Safe Drugs Save Lives

PROFESSIONAL GUIDELINES 2018

LICENSING NEW PHARMACIES IN KAMPALA

National Drug Authority

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NDA REGIONAL OFFICES

Central Region –Premier Complex, Jinja Road, Nakawa.

South Eastern Region –Plot 6 Rippon Gardens, Jinja

Eastern Region –Plot No. 27, Kwapa Road, Tororo

Northern Region – Plot 48 Ogwal Ajungu Road, Lira.

Western Region - Muganwa Centre, Plot 30, Old Toro Road, Hoima

South- Western Region - House No 29 Mbaguta Estates Kamukuzi, Mbarara.

West Nile Region – Plot 1 Mt. Wati Road, Anyaflo –Arua

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) and Licensing (S.I. No. 35), 2014. Applicants are strongly advised to familiarize themselves with the relevant laws and regulations to ensure compliance.

These professional guidelines have been prepared in line with Section 5(i) of the National Drug Policy and Authority Act (CAP 206) which states one of the functions of the Authority as *'to establish and revise professional guidelines and disseminate them to the public'*.

Approved by	
Title	Secretary to the Authority
Name	Donna Kusemererwa
Signature	
Date	20.12.17

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Notice

It is the responsibility of the supervising pharmacist to ensure full compliance of pharmacy operations with the NDP/A Act and relevant regulations

ADDITIONAL GUIDANCE ON LICENSING OF NEW PHARMACY

1.0 General Principle

1.1 All applicants for new pharmacies retail and wholesale shall apply for certificate of suitability of premises and license to operate a retail pharmacy or wholesale pharmacy.

1.2 **New Dual applications** for both wholesale and retail pharmacies shall not be accepted.

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

1.4 All applicants must apply for NDAMIS login credentials through their pharmacist in order to be able to access the NDAMIS platform.

2.0 Requirements for Applications

2.1 An applicant for a new pharmacy licence 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) memorandum and articles of association in case of a body corporate and partnership deed in case of a partnership;

e) evidence that one of the directors in the company is a pharmacist;

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

g) certified copy of the certificate of registration of the supervising pharmacist;

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

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

j) for Retail/Wholesale Pharmacy (Veterinary), a copy of the certificate of the qualified veterinary professional (Veterinary Surgeon or Animal Husbandry Officer); and

k) URA TIN certificate.

2.2 Incomplete application documents for licensing a new retail or whole pharmacy shall be rejected.

3.0 Inspection of Pharmacy Premises

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, inspection of the proposed pharmacy premises shall be conducted to determine the suitability of premises for which the certificate is to be issued.

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.

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.

4.0 Approval of Pharmacy Premises

4.1 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. The applicant shall then be required to pay all applicable fees before the certificate of suitability and licenses to operate a pharmacy are issued.

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

5.0 Supervision of Pharmacies

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

5.2 All supervising pharmacists shall indicate to NDA at the time of application:

a) the time and duration he/she is expected to be physically present at the premises; and

b) the name and qualification of the Professional Auxiliary Staff (PAS) to assist the pharmacist during the operational hours of the pharmacy.

6.0 Distribution of Pharmacy Outlets

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

a) particular location of a proposed outlet;

b) infrastructural development in the area;

c) population living in that area;

d) number of pharmacies in that area; and

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

6.2 In the application of distance to determine the distribution of pharmacies, the distance shall be measured from **door** to **door** of the existing pharmacy to the proposed new pharmacy premises.

6.3 In a bid to streamline the distribution of pharmaceutical outlets and pharmaceutical services in Kampala, only hospital pharmacies shall be allowed to open up as new pharmacies in Kampala. For avoidance of doubt, hospital pharmacies shall be those pharmacies located within established hospitals and medical centers for purposes of serving clients within that medical facility.

7.0 Other Requirements for Licensing of Pharmacies

7.1 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.

c) Blacklisting of the in-charge and/or the owners of the drug outlet.

7.2 All pharmacies in private hospitals, medical centers and other institutions must apply for licensing by National Drug Authority.

7.3 A new pharmacy that has been granted a licence shall have a clearly visible signpost indicating the name and type of outlet, i.e. Human or Veterinary Retail Pharmacy or Wholesale Pharmacy.

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