GUIDELINES ON LICENSING OF PHARMACIES AND PHARMACEUTICAL MANUFACTURERS

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Citation

These guidelines shall be cited as the *"Professional* Guidelines on *Licensing of Pharmacies and Pharmaceutical Manufacturers". Doc. No. INS/GDL/035, Revision No.: 1"*

Adoption and approval of these professional guidelines

In EXERCISE of the powers conferred upon the Drug Authority by Section 5(i) of the National Drug Policy and Authority Act, Cap. 206 of the Laws of Uganda (2000 Edition), the Drug Authority hereby ADOPTS and ISSUES these **"Professional Guidelines on Licensing of Pharmacies and Pharmaceutical Manufacturers"** Doc. No. INS/GDL/035, Revision No. 1", made this 1st day of November 2023, that take effect on 1st December 2023.

Signature _____

Dr. Medard Bitekyerezo

CHAIRPERSON

National Drug Authority

Kampala, Uganda

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BACKGROUND

Pharmacy business is a regulated Professional business under the National Drug Policy and Authority Act, Cap 206 of the Laws of Uganda and Regulations on Certificate of Suitability of Premises (S.I. No. 36) as amended in 2021 and Licensing (S.I. No. 35), 2014 as amended in 2021. Applicants are strongly advised to familiarize themselves with the relevant laws and regulations to ensure compliance.

The licences issued under these guidelines shall be valid for 3 calendar years.

These Professional Guidelines-Licensing have been prepared in line with Section 5 (a) and 5 (i) of the National Drug Policy and Authority Act (CAP 206) which provides for the functions of the Authority which among others are 'to deal with the development and regulation of the pharmacies and drugs in the country and to establish and revise professional guidelines and disseminate information to health professionals and the public.'

1.0 APPLICATION FOR LICENSES

1.1 General Requirements

1.1.1 All applicants for premise licenses (Drug Manufacturers, retail and wholesale pharmacies) shall apply for certificate of suitability of premises and license to operate.

1.1.2 All pharmacy and manufacturing license applications shall be submitted and processed through the NDA Management Information System (NDAMIS) online platform.

1.1.3 Applicants without NDAMIS login credentials shall apply for them through their pharmacist in order to be able to access the NDAMIS platform.

1.1.4 An applicant for a pharmacy license shall submit (upload) the following at the time of application, in the NDAMIS:

a) duly filled application forms for certificate of suitability of premises;

b) duly filled application forms for the license;

c) evidence of payment of the prescribed fees;

d) certified copies of the certificate of registration and annual membership certificate of Pharmaceutical Society of Uganda for the supervising pharmacist.

e) commitment letters from the supervising pharmacist and professional auxiliary staff;

f) a certified copy of a valid certificate of registration/enrollment with the relevant professional body for the professional auxiliary staff;

g) for Retail/Wholesale veterinary Pharmacy, a copy of the certificate of the qualified veterinary professional (Veterinary Surgeon);

1.1.5 Applicants shall pay **all** the **prescribed fees** as per the regulation at the time of application through the online payment system. Such payments do not amount to grant of a license.

1.1.6 Applicants for Wholesale Pharmacies will be required to meet the Good Distribution Practices (GDP) requirements

1.1.7 All applicants for licenses shall be subject to the approved guidelines.

1.1.8 Applicants wishing to deal in both human and veterinary medicines shall meet the minimum requirements for suitability of premises and personnel for each section but shall apply for a single certificate of suitability of premises and licence. The two sections shall be segregated.

1.2 Pharmacy Personnel

1.2.1 A supervising pharmacist may be issued a maximum of two licenses in his/her name.

The supervising pharmacist shall provide a commitment in writing stating the names and qualifications of the professional auxiliary staff (PAS) to assist him/her during the operational hours of the pharmacy.

1.2.2 It is the responsibility of the supervising pharmacist to ensure that duly registered auxiliary staff are employed to handle medicines.

1.2.3 In the event that the pharmacist is unavailable at the scheduled inspection time and has notified the inspection team in advance, he\she shall be required to report to the NDA office in the region where the pharmacy is located for a debrief on the inspection findings prior to issuance of a license.

1.3 Inspection of Pharmacy Premises

1.3.1 Upon receipt of a complete application for a certificate of suitability of premises and license to operate a retail pharmacy or wholesale pharmacy and payment of the requisite fees, inspection of the proposed pharmacy premises shall be conducted.

1.3.2 Prior to issuance of a Certificate of Suitability for Wholesale Pharmacy, the intended premises must comply to the minimum standards of suitability stipulated in Part III of National Drug Policy & Authority Act (certificate of suitability of premises) Regulations 2014, S.I. No. 36.

1.3.3 Prior to issuance of Certificate of Suitability for Retail Pharmacy, the intended premises must comply with the minimum standards stipulated in Part IV of National Drug Policy and Authority (certificate of suitability of premises) Regulations 2014 S.I. No. 36.

1.3.4 The issuance of the certificate of suitability of premises does not amount to the grant of a license.

Approval of Pharmacy Premises

1.3.5 A person who wishes to apply for a certificate of suitability of premises shall, prior to the application, seek an approval of the proposed location of the premises from the Authority.

i. This approval shall be valid for 3 months in which the applicant shall have applied for certificate of suitability of premises.

ii. Upon approval of the location, the applicant shall be required to display a sign post indicating the approval of the location and the type of business that will be carried out.

iii. The validity of the approval may be extended once, upon request from the applicant with reasonable justification.

1.3.6 Upon approval of an application for certificate of suitability and license to operate a retail pharmacy or wholesale pharmacy, NDA shall notify the applicant of this approval and a license to operate the pharmacy shall be issued.

1.3.7 In case the application is rejected, the applicant will be notified in writing.

2.0 ADDITIONAL GUIDANCE ON LICENSING OF NEW PHARMACIES

2. 1 General Principle

2.1.1 New Dual applications for both wholesale and retail pharmacies shall not be accepted in Kampala Metropolitan area (Kampala, Mukono and Wakiso) and other cities.

2.2 Additional requirements for new applications

2.2.1 An applicant for a new licence for a pharmacy shall additionally submit (upload) the following at the time of application, in the NDA MIS:

a) memorandum and articles of association in case of a body corporate and partnership deed in case of a partnership and a certificate of incorporation;

b) certified copies of company Form 20 and a resolution appointing the directors as evidence that one of the directors in the company is a pharmacist;

c) a sketch plan of the premises taking into consideration the minimum floor area for wholesale, retail, and additional storage area; and

d) URA TIN certificate.

2.2.2 Incomplete application documents for licensing a new retail or wholesale pharmacy shall be rejected.

2.3 Distribution of Pharmacy Outlets

2.3.1 Distribution of pharmaceutical outlets shall be based on the following:

a) number of pharmacies in that area; and

b) distance of the proposed outlet from existing licensed outlets.

2.3.2 In the application of distance to determine the distribution of pharmacies, the distance to the proposed new pharmacy premises shall be measured from any direction to the nearest ‘like’ pharmacy. In determining distance between pharmacies ‘like to like’ shall be defined as the distance between a human to human pharmacy or veterinary to veterinary pharmacy and retail to retail or wholesale to wholesale.

For avoidance of doubt:

a) Institutional pharmacies shall be those pharmacies embedded within the established institutions for purposes of serving clients in that institution.

b) existing pharmacies shall include applicants with approval of location given under clause 1.3.5 of these guidelines

c) a pharmacy which is temporarily closed or not in operation for a period exceeding 6 months shall not be considered.

d) Retail shall refer to supply of drugs directly to the users (patients or their agents/caregivers) for use and not for resale.

e) Wholesale shall refer to supply of drugs to another licensed/authorized business for resale or to a healthcare institution for treatment of patients.

2.3.3 In a bid to streamline the distribution of pharmaceutical outlets and pharmaceutical services in the country, new pharmacies shall only be allowed in areas complying with regulation 4(4) of the licensing amendment regulations 2021. *However, institutional pharmacies shall not be affected by the distance limitations above.*

2.3.4 A Licensed seller seeking a license to operate a pharmacy shall be handled in accordance with Regulation Number 9 of SI 35.

2.3.5 A licensed seller that seeks to convert into a retail pharmacy may do so in accordance with regulation 9 of the National Drug Policy and Authority (Licensing) (Amendment) regulations, 2021

3.0 ADDITIONAL GUIDANCE ON RENEWAL OF PHARMACY LICENSES

3.1 General Requirements

3.1.1 An application for renewal of a licence for a manufacturer, wholesale pharmacy or retail pharmacy shall be made at least three months before the expiry of the licence.

3.1.2 All unlicensed pharmacies must **close** effective **1st January.**

3.1.3 Pharmacies carrying out both retail and wholesale businesses on the same premises may be licensed; but each section must be supervised by a pharmacist.

3.1.4 License renewal shall only apply for pharmacies which had a license to operate for at least one of the two preceding calendar years in the same premises.

3.1.5 All pharmaceutical outlets are expected to routinely destroy expired drugs following the NDA procedures for destruction of expired drugs. Any pharmaceutical outlet

found with expired drugs during inspection will be expected to submit a certificate of destruction prior to issuance of licenses.

3.1.6 In case of change of the supervising Pharmacist, evidence that a company has a Pharmacist as a director shall be presented to NDA.

3.1.7 Every licenced pharmacy shall, annually in the month of January, send to the authority returns as prescribed in the return of details of pharmacy business Form (Appendix I). If any alteration occurs in the particulars stated in the last return made, the person carrying on the business shall, within twenty-one days of the alteration, send notice in writing to the Authority.

3.2 Relocation of Pharmacies

3.2.1 Pharmacies seeking to relocate must have a valid license or a license eligible for renewal.

3.2.2 Applicants seeking to relocate shall apply and obtain approval in writing prior to relocation.

3.2.3 Pharmacies can relocate within the same district as long as the respective distance is observed.

3.2.4 Relocation of retail and wholesale pharmacies shall be handled in accordance with regulation 8 of the National Drug Policy and Authority (Licensing) (Amendment) regulations, 2021

3.2.5 Notwithstanding clauses 3.2.4 above, a pharmacy forced to relocate by extra ordinary circumstances approved by the Secretary to the Authority, such as natural disasters or infrastructure developments; may be approved.

3.3 Change of Management / Nature of Business Operations

3.3.1 Pharmacies seeking to change management must have a valid license or a license eligible for renewal.

3.3.2 In case of change of ownership, the applicant must submit evidence of the sale such as: copies of the sales agreement between seller and the buyer and a certified board resolution for the sale and the updated articles and memorandum of association where applicable.

3.3.3 The license holder shall in writing introduce the new owner of the pharmacy and return the license. The new owner in turn shall apply for a new license for the pharmacy; however, the application shall not be subjected to the licensing conditions for new pharmacies.

3.3.4 Upgrading of retail license to wholesale license in the same premises shall be allowed provided the application meets the other relevant licensing requirements. However, conversion of wholesale license to retail licence and any pharmacy licence to drug shop license shall not be allowed and shall be handled as new applications and be subjected to the relevant regulations.

3.4 Other Requirements for Licensing of Pharmacies

3.4.1 It is the joint responsibility of the applicant or owner of a pharmacy to ensure that the certificates of the in-charges and auxiliary staff submitted to NDA are valid and authentic. Submission of an invalid or non-authentic certificate and or employment of unqualified persons may lead to:

a) Denial or revocation of a license.

b) Prosecution of the in-charge and /or the owners of the drug outlet.

3.4.2 The premises, in respect of which a license is issued by the Authority, shall have a clearly visible signpost indicating the name and type of outlet, i.e. Human or Veterinary Retail Pharmacy or Wholesale Pharmacy.

3.4.3 The Authority may suspend or revoke a licence or a certificate issued under The National Drug Policy and Authority (Licensing) Regulations 2014 S.I No. 35 in line with regulation 26.

4.0 ADDITIONAL GUIDANCE ON LICENSING OF PHARMACEUTICAL MANUFACTURING FACILITIES

4.1 General Principles

4.1.1 Manufacture of pharmaceuticals is regulated under the National Drug Policy and Authority Act, Cap 206 of the Laws of Uganda and Regulations on Certificate of Suitability of Premises (S.I. No. 36) and Licensing (S.I. No. 35), 2014. Applicants are strongly advised to familiarize themselves with the relevant laws and regulations and ensure compliance.

4.1.2 All applicants intending to establish new pharmaceutical manufacturing facilities are advised to contact NDA for guidance before embarking on any establishment.

4.2 Renewal of Pharmaceutical Manufacturing License

4.2.1 Application for renewal of a license to manufacture drugs shall be made using Form 19 (Schedule to the Licensing Regulations SI No. 35 of 2014)

4.2.2 The application shall be accompanied by—

a) A list of the drugs to be manufactured.

b) A certified copy of the certificate of registration of the pharmacist to be in charge of the manufacturing process.

c) The certificates of qualification of the key personnel to be involved in the manufacturing process.

d) The prescribed fees.

4.3 Personnel

4.3.1 The manufacturing process shall be supervised by a registered pharmacist resident in Uganda for each production line.

4.3.2 The process of quality control and quality assurance shall be under the supervision of a registered pharmacist and resident in Uganda.

4.3.3 The pharmacists in charge of the manufacturing processes and the pharmacists in charge of quality control and quality assurance shall be independent of each other.

NDA reserves the right to approve or reject any application for licensing in accordance with the National Drug Policy and Authority Act Cap 206 in an effort to promote equitable access to medicine.

Appendix 1: Return of Details of Pharmacy Business

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RETURN OF DETAILS OF PHARMACY BUSINESS

(Issued under Section 34 of the National Drug Policy and Authority Act)

1.	**Name of Pharmacy**	
2.	**Location and postal address of the premises**	Plot and Street Number: ……..…… City / Town: …… District: …… Postal Address: …… Telephone Number……....
3.	**Premise Number**	
4.	**The return covers the year ending**	……/……./……. (Day / Month / Year) *(With the information provided effective as of that date)*
5.	**Name of Pharmacist supervising the sale of drugs at these premises**	Name: ……..…… Registration Number: …… Email Address: …… Telephone Number…….....
6.	**List of Pharmacy Auxiliary Staff**	Name (Last, First) — Qualification i. ……..…… — ……..…….. ii. ……..…… — ……..……..

		iii. ……..…… ……..……..
7.	**Name and principal postal address of the Managing Director**	Name: ……..…….. Postal Address: ……
8.	**Name and Email address of the other Directors of the pharmacy**	Name (Last, First) Qualification i. ……..…… ……..…….. ii. ……..…… ……..…….. iii. ……..…….. ……..……..
I certify that the above information is correct Signature of the Pharmacist …… Date: ……/……./……. (Day / Month / Year)		

Notes:

a) *This form shall be accompanied by:*
   i. *A certified copy of the pharmacist's certificate of registration*
   ii. *A valid PSU annual membership certificate*
   iii. *Company forms 7 and 20 (where applicable)*

b) *The return shall be submitted to the National Drug Authority before the 31st day of January of each year*

c) *If any alteration occurs in the particulars stated in the last return made, the person carrying on the business shall, within twenty-one days of the alteration, send notice in writing to the Authority.*

d) *This form shall be rejected if it is incomplete or not properly filled.*

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and reasons for revision
11th September 2019	0	INS/GDL/035	*Authors* Muhammad Lukwago Amos Atumanya James William Tamale *Reviewers* Denis Mwesigwa Peter Ssali David Nahamya	First issue of document
1st November 2023	1	INS/GDL/035	*Authors* Muhammad Lukwago Amos Atumanya James William Tamale Zaidi Mwondha *Reviewers* Denis Mwesigwa David Nahamya	1. Document title revised from Licensing *"Guidelines for Pharmacies and Pharmaceutical Manufacturers"* to ***"Guidelines on Licensing of Pharmacies and Pharmaceutical Manufacturers"*** 2. Clause 1.3.5 Amended as follows: A person who wishes to apply for a certificate of suitability of premises shall, prior to the application, seek an approval of the proposed location of the premises from the Authority. This approval shall be valid for 3 months in which the applicant shall have applied for certificate of suitability of premises. i. Upon approval of the location, the applicant shall be required to display a sign post indicating the approval of the location and the type of business that will be carried out. ii. The validity of the approval may be extended once, upon request from the applicant with reasonable justification. 3. Clause 2.1.1 Amended to; New Dual applications for both wholesale and retail pharmacies shall not be accepted in Kampala Metropolitan area (Kampala, Mukono and Wakiso) and other cities. 4. clause 2.3.2 amended to: 2.3.2 In the application of distance to determine the distribution of pharmacies, the

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