



## Pharmacy Council

# PHARMACY BUSINESS APPLICATION GUIDELINES/FORMS

## 1.0 INTRODUCTION

The Pharmacy Council issues two types of pharmacy licences. They are **Wholesale** and **Retail Licences**.

The Council registers five (5) kinds of Pharmacies in Ghana, namely

- a) **Retail Pharmacies**
- b) **Wholesale Pharmacies**
- c) **Retail and Wholesale Pharmacies**
- d) **Pharmacies within hospitals, clinics, and any other facility that requires a pharmacy.**
- e) **Manufacturing Wholesale Pharmacies (a different application form and guidelines has been designed for this kind of Pharmacy).**

Pharmacies are permitted to supply all classes of medicines, that is:

- **Class A – being prescription only medicines (POM);**
- **Class B – being Pharmacist’s list of medicines (P) i.e. medicines that may be dispensed by a pharmacist without a prescription.**
- **Class C – being over-the-counter (OTC) preparations.**

All pharmacies should be supervised by registered Pharmacists in good standing with the Pharmacy Council.

It shall be the responsibility of the prospective applicant to employ the services of a pharmacist(s) where applicable.

The proposed location/premises should conform to the guidelines on regulation of distribution of pharmacies in the country.

## **2.0 APPLICATION**

A body corporate that has employed a pharmacist or a pharmacist or any other medical treatment centre that has engaged a pharmacist shall apply to the Pharmacy Council to establish a Pharmacy. Such applications should specify the proposed location.

Any body corporate (registered company) applying to establish a Pharmacy should have it so indicated in its Registrar General's documents. The name should not bear semblance to an existing one and should reflect the professional nature of pharmacy.

### **2.1a PROCESSING**

All pharmacy applications shall be made through the offices of the Pharmacy Council. Upon receipt of the application an authorised officer of the Pharmacy Council shall inspect the proposed site for the pharmacy.

- ***The Pharmacy Council shall not be under any obligation to approve an application because of financial commitments made by the applicant before approval.***
- ***Approval granted by the Council is valid for a specified period of time. Note that Approval of an application does not constitute authorization to commence business until all conditions and requirements for the issuance of Licence are fulfilled.***
- ***The Council reserves the right to consider other applications for the same area after the period specified in the approval has elapsed.***

**2.1b** Application to operate a pharmacy is made by duly completing and submitting the prescribed application forms. (**PA-I, PA-II** and **PA-III** form).

1. Prospective applicant may obtain application forms from any of the Pharmacy Council offices.

2. Applicant shall then complete the forms appropriately and submit them (together with all relevant documents including documents from the Registrar-General's) to the Pharmacy Council office responsible for the area the applicant intends to operate. An application fee determined by the council is paid at the point of submission.
3. A site inspection will be done by officers of the regional offices of the Pharmacy Council after which a recommendation will be made to the Council.
4. If the application is approved by the Pharmacy Council the applicant shall be duly notified in writing and allowed six (6) months to prepare the premises for a final premises inspection.
5. The final inspection report is submitted to the Registrar and if the premises conforms to specifications and other conditions stated in Section 3.0 of this document, the applicant shall pay the prescribed registration fee for the issue of the licence. A Pharmacy Council certificate shall be issued for the commencement of the business.
6. The certificate issued in respect of the pharmacy shall include ***the name and registration number of the Superintendent Pharmacist***.

## **2.2 INTERVIEW**

The superintendent pharmacist may be invited for an interview on submission of the application and where applicable, together with the proprietor, directors and/or partners or an authorised representative of the company.

## **3.0 PRE-APPROVAL REQUIREMENTS FOR A PROSPECTIVE PHARMACY**

The following are minimum requirements for any prospective pharmacy.

### **A. Documentation/Documents**

A1. Completely filled prescribed application form:

A2. Registrar General's Documents:

- i. Certificate of Incorporation
- ii. Certificate to Commence Business
- iii. Companies code

Object of Business must include Pharmacy Business.

## **B. Pharmacist**

Proposed Superintendent Pharmacist must have done at least 12 months of post – registration practice in Ghana and must be employed full time for this proposed pharmacy.

## **C. Location**

1. The structure shall be geographically and structurally permanent and the proposed Pharmacy shall be accessible to all clients
2. A washroom must be provided within the structure or within adjoining parts of the structure.

### ***C1. Retail Pharmacy***

1. The distance between the proposed site and other retail facilities shall be guided by accessibility to the facilities, population and distance criteria (400m radius).
2. The size of the proposed premises shall be at **least 36sqm and ceiling height of at least 3.2m**

### ***C2. Wholesale Pharmacy***

1. The size of the proposed premises shall be at **least 36sqm with ceiling height of at least 3.2m.**

### ***C3. Wholesale/Retail***

1. Not allowed in metropolitan areas.
2. The size of the proposed premises shall be at **least 48sqm.**
3. For this type of pharmacy, it is important that the physical arrangements within the premises be made in such a manner that the wholesale business does not interfere with the retail business.

#### ***C4. Wholesale Manufacturing***

A different guideline has been designed for Wholesale manufacturing.

***Irrespective of the above guide, the council may apply any other prevailing policy on the regulation of the distribution of Pharmacies in deciding on an application.***

### **3.1 POST APPROVAL REQUIREMENTS**

- i) Adequate ventilation and lighting shall be provided.
- ii) Well painted/polished shelves, counters and walls with washable floor.
- iii) Appropriate storage facilities for all products available.
- iv) A well-written signboard bearing the Pharmacy's name. **(To be displayed after final approval).**
- v) Toilet facilities are required.
- vi) Relevant equipment and reference books shall be made available.
- vii) A valid written contract agreement between the Superintendent Pharmacist and employer shall be required where applicable.

**In addition to the general requirements above, the following requirements shall be met depending on the type of business:**

#### **A. *Retail Pharmacy***

A minimum floor space of 36sq meters and a ceiling height of 3.2m. This floor space shall include the

- i) Main customer area,
- ii) Dispensary,
- iii) Office
- iv) A counselling area.

**Potable water, a sink and a working surface for extemporaneous preparations should be provided.**

**Any other conditions specified in the approval letter.**

## ***B. Wholesale Pharmacy***

1. A minimum floor space of 36 sq meters and a height of 3.2m.
2. A minimum of **four (4)** rooms comprising a reception, a storeroom, an office and cashier's/accounts room.
3. The reception should have waiting chairs for clients as well as a showcase with **samples** of the medicines on sale. There should be **no** external shelves in the reception area.
4. The storeroom must be well ventilated and shelves and/or pallets must be provided.
5. Signboard should state the name and address of the facility and also the inscription - "**Wholesale only**" conspicuously written.
6. Pharmacy Council list of Retailers and Food & Drugs Board list of manufacturers, registered medicines and guidelines on drug advertisements should be available.
7. In addition to the above the business of wholesaling should comply strictly with the prescribed standards of good wholesale practices. (**See appendix A**)
- 8. Any other conditions specified in the approval letter.**

## ***C. Wholesale/Retail***

1. Not allowed in metropolitan areas.
2. For this type of pharmacy, it is important that the physical arrangements within the premises be made in such a manner that the wholesale business does not interfere with the retail business.
3. The post approval conditions for wholesale pharmacies and Retail pharmacies as stated above shall apply to wholesale/Retail Pharmacy.

#### **4. Any other conditions specified in the approval letter.**

#### **4.0 RENEWAL OF LICENCE**

The Pharmacy certificate of registration shall be renewed every year and this shall be made before 31<sup>st</sup> January of the ensuing year. The superintendent pharmacist shall complete the pharmacy renewal form of the Pharmacy Council every year. This shall serve as renewal of his/her commitment as a superintendent Pharmacist in the business.

The renewal form shall be accompanied by a current written contract agreement between the superintendent pharmacist and the employer where applicable.

#### ***Suspension of Pharmacy Business***

Any pharmacy that suspends business shall accordingly notify the Council giving a set time frame when premises shall be closed to the general public **but such period shall not exceed two years.**

#### ***Change of Ownership***

There is a new application form for this purpose.

Where a change occurs in ownership of a pharmacy, the Pharmacy Council shall be notified by the new owner indicating the new share holding position, and directors or owner if it is a sole proprietorship. This notification shall be supported with the following documents:

- 1. Deed of transfer.**
- 2. Registrar Generals Documents**

## 5.0 REGULATORY REQUIREMENTS

All pharmaceutical businesses are required to strictly comply with all regulations and conditions governing the business.

Some of the offences that shall attract regulatory sanctions after due investigation includes:

- i) Continuous absence of pharmacists from the premises when the pharmacy is open to the public.
- ii) Display and supply of expired, unregistered, fake and substandard medicines.
- iii) Supply of medicines from unregistered premises.
- iv) Improper record keeping on procurement and supply of restricted drugs or pharmaceuticals.
- v) Operating under insanitary conditions.
- vi) Non renewal of pharmacy licence
- vii) Any unethical/unprofessional practices as specified by Pharmacy Council
- viii) Any act of commission or omission specified by the Pharmacy Council as constituting breach of standards.

## 6.0 ROLES AND RESPONSIBILITIES OF THE SUPERINTENDENT PHARMACIST

The pharmacist is enjoined by law and by professional standards to show a high sense of responsibility in the discharge of his duties.

A pharmacist must be free to exercise his professional judgement when carrying out his duties as a pharmacist and his employer must recognise he has such professional responsibility. Thus a pharmacist should **not** agree to practise under any conditions of service, which may prevent his **professional independence or** impose such conditions on other pharmacists.



The pharmacist shall be responsible for the management of the pharmacy so far as it concerns the keeping, preparing, dispensing and supply of medicinal products.

Among the responsibilities of the Superintendent Pharmacist shall be:

1. Active involvement in the selection of medicines for purchasing and the supply of medication to patients, customers as well as other healthcare providers.
2. To ensure that records are duly and properly kept.
3. To prepare or supervise the preparation of extemporaneous preparations.
4. To update himself and other staff of the pharmacy on new trends in the management of diseases and on other professional issues.
5. To ensure that shelves and stocks are rid of deteriorated, expired, banned, fake and substandard medicines.
6. To ensure clean, decent and attractive professional environment.
7. To uphold moral and professional conduct that will not bring the profession of Pharmacy into disrepute.
8. To ensure that the premises is duly registered and staff have adequate training in providing the required services.
9. Subject to the provisions of Section 40 of Act 489, 1994, to supply class A medicines only on prescription and ensure that class B medicines are only supplied to persons reasonably believed to be responsible.

A pharmacist should ensure that the service he provides is efficient and meets the needs of the community he serves.

He/she should respect and ensure that regulations concerning advertisement of medicines and professional services are adhered to. He/she shall avoid discussing

the therapeutic efficacy of prescriptions with patients or others in a manner as to impair confidence in the prescriber.

**Once business commences, the name of the Pharmacist on duty together with the certificate of registration of the premises must be conspicuously displayed in the facility during business hours.**

***The Pharmacy Council reserves the right to amend these guidelines without any prior notice.***

## ***APPENDIX A***

# **STANDARDS FOR GOOD WHOLESALE PRACTICE**

## ***WHOLESALE PHARMACY:***

A Wholesale Pharmacy is a pharmaceutical business registered in accordance with Section 30 of the Pharmacy Act 1994, Act 489.

Any Pharmaceutical Company that engages in wholesale supply of medicine shall

1. Be duly registered with the Pharmacy Council and hold a valid wholesale licence for that premises from which the business is conducted.
2. A pharmacist shall supervise the supply of restricted drugs
3. Medicines shall be supplied to **only authorised person(s)** without prejudice to Section 30 of Act 489. Class A or B medicines shall be supplied on signed orders issued by an authorised person.
4. The supply of medicines shall be by **wholesale only**
5. Only medicines registered by the Food and Drugs Board shall be supplied.
6. Appropriate records and documentation shall cover every transaction covering pharmaceuticals.
7. Supply of all pharmaceuticals shall be made from the registered premises only

8. Direct supply of pharmaceuticals shall not be made from vehicles, except deliveries made on appropriately signed orders.
9. Pharmaceutical Wholesalers shall have available at all times all necessary information on pharmaceutical products they supply.

## **STORAGE AND DISTRIBUTION**

The receiving and despatch areas of drug consignments shall be properly designed without causing undue inconvenience to customers taking into account the safety of the public and the workers.

1. Wholesalers must carry a comprehensive stock of those items for which there is a demand; also sufficient depth of stock to ensure continuity of supply to the customer from shelf stock.
2. The wholesaler is to hold a current Wholesalers Licence issued by the Pharmacy Council.
3. Key personnel involved in the wholesaling of pharmaceutical products should be suitably trained to ensure that the products are properly handled.
4. Stocks shall be received in a separate area, and inspected for correctness against order. There shall be a system for the recognition and prompt handling of narcotic and psychotropic drugs.
5. All products shall be stored under acceptable condition which takes account of specific storage requirements. Products with known risk of cross contamination shall be stored separately to prevent cross contamination.
6. All pharmaceuticals shall be protected from excessive heat, exposure to direct sunlight, and (unless they are known to be unaffected) from freezing.
7. Sufficient provision shall be made to ensure that temperature storage limitations imposed by the manufacturers are adhered to.
8. There should be a system to ensure efficient drug inventory management with regular and frequent checks to ensure that only products of good quality are sold or supplied.

9. Unwholesome, substandard and expired products shall be quarantined for appropriate disposal. Disposal of such products shall be done in accordance with laid down regulations.
10. A product shall be transported in such a way as to
  - ◆ maintain its identity
  - ◆ keep it free from contamination
  - ◆ protect it against spillage or breakage
  - ◆ protect it from excessive heat, cold, light moisture or other adverse influence, and
  - ◆ prevent attacks by pests and micro organisms
11. Pharmaceutical consignments which have been rejected, recalled or returned shall be placed in adequately segregated storage to avoid confusion with other materials and products and prevent redistribution, until a decision has been reached as to their disposition.
12. There shall be a documented procedure for product-recalls.
13. Storage of medicines on bare floor shall not be permitted.

## **RETURNED GOODS**

Supplies that have been returned shall only be re-sold/re-shipped under the following conditions:-

1. The goods are in their original unopened containers and in good condition.
2. It is known that the goods have not been subject to adverse conditions
3. They have been examined and assessed by the Superintendent Pharmacist. This assessment should take into account the nature of the product, any special storage conditions it requires, and the time elapsed since it was issued. As necessary, advice should be sought from the person responsible for the Quality of the manufactured product.

## **RECORDS**

Clear, readily available records shall be kept on each sale/supply made. The record shall indicate date of supply, customer, product name and quantity. The records shall be retained for the statutory period in force for the product concerned.

## **EQUIPMENT**

Appropriate and sufficient equipment shall be provided to ensure:-

1. safe and efficient handling of the product received
2. Protection against hazardous pharmaceuticals, injury from breakage or accidents.
3. safe and efficient movement of all products
4. maintenance of high standard of housekeeping within the premises,
5. efficient control of temperature, humidity and light
6. proper maintenance of records and proper storage

## **Definitions**

**"Wholesale Supply"** means distribution of prescription medicines and over-the-counter (OTC) medicines to persons other than end users or patients/Clients.

**"Wholesaler"** means any person engaged in wholesale supply of prescription and over-the-counter (OTC) medicines.

## **NOTE**

**Please detach guidelines and submit application forms  
(duly filled) inside the cover jacket.**

**You may attach any other relevant documents.**