PROFESSIONAL GUIDELINES 2018 – LICENSING

RENEWAL OF LICENSE FOR: PHARMACEUTICAL MANUFACTURING FACILITIES.

National Drug Authority
Secretariat Office
Rumee Towers Plot 19 Lumumba Avenue.
P.O. Box 23096
Kampala, Uganda
Phone: (+256) 41-255665 / 347391/ 347392
Fax: (+256) 41-255758
E-mail: ndaug@nda.or.ug

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 (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 will take effect on the 1st October 2017 and will be valid till the 30th September 2018.

Approved by:	
Title	Secretary to the Authority
Name	Donna Kusemererwa
Signature	
Date	5/10/17

All applicants interested in establishing new pharmaceutical manufacturing facilities are advised to contact the following NDA offices for guidance before embarking on any works.

- 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, Plot30, 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.

1.2 The application shall be accompanied by—

- A list of the drugs to be manufactured.
- The certificates of qualification of the key personnel to be involved in the manufacturing process.
- A valid certificate of Good Manufacturing Practice (cGMP).
- 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.

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.

END