

VOLUME 5

SECTION 8

POLICIES AND PROCEDURES OF THE PHARMACY COUNCIL OF JAMAICA

**For the Registration of Pharmaceutical Students,
Pharmacists, Pharmacy Owners and Shops/Pharmacies**

**The Responsibility of
The Pharmacy Council of Jamaica
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CHAPTER I

PHARMACEUTICAL COUNCIL OF JAMAICA

1.0 BACKGROUND

The Pharmacy Council of Jamaica was established in August 1975 as an agency of the Ministry of Health, with responsibility for the regulation of pharmacists, pharmaceutical students, pharmacy owners and authorized sellers of poisons in accordance with The Pharmacy Act and Regulations (1975). The Council maintains the Registers for all these persons and sets standards for pharmacists' education, scopes of practice and conduct.

The council consists of ten members, six of whom are nominated by the Pharmaceutical Society of Jamaica and the remaining four by the Minister of Health. The Minister appoints all 10 persons for a period of three years. The Registrar is the secretary employed to the Council. The Council meets on the last Thursday of each month except the months of August and December.

The Council has an inspectorate which monitors pharmacies to ensure compliance with the Pharmacy Act and Regulations.

1.1 MISSION OF THE PHARMACY COUNCIL

The mission of the Pharmacy Council is to maximize pharmacy's contribution to the protection of the health and welfare of the Jamaican people.

In accordance with the authority united in the Council under the Pharmacy Act and Regulations, the council aims to ensure the maintenance of the highest standards of conduct and practice.

The Council is dedicated to the advancement of Pharmacy and promotes the pursuit of excellence in life-long learning and research. Guided by a spirit of commitment to integrity, honesty and cooperation, the Council will achieve its goals.

1.2 REGISTRATION

The Pharmacy Council of Jamaica registers pharmaceutical students, pharmacists,

pharmacy owners and authorized sellers of Poisons.

1.2.1 Authorized Sellers of Poisons

The following are the requirements for applicants to become authorised sellers of poisons:

- Must be 21 years and older
- Submit two testimonials
- Submit two copies of a recent photograph of the applicant certified by a Justice of the Peace
- Apply to the Council using form set out as Form F (See Appendix 1)

1.2.2 Pharmaceutical Students

The following are the requirements for applicants who wish to become pharmaceutical students:

- Be 16 years and over
- Be accepted in an approved college of Pharmacy
- Apply to the Council using Form A (See Appendix 2)

1.2.3 Pharmacy Owners/Shop

The following are the requirements for persons wishing to establish a pharmacy:

- Be 21 years and over
- Satisfy the Council that the proposed shop meets the requirements to operate as a pharmacy (Retail, Professional, Manufacturing, Distributing)
- Apply to the Council on Form D (Appendix 3)
- Pay the requisite ownership fee of \$15,000.00 (one fee)
Fees for shops vary according to type

1.2.4 Pharmacists

The following are the requirements for new pharmacists to be requested:

New Pharmacists

- Be 21 years and over

- Have successfully completed a course of Study in Pharmacy and passed the final examination to obtain a Bachelor's degree
- Have undergone vocational training
- Apply to the Council on Form B (See Appendix 4)
- Pay the requisite fee of \$2500.00

1.3 RENEWAL OF REGISTRATION OF PHARMACISTS

The requirement for the annual renewal of registration came into effect in April 2003. All registration therefore expires each year on the 31st of March. Registration is renewed if the requisite twelve Continuing Education (CE) credits have been obtained and the pharmacist:

- Applies to the Council in form set out as Form CI (See Appendix)
- Pay the requisite fee of \$2500.00

1.3.1 Reinstatement

For pharmacists who do not remain on the register; reinstatement requirements are as follows:

Number of years off the register	Requirements
1	Satisfy the CE requirements for that year Pay the annual registration fee Pay late registration fee
2- 5	Satisfy CE requirements for that year Pay reinstatement fee that is 75% of annual registration fee Pay regular annual registration fee Undergo assessment on a case by case by case basis
> 5	Assessment done on a case by case basis Sit and pass competency exam Pay reinstatement fee that is 75% of annual registration fee Pay regular annual registration fee

1.4 REGISTRATION OF FOREIGN PHARMACISTS

Foreign trained pharmacists are required to provide the following for registration as a pharmacist in Jamaica:-

- i CERTIFIED COPY OF BIRTH CERTIFICATE
- ii THREE (3) LETTERS OF RECOMMENDATION
- iii CERTIFIED COPY OF CURRENT STATE LICENCE(S)(If applicable)
- iv CERTIFIED COPY OF PHARMACY DEGREE
- v CURRICULUM VITAE
- vi EXAMINATION FEE OF **US\$400.00** OR EQUIVALENT IN JAMAICAN DOLLARS - Payable one (1) month before the date of the exam (non-refundable and subject to change without notice)
- vii TRANSCRIPT (To be sent directly from the University to the Pharmacy Council of Jamaica)

Documents are checked with issuing institutions and embassies before the Council responds. If the application is approved, the candidate is required to sit and pass a Foreign Pharmacists Examination (FPQE). Candidates may have three (3) opportunities at sitting the examination.

1.5 EXAMINATION INFORMATION/INSTRUCTIONS

The following information on Examinations / Instructions is:

1.5.1

The examination is divided into four(4) broad subject areas:

- i **Comprehensive multiple choice/objective type examination** which tests pharmaceutical knowledge base and ability to dispense drug products safely and legally
- ii **Forensic Pharmacy Examination** which tests knowledge of the Jamaican Laws and Regulations.
- iii **Prescriptions filling section** where several prescriptions are given and the candidate should apply all the rules in the proper filling of same.

- iv **Oral Examination** – The candidate is presented with practical, job-related questions to assess his/her understanding and application of important knowledge, skills and abilities used in the proficient practice of pharmacy (**maximum 30 mins**)

1.5.2.

The following additional information should be noted:

- i All sections of the written examination will be completed on the same day.
- ii There is a scheduled break for lunch.
- iii All instructions should be carefully followed and answers clearly stated on the answer sheets.
- iv Answer sheet/booklets should be returned to the examination invigilator promptly at the end of each section.
- v The candidate will be notified of the examination results within eight (8) weeks of the date of the examination.

N/B Failure of the examination will necessitate a re-examination at a future date

- vi The examination is administered twice each year at the scheduled times:
- Last Friday in January
 - Last Friday in July
- vii Candidates should apply to the Council in writing at least one (1) month before the date of the exam.

1.5.3 Orientation Period

It is recommended that candidates be in the country at least six (6) months before the exam and be assigned to a community pharmacy for a specified period of orientation under the supervision of a Registered Pharmacist. The exposure over the period is intended to enable the candidate to become competent in counselling patients and communicating with members of the

health team. Language barriers and cultural norms would also be addressed.

I.6 SPECIAL EXAMINATION INSTRUCTIONS

I.6.1 Multiple Choice Questions

- i The test is divided into five(5) parts and covers the following subject areas:-
 - Pharmaceutical Calculations
 - Medicinal Chemistry
 - Pharmacology
 - General Pharmacy
 - Pharmacy Practice
- ii For multiple choice questions, circle the appropriate answer in the question booklet. For matching questions, write the matching letters beside the appropriate statement.

I.6.2 Forensic

- i Answer the prescribed number of questions.
- ii Unless specifically requested, answer should include more than a listing of items, that is; concepts should be clearly explained or discussed wherever possible.
- iii Begin each answer on a separate page and leave space for assigning grades or for comments.
- iv The forensic component comprises questions on:
 - The Pharmacy Act & Regulations
 - The Dangerous Drug Act & Regulations
 - The Food & Drug Act & Regulations
 - The Precursor Act
 - Various amendments to the Pharmacy Act and Regulations

1.6.3 Prescription Filling

For the examination on prescription filling the candidate should:

- i Dispense prescriptions generically unless otherwise instructed.
- ii Carry out all the prescribed rules for filling prescriptions in the test.
- iii Prepare labels for all items dispensed.

The use of reference texts is allowed for this section of the test.

1.6.4 Oral Examination

For the oral examination the following should be noted:

- i Practical scenarios are raised to test how the candidate's ability to handle similar situations in the practice setting.
- ii Tests the candidates' ability to manage unique situations, such as requests for prescription drugs without prescriptions and other breaches of the act.
- iii Tests the candidate's ability to advise clients on the proper use of medical devices and correct administration of various dosage forms such as eye, ear and nose drops, Metered Dose Inhalers etc.

CHAPTER 2

APPLICATION PROCEDURES FOR SETTING UP SHOPS AS PHARMACIES

2.0 REGISTRATION OF SHOPS AS PHARMACIES

One of the requirements under the Pharmacy Act 1966, for the registration of a shop as a pharmacy, is that the Council must be satisfied that the shop, in which the business of a pharmacy is proposed to be carried out, is suitable for the purpose.

2.1 REGISTRATION PROCEDURES

All persons wishing to establish shops as pharmacies are required to submit the necessary proposals in detail to the Pharmacy Council for acceptance before embarking on any expenditure to prepare the premises for the purpose of a pharmacy. The Pharmacy Council is not obliged to approve every application it receives for the registration of a pharmacy. The application, however, must satisfy the requirements as prescribed in the Regulations / Guidelines before

The council gives particular attention to the name of the proposed pharmacy which should be appropriate and in accordance with the standards related to the practice of the profession e.g. a business name should not give the impression or imply that a pharmacy can offer special feature, commercial or professional, over and above the services offered by another pharmacy.

2.2 ACCEPTANCE OF PROPOSALS

When a proposal is accepted by the Council, a letter is sent to the proposed owner that the shop should be prepared for the purposes of a pharmacy in accordance with the provisions of the Pharmacy Act 1966, its Regulations, and the guidelines. As soon as the premises are prepared, the proposed owner should inform the Council in writing inviting an inspection of the premises. The Council's Inspectors will inspect the prepared premises, and if they are found to be satisfactory, the applicant can then apply to the Council for Registration under the Pharmacy Act.

If the application is approved in accordance with Section 13 (iii) of the Pharmacy Act, the Registrar will then issue a certificate of registration. The owner must apply to the Council on the prescribed form (See Appendix 3 for Form D) for

registration of the shop as a pharmacy and for the Registration of the owner of the business.

2.3 REVIEW OF PHARMACY PROPOSALS BY COUNCIL

The reviews of application proposals for pharmacies by the council takes place in January, April, July, and October each year on the fourth (4th) Thursday of each of these months. The final date for receipt of proposals is 2 weeks before each of these proposal meeting.

2.4 PROCEDURE FOR OPENING A SHOP AS A PHARMACY (RETAIL/PROFESSIONAL)

The following are the requirements and procedures to open a shop as a pharmacy:

2.4.1 Apply in writing to the Pharmacy Council indicating and submitting the following:-

- i Name of Pharmacy
- ii Location and type of Pharmacy (Professional /Retail)
- iii Name and Address of Registered Pharmacist
- iv Opening hours
- v Name(s) of pharmacist(s) who will cover opening hours
- vi Name, address and occupation of each owner/partner/shareholder
(NB: Professional Pharmacy can only be owned by a pharmacist(s) and spouse)
- vii If the shop is situated in a residential area an approval from the KSAC, the Parish, the National Environment and Planning Agency or the Town and Country Planning Authority will be needed
- viii List of items to be stored for sale.

2.4.2 Provide:

- i Birth Certificate and Photograph of each owner/partner/shareholder
- ii Articles of Incorporation if applicable
- iii Police report for all shareholders.
- iv Letter of commitment from a Registered Pharmacist signed in the presence of a Justice of the Peace (J.P.), indicating willingness to be the Registered Pharmacist for not less than one (1) year (This pharmacist should not be currently that is in the process of registering a pharmacy; if however that is the case but he/she intends to resign from that pharmacy, a letter of intent to resign

should be submitted along with the commitment letter.)

2.4.3 Physical Features of the Pharmacies

A physical floor plan and layout of proposed pharmacy should be submitted. (It is advised that professional assistance be sought in the layout of the pharmacy) indicating:-

- i Measurement of entire shop which should not be less than [640sq. ft. (60m²): RETAIL/ 400sq. ft: PROFESSIONAL]
- ii Measurement of the dispensary area. This should not be less than 130sq. ft. (12m²)
- iii Confidential area (to accommodate 2 chairs and a small desk/table) for counselling. **In special circumstances within a retail pharmacy; a private alcove or window is acceptable. (The Confidential Corner should not be considered as an entrance to the dispensing area and should be contiguous with the dispensing area.)**
- iv Waiting area with chairs
- v Display area in dispensary for List 2 products
- vi Sink (potable water)
- vii Narcotic Control Substances Cupboard with lock (if required)
- viii Refrigerator
- ix Work area – including compounding area (counter top) adjoining the sink with potable water.
- x Two distinct entrances are required for the pharmacy area.
- xi Adequate storage area
- xii Antibiotic cupboard

The layout should be such that the establishment is separated from and not be part of another business. Proper partitions should be in place with an independent

entrance if the establishment is associated with a supermarket or other business.

NB:No toilet facility should be in the dispensing area.

2.5 PROCEDURE FOR OPENING A SHOP AS A PHARMACY (WHOLESALE)

The following are the requirements to open a wholesale pharmacy:

2.5.1 Apply in writing to the Pharmacy Council indicating and submitting the following:

- i Name of Pharmacy
- ii Location and type of Pharmacy (**Distributing pharmacies must be in a commercial area**)
- iii Name and Address of Registered Pharmacist
- iv Opening hours
- v Name(s) of pharmacist(s) who will cover opening hours
- vi Name, address and occupation of each owner/partner/shareholder
- vii List of items to be stored for sale.

2.5.2 Provide the following:

- i Birth Certificate and Photograph of each owner/partner/shareholder
- ii Articles of Incorporation if applicable
- iii Police report required for all shareholders.
- iv Letter of commitment from a Registered Pharmacist signed in the presence of a Justice of the Peace (J.P)., indicating willingness to be the Registered Pharmacist for not less than one (1) year (This pharmacist should not be currently that is in the process of registering a pharmacy; if however that is the case but he/she intends to resign from that pharmacy, a letter of intent to resign should be submitted along with the commitment letter.)

2.5.3 Physical Features of the Wholesale Pharmacy

The following must be submitted along with the application for registration:

- i Floor Plan indicating
 - Customer Service
 - Receival and Delivery
 - Storage areas (internal and external products should be stored in separate rooms)
 - Cold Room and/or Refrigerator (for Biologicals/Injectables)
 - Customer Service/Offices
 - Special storage areas for certain for certain items (e.g. Controlled substances, pesticides, Insecticides, anti-corrosives etc.)
 - Bathroom (Should not be in the warehouse area)
 - Sufficient space for the purpose of further expansion of the plant
- ii Incinerator or access to an incinerator for the proper disposal of waste

2.5.4 Post Approval of Plan Requirements

- i After the approval of the Proposals are obtained, the facility should be prepared in accordance with the approved plan ensuring that the following are in place before inspection:
 - Lights must be flush with the ceiling – material must be easily cleanable
 - Cupboards must laminated
 - Benches and tables must be made of material that can be easily cleaned and scrubbed
 - Pallets and shelves for the storage of goods
 - All shelves (sides, under, top, bottom) must be laminated – for easy cleaning
 - Stainless Steel Sinks

- Corners should be curved/coved to facilitate cleaning
- Floor, walls and ceiling of smooth, hard surfaces that are easily cleanable, preferable rendered concrete (Epoxy Surface) – no dry wall
- Temperature and humidity Controls
- All outside openings protected against entrance of insects, dust and airborne contamination

GENERAL MANUFACTURING PRACTICE (G.M.P) INSPECTION MUST BE DONE BY THE PHARMACEUTICAL SERVICES DIVISION, MINISTRY OF HEALTH, AND APPROVED AFTER THE PLAN HAS BEEN APPROVED BY THE PHARMACY COUNCIL AND BEFORE INSPECTION FOR REGISTRATION

2.6 PROCEDURE FOR OPENING A SHOP AS A PHARMACY (MANUFACTURING)

The following are the procedures for opening a shop as a pharmacy (manufacturing):

2.6.1 Apply in writing to the Pharmacy Council indicating and submitting the following:

- i Name of Pharmacy
- ii Location and type of Pharmacy (Manufacturing)
- iii Name and Address of Registered Pharmacist(s)
- iv Opening hours
- v Name(s) of pharmacist(s) who will cover opening hours
- vi Name, address and occupation of each owner/partner/shareholder
- vii If situated in a residential area an approval from the Town Planning Department of NEPA will be needed
- viii List of items to be stored for sale.

2.6.2 Provide the following:

- i Birth Certificate and Photograph of each owner/partner/shareholder
- ii Articles of Incorporation if applicable

- iii Police report required for all shareholders.
- iv Letter of commitment from a Registered Pharmacist signed in the presence of a Justice of the Peace (J.P)., indicating willingness to be Registered Pharmacist for not less than one (1) year. (This pharmacist should not be currently that is in the process of registering a pharmacy; if however that is the case but he/she intends to resign from that pharmacy, a letter of intent to resign should be submitted along with the commitment letter.)

2.6.3 Physical Features

The Application Proposal should include:

- i Floor plan outlining:
 - Specific areas for the manufacturing of different products that allow for proper separation across product lines
 - Storage areas (internal and external product ingredients should be stored in separate rooms)
 - Cold Room and/or Refrigerator (for Biologicals/Injectables)
 - Packaging areas
 - Receival/Delivery area
 - Customer Service/Offices (separate from general Manufacturing area)
 - Sufficient space for the purpose of further expansion of the plant
 - Special storage areas for certain items e.g. Controlled substances
 - Bathrooms (which should not be in the manufacturing area)
 - Sink

2.6.4 Technical Features

The application should also include the following:

- i An outline of systems indicating:
 - Temperature and humidity controls (Air Condition)
 - Air supply which can be filtered through high-efficiency particulate air filters under positive pressure regardless of whether flow is laminar or non-laminar
 - Monitoring of environmental conditions
 - Proper Air Handling Methods
 - Provision for proper storage of waste
 - Cleaning and disinfecting of rooms and equipment to produce aseptic conditions
- ii Waste disposal
 - Appropriate methods for proper waste disposal including an incinerator or access to an incinerator.

2.6.5 Approval of Plan Requirements

After the approval of Proposals has been obtained the facility should be prepared in accordance with the approved plan ensuring that the following are in place before inspection:

- Lights must be flush with the ceiling – material must be easily cleanable
- Cupboards must be laminated
- Benches and tables must be made of material that can be easily cleaned and scrubbed
- Pallets and shelves for the storage of goods

- All shelves (sides, under, top, bottom) must be laminated – for easy cleaning
- Stainless Steel Sinks
- Corners should be curved/coved to facilitate cleaning
- All outside openings are protected against entrance of insects, dust and airborne contamination
- Floor, walls and ceiling of smooth, hard surfaces that are easily cleanable, preferable rendered concrete (Epoxy Surface) – dry walls are not allowed.

GENERAL MANUFACTURING PRACTICE (G.M.P) INSPECTION MUST BE DONE BY THE PHARMACEUTICAL SERVICES DIVISION, MINISTRY OF HEALTH AND APPROVED, AFTER THE PLAN HAS BEEN APPROVED BY THE PHARMACY COUNCIL AND BEFORE INSPECTION FOR REGISTRATION

CHAPTER 3

CHANGE OF OWNERSHIP OF A PHARMACY/ RELOCATION OF A PHARMACY

3.0

The Pharmacy Council maintains registers for pharmacies and owners of pharmacies. The operation, relocation or acquisition of a pharmacy therefore shall be with the Council's prior approval. The provisions of paragraph (c) of subsection (5) of Section 13 of the Pharmacy Act states that, the registration of every shop as a pharmacy shall become void on the expiration of one month from the date of any change in the ownership of the business carried on in such pharmacy. The Council is not obliged to approve every application it receives for the registration of a pharmacy and other individual (s) as owners(s) of the said pharmacy therefore it is of paramount importance that the action as stated below take place prior to any transactions.

3.1 SELLING A PHARMACY

Every owner of a pharmacy who proposes to sell his business shall:

- i inform the Council of this intention at least **THREE MONTHS** before the sale is concluded
- ii inform the Council as to the name, address and occupation of the proposed purchaser of the business.

3.2 BUYING OR RELOCATING A PHARMACY

Every person who proposes to acquire an existing pharmacy shall file with the Registrar of the Council, at least **THIRTY (30) DAYS** before he/she acquires or relocates the pharmacy, a signed statement setting out:

- i The full name and address of the proposed owner of the pharmacy
- ii The name by which the pharmacy will be known to the public
- iii The location of the pharmacy
- iv The proposed date of acquiring or relocating the pharmacy and the the proposed date for commencing the operation of the pharmacy
- v The name and address of the proposed manager of the pharmacy
- vi The name and address of the registered pharmacist who will be in control of the drugs in the pharmacy

3.3 CHANGE OF OWNERSHIP

The Council must be advised of any changes to the registered ownership of the business (sole-trader to partnership).

3.4 RELOCATION OF PHARMACY

Any relocation of an existing establishment is required to have the new proposal and the floor plan approved by the Council **BEFORE** the move is made.

The Council is NOT obliged to approve any application for the transfer of registration, ownership or location of the business

CHAPTER 4

GUIDELINES FOR THE ESTABLISHMENT AND MAINTENANCE OF SHOPS AS PHARMACIES

4.0 REGISTRATION OF A SHOP AS A PHARMACY

The Pharmacy Act 1966 requires for the registration of a shop as a pharmacy that the Council must be satisfied that the shop in which the business of a pharmacy is proposed to be carried on is suitable for the purpose.

Upon the acceptance of the proposal for a shop to be set up as a pharmacy, the shop should be prepared for the purposes of a pharmacy in accordance with the provisions of the Pharmacy Act 1966 and its Regulations. The following guidelines are set out below.

4.1 SETTING UP

In order to satisfy the Council that the required preparations have been made for the shop to be set up as a pharmacy; every such shop shall be so constructed that:

- i It contains an enclosed dispensing area which can be locked in a defined area having a floor area adequate for the efficient operation of the pharmacy but not less than 130 square feet; (12 square meters)
- ii It is free from any condition that may:
 - Be dangerous to health,
 - Injurious affect the drugs prepared, compounded dispensed or stored therein,
- iii Floors and floor coverings (double glazed tile) that is of material that may be easily cleaned in rooms where:
 - Drugs are prepared, compounded, dispensed or stored
 - Equipment is washed
 - Washing fixtures and toilet fixtures are located,
- iv The walls and ceiling of rooms and passage-way may be readily cleaned and painting or decorating maintained in good condition.

- v All rooms and passage-ways are well lighted and ventilated.
- vi Suitable areas are provided for the storage and controlled sale of drugs by the pharmacist or under his/her supervision.

4.2 OTHER REQUIREMENTS

The shop shall also be provided with:

- i A supply of potable water for the sufficient operation of the pharmacy,
- ii A hot plate or other heating device to provide heat process and hot water when necessary,
- iii facilities for washing utensils used in the preparation or storage of drugs, and also hand washing facilities, preferable separate, located in a convenient area in the shop,
- iv A system for filing prescriptions
- v A prescription counter (laminated) adequate for the efficient operation of the pharmacist with not less than 12 sq ft (1 square metre) of free working space
- vi A refrigerator for the storage of drugs requiring refrigeration, *
- vii Sufficient containers for storing refuse in a sanitary manner,
- viii Laminated dispensing counter or cubicle for handing in/handing out prescriptions
- ix Laminated shelves in the pharmacy,
- x Antibiotic cupboard with lock, (if applicable)
- xi Cupboard for narcotics and controlled substances with lock, (if applicable)

- xii The compounding and dispensing equipment and materials set out below:
- One prescription balance *
 - One set metric weights
 - Graduated measure glasses, (mls/various sizes) (at least three) *
 - Mortars & Pestle (various sizes) (at least one set)*
 - Spatulas (stainless steel) small, medium, and large
 - Funnels (glass or plastic)
 - Ointment Tile (glass or plastic not less than 0.5 cm square)*
 - Stirring Rods (glass or plastic)
 - Tablets Counters
 - Bottles and Caps
 - Tablets Vials (glass or plastic)
 - Labels
 - Filter Papers
 - Ointment Jars
 - Distilled or de-ionized water
 - Dropper Bottles

4.3 LIBRARY FOR THE PHARMACY

The shop / pharmacy is required to have a library which must include:-

- i Current Edition Martindale *
- ii Pharmacy Act and Regulations *
- iii Food and Drug Act and Regulations *
- iv Dangerous Drug and Regulations*
- v The Precursor Chemical Act
- vi Code of Ethics

4.4 MAINTENANCE

All drugs stored in a pharmacy shall be stored on, or in shelves, drawers, cupboards of fixtures provided for that purpose.

4.4.1 Pharmacy Equipment and condition

Every pharmacy shall maintain:-

- i Furniture, equipment and appliance used in the interior of the pharmacy so that thorough cleaning of all areas is possible

(laminated shelves).

- ii In a clean and sanitary condition,
 - all furniture, equipment and appliances, and,
 - All rooms in the pharmacy used for the storage, compounding or dispensing of drugs or not
- iii The painting and decorating of the interior and exterior of the pharmacy in good condition.

4.5 STORAGE

Every room where drugs are prepared, compounded, dispensed or stored in a pharmacy shall be kept free from materials and equipment not regularly used in the room.

4.5.1 Refrigerators

Refrigerators for the storage of drugs in a pharmacy shall:

- i Be maintained at a temperature between 1.3 Celsius, 4.5 Celsius or 34 Fah and 40 Fah,
- ii Be kept clean and in sanitary condition, and,
- iii Be located in an area not accessible to Public

4.6 DISPOSAL OF WASTE

All refuse and waste materials in a pharmacy:-

- i Shall be removed from the premises at least twice weekly and more often if necessary to maintain a sanitary condition and,
- ii Filled containers of waste shall be removed from any room in which drugs are prepared, compounded, dispensed or stored.

4.7 PHYSICAL REQUIREMENTS

The following are the physical requirements of a pharmacy:

- i It must be established in a COMMERCIAL area
- ii The measurement of the total area of a pharmacy must not be less than 650 square feet

- iii A confidential Area *
- iv A waiting Area with chairs
- v A generic sign to be displayed as required by Law *

When all of the above requirements have been put in place, the owner may then apply to the council on the prescribed form for registration of the shop as a pharmacy. (A sample form is at Appendix 3)

THE ABOVE STATED ITEMS MUST BE IN PLACE PRIOR TO ALL INSPECTIONS WHETHER FOR NEW OR ESTABLISHED PHARMACIES FOR REGISTRATION PURPOSES

4.8 REDESIGN & REFURBISHING OF A PHARMACY

Every owner of a pharmaceutical establishment who wishes to redesign or refurbish such establishment must submit to the Council, a floor plan and layout showing the proposed changes to be made. The new design must be approved by the Council before implementation. This will be treated as a new proposal which will attract the necessary fees.

CHAPTER 5

CODES OF CONDUCT

5.0 PHARMACY PROFESSION

The practice of the Pharmacy Profession operates within the ambit of the prescribed Regulations. The Council monitors and enforces compliance with these Regulations in order to safeguard the public's interest and to maintain the integrity of the profession. For further information please refer to the relevant provisions under the Pharmacy Act.

5.1 REGISTERED PHARMACISTS

The Registered Pharmacist is expected to:

- i Conform to the required standards of practice
- ii Control all activities relating to the delivery of the pharmaceutical service.
- iii Observe the standard dress code while on the job.
- iv Observe all the provisions of the Pharmacy Act.
- v Comply with the Code of Ethics.
- vi Must display his/her certificate of registration while on duty at a conspicuous place

5.2 DISPENSING OF PRESCRIPTIONS

Pharmacists are required to observe the requirements of the Pharmacy Act Regulations as they relate to the dispensing of prescriptions, such as:

- i Ascertaining the bona fide of the prescriber.
- ii Signing and dating of prescriptions.
- iii Appropriate documentation on prescriptions, etc.
- iv Retention of the prescriptions for the prescribed period of two (2) years.

5.3 LETTER OF COMMITMENT

Pharmacists who have given a letter of commitment have the following responsibilities:

- i To ensure that the pharmacy is laid out in accordance with the approved floor plan.
- ii To indicate to the Council any deviation with the approved plan promptly, and withdraw the commitment if the owner persists.
- iii To ensure that the non-pharmaceutical items also sold in pharmacies are compatible with the pharmaceutical items. In particular, the following items are prohibited from being sold in the pharmacy:
 - Meats,
 - Fruits,
 - Vegetables
 - Cheeses
 - Alcoholic beverages
 - Tobacco
 - Grocery items
 - Yogurt
 - Ground provisions

Failure to comply may result in disciplinary action being taken by the Council

5.4 OWNERS OF PHARMACIES

The Pharmacy Owner is required to:

- 5.4.1 Ensure that the dispensary is locked and that no Lists #4 or List #2 drugs are dispensed or sold in the absence of the pharmacist.
- 5.4.2 Comply with the professional decisions of the pharmacist as it relates to:
 - i Dispensing of prescriptions
 - ii Recommending of Lists # 1 and #2 drugs and appropriate patient counselling.
- 5.4.3 Ensure that pharmacists who are within their employment are registered

with the Pharmacy Council of Jamaica.

- 5.4.4** Ensure that good conduct and decorum are observed by all members of staff in their employment.
- 5.4.5** Cooperate with the pharmacist to ensure that all relevant reference materials and equipment are in place.
- 5.4.6** Cooperate with the pharmacist to ensure that all other stipulated requirements are met.
- 5.4.7** Ensure that Lists # 4 and #2 drugs are stored in the dispensary and sold under the supervision of a registered pharmacist.
- 5.4.8** Ensure that the dispensing area is properly supervised in accordance with the Pharmacy Act and Regulations.
- 5.4.9** Ensure that the pharmacy is operated as a separate and independent entity from any other commercial activity.
- 5.4.10** Comply with all other relevant requirements of the Pharmacy Act.

Failure to comply with the above constitutes a breach by the owner that is punishable by prosecution and the loss of the licence to operate a pharmacy.

5.5 PHARMACY INTERNS, PHARMACEUTICAL STUDENTS AND PHARMACY TECHNICIANS

Pharmacy Interns, Pharmaceutical Students and Pharmacy Technicians must operate under the control of a registered pharmacist

CHAPTER 6

CONTINUING EDUCATION AND CLASSIFICATION OF DRUGS

6.0 SUB-COMMITTEES

There are four sub-committees of the Pharmacy Council of Jamaica. These are:

- i Education Committee
- ii Finance Committee
- iii List Committee
- iv Standards

6.1 CONTINUING EDUCATION

The Education Committee sits on the second Tuesday in each month. Its has responsibility for:

- i Continuing Education Accreditation
- ii Monitoring of Internship programme

6.1.1 Continuing Education (CE) Accreditation

Providers of Continuing Education are required to:

- i Apply to the Council on the requisite form one month in prior to the Continuing Education (CE) (see Appendix)
- ii Pay the requisite fee(s) as follows:
 - One hour presentation - \$2500.00
 - Weekday/Weekend 1 day presentation - \$3500.00
 - Weekend presentation - \$ 6500.00
 - One Week presentations - \$20,000.00

6.2 CLASSIFICATION OF DRUGS

The classification of drugs in Jamaica falls into four categories. These are:

- i List 1— Can be sold in any shop
- ii List 2—Sold in pharmacies only (This requires the intervention of

- the pharmacist)
- iii List 3—Poisons
- iv List 4—Prescription only medicines

The List Committee meets the fourth Monday of every other month and is responsible for the classification of List 1 and 2 products as well as the re-classification of List 4 drugs.

6.3 PROCEDURES FOR CLASSIFICATION OF DRUGS

The registration of drugs is done by the Pharmaceutical Regulatory Division of the Ministry of Health in accordance with The Food & Drug Act and Regulation (1975). The Division having registered the drugs would then submit to the Council the products, which they consider should not be given List 3 or 4 status for them to be classified as List 1 or 2.

6.4 RE-CLASSIFICATION OF DRUGS

Companies requiring re-classification of products from List 4 to List 1 or 2 should direct the registered pharmacists within their employ to apply in writing to the List Committee, Pharmacy Council indicating so and submitting the following:

- i Evidence for re-classification such as Post-Marketing Surveillance results or any other studies deemed to be relevant to the application.
- ii Labeling changes in accordance with section 21 subsection (1) which states:

Any person who dispenses, compounds, retails or supplies any drug other than in accordance with the prescription of a registered medical practitioner, registered dentist or registered veterinary surgeon or veterinary practitioner shall deliver such drug in a container labeled with-

- The name of the drug
 - Adequate direction for use
 - words of caution respecting the drug, if necessary
- iii Itinerary for training of pharmacists (pending approval)

6.5 APPROVAL

Applications which are approved by the Council for re-classification will be sent to the Minister for endorsement. **The Minister is not obliged to endorse every approved application from the Council.** On endorsement of the product, the Council will respond in writing to the Company's pharmacist and approval given for marketing the product in its new status.

NB. Marketing of products, by any means, as List 1 or 2 should not be done prior to receiving the written statement from the Council that such can be done. All new classifications of pharmaceutical products must be gazetted, by law, before they can be put on the market for sale to public.

CONTACT INFORMATION

For further information please contact:

The Pharmacy Council of Jamaica
3rd Floor ICWI Building
2 St. Lucia Avenue
Kingston 5

Tel: (876) 926-2637/926-4353

Fax: (876) 926-6935

Email pharmacycouncil@cwjamaica.com

Appendix I

**FORM F
THE PHARMACY ACT
[REGULATION 15 (1)]**

APPLICATION FOR REGISTRATION AS AN AUTHORISED SELLER OF POISONS

**NAME AND ADDRESS OF
BUSINESS.....**

**NAME AND ADDRESS OF
APPLICANT.....
.....
.....
.....**

**DATE OF BIRTH OF
APPLICANT.....**

I **HEREBY APPLY FOR
REGISTRATION AS AN AUTHORISED SELLER OF POISONS PURSUANT TO
SECTION 15 OF THE PHARMACY REGULATIONS 1975 AND ENCLOSE:**

- (1) A FEE OF \$1000.00
- (2) A CERTIFIED COPY OF BIRTH CERTIFICATE
- (3) TWO RECENT PHOTOGRAPHS DULY CERTIFIED
- (4) TWO TESTIMONIALS

DATED THISDAY OF.....20.....

.....
SIGNATURE OF APPLICANT

.....
DATE

P.S. ITEM (1) AND (3) MUST BE SUBMITTED YEARLY

Appendix 2

THE PHARMACY ACT, 1966
(Act 5 of 1966)

Regulations 3(1)

Application for registration as a Pharmaceutical Student

To the Pharmacy Council

Name of applicant.....
(In block letters)

Address of applicant.....
(In block letters)

Telephone Number Date of application.....

Age of application.....
(Photostat/certified copy of Birth Certificates should be attached)

Qualification of applicant.....
.....
.....
(Photostat/certified copies of qualifications should be attached)

Testimonials (3 to be attached)

Name of Parent/Guardian (if under 21).....
(In Block Letters)

Address of Parent/Guardian
.....

.....
Signature of applicant

To be completed by the approved college at which applicant has been admitted as pharmaceutical student

Date of admission.....

Recommendation.....
.....
.....

.....
Principal or Head of Faculty

To be completed by Registrar,
Date approved/Refused by the Council.....

Date registered, if registered.....

Reason for refusal, if refused.....

.....
Signature of Registrar

Appendix 3

THE PHARMACY ACT, 1966

(ACT, 5 OF 1966)

[Regulation 5 (1)]

APPLICATION OF REGISTRATION OF A SHOP AS A PHARMACY AND FOR THE REGISTRATION OF THE OWNER OF THE BUSINESS

TO THE PHARMACY COUNCIL:

BUSINESS NAME OF SHOP – TYPE OF PHARMACY.....

ADDRESS OF SHOP.....

NAME OF OWNER OF SHOP.....

ADDRESS OF OWNER OF SHOP.....

NAME AND ADDRESS OF REGISTERED PHARMACIST

HAVING CONTROL OF THE SHOP.....

Ihereby apply

(Name of Applicant)

For registration of the above shop as a pharmacy and for registration of myself as the owner of the business in which the pharmacy is carried on and enclose –

- i. A fee of \$.....
- ii. A certified copy of birth certificate.
- iii. Two recent photographs of myself certified by a certified J.P.

Dated this..... day of 20.....

.....

Signature of Applicant

PS. If the business is operated by a **Company** or **Partnership**, please list the **Name** and **Address** of every **Shareholder** or **Officer** of that **Company** or of every **Partner**

NAME(S)

ADDRESS (ES)

Appendix 4

**THE PHARMACY ACT, 1966
(ACT 5 OF 1966)**

APPLICATION FOR REGISTRATION AS A PHARMACIST

To the Pharmacy Council,

NAME OF APPLICANT.....
(IN BLOCK LETTERS)

AGE OF APPLICANT.....
(Photostat of certified copies of Birth Certificate should be attached)

DATE OF APPLICATION..... **TELEPHONE NO.**

ADDRESS.....

EMAIL.....

QUALIFICATION OF APPLICANT.....
.....
.....

(Photostat of certified copies of Qualifications should be attached)

Three testimonials to be attached (Two from registered pharmacists and one other)

Registration fee of \$2500.00

Two (2) Passport size photographs (certified to be true copies by a Justice of the Peace)

.....

Signature of applicant

To be completed by the Registrar

DATE REGISTERED/REFUSED.....

REGISTRATION NO......

Date and No. of Gazette Notice in which registration published

.....

REASON FOR REFUSAL, IF

REFUSED.....

.....

.....

Signature of Registrar

Appendix 5

ANNUAL REGISTRATION OF PHARMACISTS

Print or type clearly the information as is now shown on your licence

Surname..... **EMPLOYMENT RECORD**
 Maiden Name (if applicable)..... Present Employer.....
 Present Employer..... Address.....
 Christian Name(s)..... Phone/Fax.....

Gender: Male - Female - Email.....

Fax..... **YEARS OF EXPERIENCE**
 Date of Birth..... 0-2 - 3-5 6-10
 Registration No. 11-15 16-20 21-25
 Date of Registration..... 26-30 > 31

Employment Status Full-time Part-time Unemployed

Status: Single Married

Home Address.....
 Telephone.....
 Email.....

ANY OTHER INFORMATION

.....

QUALIFICATIONS

PharmD MSc
 BSc/Bpharm Dip Pharm
 Ass. Degree Other (please specify)

No. of Credits.....
 (Include documentary Proof)

declare that the information provided herein is a truthful and complete statement of the information required.

Signature..... For official use only
 Date..... Fee.....
 Registration Fee \$2500.00 Date received.....
 Receipt No.....
 Signature