Laboratory Practice (Guide to GMP & GLP – WHO, EU and local guidelines)

	WEEKS			
	13	26	39	52
Concept of quality assurance				
Concept of GMP				
Achieving objectives (Quality Assurance)				
Achieving requirements of GMP				
Achieving effective control of quality				
Premises and equipment requirements for manufacture				
Production area (construction materials, material flow, self contained facilities)				
Storage areas (receiving, dispatch, quarantine and other areas)				
Ancillary areas				
Equipment (installation, balances and other electronic equipment, maintenance)				
Quality control areas (chemical analysis, biologicals, validation)				
Concept of good laboratory practice				
Training (GMP, clean room procedures, hygiene)				
The role of the Drug Regulatory Authority Inspectorate				
Self Audit				

12.11.11.4 Documentation

	WEEKS			
	13	26	39	52
Standard Operating Procedures				
Batch manufacturing records (formulae, processing and packaging instructions)				
Specifications (raw material, packaging materials, intermediate and finished products)				
Procedures for receipt, sampling, testing and release of products and materials				
Product dossiers and registration				

12.11.11.5 16.12.12.5. FORMULATION

1) Formulation of sterile and non-sterile preparations

	WEEKS			
	13	26	39	52
Product stability and shelf-life prediction				
Routes of product degradation				
Bioavailability of products				
Dissolution rate and disintegration evaluation				
Microbiological degradation				
Preservatives				
Content uniformity				
Pilot production and scale-up risks				
Patient acceptance and compliance				

12.11.11.6 Manufacturing

1) Manufacturing of sterile and non-sterile products

	WEEKS			
	13	26	39	52
Factory organization				

	WEEKS			
	13	26	39	52
Cross contamination avoidance				
Mix-ups avoidance				
Batch processing				
Continuous processing				
In-process controls				
Processing operations				
Validation				
Production plans/schedules and targets (daily, weekly planning)				
Rejected, returned and recovered/re-processed materials/products				

12.11.11.7 Quality Control

1) Quality Control of sterile and non-sterile products

	WEEKS			
	13	26	39	52
Sampling (raw and packaging materials, in-process, finished product)				
Quarantine (raw and packaging materials, finished product)				
Good Laboratory practice (as per GMP & GLP guidelines)				
Documentation (specifications, sampling procedures, test procedures, analytical reports/ certificates, environmental monitoring data)				
Validation (records and test methods)				
Equipment calibration (procedures and records)				

12.11.11.8 Contract Manufacture and Analysis

	WEEKS			
	13	26	39	52
Contract giver				
Contract acceptor				
The contract, including responsibilities of the giver, the acceptor and "qualified persons"				

12.11.11.9 Product complaints and recalls

	WEEKS			
	13	26	39	52
Product complaints (procedure for, and processing of)				
Product recall (procedures for, informing regulatory authority)				

12.11.11.10 Research and Development

	WEEKS			
	13	26	39	52
Evaluation of literature				
Pre-formulation problem identification and solution				
Accelerated stability studies				

12.12 FORM A

INTERNSHIP EXPERIENCE APPRAISAL FORM

Name of Intern _____

Address of establishment _____

Period to which this form relates:

Commencement _____

Completed on _____

The appraisal should be based on expectations of the intern's progress thus far and not expectations to be met at the end of the internship.

The appraisal should be objective, based on overall performance and not influenced by one or particular incident(s).

A tick should be placed under each item being assessed and where the intern cannot be assessed on a particular item then "N/A" (not applicable) should be written and reasons given under the comments section.

An intern's strength or weakness in one item should not cloud the preceptor's judgment of the intern's quality on another.

The intern should be allowed to make brief comments/report (on the back page) on progress being made.

12.12.1 APPLICATION TO WORK

	Excellent	Good	Average	Indifferent	
Industriousness (keen and willing)					Does little more than she/he has to.
Tendency to extend knowledge and skill					Shows little interest in wanting to extend knowledge and skill.
Ability to quickly grasp essentials					Has difficulty in grasping essentials
Punctuality					Not always punctual
Promptness in execution of duties					Tends to hold up work

Comments:

_____

_____

12.12.2 QUALITY OF WORK

Standard of work					Doesn't show a good enough standard
Application of theory to practical work					Appears not to apply theory to practical work.
Attention to detail and finish					Work shows inadequate attention to detail and finish

Reliability in carrying out and following procedures					Needs more supervision than most.
Ability to observe and report relevant information					Not sufficiently observant and at times omits to observe / pass on relevant information
Resourcefulness and self-reliance					Needs support to cope with routine work
Ability to plan and complete own work/organize others					Still to learn to plan and organize own work effectively / organize others
Reliability in making the necessary records					Tends to delay in making the necessary records
Ability to produce well written, complete and clearly expressed reports					Written reports are not always complete and clear.

Comments:

12.12.3 3) ATTITUDE TO PATIENTS

	Excellent	Good	Average	Indifferent	
Ability to anticipate and meet patient's needs					Sometimes fails to recognize and meet patient's needs
Ability to understand patients as individual persons					Seldom adapts approach to suit the needs of individuals
Ability to gain confidence and cooperation of patients (tactfulness and considerate)					Still to gain the skills required in gaining confidence and cooperation of patients.

Comments:

12.12.4 4 .ATTITUDE TO COWORKERS AND COLLEAGUES

Ability to work well as a member of the team					Appears to have difficulty working as a team member
Ability to deal with other health professionals in an alert and informed manner					Appears to be casual in manner and inadequately informed when dealing with other health professionals
Courtesy and helpfulness towards other colleagues					Appears rather off-hand in dealing with other colleagues
Ability to respond with grace to instructions / advice / constructive criticism					Often reluctant to accept instructions / advice / constructive criticism
Ability to instruct and supervise others					Ability to instruct and supervise others not yet displayed.

Comments:

12.12.5 PERSONAL BEHAVIOUR

Neatness and decorum					Appears unaware of decorum and not always well groomed
Ability to act effectively in stressful situations and with poise					Easily raffled (put out by unusual or difficult situations)

Comments:

12.12.6 OVERALL ASSESSMENT

	Excellent	Good	Satisfactory	Requires some improvement	Require much improvement	Is unsatisfactory
At this stage of internship the intern's development towards a professional attitude and a sense of responsibility is						

General Comments by Preceptor

Signature of Preceptor

Date

Comments by Intern

Signature of Intern

Date

12.13 FORM B

REGISTRATION AS A PHARMACIST AND INTERN IN BOTSWANA

It is an offence to practice as a Pharmacist in Botswana without prior registration with the Botswana Health Professions Council.

12.13.1 REQUIREMENTS FOR REGISTRATION OF A PHARMACIST

1) To practice as a Pharmacist in Botswana one has to be registered with the Council and the following are requirements for registration as a Pharmacist:

   i) Certified copy of the applicant's identity document

   ii) Certified copy of the applicant's degree certificate

   iii) Certified copy of university transcripts for above degree

   iv) Certified copy of certificate of good character and standing from a professional body that the applicant is currently a member.

   v) Complete assessment reports (all intervals) for the internship period as would have been stipulated by the Council and undergone by the applicant in Botswana.

   vi) Certified copy of results of the Council's Board Examination

   vii) Certified letter of offer of employment from an institution in Botswana (Non-citizens only)

   viii) Declaration by the preceptor about internship of a pharmacist intern, signed in the presence of a Commissioner of Oaths.

   ix) Declaration by a pharmacist intern desiring registration as a pharmacist in terms of the Botswana Health Professions Act, signed in the presence of a Commissioner of Oaths

   x) Declaration by a pharmacist registered with the Botswana Health Professions Council to whom the pharmacist intern / a person desiring registration as a pharmacist is personally known, signed in the presence of a Commissioner of Oaths.

2) The Council may waive, some of the above requirements in as far as the circumstances of the applicant satisfy conditions set forth in the Botswana Internship Programme Manual, under internship programme duration.

12.13.2 REQUIREMENTS FOR REGISTRATION OF A PHARMACIST INTERN

1) To register as a pharmacist intern the following shall be submitted to the Council by the person who shall be supervising the intern (preceptor):

   i) Certified copy of the applicant's identity document;

   ii) Certified copy of the applicant's degree certificate;

   iii) Certified copy of university transcripts for above degree;

iv) Certified copy of certificate of good character and standing from a professional body that the applicant is currently a member (where applicable);

v) Certified letter of offer of employment from an institution in Botswana (Non-citizens only);

vi) Declaration by the preceptor about internship of a pharmacist intern, signed in the presence of a Commissioner of Oaths;

vii) Declaration by a pharmacist intern desiring registration as a pharmacist in terms of the Botswana Health Professions Act, signed in the presence of a Commissioner of Oaths;

viii) Certified copy of current certificate issued by the Council authorizing the supervisor to be a pharmacist preceptor at the place at which internship training is to take place.

12.13.3 DECLARATION FORMS

1) Declaration forms must be completed by each preceptor under whom the intern has worked.

2) The periods of internship under each tutor must, in the aggregate, amount to a period not less than that stipulated by the Council for the intern.

3) An intern who completed the whole of his/her internship in the same institution (e.g. hospital), but under different preceptors, may submit only one "declaration by preceptor about internship of a pharmacy intern" form completed by his/her current preceptor.

4) All declaration forms must be signed in the presence of a Commissioner of Oaths.

12.14 FORM C

APPLICATION FOR PERMISSION TO ACT AS PHARMACIST PRECEPTOR

The Botswana Health Professions Council

Private Bag 0038

Gaborone

I, the undersigned do hereby apply for permission to become a Pharmacist Preceptor.

I am pharmacist of good standing and consider myself to be professionally competent, highly motivated and maintain high ethical standards. I do undertake to be fully responsible for the practical training of the pharmacist intern(s). I am knowledgeable of the requirements of the Botswana Health Professions Council requirements for the internship training of graduate pharmacists and the law relating to the practice of pharmacy in Botswana.

I submit the following particulars and agree to permit inspection of the premises for this purpose. Should this application be approved, the Council's requirements and conditions relating to the internship programme shall be observed.

Particulars of the Preceptor

Name: (Dr/Mr/Mrs.) _____

Registration certificate No: _____ Date of Registration _____

Qualifications of the Preceptor (List all formal qualifications)

_____

_____

Post – Registration work experience (in the field(s) of pharmacy)

FIELD	LENGTH OF EXPERIENCE (months or years)
Hospital	
Community	
Industry	
Academia	
Others (specify)	

I am a member of the following professional bodies (associations, societies, organizations)

_____

_____

Other than the day-to-day work in my field of pharmacy, I have been active in the following spheres relating to pharmacy (e.g. community matters, academic endeavours, Pharmaceutical Society of Botswana)

_____

_____

I have during the past three years attended the following scientific, professional, management courses and continued education / professional development programmes. (Specify courses / programmes attended, dates and duration)

_____
_____
_____

_____

REGISTERED NAME AND ADDRESS OF PREMISES (including physical address)

_____
_____
_____

Telephone: _____ Facsimile: _____

NAME OF PROPRIETOR: _____

DATE OF ESTABLISHMENT: _____

I am **ENGAGED FULL-TIME** in these premises.

I have never been convicted in any country of a criminal offence or been debarred from practice by reason of misconduct and to the best of my knowledge and belief no proceedings involving or likely to involve charges of any such nature are pending against me in any country at the present time.

_____

(Signature of applicant)

COMMISSIONER OF OATHS

The above mentioned SIGNED and SWORN before me at _____

on this _____day of _____ 20 _____that she / he knows and understands the contents of this form and attests to them to be nothing but the truth.

_____ _____

(Signature) Official Stamp

12.15 FORM D

The Botswana Health Professions Council

Private Bag 0038

Gaborone

DECLARATION BY THE PRECEPTOR ABOUT INTERNSHIP OF A PHARMACIST INTERN

Dear Sir / Madam,

I, the undersigned (full names) _____

of (address) _____

_____

hereby declare that:

I have acted / will be acting as the responsible preceptor for the pharmacist intern,

_____

(Full names of intern / person desiring registration)

during his/her period of practical training at _____

_____

_____

(Insert address of institutions)

The period of practical training (internship) to be undergone / undergone under my supervision by the pharmacist intern referred to in (1) above will commence / commenced on (date) _____ and will terminate / terminated on (date) _____

The internship referred to in (2) above will take / took place in accordance with the requirements of the Botswana Health Professions Council.

I am satisfied in my own professional opinion that the intern, referred to in (1) above, meets with the requirements of the Botswana Health Professions Council for registration as a Pharmacist Intern / Pharmacist.

_____ _____

Signature of commissioner of oaths Signature of preceptor

Official Stamp Date _____

12.16 FORM E

DECLARATION BY A PHARMACIST INTERN DESIRING REGISTRATION AS A PHARMACIST IN TERMS OF THE BOTSWANA HEALTH PROFESSIONS ACT

The Botswana Health Professions Council

Private Bag 0038

Gaborone

I, the undersigned (insert full name) _____

of (address) _____

hereby declare that:

I obtained the following pharmacy degree qualification _____

_____ of (university) _____

in the year _____

The Pharmacy degree was granted to me after examination and entitles me as far as professional qualifications are concerned to practice as a pharmacist in its country of

origin namely_____ and is also

recognised in Botswana _____ (No / Yes) and the following countries

_____

I will have/have completed at least twelve months/_____ weeks /months

training as an intern as prescribed by the Botswana Health Professions Council by the (date)

_____

I have never been convicted of any criminal offence or been barred from professional practice by reason of misconduct and to the best of my knowledge no such proceedings are pending against me in Botswana or any other country.

OR

I wish to bring to the attention of the Registrar of the Botswana Health Professions Council the following information on criminal offences and acts of professional misconduct.

Nature of Offence	Date Committed	Outcome of Proceedings

(NB. All applicants are required to make this declaration and failure to do so automatically disqualifies the applicant)

(Signature of pharmacist intern) (Date)

COMMISSIONER OF OATHS

The above mentioned has made this oath before me at _____

on this day _____ of _____ 20 _____
and

understands the legal implications of this sworn statements.

(Name) (Signature)

Official Stamp

12.17 FORM F

DECLARATION BY A PHARMACIST REGISTERED WITH THE BOTSWANA HEALTH PROFESSIONS COUNCIL TO WHOM THE PHARMACIST INTERN DESIRING REGISTRATION AS A PHARMACIST IS PERSONALY KNOWN

The Botswana Health Professions Council

Private Bag 0038

Gaborone

I, the undersigned (insert full name) _____

of (address) _____

hereby declare that:

I personally know _____

(insert full name of person desiring registration as a pharmacist)

To the best of my knowledge and belief the statements in his/her declaration are true and I consider him / her to be a fit person to be registered as a pharmacist with the Botswana Health Professions Council.

_____ _____

(Signature) (Date)

COMMISSIONER OF OATHS

The above mentioned has made this oath before me at _____

on this day _____ of _____ 20 _____
and understands the contents of this affidavit.

_____ _____

(Name) (Signature)

_____ Official Stamp