General Notice No. 1321 of 2018.

Safe Drugs Save Lives

LICENSING GUIDELINES 2019
RENEWAL AND NEW LICENSES FOR CLASS C DRUG SHOPS.

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E-mail: ndaug@nda.or.ug
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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

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.

Approved by The Drug Authority	
Signature	
Name	Dr. Medard Bitekyerezo
Title	Chairperson, National Drug Authority
Date	27th November, 2018

Notice:

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;

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

2.0 Timelines for renewal of Licenses for Drug shops for 2019.

2.1 Applications for renewal are encouraged to be submitted not later than **23rd November, 2018** at their respective regional offices.

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

2.3 All unlicensed drug shops must close effective **1st January, 2019.**

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.

- Pharmacy Technician/dispenser
- Registered or Enrolled Nurse
- Comprehensive Nurse
- Registered or Enrolled midwife

3.3 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 closed.

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.

5.0 Distribution of Drug Shops.

5.1 No new drug shops shall be licensed to operate in Kampala District.

5.2 No new drug shops shall be licensed in municipalities with existing pharmacies.

5.3 New drug shops may be licensed in other areas; however, the premises must be at least **200 meters** from the nearest existing drug shop and **1.5 km** from any existing pharmacy.

6.0 Relocation of Drug shops.

6.1 Drug shops may relocate within a 200 meters' radius of their current premises in the same district; however, where the relocation exceeds a 200 meters' radius, the new location must be at least 200 meters from existing drug shops and 1.5 km from a pharmacy. Approval to relocate must be obtained prior to relocation.

7.0 Herbal Medicines.

7.1 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).**

General Notice No. 1322 of 2018.

Safe Drugs Save Lives

LICENSING GUIDELINES 2019
LICENSING NEW PHARMACIES OUTSIDE KAMPALA

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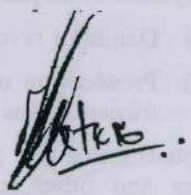
West Nile Region – Plot 1 Mt. Wati Road, Anyaflo –Arua

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(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.'*

Approved by The Drug Authority	
Signature	
Name	Dr. Medard Bitekyerezo
Title	Chairperson, National Drug Authority
Date	27th November, 2018

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 PHARMACIES.

1.0 General Principles.

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 except where there is no existing pharmacy in a district.

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.

1.5 All applications for 2019 licenses shall be subject to these guidelines.

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 and a certificate of incorporation.

e) Certified copies of company form 20 and a company resolution appointing the directors in the company one of whom must be 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 for veterinary drugs, a copy of the certificate of registration of the qualified veterinary professional (Veterinary Surgeon);

k) URA TIN certificate.

2.2 Incomplete application documents for licensing a new retail or wholesale 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 and payment of the requisite fees, inspection of the proposed pharmacy premises shall be conducted within 20 days from the date of receipt of a complete application.

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 And Authority (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.

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

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. Upon approval of pharmacy premises and payment of requisite fees, a license to operate a pharmacy shall be 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 except in instances where dual applications have been allowed in Clause 1.2

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) number of pharmacies in that area; and

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

6.2 In the application of distance to determine the distribution of pharmacies, the distance from the nearest existing pharmacy shall be measured using radius. That is the distance between a human to human pharmacy or veterinary to veterinary pharmacy and the proposed new pharmacy premises.

6.3 In a bid to streamline the distribution of pharmaceutical outlets and pharmaceutical service in the country, new pharmacies in the following municipalities shall only be allowed in outlying areas where the minimum distance shall be 300 meters from the nearest existing 'like' pharmacy.

These municipalities include;

❖ Arua.	❖ Jinja
❖ Entebbe	❖ Kira
❖ Fort Portal	❖ Makindye Sabagabo
❖ Gulu	❖ Lira
❖ Hoima	❖ Masaka
❖ Mbarara	❖ Mbale
❖ Mityana	❖ Nansana
❖ Mubende	❖ Soroti
❖ Mukono	❖ Tororo

6.4 A pharmacy may be licensed to operate in other areas. In that case, the minimum distance from any existing nearby pharmacy will be 100 meters.

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

6.6 Where the licensed seller meets the requirements for a pharmacy, the license to operate a pharmacy will be allowed:

a) The pharmacy is to be located on the same premises where the drug shop is currently licensed.

b) The ownership of the drug shop is the same as the new pharmacy.

c) The name of the pharmacy is the same as that of the drug shop

d) The Drug shop if first licensed after 2014 was 1.5 km from any existing pharmacy as required under the regulation

e) Must not be joined to a clinic

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.

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.

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

General Notice No. 1323 of 2018.

Safe Drugs Save Lives

LICENSING GUIDELINES 2019
LICENSING NEW PHARMACIES IN KAMPALA

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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(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.'*

Approved by The Drug Authority	
Signature	
Name	Dr. Medard Bitekyerezo
Title	Chairperson, National Drug Authority
Date	27th November, 2018

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 PHARMACIES IN KAMPALA.

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.

1.5 All applications for 2019 Licenses shall be subject to these guidelines.

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 and a certificate of incorporation;
e) 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;
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, a copy of the certificate of the qualified veterinary professional (Veterinary Surgeon); and
k) URA TIN certificate.

2.2 Incomplete application documents for licensing a new retail or wholesale 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 and payment of the requisite fees, inspection of the proposed pharmacy premises shall be conducted within 20 days from the date of receipt of a complete application.

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.

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

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. Upon approval of pharmacy premises and payment of requisite fees, a license to operate a pharmacy shall be 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 In a bid to streamline the distribution of pharmaceutical outlets and pharmaceutical services in Kampala, only institutional pharmacies shall be allowed to open up as new pharmacies in Kampala.

For avoidance of doubt, institutional pharmacies shall be those pharmacies embedded in the established institutions for purposes of serving clients in that institution.

Stand-alone pharmacies shall not be allowed to open up new pharmacies in Kampala.

6.2 Where drug shops in Kampala meet the licensing requirements for pharmacies in their current premises and:

a) The pharmacy is to be located on the same premises where the drug shop is currently licensed.

b) The ownership of the drug shop is the same as the new pharmacy.

c) The name of the pharmacy is the same as that of the drug shop.

d) The Drug shop if first licensed after 2014 was 1.5km from any existing pharmacy as required under the regulation.

e) Must not be joined to a clinic.

The license to operate a pharmacy will be allowed.

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.

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

7.3 The premises, in respect of which a license is issued by the Authority, shall have a conspicuous signpost indicating the name and type of business carried out at the premises.

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

General Notice No. 1324 of 2018.

Safe Drugs Save Lives

LICENSING GUIDELINES 2019
LICENSING RENEWAL OF LICENCE FOR PHARMACIES

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

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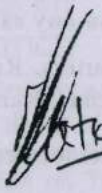
These Professional Guidelines 2019-Licensing have been prepared in line with Section 5 (a) and 5 (i) of the National Drug Policy and Authority Act (CAP 206) which provides for the functions of the Authority which among others are 'to deal with the development and regulation of the pharmacies and drugs in the country and to establish and revise professional guidelines and disseminate information to health professionals and the public.'

Approved by The Drug Authority	
Signature	
Name	Dr. Medard Bitekyerezo
Title	Chairperson, National Drug Authority
Date	27th November, 2018

Notice:
It is the responsibility of the supervising pharmacist to ensure full compliance of pharmacy operations with the NDP/A Act and the regulations made thereunder.

ADDITIONAL GUIDANCE ON RENEWAL OF PHARMACY LICENSES.

1.0 Application for renewal of pharmacy licenses.

1.1 All renewal of pharmacy license applications shall be made through the NDAMIS online platform. All applicants seeking renewal of their licenses shall be provided with **access credentials** to NDAMIS upon request.

1.2 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.

1.3 All applicants seeking renewal of pharmacy licenses for 2019 will be subject to these guidelines.

2.0 Timelines for renewal of pharmacy licenses for 2019.

2.1 Applicants are encouraged to apply for renewal of licenses not later than **23rd November 2018.**

2.2 All unlicensed pharmacies must **close** effective **1st January 2019.**

3.0 Pharmacy personnel.

3.1 Supervising pharmacists may be issued a maximum of two licenses in their name.

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

3.3 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.

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

3.5 Wholesale pharmacies dealing in veterinary medicines and vaccines, shall employ a named registered veterinary surgeon.

3.6 The pharmacist shall be required to be present in the pharmacy at all times.

3.7 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.

4.0 Relocation of pharmacies.

4.1 Pharmacies seeking to relocate must have a valid license.

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

4.3 Pharmacies may relocate within the same district but the new location must be at least in a radius of **200 meters** from the nearest existing and licensed pharmacy.

4.4 Notwithstanding clause **4.3** above, a pharmacy relocating within a 200 meters radius of its original location shall not be required to meet a minimum distance requirement from existing pharmacies.

5.0 Change of management / nature of business operations.

5.1 Pharmacies seeking to change management must have a valid license.

5.2 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.

5.3 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.

5.3 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 regulations.

6.0 Other requirements for renewal.

6.1 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.

6.2 License renewal shall only apply for pharmacies which had a license to operate in 2018 and 2017 in the same premises.

6.3 In case of change of supervision by a pharmacist from one pharmacy to another, evidence that a company has a pharmacist as a director should be presented to NDA.

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

General Notice No. 1325 of 2018.

Safe Drugs Save Lives

LICENSING GUIDELINES 2019
LICENSING PHARMACEUTICAL MANUFACTURING FACILITIES.

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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.

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 pharmacies and drugs in the country and to establish and revise professional guidelines and disseminate information to health professionals and the public.' The guidelines will apply to all 2019 applications.

Approved by The Drug Authority	
Signature	
Name	Dr. Medard Bitekyerezo
Title	Chairperson, National Drug Authority
Date	27th November, 2018

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

- NDA Headquarters, Rumee Towers, Plot No.19, Lumumba Avenue, Kampala.
- Regional offices located at the following locations;
  - * 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.

1.0 Renewal of Pharmaceutical Manufacturing License.

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

1.2 The application shall be accompanied by—

- A list of the drugs to be manufactured.
- A certified copy of the certificate of registration of the pharmacist to be in charge of the manufacturing process.
- The certificates of qualification of the key personnel to be involved in the manufacturing process.
- The prescribed fees.

2.0 Personnel.

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

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

2.3 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 to establish a new manufacturing facility in accordance with the National Drug Policy and Authority Act, Cap. 206 in an effort to promote equitable access to medicine.