

DRUG
NATIONAL AUTHORITY



PROFESSIONAL GUIDELINES 2017

LICENSING


(Amended)

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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'. The guidelines published on November 1 have been amended with effect from December 13 2016.

Approved by:	
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Date	21/12/2016

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1.0 INTRODUCTION

National Drug Authority was established by an act of Parliament, the National Drug policy and Authority Act, Cap 206 of the laws of Uganda. The Authority is mandated to ensure the availability at all times of essential, efficacious, and cost effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs. In accordance, NDA endeavors to achieve this mandate for which it was established in general and more specifically through inspection and licensing of pharmaceutical manufacturers and outlets to ensure they meet the necessary requirements for manufacture, storage and sale of medicines and other pharmaceutical products.

1.1 The Licensing requirements and guidelines stipulate all necessary requirements for licensing of pharmaceutical manufacturers and outlets including wholesale and retail pharmacies, drug shops and medical device outlets. The document provides a list of minimum requirements that all applicants must meet in order to receive authorization from NDA for their respective businesses, in form of a certificate for suitability of premises, and manufacturing or operating licenses. The requirements for all applicants include;

1.1.1 Requirements for pharmaceutical and medical device premises.

1.1.2 Requirements for personnel.

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1.1.3 Requirements for quality management systems.

1.2 The document also stipulates guidelines for equitable distribution of pharmaceutical outlets that guides all potential applicants on the restrictions and provisions for setting up of pharmaceutical premises in the various parts of the country. This section intends to promote equity in distribution of pharmaceutical services as a means of achieving NDA's mandate of ensuring access to medicines in Uganda.

2.0 GENERAL

2.1 In line with these guidelines, no person shall carry on the business of supplying drugs by wholesale or retail without a license issued by the National Drug Authority.

2.2 All applicants are advised to read these guidelines and understand all requirements for setting up pharmaceutical outlets and manufacturing facilities and do due diligence on the suitability of the proposed pharmacy premises prior to application for inspection. In line with the above, NDA will not be obliged to approve any premises that do not meet the licensing requirements prescribed in these guidelines. Furthermore, NDA will not be held liable for any financial losses occurring as a result of rejected applications.

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3.0 APPLICATION FOR LICENSING

3.1 Applicants shall collect application forms from the following locations;

3.1.1 NDA Headquarters, Plot No. 46-48, Lumumba Avenue, Kampala

3.1.2 District Drug Inspector (DDI) based in the office of the DHO in every district.

3.1.3 Regional offices located at the following locations;

3.1.3.1 Central Region –Premier Complex, Jinja Road Nakawa.

3.1.3.2 South Eastern Region –Plot 6 Rippon Gardens, Jinja

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

3.1.3.4 Northern Region – Plot 48 Ogwal Ajungu Road, Lira.

3.1.3.5 Western Region:- Muganwa Centre, Plot30, Old Toro Road , Hoima

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

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

Please note that all application forms and banking slips are free of charge.

An online application platform for licensing shall soon be available. Applicants are encouraged to use the online application as their preferred method once this is availed.

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4.0 LICENSING OF PHARMACIES

4.1 Requirements for Application

4.1.1 Applicants for a pharmacy license must submit the following at the time of application

4.1.1.1 Duly filled application forms for certificate of suitability of premises

4.1.1.2 Duly filled application forms for the license

4.1.1.3 Evidence of payment of the prescribed inspection fees.

4.1.1.4 Memorandum and articles of association in case of a body corporate and partnership deed in case of a partnership (to be submitted as hard copies).

4.1.1.5 Evidence that one of the directors in the company is a pharmacist.

4.1.1.6 A sketch plan of the premises taking into consideration the minimum floor area for wholesale, retail, and additional storage area.

4.1.1.7 The certified copy of the certificate of registration of the supervising pharmacist.


4.1.1.8 Commitment letters from the supervising pharmacist and Professional Auxiliary staff.

4.1.1.9 A certified copy of a valid certificate of registration/enrollment with the relevant professional body for the professional auxiliary staff.

4.1.1.10 For Retail/Wholesale pharmacies (Veterinary): a copy of the certificate of the qualified veterinary professional (Veterinary Surgeon or Animal Husbandry Officer).

4.1.1.11 URA TIN certificate.

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4.1.2 Renewal applicants **shall not** be obliged to submit requirements ;(2.4.1.4), (2.4.1.5), (2.4.1.6) and (2.4.1.11) in case there have been no changes that would otherwise warrant a re-submission of the same.

4.2 Inspection of Pharmacy Premises

4.2.1 Upon application, inspection of the proposed pharmacy premises shall be conducted on receipt of a complete application. A response on the outcome of the inspection shall be communicated to the applicant by 31st January 2017.

4.3 Approval of Pharmacy Premises

4.3.1 Upon approval of an application, NDA shall notify the applicant of this approval.

The applicant shall then be required to pay the prescribed license fees before the licenses are issued.

4.3.2 In case of a rejection of the application, the applicant will be notified.

4.4 Timelines for renewal of pharmacy Licenses for 2017.

4.4.1 A pharmacy outlet shall be considered unlicensed and shall close its operations to the public if licenses have not been renewed **by 31st January 2017.**

4.4.2 Applicants are required to apply for license renewal at least two months before the expiry of the current licenses, for avoidance of doubt, by the **1st November 2016** and in any case, **not later than 15th December 2016** at their **respective regional offices.**

4.4.3 Incomplete application documents for licensing will not be accepted at the time of submission.

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4.4.4 In case of any queries raised during the inspection of premises, applicants shall be required to submit **corrective and preventive actions (CAPA)** by **31st January 2017**.

4.4.5 All non-compliant pharmacies shall **close** effective **1st February 2017**.

4.5 Supervision of Pharmacies

4.5.1 All supervising pharmacists must indicate to NDA at the time of application:

4.5.2 The time and duration he/she is expected to be physically present at the premises:

4.5.3 The name and qualification of the Professional Auxiliary Staff (PAS) to deputize the pharmacist during the operational hours of the pharmacy.

4.5.4 In addition to the above, all supervising pharmacists shall develop a timetable clearly indicating the times they will physically be available at the pharmacy premises. This should be made available at the pharmacy premises.

4.6 Pharmacy Auxiliary Staff

4.6.1 The following professionals shall be allowed as professional auxiliary staff in human pharmacies.

4.6.1.1 Pharmacy technician/dispenser.

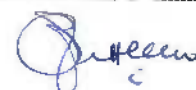
4.6.1.2 Registered or Enrolled Nurse

4.6.1.3 Comprehensive Nurse.

4.6.1.4 Registered or Enrolled midwife

4.6.1.5 Clinical Officers.

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4.6.2 The following professionals shall be allowed as professional auxiliary staff in veterinary pharmacies.

4.6.2.1 Veterinary Surgeon (BVM).

4.6.2.2 Animal Husbandry Officer (Diploma in Animal Husbandry /Dip. In Animal production and management) from Institutions recognized by the National Council for Higher Education.

4.6.2.3 Veterinary assistants from former veterinary training institute.

4.6.3 Wholesale pharmacies dealing in veterinary medicines and vaccines, shall employ a named registered veterinary surgeon to be supervised by a pharmacist.

4.7 Requirements for Premises for pharmaceutical outlets

All applicants shall apply for a certificate of suitability of premises.

Pharmaceutical premises **must** comply with the following requirements

4.7.1 Location of premises.

The premises shall be located in a place where the premises cannot be contaminated from the external environment or other activities.

4.7.2 Standards of construction

The premises shall;

4.7.2.1 Be of a permanent nature;

4.7.2.2 Be protected against, adverse weather conditions including dust, ground water seepage, vermin and pest infestation;

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4.7.2.3 Have sufficient space for the carrying out and supervision of the necessary operations;

4.7.2.4 Have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning.

4.7.2.5 Be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

4.7.3 Premises to be in good state of repair and decoration.

4.7.3.1 The premises shall be maintained in a good state of repair and decoration.

4.7.3.2 The process of maintenance and repair shall not while being carried out cause any contamination of ingredients or products.

4.7.4 Premises to be clean and tidy.

4.7.4.1 The premises including the external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

4.7.5 Materials to be protected against light.

4.7.5.1 The drugs in the dispensing and storage areas shall be adequately protected from light, heat and moisture.

4.7.5.2 The drugs that are temperature sensitive shall be kept in a temperature controlled suitable storage facility.

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4.7.6 Medicines to be stored separately.

4.7.6.1 The recalled, expired or rejected drugs shall be stored in a separate area in the storage facility.

4.7.7 Toilet facilities

4.7.7.1 The premises shall have adequate toilet facilities, one of which shall not be shared with any other premises. The toilet facilities shall;

4.7.7.1.1 Be well ventilated;

4.7.7.1.2 Not be directly open to any storage area;

4.7.7.1.3 Be fitted with a sink; and

4.7.7.1.4 Have running water

4.7.8 Class A and class B drugs to be separated from class C drugs.

4.7.8.1 Class A and class B drugs shall be kept separate from the class C drugs.

4.7.8.2 The narcotic and psychotropic drugs shall be kept in a secure, fixed and lockable storage place.

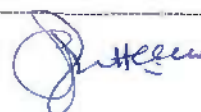
4.7.9 Premises to be of sufficient space

4.7.9.1 The premises shall have sufficient space to avoid overcrowding of customers and staff.

4.7.9.2 The premises shall be well lit, ventilated and secure.

4.7.9.3 The minimum floor area acceptable for pharmacies is;

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4.7.9.3.1 20 square meters of continuous floor space for retail pharmacies (at least 4m² dispensing and 16m² for shop area).

4.7.9.3.2 41 square meters for wholesales pharmacies (*at least 16m² shop area and 25m² for storage area*).

4.7.9.3.3 **Dual applications** for both wholesale and retail pharmacies **may** be considered for the same premise however, the premises must meet the minimum floor space requirement of **61m²** in addition to other requirements for suitability of premises.

4.7.9.4 **Administrative area.**

There shall be a separate office or administrative area, with a full view of the sales area, for the pharmacist and the prescriptions, purchase records and other administrative records shall be maintained in this office or area.

4.8 Distribution of Outlets:

4.8.1 Distribution of pharmaceutical outlets shall be based on the particular location of a proposed outlet, infrastructural development in the area, the population living in that area, number of pharmacies in that area and the distance of the proposed outlet from existing licensed outlets.

4.8.2 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.

4.8.3 **New pharmacies may only** be licensed to operate in Kampala District in the following cases;

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4.8.3.1 Veterinary pharmacies in areas **excluding container village**

4.8.3.2 Wholesale pharmacies engaged in importation, and/or distribution of registered products

4.8.3.3 Retail pharmacies in areas proven to be outlying and underserved. (For guidance purposes these shall be areas with no retail pharmacy within a radius of 500 meters)

4.8.4 **Municipalities: New pharmacies may only** be licensed to operate in the following municipalities; Nansana, Entebbe, Kira, Jinja, Mukono, Masaka, Mbarara, Mbale, Gulu, Soroti, Tororo, Lira, Fort portal, and Arua in the following circumstances;

4.8.4.1 Veterinary pharmacies

4.8.4.2 Wholesale pharmacies engaged in importation, and/or distribution of registered products

4.8.4.3 Retail pharmacies in areas proven to be outlying and underserved. (For guidance purposes these shall be areas with no retail pharmacy within a radius of 500 meters)

4.8.5 **Other towns and Municipalities:** Pharmacies may be licensed to operate in other towns and municipalities excluding those in 3.7.7 where the minimum distance from existing pharmacies is 100 meters.

4.9 Relocation of Pharmacies

4.9.1 Applicants for relocation shall apply and obtain approval in writing prior to relocation.

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- 4.9.2 Relocation of pharmacies shall not be allowed from one district to another.
- 4.9.3 Relocation of pharmacies within the same district may be considered under **special circumstances**.
- 4.9.4 Pharmacies in Kampala district may relocate within the district but the new location must be at least **200 meters** from existing pharmacies except
- 4.9.4.1 If the relocation is within a 200 meter radius of the previous location and the cause of the relocation is outside the control of the license holder
- 4.9.4.2 if the relocation involves a wholesaler whose move is intended to increase compliance to Good Distribution Practice (GDP) and other NDA regulations/guidelines and the move is not expected to impact adversely on existing pharmacies
- 4.9.5 Pharmacies in other towns may relocate but the new location must meet the relevant minimum distance of **100 meters** from existing licensed pharmacy. Exceptions may be made where the cause of relocation is beyond the license holder's control.
- 4.9.6 Pharmacies located within a **mall** shall not relocate outside the mall except under **extenuating circumstances**.

4.10 Other requirements for licensing of Pharmacies.

4.10.1 Pharmacies that sell human medicines, but desire to sell veterinary medicines as well can apply for certificates of suitability of premises and operating licenses for retail sale of veterinary medicines provided they meet the minimum floor area required (**20m²** for each retail pharmacy and **25m²** for storage space for each wholesale pharmacy).

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4.10.2 In case the pharmacist ceases to be responsible for the pharmacy before the expiry of the operating license issued in his/her name, it shall be his/her responsibility to return to the license to NDA.

4.10.3 In case of change of the pharmacist director, the applicant must submit evidence that one of the directors of the pharmacy is a pharmacist.

4.10.4 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, certified board resolution for the sale and the updated articles and memorandum of association.

4.10.5 It is the joint responsibility of the applicant/ owner of the Pharmacy to ensure that the certificates of the in-charges and Axillary Staff submitted to NDA are valid and authentic. Submission of an invalid or non-authentic certificate may lead to:

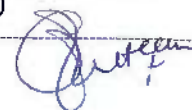
4.10.5.1 Denial or revocation of a license.

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

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

4.10.6 All licensed pharmacies shall have a clearly visible signpost indicating the name and type of outlet, namely: Human or Veterinary Drug Shop, Retail pharmacy or wholesale pharmacy.

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4.10.7 All pharmacies **should** ensure that **proper records of operations or transactions** are maintained. These shall include;

4.10.7.1 The source of supply of the drugs;

4.10.7.2 The date of purchase of the drugs;

4.10.7.3 The name and quantity of the drug;

4.10.7.4 The Dispensing Register containing the details of the patient and drug information;(for retail outlets)

4.10.7.5 The batch number and date of expiry of the drugs.

4.10.7.6 List of all expired medicines.

4.10.7.7 The records shall be retained for a minimum of five years and shall be available for inspection by an inspector of drugs at all reasonable times.

4.10.8 Change of licenses i.e. pharmacy to drug shop license, wholesale licenses to retail licenses and vice-versa shall be handled as new applications and will be subjected to the relevant sections of these guidelines.

4.10.9 All pharmacies in Private Hospitals and Medical centers shall apply for licensing by the National Drug Authority.

4.10.10 Wholesale Pharmacies shall be required to comply with **phase I of the implementation plan on Good Distribution Practices.**

4.10.11 External stores or additional storage premises for wholesale pharmacies shall not be used as a sale point.

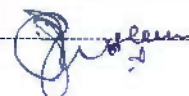
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4.10.12 Pharmacies involved in holding, distribution and sale of cold chain pharmaceutical products including vaccines shall ensure the cold-chain is maintained throughout the shelf life of the product. This will include; having appropriate cold chain refrigerators, routine calibration of all equipment involved in maintenance of the cold chain, regular temperature monitoring of the refrigerators, power backup supply to the refrigerators and any other strategies to ensure appropriate storage conditions for cold chain products.

4.10.13 All pharmaceutical outlets are expected to routinely submit expired drugs for destruction following the NDA procedures for destruction of expired drugs. Any pharmaceutical outlet found with expired drugs during inspection will be expected to submit these for destruction prior to processing of licenses.

4.10.14 A pharmacy license may be revoked without notice if in the opinion of the Authority, any provision of the NDA/P Act has been contravened or any condition contained in the license has been violated or if the premises have ceased to be suitable.

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5.0 LICENSING OF DRUG SHOPS

5.1 Requirements for Application

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

- 5.1.1 Duly filled application forms for certificate of suitability of premises
- 5.1.2 Duly filled application forms for the license
- 5.1.3 Proof of payment of the prescribed inspection fees
- 5.1.4 A certified copy of the certificate of registration of the qualified in-charge.
- 5.1.5 A letter of commitment from the in-charge.
- 5.1.6 A sketch plan of the premises taking into consideration the minimum floor area.
- 5.1.7 Two recent passport size photos of the qualified professional.

5.2 Timelines for renewal of Licenses for Drug shops for 2017.

5.2.1 Renewal applicants are encouraged to apply for license renewal at least **2 months** before the expiry of the current licenses, for avoidance of doubt, by the **1st November 2016** and in any case, **not later than 15th December 2016** at their respective regional offices.


5.2.2 Incomplete application documents for licensing will not be accepted at the time of submission.

5.2.3 All non-compliant drug shops should close shop effective 1st February 2017.

5.3 Inspection of Drug shop Premises.

5.3.1 Upon application, Inspection of the drug shop premises shall be conducted within 20 working days from the date of receipt of a complete application. A

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response on the outcome of the inspection shall be communicated to the applicant within 30 working days from the date of receipt of the application.

5.4 Approval of Drug shop License application.

5.4.1 Upon approval of an application, NDA shall notify the applicant of this approval.

The applicant shall then be required to pay the prescribed license fees before the licenses are issued.

5.4.2 In case of a rejection of the application, the applicant will be notified.

5.5 Premises for Class C drug shops

All applicants for a class C license shall apply for a certificate of suitability of premises. Premises **must** comply with the following requirements.

5.6 Location of premises

The premises shall be located in a place where the premises cannot be contaminated from the external environment or other activities.

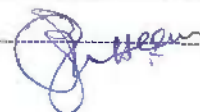
5.6.1 Have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning.

5.6.2 Premises to be in good state of repair and decoration.

5.6.2.1 The premises shall be maintained in a good state of repair and decoration.

5.6.2.2 The process of maintenance and repair shall not while being carried out cause any contamination of ingredients or products.

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5.6.2.3 The premises shall have a regular and sufficient supply of water.

5.6.3 Premises to have direct access.

The premises shall be of a permanent nature with direct access to the public.

5.6.4 Premises shall not be shared with similar business.

The premises shall not be shared with any medical clinic, veterinary surgery or any other business.

5.6.5 Drugs to be protected against light, heat and moisture

Class C drugs shall be adequately protected against light, heat and moisture.

5.6.6 Premises to be of sufficient space

5.6.6.1 The premises shall have sufficient space to avoid overcrowding of customers and staff.

5.6.6.2 The minimum floor area of the premises shall be at least 4square meters.

5.6.6.3 The premises shall be well lit, ventilated and secure.

5.7 Supervision of Drug shops

5.7.1 Drug shops shall only be run by one of the following professionals with an approved medical, pharmaceutical or veterinary qualification and must be **active members of their professional councils.**

5.7.2 The following professionals shall be accepted to supervise Human Drug Shops.

5.7.2.1 Pharmacy Technician/dispenser.

5.7.2.2 Registered or Enrolled Nurse

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5.7.2.3 Comprehensive Nurse

5.7.2.4 Registered or Enrolled midwife

5.7.2.5 Clinical Officer (Medical, Psychiatric, Orthopedic, Dental).

5.7.3 The following professionals shall be accepted to supervise Veterinary Drug Shops.

5.7.3.1 Veterinary Surgeon (BVM)

5.7.3.2 Animal Husbandry Officer (Diploma in Animal Husbandry /Dip. In Animal production and management) from institutions recognized by the National Council for Higher Education.

5.7.3.3 Veterinary assistants from former veterinary training institute.

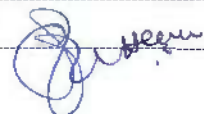
5.7.4 The premise must be operated by a licensed seller on a full- time basis, i.e. throughout the entire opening hours of the drug shop. If the licensed seller must leave the premises for any reason, the drug shop must be closed and locked, unless another person who is appropriately qualified is employed to dispense or supply medicines.

5.8 Distribution of Drug Shops

5.8.1 Class 'C' drug shops shall have a minimum separation distance of **1.5km** from any existing **retail pharmacy**, and in rural trading centers shall be within a distance of **500m** apart from each other.

5.8.2 Existing class 'C' drug shops which are located within **1.5km** from a licensed retail pharmacy shall be given an opportunity to upgrade to a pharmacy in the

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same location or relocate as per the section on distribution of pharmacies in these guidelines, within one calendar year.

5.8.3 Drugs shops upgrading to a pharmacy shall not be subjected to restriction on distance provided the current premises are suitable for a pharmacy business. However, if the current premises do not meet the requirements for a pharmacy and they relocate, the new location must be within **200 meters** of their current premises.

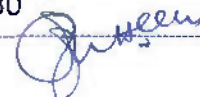
5.9 Relocation of Drug shops

5.9.1 Relocation of drug shops from one district to another district shall not be allowed.

5.9.2 Drug shops may relocate under special conditions; however the new location must be at least 100 meters from existing drug shops. Approval to relocate must be obtained prior to relocating.

NDA reserves the right to approve or reject any application for licensing a drug outlet in any area in accordance with National Drug Policy and Authority Act Chapter 206 in an effort to promote equitable access to medicines.

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6.0 REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURING FACILITIES

6.1 Supervision of Pharmaceutical Manufacturing Facilities

6.1.1 All applicants interested in establishing new pharmaceutical manufacturing facilities are advised to contact the National Drug Authority for guidance before embarking on any works.

6.1.2 All new applicants are required to follow NDA guidelines for establishing pharmaceutical manufacturing facilities.

6.1.3 An application for a licence to manufacture drugs shall be made using Form 19.

6.1.4 The application shall be accompanied by;

5.9.2.1 A certified copy of the certificate of registration of the pharmacist to be in charge of the manufacturing process;

5.9.2.2 A list of the drugs to be manufactured and proof of registration of the drugs;

5.9.2.3 The certificates of qualification of the key personnel to be involved in the manufacturing process, as may be determined by the Authority;

5.9.2.4 Certificate of compliance with the internationally accepted Good Manufacturing Practice Guidelines adopted by the Authority.

5.9.2.5 The prescribed fees.

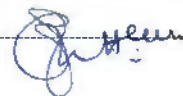
6.1.5 The manufacturing process shall be supervised by a registered pharmacist resident in Uganda.

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- 6.1.6 The process of quality control and quality assurance shall be under the supervision of a registered pharmacist and shall be conducted by a team of qualified pharmacists approved by the Authority.
- 6.1.7 The pharmacist in charge of the manufacturing process and the pharmacist in charge of quality control and quality assurance shall be independent of each other.
- 6.1.8 The pharmaceutical manufacturing operations must comply with the NDA Guidelines on Good Manufacturing Practices (GMP).
- 6.1.9 The GMP Certificate of compliance issued by NDA shall be valid for 3 years.
- 6.1.10 For local manufacturing facilities, licenses shall be issued on an annual basis.

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7.0 MEDICAL DEVICES AND MEDICAL LABORATORY SUPPLIES SELLERS.

7.1 Requirements for medical devices and medical laboratory supplies sellers

- 7.1.1 All medical and diagnostic equipment sellers shall be required to apply for certificates of Suitability of premises.
- 7.1.2 In addition, their activities shall be carried out under the supervision of a duly qualified professional with a pharmaceutical, medical and or biomedical qualification.
- 7.1.3 Firms involved in the importation of medical and /or diagnostic reagents, equipment and consumables shall be required to apply for import permits and have their imports verified and inspected by NDA.

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8.0 HERBAL MEDICINES

8.1 Requirements for Herbal Medicines

- 8.1.1 All herbal medicine sellers will be required to apply for certificates of suitability of premises.
- 8.1.2 All herbal medicine manufacturers will be expected to comply with GMP standards for the manufacture of herbal medicines.
- 8.1.3 Upon application, inspection of the herbal medicine shop or manufacturer premises shall be conducted within 20 working days from the date of receipt of an application. A response on the outcome of the inspection shall be communicated to the applicant within 30 working days from the date of receipt of the application for herbal medicine sellers and within 45 working days for herbal medicine manufacturers.
- 8.1.4 Hawking of herbal medicines and unauthorized advertisement of herbal medicines **are not allowed** and are considered **punishable offences according to the NDP/A act cap 206.**

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9.0 PAYMENT OF LICENSE FEES

9.1 Requirements for payment of license fees

9.1.1 All license fees shall be paid upon approval of applications.

9.1.2 All applicants for licenses to manufacture operate pharmacies and drug shops should pay the relevant fees through any branch of Stanbic bank within their areas using NDA Banking slips (please indicate your NDA FIN on the Bank slip). The details of the account number and bank branch are pre-printed on the customized bank slips.

9.1.3 **No license fee or inspection fee should be paid to the DDI or any other inspector. NDA shall not be responsible for any money paid to any inspector or any other official.**

9.1.4 The NDA banking slips (in triplicate) should be collected from any of the following offices nearest to you:

5.9.2.6 District Drug Inspector (DDI) based in the office of the DHO in every district.

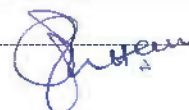
5.9.2.7 Regional offices found at the locations as indicated in section 2.3.1

5.9.2.8 NDA Headquarters', Plot No. 46-48, Lumumba Avenue, Kampala.

9.1.5 During payment, the banking slip should be filled in triplicate and should clearly show the name of the drug shop or pharmacy and amount paid. **Each of the 3 copies shall be originally signed and stamped by the bank.**

9.1.6 The inspector /DDI shall deliver a copy to the Regional Office to be issued with a receipt in exchange which shall also bear your NDA FIN for ease of

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reconciliation. This should be done promptly to facilitate bank reconciliation. **NDA shall issue a receipt only on receipt of a copy originally endorsed by the Bank.** The applicant shall make good any deficit plus any related charges found during bank reconciliations.

For further information please contact NDA Headquarters or the NDA Regional offices.

Secretary to the Authority
National Drug Authority
P. O. Box 23096
Kampala

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