LICENSING REQUIREMENTS AND GUIDELINES FOR 2015

1. General Requirements For all Applicants

1.1 Applicants should collect application forms from the following locations;

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

Regional office located at the following locations;

- Central Region –Premier Complex, Nakawa.
- South Eastern Region –Plot 6 Rippon Gardens, Jinja
- Eastern Region –Plot No. 27, Kwapa Road, Tororo
- Northern Region – Erute road, Lira.
- Western Region:- Muganwa Centre, Plot30, Old Toro Road , Hoima
- South- Western Region: -Kamukuzi, Mbarara.
- West Nile Region – Plot 1 Mt. Wati Road, Anyaflo –Arua

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

PLEASE NOTE THAT ALL APPLICATION FORMS AND BANKING SLIPS ARE FREE

1.2 In line with Guidelines for Equitable Distribution of Drug Outlets ", no person shall open up or transfer any drug outlet anywhere without the prior approval of the location by National Drug Authority. **An application for pre-inspection of the location of the proposed premises should be submitted to NDA prior to any financial or legal commitment to the premises and the approval should be obtained in writing following pre-inspection.** This is to avoid loss in cases of rejection of application based on these and any other guidelines. NDA shall not be obliged to license premises opened without following these procedures and shall not be liable to any claims of resultant financial loss. This approval shall be valid for a period of 3 months and, if not implemented or delay not justified in writing, thereafter be null and NDA may authorize a new applicant in the location

1.3 A Drug outlet shall be considered unlicensed and should close its operations to the public if National Drug Authority has not licensed it **by 31st Jan 2015**. Applicants are encouraged to apply to renew their licenses before the expiry of the current licenses

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1.4 All applicants should ensure that proper records of operations or transactions are maintained.

1.5 All licensed drug outlets must have a clearly visible signpost indicating the name and type of outlet, namely: Human or Veterinary Drug Shop, Retail pharmacy or wholesale pharmacy and Facility Identification Number (FIN) – Ten Digit

1.6 Licenses shall be withdrawn where it is confirmed that:

a) Unqualified staff has been allowed to **handle drugs or have been left in charge of a drug outlet.** All pharmacy staff must be identified at all times while in these premises

b) The drug outlet has been involved in **stocking and /or selling drugs beyond those prescribed by the respective license, or unregistered, unauthorized, smuggled or counterfeit drugs.**

1.7 In case the pharmacist or in-charge of drug shop ceases to be responsible for the outlet before the expiry of the operating license issued in his/her name, it shall be his/her responsibility to return to NDA the said license if he/she has not returned the valid license previously issued in his or her name.

1.8 Any drug outlet that does not renew its license for at least one year without written acceptable and prior approved reasons shall, on re application, be treated as new applicants with respect to location and fees.

Applicants must also comply with these and all other statutory and regulatory requirements

2.0 SUPERVISION REQUIREMENTS

2.1 DRUG SHOPS

2.11 These may only be supervised by one of the following professionals with an approved medical, pharmaceutical or veterinary qualification and **active members of their professional councils**

2.1.2 HUMAN DRUG SHOPS

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

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- Clinical Officer (Medical, psychiatric, othopaedic, Dental)
- Anaesthetic Assistant/officers

2.1.3 Veterinary Drug Shops

- Veterinary Surgeon (BVM)
- Animal Husbandry Officer (Diploma in Animal Husbandry /Dip. In Animal production and management) as approved by the veterinary board.
- Veterinary assistants from former veterinary training institute.

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

2.2 Pharmacies

2.2.1 Must be supervised by a named **registered pharmacist** who is an active member of PSU resident in Uganda.

2.2.2 A pharmacist in community pharmacy practice shall be allowed to supervise pharmaceutical operations of two pharmacy premises and must indicate to NDA at the time of application:

- The time and duration he/she is expected to be physically present in each premises
- The name and qualification of the Professional Auxiliary Staff (PAS) to deputize the pharmacist during the hours of his/her physical absence,

2.2.3 Premises applying for renewal of both **wholesale and Retail Licenses** are required to have at least **two PAS**

2.2.4 For wholesale dealing in veterinary medicines and vaccines, a registered named veterinary surgeon must be employed in each premise supervised by the pharmacist

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2.3 PHARMACEUTICAL MANUFACTURING FACILITIES

2.3.1 Manufacturing must be carried out under the direct supervision of a registered named production Pharmacist

2.3.2 All pharmaceutical manufactures should employ at least two registered pharmacists to supervise production, quality assurance and regulatory affairs. **The pharmacist must not supervise any other pharmaceutical business whether on the same or any other premises**

2.3.3 The production pharmacist shall be the in charge of production and must be supported by suitably qualified personnel such as pharmacists, pharmacy **technicians or approved chemists.**

2.3.4 **Quality control/ Quality Assurance of Manufactured products must be supervised by a registered named Quality Control Pharmacist** or Chemist

2.3.5 The Quality Control /Quality Assurance of Manufactured products must be supported by suitably qualified personnel such as pharmacists, pharmacy technician or approved chemists

2.3.6 The pharmaceutical manufacturing operations must comply with NDA Guidelines on Good Manufacturing Practices (GMP)

3 LICENSING REQUIREMENTS FOR PHARMACIES AND DRUG SHOPS

3.1 Applicants for Licence Renewal

3.1.1 **All Renewing applicants should submit the following not later than 15TH NOVEMBER 2014**

3.1.2 The completed application forms,

3.1.3 Letter of acceptance from the professional in charge plus a copy of his/her relevant Registration/ Enrolled certificate, certified by relevant professional bodies.

3.1.4 A copy of the previous year's license.

3.1.5 Proof of payment of the prescribed fees

3.1.5 PHARMACIES

3.1.6 In addition to the above requirements, the applicant should submit also the following:

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3.1.7 A valid Certificate of Registration of the supervising pharmacist as issued by the registrar of pharmacy council, Ministry of Health and proof of subscription to PSU.

3.1.8 A letter of commitment from the supervising pharmacist

3.1.9 For Retail/Wholesale pharmacies (human): a copy of the certificate of registration/enrollment with the relevant professional body for the auxiliary staff.

3.1.10 For Retail/Wholesale pharmacies (veterinary): a copy of the certificate of the qualified veterinary professional (veterinary surgeon or Animal Husbandry Officer)

3.1.11 **In case of change of pharmacist the applicant must submit proof that the pharmacist is one of the directors**

3.1.12 **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 update/ current articles and memorandum of association**

3.1.13 DRUG SHOPS

3.1.14 In addition to the general requirements, the applicant should submit also the following:

3.1.15 Two recent passport size photos of the qualified professional in charge.

3.1.16 A copy of the certificate of the qualified medical/ pharmaceutical/ veterinary profession in- charge and current certificate of practice from the professional council.

3.1.18 Note: **it is a joint responsibility of the in-charge and the applicant/ owner of the drug shop to ensure that the certificate of the in-charge submitted to NDA is valid and authentic**

3.1.19 Submission of an invalid or non-authentic certificate may lead to:

- Denial or revocation of a license
- Prosecution of the in-charge and /or the owners of the drug shop
- Blacklisting of the in-charge and/or the owners of the drug shop

3.2 REQUIREMENTS FOR NEW APPLICANTS:

3.2.1 Pharmacies

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3.2.2 All new applicants are required to submit an application for pre-inspection indicating the specific physical location of the premises, telephone/email contacts of the applicant, name and distance to the nearest existing drug outlets in the area.

3.2.3 All new applicants for a pharmacy license must submit the following after pre-inspection approval:

- Copy of pre-inspection approval letter from NDA.
- **A certified copy of the Articles and Memorandum of Association or Partnership Deed showing the supervising Pharmacist as one of the Directors of Partnership of the firm, respectively.**
- A sketch plan of the premises taking into consideration the minimum floor area for wholesale, retail and additional storage area.
- The certificate of registration of the supervising pharmacist
- Commitment letter from the supervising pharmacist and PAS.
- Certificate of registration of the auxiliary pharmacy staff, issued by the respective professional councils.
- Note that the minimum floor area acceptable for pharmacies is;
    - 20 square meters for area acceptable retail pharmacies *(atleast 4m^2 dispensing and 16m^2 for shop area).*
    - 41 square meters for wholesales pharmacies *(atleast 16m^2 shop area and 25m^2 for storage area).*

3.2.4 **New dual** applications for both wholesale and retail pharmacies will no longer be accepted for the same premise. Applicants will have to apply for license to operate either wholesale or retail pharmacies only.

3.2.5 New dual applications for both wholesale and retail pharmacies with respect to premises and location may be considered for only **Underserved areas as declared by NDA.** However this has to be in line with guidelines for equitable distribution of pharmaceuticals outlets.

3.2.6 Pharmacies that sell human medicines , but desiring 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

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required ($20m^2$ for each retail pharmacy and $25m^2$ for storage space for each wholesale pharmacy).

3.2.7 DRUG SHOPS

3.2.8 All New applicants for a drug shop license are required to submit the following before inspection:

3.2.9 The completed application forms.

3.2.10 Two recent passport size photos of the qualified professional in charge.

3.2.11 A copy of the certificate of the qualified medical/pharmaceutical/veterinary profession in- charge.

3.2.12 Note

- **It is joint responsibility of the in-charge and the applicant/owner of the drug shop to ensure that the certificate of the in-charge submitted to NDA is valid and authentic**
- **The minimum floor area acceptable for drug shops is 4 square meters**

3.3 MEDICAL DEVICES AND MEDICAL LABORATORY SUPPLIES SELLERS

3.3.1 All medical and diagnostic equipment sellers will be required **to apply for certificates of Suitability of premises.**

3.3.2 In addition, their activities shall be carried out **under the supervision of a duly qualified professional with a pharmaceutical, medical and or biomedical qualification.**

3.3.3 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**

4. LICENSING REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURERS

4.1 Renewal Applicants

4.1.2 In addition to the general requirements, the applicant should submit also the following:

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4.1.3 The certificates of Registration of two registered supervising pharmacists as issued by the Registrar of the pharmacy council, Ministry of Health and proof of subscription to PSU.

4.1.4 A Certificate and letter of commitment of an authorized person to carry out Quality Control and Quality Assurance

4.1.5 Certificate of the dispenser

4.1.6 A letter of commitment from the supervising pharmacist

4.1.7 A letter of commitment from the dispenser

4.18 A complete list of all the products to be manufactured and their registration status

4.1.9 A complete list of all the technical staff, stating their positions, qualifications, nationalities and registration numbers, if any

4.1.10 A complete list of all laboratory equipment

4.2 NEW APPLICANTS

4.2.1 All applicants interested in establishing new pharmaceuticals manufacturing facilities are advised to contact the National Drug Authority at the above mentioned addresses for guidance before embarking on any works.

4.2.2 All new applicants are required to follow NDA guidelines for establishing new pharmaceutical manufacturing facility

5. PAYMENT OF LICENSE FEES

5.1 a) All fees for renewal of licenses shall be paid upon submission of application. **No application for renewal shall be received without full payment of the necessary fees.**

a) All applicants for licenses to 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. No license 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.**

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

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

5.4 Regional offices found at the locations as indicated in section 1.1

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

5.6 During payment, the banking slip should be filled in quadruplicate 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.**

5.7 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 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

5.8 The inspector, DDI shall promptly forward the receipt to the applicant.

- For further information on these and other drug regulatory issues contact NDA officials at the above addresses **(section 1.1)**

5.11 **Incomplete applications shall not be accepted.**

FEES STRUCTURE

1. FEES FOR REGISTRATION OF DRUGS, RETENTION, NOTIFICATION AND AMENDMENT

REGISTRATION/ RETENTION/NOTIFICATION/AMENDMENTS	**Fees in US $ except where indicated in Shillings**
1. First registration	

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(a) Human/Veterinary products	US $1250
(b) Imported Human Nutritional Supplements	US $500
(c) Imported Vet Nutritional Supplements	US $500
(d) Local Human/Vet NS	not applicable
(e) Locally manufactured medicine registration (LSM)	US $200
(f) Locally manufactured medicine registration (SSM)	150,000/=
(g) EDLU item, Low Commercial Value, not currently registered, registration	US $250
(h) OTC/PIM medicines, Low Commercial Value registration	US $1250
(i) Registration Traditional (Herbal) Medicines	US $500
(j) Registration of a locally repackaged foreign product	US $300
2. Annual Retention of registration	
(a) Human/Veterinary products	US $500
(b) Traditional (Herbal) Medicines (foreign)	US $250
(c) Imported Human NS	US $200
(d) Imported Vet NS	US $200
(e) Local Human/Vet NS	US $50
(f) Locally manufactured medicine retention (LSM)	US $100
(g) Locally manufactured medicine retention (SSM)	US $100
Note: Products not retained for year 2013/14 will have to pay for both 2013/14 and 2014/2015 before re-instatement on the Register. This policy will remain in effect for subsequent years.	
3. Fees for notification	
(a) Traditional (Herbal) products (local)	10,000/=
(b) Traditional (Herbal) products (foreign)	US $250
(c) Food supplements (local)	20,000/=
(d) Food supplements (foreign)	US $20
(e) Public Health products (local)	20,000/=
(f) Public Health products (foreign)	US $50
4. Fees for amendment	
Amendment Human/Vet	
Major	US $ 600
Minor	US $300
Notification	US $100
Amendment food supplements (foreign)	
Major	US$ 300
Minor	US$ 150
Notification	US $ 50
Amendment herbals (foreign)	
Major	US$ 300
Minor	US$ 150
Notification	US $ 50

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Amendment locally manufactured products	
Major	US$ 120
Minor	US$ 60
Notification	US$ 20

Note: The amendments (major, minor and notification) are clearly justified in the Variation Guidelines available on the NDA Website.

2. FEES FOR A DRUG SHOP

ITEM	New Application for a licence			Application for renewal of licence		
	Kampala	Municipal	Rural	Kampala	Municipal	Rural
1. Inspection	15,000	15,000	15,000	15,000	15,000	15,000
2. Suitability of premises	120,000	75,000	52,500	60,000	37,500	30,000
3. Operating License	120,000	75,000	45,000	120,000	75,000	45,000
Total Fees payable	**255,000**	**165,000**	**112,500**	**195,000**	**127,500**	**90,000**

3. FEES FOR A RETAIL PHARMACY

a) Within Kampala District

Item for fees payment	Application for a licence		Application for renewal of licence	
	Central division	Other divisions	Central division	Other divisions
1.Inspection	60,000	45,000	60,000	45,000
2.Suitability of Premises	1,000,000	600,000	600,000	375,000
3.Operating license	600,000	300,000	600,000	300,000
Total Fees payable	**1,660,000**	**945,000**	**1,260,000**	**720,000**

b) Outside Kampala District

Item	Application for a licence		Application for renewal of licence	
	Municipal	Rural	Municipal	Rural
1. Inspection	36,000	36,000	36,000	36,000
2. Suitability of Premises	240,000	240,000	120,000	120,000
3. Operating License	120,000	120,000	120,000	120,000
Total Fees payable	**396,000**	**396,000**	**276,000**	**276,000**

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4. FEES FOR A WHOLESALE PHARMACY

a) Within Kampala

Item	Application for a licence		Application for renewal of licence	
	Central division	Other divisions	Central division	Other divisions
1. Inspection	70,000	52,500	70,000	52,500
2. Suitability of Premises	1,000,000	600,000	500,000	300,000
3. Operating license	850,000	450,000	850,000	450,000
Total fees payable	**1,920,000**	**1,102,500**	**1,420,000**	**802,500**

b) Outside Kampala

Item	Application for a licence		Application for renewal of licence	
	Municipal	Rural	Municipal	Rural
1. Inspection	42,000	42,000	42,000	42,000
2. Suitability of Premises	240,000	240,000	120,000	120,000
3. Operating License	250,000	250,000	250,000	250,000
Total fees payable	**532,000**	**532,000**	**412,000**	**412,000**

5. FEES FOR A PHARMACEUTICAL MANUFACTURING LICENCE

a) Fees for operating licences and certificate of suitability of premises

	Licence Category	New Applicant			Renewing applicant		
		Operating licence	Certificate of Suitability of premises	Total	Operating licence	Certificate of Suitability of premises	Total
a	Manufacture of external preparation OR Oral liquid preparations	420,000	350,000	**770,000**	350,000	350,000	**700,000**
b	Manufacture of external preparations AND/ OR Oral liquid preparation	480,000	400,000	**880,000**	400,000	400,000	**800,000**
c	Manufacture of sterile preparations AND/OR other types of dosage forms	700,000	700,000	**1,400,000**	600,000	600,000	**1,200,000**
d	Primary packaging	350,000	300,000	**650,000**	300,000	300,000	**600,000**
e	Secondary packaging	300,000	250,000	**550,000**	250,000	250,000	**500,000**

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b) Inspection fees for the above categories

i) Manufacturers in category e		70,000	
ii) Manufacturers in category a,b,c		130,000	

c) Re-inspection fees for the above categories (after failure to comply with NDA standard)

i) Manufacturers in category e		200,000
ii) Manufacturers in category a,b,c		500,000
d) Application to amend a manufacturing licence		
i) with site inspection (for manufacturer)		250,000
ii) with site inspection (for packaging activities)		150,000
iii) without inspection		100,000

6. FEES FOR IMPORTATION OF DRUGS

Description	Fees
1. Annual Import or Export Permit	300,000
2. Provisional Import or Export Permit (*Per consignment*)	100,000
3. Verification fees for commercial consignments and donations to commercial organizations and Government Ministries, Departments, Projects, Programmes and Institutions	2.0%
4. Verification for unregistered drugs from authorized and approved sources	2%
5. a) Verification fees for donations to non-profit making charitable NGOs (0 to $ 1,000=)	100,000/=
5. b) Verification fees for donations to non-profit making charitable NGOs ($ 1,001= to $5,000)	200,000=
5. c) Verification fees for donations to non-profit making charitable NGOs (over $5000)	300,000=
6. Verification for consignments for disasters, outbreaks, vaccines, raw materials,	exempted
7. Fine for a consignment of drugs **imported without prior authorization by NDA and/or arrives at the port of entry before the product is registered or amendments are applied for and approved***	US $1000

**Such consignments shall only be inspected for release on condition that the amendments have been approved and the fine has been paid*

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7. FEES FOR ANALYSIS OF SAMPLE IN A LABORATORY

Description	Fees
1. Routine drug analysis of one batch in the NDA Lab	$300
2. Male Latex Condoms per batch	US$280
3. Long Lasting Insecticide Treated Nets (LLINs), per batch of size up to 30,000 nets and every 30,000 nets.	US$200
4. Samples analyzed at laboratories outside NDA	cost + 10% service charge
5. Re-analysis of a sample at owner's or importer's request	US $1000
6. Detailed Certificate of Analysis at the request of the owner/Importer	$100
7. Analysis for gloves	US$150
8. Analysis for more than three batches	100,000/= per batch

8. FEES FOR GMP INSPECTION FOR FOREIGN PLANTS

a) On site GMP inspection per manufacturing site

	Processes at the site	Within East Africa	Within the rest of Africa	Outside Africa (Asia/Europe/America/ New Zealand/Australia)
1	Site with all processes at one site for 5 product lines	US$3,000	US$4,000	US$6,000
2	Any additional production line	$ 1000 per line		
3	For products moving through several sites, additional Sites in the same country as main site:			
	Warehousing of raw materials up to finished bulk product	US $1,500	US$2,000	US$3,000
	Final packaging, quality control and final release	US$1,000	US$1,500	US$2,000
	Quality control and final release	US$500	US$750	US$1,000

b) GMP document evaluation (Desk Audits) shall be charged at $ 5000 per manufacturing site.

9. FEES FOR CLINICAL TRIALS (HUMAN AND VETERINARY)

	Stage of clinical trial	Product	Fees in US $
1	Phase I	Registered or unregistered	2500
2	Phase II or III	New investigational product: (Unregistered)	4000
3	Phase II or III	Known product (Registered)	3000
4	Phase IV		1000

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	Others	including Device, Nutritional Supplement, herbal and (always with registered product) public health products	1000
5	Amendments to Clinical Trial Application		200
6	Fees for Field Trial (Veterinary)		
	All phases	Arcaricides	1000

10. FEES FOR CHANGES IN PARTICULARS REGISTERED WITH NATIONAL DRUG AUTHORITY

Nature of change	Fees (Shs & US$)
1. Change of name, **ownership** or management of a pharmacy	500,000/-
2. Change of name, **ownership** or management of a drug shop	100,000/=
3. Change of pharmacist or in-charge person during the licensing period	100,000/-
4. Change in professional Auxiliary staff	50,000/-
5. Change of person in charge of a drug shop	50,000/-
6. Change of Local Technical Representative	$ 1,000

11. FEES FOR NDA PUBLICATIONS

Nature of publication	Fees in Shs
1. Set of statutes and Statutory Instruments	25,000
2. Purchase Order Book	25,000
3. Classified Book	25,000
4. Delivery Book	25,000
5. Drug Prescription Book	25,000
6. List of licensed drug outlets	25,000
7.GMP Audit Checklist	25,000
8.Drug Register(Human)	25,000
9. Drug Register(Veterinary)	25,000
10. Application for verification of Proforma invoices-(booklet of forms)	25,000

12. FEES FOR VETTING DRUG PROMOTIONAL MATERIALS

Nature of task	Fees in Shs
1. Screening of Promotional materials per language:	
(a) Written materials	200,000
(b) Audio/video + written Scripts	200,000
(c) Posters/Bill boards on any medium including internet	200,000
(d) Posters on Vehicles	200,000
(e) T- shirts	200,000
(f) Other materials e.g. caps, wall clocks, watches, umbrellas, bags etc	200,000
2. Organising a launch / a symposium	200,000
3. Participating in exhibitions	200,000

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4. Miscellaneous: (a) Roadside shows (b) Sponsorship of functions	200,000

13. FEES FOR OTHER TASKS CARRIED OUT BY THE AUTHORITY

Nature of task	Fees payable in Uganda shillings
1. Supervision of specialized tasks e.g. Drug destruction (per hour)	2457/= per kg plus 100,000 supervision

THE FOLLOWING ARE THE GUIDELINES ON EQUITABLE DISTRIBUTION OF PHARMACEUTICAL SERVICES IN UGANDA, 2015

First Published in November 2004

INTRODUCTION

One of the mandates of NDA is to put in place policies to ensure that safe, efficacious and good quality **drugs are available to the entire human and animal population of Uganda**. To achieve this, the distribution of pharmaceutical services/drug outlets is controlled by the National Drug Authority under the provisions of section 5(a) of National Drug Policy and Authority Act, Cap. **206 through encouraging their equitable distribution**. This has been achieved by implementing a policy of:-

- Charging **reduced fees** for applicants from up country towns and r**ural areas**.
- **Restricting the opening up of new drug outlets** in certain defined areas considered to be sufficiently served compared with other areas that are under served Consequently, a number of pharmaceutical outlets have opened up in hitherto underserved areas of the country, hence improving the accessibility of pharmaceutical services to the rural population of Uganda.

The strategy of equitable distribution was **first implemented in 1998 by banning the opening of new drug outlets in Kampala Central Division and subsequently piloted in Jinja District in 2003.** The guidelines were subsequently discussed with stakeholders and first published in January 2004. Since the initial implementation, a

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number of improvements on the guidelines have been found necessary. These have been discussed and agreed upon with stakeholders and the guidelines updated to this version. They shall, until notified otherwise, be used in assessing new applications and applications for relocating drug outlets.

A) General

1) The National Drug Authority, in collaboration with the Relevant Professional Councils, shall be responsible for ensuring equitable distribution of pharmaceutical/ drug/medicines outlets.
2) Methods used to control the distribution of outlets shall take into account, the prevailing situation (human population density and patterns, exiting drug outlets and infrastructure) in particular parts of the country
3) **In accordance with section 15(1) (b) of the NDP/A Act, Licensed sellers (Class c Drug Shops) are considered interim drug retail outlets for a limited range of simple products which may no longer be licensed once the area is sufficiently served by other more comprehensive drug retail outlets.**
4) No persons shall open up any pharmaceutical/drug/medicine outlet anywhere without the prior approval of National Drug Authority.

Application for pre-inspection of the location of the proposed premises should be submitted to the NDA prior to any financial or legal commitment to the premises and the approval should be obtained in writing following pre- inspection report.

This is to avoid loss in case of rejection of application based on these and other guidelines. NDA shall not be obliged to license premises opened without following these procedures and shall not be liable to any claim or resultant financial loss. This approval shall be valid for period of 3 months and if not implemented or delay not justified in writing, thereafter **be null** and NDA may authorize a new applicant in the location.

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5) These guidelines and related strategies shall apply to wholesale pharmacies, retail pharmacies, drug shops and other outlets handling pharmaceutical/drugs/medicine, for human use

6) If a drug outlet (pharmacy or drug shop) **does not renew its license for a period or one year**, it shall, on **re-application**, be considered as a new applicant with respect to location and fees.

B) Strategies and Guidelines:

1) Distribution of pharmaceutical/drug/medicine outlets shall be based on the particular location of a proposed outlet, the population living in that area and the distance of the proposed outlet from exiting licensed outlets.

2) The allowed minimum distance between pharmacies shall vary according to the infrastructural development of the different towns as follows:

a) **Kampala Central Division: No more new outlets for human drugs (pharmacies and drug shops)** shall be licensed to operate in Kampala Central Division except in outlying areas which are considered **underserved** and **shopping malls**. New veterinary pharmacies may be considered for Kampala Central Division, other than **"container village** " Nakivubo place , Kampala which is already sufficiently served by exiting pharmacies

Shopping malls with more than 100 shops shall be allowed one pharmacy provided they are within the mall and not on the outer shops

b) **Other divisions of Kampala district** : New pharmacies may be licensed but they must be at least **100m** from exiting licensed pharmacies and **no new drug shops** shall be licensed in Kampala District except in areas where there is no retail pharmacy within a radius of **1.5km**

2(d) **Municipal towns**: New pharmacies for human drugs) shall be licensed to operate in municipal towns but within a **radius of 100m** from existing pharmacies. New drug shops shall not be licensed to operate in municipalities except in localities that are considered to have **poor accessibility** of pharmaceutical services.

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A Pharmacy relocating within 100M of its current location shall not be limited by distance from the nearest pharmacy. Shopping malls with more than 50 shops shall be allowed one retail pharmacy provided they are within the mall and not on the outer shops

2(e) **Other towns**: The minimum distance of **100m** shall be allowed between pharmacies. The criteria of population shall also be applied to determine the maximum number of pharmacies allowed in suburb or town.

2 (f) No pharmacies for human drugs shall relocate into Kampala Central Division from outside the division. Pharmacies in Kampala Central Division may relocate within but the new location must be at least **200m** from existing pharmacies. However, a pharmacy relocating within **100m** of its current location shall not be limited by distance from the nearest pharmacy. Drug outlets in other areas may relocate but the new location must meet the relevant minimum stipulated distances from exiting drug outlets.

3 (a) **Class 'C' drug shops** shall have a minimum separation distance of **1.5km from any exiting retail pharmacy: and in rural trading centers shall be within a distance of 100m apart from each other.**

(b) Exiting class 'C' drug shops which are located within **500m** from a licensed retail pharmacy shall be given an opportunity to **upgrade to a pharmacy in the same location or relocate as per equitable distribution guidelines, within one** calendar year.

(c) **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 200M of their current premises. **Implementation of 3(b) and (c) shall be in a phased manner**, It started with pilot In Jinja in 2003. It was extended to Kampala District starting with sensitization in 2005 and implementation in Kampala started January 2006 and continued in 2007. Sensitization began in Mbarara and Mbale

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in 2007 and implementation started in January 2012. Sensitization began in Masaka and Lira in 2013 for implementation in 2014.

Any other strategy approved by the National Drug Authority from time to time to promote provision of improved public health.

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.

For further information please contact NDA Headquarters, the NDA Regional offices or District Drug Inspectors in respective district

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