PHARMACY BUSINESS APPLICATION GUIDELINES/FORMS (PCG/GL/01)

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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) **Importing Wholesale Pharmacies**
d) **Pharmacies within hospitals, clinics, and any other facility that requires a pharmacy.**
e) **Manufacturing Wholesale Pharmacies**

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

- **Class A – prescription-only medicines (POM);**
- **Class B – Pharmacist's list of medicines (P), i.e. medicines that may be dispensed by a pharmacist without a prescription.**
- **Class C – 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 the regulation on the distribution of pharmacies in the country.

2.0 APPLICATION

A body corporate that has employed a registered pharmacist or any 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.

A 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 a semblance to an existing pharmacy and should reflect the professional nature of pharmacy.

2.1a PROCESSING

All pharmacy applications shall be made to the Pharmacy Council through the Pharmacy Council Website or the online application portal (***applypharmacy.pcghana.org***). 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 prior financial commitments made by the applicant.**
- **Approval granted by the Council is valid for a specified period of time. Note that approval of an application does not constitute authorisation to commence business until all conditions and requirements for the issuance of a 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 applicants may apply through the Council website (**www.pharmacycouncilghana.org)** or ***applypharmacy.pcghana.org***
2. Applicant shall then complete the forms appropriately and submit them (together with all relevant documents, including documents from the Registrar-General's

Department). A prescribed application fee shall be paid at the time of submission of an application.

3. On successful submission of an application, the applicant will receive a notification within one (1) working day from the Pharmacy Council confirming receipt of the application

4. Where an application fails to meet all the requirements, the applicant will be notified of the shortcomings within ten (10) working days after submission of the application.

5. An authorised officer of the Council will contact the applicant within ten (10) working days to schedule a site inspection of the proposed location. A site inspection will be conducted within twenty-five (25) working days from the date of contact.

6. A site inspection report shall be filed by the authorised officer within five (5) working days from the date of inspection.

7. If the application is approved by the Pharmacy Council, the applicant shall be duly notified in writing and given up to six (6) months to prepare the premises for a final inspection.

8. A signed final inspection report will be completed within a maximum of five (5) working days after the final premises inspection. The site and final inspections will be conducted following the specifications and conditions outlined in Section 3.0 of this document and the Food and Drugs Authority (FDA) guidelines on Good Storage and Distribution Practices (GSDP).

9. If an applicant satisfies the minimum requirements for final inspection, a final inspection report shall be submitted to the Registrar. The applicant shall pay the prescribed registration fee for the issue of the pharmacy licence.

10. If the premises do not conform to the specifications and conditions outlined in Section 3.0 of this document and the FDA GSDP Guidelines, the applicant will be required to address the observations and provide a response/Corrective Action and Preventive Action (CAPA) not more than twenty-five (25) days after inspection for review. A follow-up inspection may be conducted after receipt and review of CAPA.

11. A Pharmacy certificate of registration shall be issued for the commencement of pharmacy operations within thirty (30) working days after the payment of the prescribed registration fee.

12. 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 the minimum requirements for any prospective pharmacy.

A. Documentation/Documents

A1 Complete the prescribed application form:

A2. Registrar General's Documents:

i. Certificate of Incorporation

ii. Certificate to Commence Business

iii. Companies code

The object of the 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 adjoining rooms to 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 36 square metres, and the ceiling height shall be at least 3.2 metres**

C2. Wholesale Pharmacy

The size of the proposed premises shall be at **least 48 sqm, with a ceiling height of at least 3.2m.**

C3. Wholesale Manufacturing

The size of the proposed premises shall be at **least 48 sqm, with a ceiling height of at least 3.2m.**

C4. Importing Manufacturing

The size of the proposed premises shall be at **least 48 sqm, with a ceiling height of at least 3.2m.**

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

a) Adequate ventilation and lighting shall be provided.
b) Well-painted/polished shelves, counters and walls with washable floor.
c) Appropriate storage facilities for all products available.
d) A well-written signboard bearing the Pharmacy's name. **(To be displayed after final approval).**
e) Toilet facilities are required.
f) Relevant equipment and reference books shall be made available.
g) A valid written contract agreement between the Superintendent Pharmacist and the 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 36 square 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

i. A minimum floor space of 36 square meters and a height of 3.2m
ii. A minimum of **four (4)** rooms comprising a reception, a storeroom, an office and a cashier's/accounts room.
iii. The reception should have waiting chairs for clients as well as a showcase with **samples o**f the medicines on sale. There should be **no** external shelves in the reception area.
iv. The storeroom must be well ventilated, and shelves and/or pallets must be provided.
v. The signboard should state the name and address of the facility, and also the inscription - "**Wholesale only"** conspicuously written.
vi. The Pharmacy Council list of Retailers and the Food & Drugs Authority list of manufacturers, registered medicines and guidelines on drug advertisements should be available.
vii. In addition to the above, the business of wholesaling should comply strictly with the prescribed standards of good wholesale practices. **(See Appendix A)**

Any other conditions specified in the approval letter.

C. Wholesale/Retail

1. Not allowed in metropolitan areas.
   For this type of pharmacy, it is important that the physical arrangements within the premises are made in such a manner that the wholesale business does not interfere with the retail business.

2. The post approval conditions for wholesale pharmacies and Retail pharmacies, as stated above, shall apply to wholesale/Retail pharmacies.

3. **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 31st 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.

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 include:

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 the procurement and supply of restricted drugs or pharmaceuticals.
v) Operating under insanitary conditions.
vi) Non-renewal of the pharmacy licence
vii) Any unethical/unprofessional practices as specified by the Pharmacy Council
viii) Any act of commission or omission specified by the Pharmacy Council as constituting a 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 their **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, and 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 a 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.
10. A pharmacist should ensure that the service they provide is efficient and meets the needs of the community they serve.

He/she should respect and ensure that regulations concerning the 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 that impairs 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.

7. 0 POST-REGISTRATION VARIATION

CONDITIONS FOR VARYING PHARMACY BUSINESS OPERATING PERMIT

7.1 Change of Ownership/Directors

Where a change occurs in ownership of a pharmacy, the Pharmacy Council shall be notified in writing by the previous owners introducing the new owner(s) and a commitment to transfer all interest in the business to the new owners.

The ownership of a pharmacy business shall not be changed by the Pharmacy Council unless that applicant

(a) Completes the prescribed varying form

(b) Provides a deed of transfer/legal documents covering the transfer executed by a registered and practising lawyer, where necessary.

(c) Provides Registrar General's documents of the new owners/directors

(d) satisfies any other requirements of the Health Professions Regulatory Bodies Act 2013, ACT 857 Part IV.

(e) Pay the prescribed fee.

7.2 Change of Business Name

Where a change occurs in the name of a pharmacy, the Pharmacy Council shall be notified of the new name. This notification must be supported with the relevant Registrar General's documents.

The name of a pharmacy business shall not be changed by the Pharmacy Council unless that applicant

(a) Completes the prescribed varying form

(b) Provides the relevant Registrar General's documents covering the change of name.

(c) Provides a deed of transfer/legal documents covering the transfer executed by a registered and practising lawyer, where applicable.

(d) satisfies any other requirements of the Health Professions Regulatory Bodies Act 2013, ACT 857 Part IV.

(e) Pay the prescribed fee.

7.3 Change of Pharmacist

Where a change occurs in the superintendent pharmacist of a pharmacy, the Pharmacy Council shall be notified of the new superintendent pharmacist.

The superintendent pharmacist of a pharmacy business shall not be changed by the Pharmacy Council unless that applicant

(a) Completes the prescribed varying form

(b) Provides a resignation letter from the previous Superintendent pharmacist or notice of termination of appointment of the Superintendent pharmacist, whichever is applicable

(c) A written contract between the pharmacy and the proposed superintendent pharmacist.

(d) satisfies any other requirements of the Health Professions Regulatory Bodies Act 2013, ACT 857 Part IV.

(e) Pay the prescribed fee.

7.4 Change of Location

The location of a pharmacy business shall not be changed by the Pharmacy Council unless the applicant.

(a) Completes the prescribed varying form

(b) Provides a written explanation of the reason for the relocation

(c) satisfies any other requirements of Part IV of the Health Professions Regulatory Bodies Act 2013, ACT 857.

(d) Pay the prescribed fee.

Note: A site inspection will be conducted by the authorised officers of the Council to determine the suitability of the proposed new location.

7.5 Change of Business Type

i. Retail/ Wholesale to Retail
ii. Retail/ Wholesale to Wholesale
iii. Wholesale to Retail
iv. Retail to Wholesale

The business type of a pharmacy business shall not be changed by the Pharmacy Council unless the applicant.

(e) Completes the prescribed varying form

(f) Provides a written explanation of the reason for the change

(g) satisfies any other requirements of Part IV of the Health Professions Regulatory Bodies Act 2013, ACT 857.

(h) Pay the prescribed fee.

7.6 Variation of Premises

The structure or layout of a pharmacy shall not be changed unless authorized by the Pharmacy Council. An amendment application shall be submitted when there are changes to your approved structure, an addition to the existing structure, layout or scope of activities of a pharmacy.

The applicant must

(i) Provide details of proposed changes/additions

(j) Provides a written explanation of the reason for the variation/addition

(k) satisfies any other requirements of Part IV of the Health Professions Regulatory Bodies Act 2013, ACT 857.

(l) Pay the prescribed fee.

8.0 Suspension of Pharmacy Business

Conditions and Procedures for the Suspension of Business

1. Any pharmacy that suspends business shall accordingly notify the Council in writing, giving a set time frame when the premises shall be closed to the general public, but such suspension period shall not exceed **one year**.

2. The Council, through its regional offices, shall ensure that the pharmacy remains closed during the suspension period. The pharmacy shall notify the Council in writing of its intentions to resume operations before the suspension period ends.

3. There shall be a mandatory final inspection before the facility can resume work.

9.0 Cancellation / Suspension

The Pharmacy Council may suspend or revoke a pharmacy license if.

(a) The conditions under which the license was issued no longer exist.
(b) The information on which the approval was given is later found to be false.
(c) The circumstances under which the approval was given no longer exist.
(d) Breach of a provision under Part IV of Act 857, 2013
(e) The facility contravenes GSDP requirements.

Where the licensure is suspended or revoked, the Pharmacy Council

i. shall issue a notice to the management of the facility.
ii. shall take steps to ensure that the facility is stopped from retailing/ wholesale until otherwise decided by the Pharmacy Council.
iii. publish details of the action on its website and other relevant media.

9.1 Administrative Fines

Depending on the severity of a breach of any of the conditions under 9.0 above, the Pharmacy Council may impose an administrative fine under the Fees and Charges Act.

10.0 PUBLISHING OF LICENSED PHARMACIES

The Pharmacy Council shall update the list of licensed facilities and Pharmacists in good standing on the website every 3 months

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 95 of the Health Professions Regulatory Bodies Act, 2013, Act 857.

Any Pharmaceutical Company that engages in the 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 95 of Act 857. 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 involving 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 dispatch 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 the 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 conditions which take account of specific storage requirements. Products with a 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 the laid-down regulations.
10. A product shall be transported in such a way as to
    i. maintain its identity
    ii. Keep it free from contamination
    iii. protect it against spillage or breakage
    iv. protect it from excessive heat, cold, light moisture or other adverse influences, and
    v. prevent attacks by pests and microorganisms
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 the bare floor shall not be permitted.

RETURNED GOODS

Supplies that have been returned shall only be resold/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 the date of supply, the customer, the 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 the 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 the 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.