



Safe Drugs Save Lives

GUIDELINES ON LICENSING OF CLASS C DRUG SHOPS

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Guidelines on Licensing of Class C Drug shops

Citation

These guidelines shall be cited as the “*Professional Guidelines on Licensing of Class C Drug Shops*”. Doc. No. INS/GDL/050, Revision No.: 0”

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 Class C Drug Shops**” Doc. No. INS/GDL/050, Revision No. 0”, 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

Supply of Class C medicines 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 and ensure compliance.

These professional guidelines 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.

It is the responsibility of the Licensed Seller to ensure full compliance of Class C Drug Shop operations with the NDP/A Act and relevant regulations

1.0 Requirements for Application

Applicants for a drug shop license should submit the following at the time of application;

- a) Duly filled application forms for certificate of suitability of premises
- b) Duly filled application forms for the license
- c) Proof of payment of the prescribed fees
- d) A certified copy of the certificate of registration of the qualified in-charge.
- e) A letter of commitment from the in-charge.
- f) Copy of the National identity card of the owner and in-charge.
- g) A sketch plan of the premises taking into consideration the minimum floor area.
- h) Two recent passport size photos of the qualified professional.
- i) Practicing licence of the in-charge
- j) Tax Identification Number (TIN) of the owner

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2.0 Timelines for renewal of Licenses for Drug shops

- 2.1 Applications for renewal shall be submitted at the respective regional offices or Office of the DHO (human) /DVO (veterinary) at least three months before the expiry of the licence.
- 2.2 License renewal shall only apply for drug shops which had a license to operate for at least one of the two preceding calendar years in the same premises; if the reason for the previous non-renewal was communicated and approved by NDA.
- 2.3 Incomplete application documents for licensing will not be accepted at the time of submission.
- 2.4 All unlicensed drug shops must close effective **1st January**.

3.0 Supervision of Drug shops

- 3.1 Drug shops shall only be run by professionals with approved medical, pharmaceutical or veterinary qualification and must be registered with their professional councils.
- 3.2 The following professionals shall be licensed to operate Human Drug Shops.
 - a) Pharmacy Technician/dispenser
 - b) Registered or Enrolled Nurse
 - c) Comprehensive Nurse
 - d) Registered or Enrolled midwife
 - e) Pharmacy Assistants
- 3.3 The following professionals shall be licensed to operate Veterinary Drug Shops.
 - a) Veterinary surgeons
 - b) Certificate/Diploma in Animal Husbandry
- 3.4 The premise must be operated by the licensed seller on a full- time basis, i.e. throughout the entire opening hours of the drug shop. If the licensed seller must leave the premises for any reason, the drug shop must be operated by another suitably qualified person.

4.0 Sale of Medicines

- 4.1 Class C drug shops shall sell only medicines as specified in their licenses. For avoidance of doubt, these shall be medicines as specified in the 3rd and 4th schedules of the NDP/A Act.

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5.0 Distribution of Drug Shops

- 5.1 No new drug shops shall be licensed to operate in Kampala district.
- 5.2 No new licensed seller shops shall be licensed in Kampala. New licensed seller shops in other areas with existing pharmacies shall only be licensed in outlying areas which are not less than 1.5km away from the nearest pharmacy as follows:

Distance for new Licensed Seller

Description	Distance ¹ from the next like ² outlet in Metres
Kampala ³	
City	300
Municipality	300
Town Council	200
Rural areas	100

¹This shall only apply if the proposed premises of the licensed seller is located not less than 1.5 kilometres from the nearest retail pharmacy.

²In determining distance between licenced seller outlets 'like to like' shall be defined as the distance between a human to human outlet or veterinary to veterinary outlet.

³In line with Section 15 of the Act, Kampala is considered sufficiently served thus no new licensed seller outlets shall be allowed in Kampala.

6.0 Relocation of Drug shops.

- 6.1 Relocation of licensed seller shall be handled in accordance with regulation 8 of the National Drug Policy and Authority (Licensing) (Amendment) regulations, 2021.
- 6.2 Notwithstanding clauses 6.1 above, a drug shop forced to relocate by extra ordinary circumstances approved by the Secretary to the Authority, such as natural disasters or infrastructure developments; may be approved.

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7.0 Herbal Medicines

- 7.1 Drug shops selling only herbal medicines shall be licensed under these guidelines. They shall be operated by in charges with minimum qualification of certificate in herbal training issued by the directorate of Industrial training (Ministry of Education and Sports) or its equivalent.
- 7.2 The licensed herbal drug shops shall only stock notified herbal medicines. For avoidance of doubt, they will not be allowed to stock conventional medicines.
- 7.2 Hawking of herbal medicines and unauthorized advertisement of herbal medicines **are illegal** and are considered **punishable offences in accordance with the provisions of the NDP/A Act (Cap 206)**.

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.

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DOCUMENT REVISION HISTORY

Date of revision	Revision number	Document Number	Author(s)	Changes made and reasons for revision
11 th September 2019	0	INS/GDL/035	<p><i>Authors</i> Muhammad Lukwago Amos Atumanya James William Tamale</p> <p><i>Reviewers</i> Denis Mwesigwa Peter Ssali David Nahamya</p>	First issue of document
1 st November 2023	0	INS/GDL/050	<p><i>Authors</i> Muhammad Lukwago Amos Atumanya James William Tamale Zaidi Mwendha</p> <p><i>Reviewers</i> Denis Mwesigwa David Nahamya</p>	<ol style="list-style-type: none"> 1. Document number changed from INS/GDL/035 to INS/GDL/050 2. Document title revised from “<i>Licensing guidelines for Class C Drug Shops</i>” to “<i>Guidelines on Licensing of Class C Drug Shops</i>” 3. Clause 1.0 amended to include <ol style="list-style-type: none"> i. Practicing licence of the in-charge ii. Tax Identification Number (TIN) of the owner 4. Clause 2.1 amended to: Applications for renewal shall be submitted at the respective regional offices or Office of the DHO (human) /DVO (veterinary) at least three months before the expiry of the licence. 5. Clause 3.2 amended to include <ol style="list-style-type: none"> i. Pharmacy Assistants 6. Clause 3.3 amended to include Veterinary surgeons 7. Clauses 5.2 and 5.3 amended to: No new licensed seller shops shall be licensed in Kampala. New licensed seller shops in other areas with existing pharmacies shall only be licensed in outlying areas which are not less than 1.5km away from the nearest pharmacy as follows:

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				<p style="text-align: center;">Distance for new Licensed Seller</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Description</th> <th style="width: 40%;">Distance¹ from the next like² outlet in Metres</th> </tr> </thead> <tbody> <tr> <td>Kampala³</td> <td></td> </tr> <tr> <td>City</td> <td>300</td> </tr> <tr> <td>Municipality</td> <td>300</td> </tr> <tr> <td>Town Council</td> <td>200</td> </tr> <tr> <td>Rural areas</td> <td>100</td> </tr> </tbody> </table> <p>¹This shall only apply if the proposed premises of the licensed seller is located not less than 1.5 kilometres from the nearest retail pharmacy.</p> <p>²In determining distance between licenced seller outlets 'like to like' shall be defined as the distance between a human to human outlet or veterinary to veterinary outlet.</p> <p>³In line with Section 15 of the Act, Kampala is considered sufficiently served thus no new licensed seller outlets shall be allowed in Kampala.</p> <p>8. Clause 6.0 revised to read "Relocation of licensed seller shall be handled in accordance with regulation 8 of the National Drug Policy and Authority (Licensing) (Amendment) regulations, 2021."</p>	Description	Distance ¹ from the next like ² outlet in Metres	Kampala ³		City	300	Municipality	300	Town Council	200	Rural areas	100
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End of Document

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