**NATIONAL DRUG AUTHORITY LICENCES**

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| **No.** | **LICENSE** | **LICENSE FEES** |  | **OTHER FEES** | **REQUIREMENTS** |
| **1** | Certificate of Registration of drugs and preparations/ Retention/Notification/AmendmentsAn application for this license is done using form 3 of schedule 3 to the National Drug Policy And Authority (Registration) Regulations 2014.The certificate of registration shall be valid for five years and valid for one year upon renewal. Regulation 40 (1) of the National Drug Policy And Authority (Registration) Regulations 2014. |  |   | * Manufacturing licence in case the applicant is not the manufacturer.
* An application for registration of a product may be made by: the patent holder, a licensed person, the manufacturer, an agent authorised by the manufacturer or patent holder.
* Name, physical address, email address, the telephone and fax number of the applicant
* Proprietary name of the product
* Approved generic name of the product
* Particulars of the product
* Strength of the intended use of the product
* Description of the product
* Packaging specifications specified
* Studies undertaken in respect of the product
* Safety and efficacy properties of the product
* Chemistry and pharmaceutical form and aspects of the product
* Registration and licensing status of the product in other countries including the country of manufacture
* Particulars relating to the toxicology and pharmacology of the product
* Any other information as may be determined by the Authority
* Two samples of the product
* All the general and specific information and documents relating to the product
* Complete index to the various appendices
* Where the original documents required are in

a language other than English, the original documents shall be presented together with certified English translations* **N.B** Where an applicant wishes to amend any part of a submitted application, the applicant shall pay the prescribed fees for each proposed amendment.
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| **First registration** |  |  |  |
| (i) | Registration of imported human and veterinary drugs andpreparations | US $1250 |  |  |
| (ii) | Registration of locally manufactured drugs by a large scalemanufacturer | US $ 200 |  |  |
| (iii) | Registration of locally manufactured drugs by a small scalemanufacturer | 150,000/= |  |  |
| (iv) | Registration of imported drugs and preparations which arerepackaged in Uganda | US $ 300 |  |  |
| **Annual retention of registration of drugs and preparations****on register** |  |  |  |
| (i) | Retention of human and veterinary drugs and preparationson the register | US $500 |  |  |
| (ii) | Retention of foreign herbal medicines on the register | US $250 |  |  |
| (iii) | Retention of locally manufactured drugs by a large scalemanufacturer | US $100 |  |  |
| (iv) | Retention of locally manufactured drugs by small scalemanufacturer | US $100 |  |  |
| **Notification of registration of herbal medicine** |  |  |  |
| (i) | Notification of local traditional medicine | 10,000/= |  |  |
| (ii) | Notification of imported traditional medicine | US $250 |  |  |
| **Amendment of application for registration of drugs****( human and veterinary)** |  |  |  |
| (i) | Major amendment of application | US$ 700 |  |  |
| (ii) | Minor amendment of application | US$ 400 |  |  |
| **Amendment of notification for imported herbal medicine** |  |  |  |
| (i) | Major amendment of notification for imported herbal medicine | US $ 350 |  |  |
| (ii) | Minor amendment of notification for imported herbal medicine | US $ 200 |  |  |
| **A Licensed seller (drug shop)**It is provided for under Regulation .5 of The National Drug Policy And Authority (Licensing) Regulations 2014with a purpose of regulating persons dealing in class c drugsApplication shall be made using form 16 in the schedule to The National Drug Policy And Authority (Licensing) Regulations 2014 | **New Application for a licence** |  | **Application for renewal of licence** | The requirements are provided for under Regulation 7 The National Drug Policy And Authority (Licensing) Regulations 2014* Certificate of suitability of premises.
* Qualification from a relevant pharmaceutical, Medical, veterinary, nursing or paramedical field.
* Compliance with internationally accepted Good Distribution Practice Guidelines adopted by the authority.
* Good criminal record.
 |
| **Kampala** | **Municipal** | **Rural** | **Kampala** | **Municipal** | **Rural** |  |  |
| (i) | Inspection for suitability of premises | 135,000/= | 90,000/= | 67,500/= | 75,000/= | 52,500/= | 45,000/= |  |  |
| (ii) | Application for a licence | 120,000/= | 75,000/= | 45,000/= | 120,000/= | 75,000/= | 45,000/= |  |  |
| **(a) Retail Pharmacies (within Kampala)**An application for this license is provided for under regulation10 of the National Drug Policy And Authority (Licensing) Regulations 2014 with a purpose of regulating retail pharmacists.The applicant shall be required to fill form 17 in the schedule to The National Drug Policy And Authority (Licensing ) Regulations 2014 | **New Application for a licence** | **Application for renewal of licence** |  | * Certificate of Suitability of premises.
* Partnership deed in case of a partnership
* Memorandum and articles of association where it’s a body corporate.
* Evidence that the pharmacist to be in charge of the pharmacy is a director or partner respectively.
* Pharmacist registered with PSU
 |
| (i) | Inspection for suitabilityof premises | **Central****division** | **Other****divisions** | **Central****division** | **Other****divisions** |  |  |
| 1,060,000/=  | 645,000/= | 660,000/= | 420,000/= |  |
| (ii) | Application for a licence | 600,000/=  | 300,000/= | 600,000/= | 375,000/= |  |  |
| **Retail Pharmacies (outside** **Kampala)** | **New Application for a licence** | **Application for renewal of licence** |  |  |
| **Municipal**  | **Rural** | **Municipal** | **Rural** |  |  |
| (i) | Inspection for suitabilityof premises | 276,000/=  | 276,000/= | 156,000/= | 156,000/= |  |  |
| (ii) | Application for a licence | 120,000/= | 120,000/= | 120,000/= | 120,000/= |  |  |
| **Wholesale Pharmacies (within Kampala)****An application to operate a whole sale pharmacy is provided for under Regulation** 15 national drug policy and authority (licensing ) regulations 2014 **Application shall be done using form 18 in the schedule to** National Drug Policy And Authority (Licensing ) Regulations 2014 | **New Application for a licence** | **Application for renewal of licence** |  | * Certificate of Suitability of premises.
* Partnership deed in case of a partnership.
* Memorandum and articles of association where it’s a body corporate.
* Certified copy of a certificate of registration of the pharmacist to be in charge of the pharmacy
 |
| **Central****division** | **Other****divisions** | **Central****division** | **Other****divisions** |  |  |
| (i) | Inspection for suitability of premises | 1,070,000/=  | 652,500/= | 570,000/= | 352,500/= |  |  |
| (ii) | Application for a licence | 850,000/=  | 450,000/= | 850,000/= | 450,000/= |  |  |
| **Wholesale Pharmacies (outside Kampala)** | **New Application for a licence** | **Application for renewal of licence** |  |
| **Municipal** | **Rural** | **Municipal** | **Rural** |  |
| (i) | Inspection for suitability ofPremises | 282,000/=  | 282,000/= | 162,000/=  | 162,000/= |  |  |
| (ii) | Application for a licence | 250,000/= | 250,000/= | 250,000/= | 250,000/= |  |  |
| **Pharmaceutical Manufacturing Licence (Local manufacturers)****An application for this license shall be made using form 19 in the schedule** to The National Drug Policy And Authority (Licensing ) Regulations 2014  | **Application for a licence** | **Application for renewal of licence** |  | * Certificate of Suitability of premises.
* Certified copy of Certificate of registration of the Pharmacist to be in charge of the manufacturing process
* List of drugs to be manufactured and proof of registration of the drugs
* Certificates of qualification of the key personnel to be involved in the manufacturing process as may be determined by the authority.
* Certificate of compliance with the internationally accepted good manufacturing practice guidelines adopted by the authority
* Approval from NEMA
 |
| **Application****for operating****licence** | **Certificate of****Suitability of****premises** | **Application****for operating****licence** | **Certificate of****Suitability of****premises** |  |  |
| (i) | Licence to manufactureexternal preparations ororal liquid preparations | 420,000/= | 350,000/= | 350,000/= | 350,000/= | Inspection of facilities -130,000/=Amendment- 250,000/=Re-inspection-500,000/= |  |
| (ii) | Licence to manufactureexternal preparationsand oral preparation | 480,000/= | 400,000/= | 400,000/= | 400,000/= | Inspection of facilities -130,000/=Amendment- 250,000/=Re-inspection-500,000/= |  |
| (iii) | Licence to manufacturesterile preparations, thepreparations in paragraphs(i), (ii) and othertypes of dosage forms | 700,000/= | 700,000/= | 600,000/= | 600,000/= | Inspection of facilities -130,000/=Amendment- 250,000/=Re-inspection-500,000/= |  |
| (iv) | Approval of primarypackaging for the local manufacturer | 350,000/= | 300,000/= | 300,000/= | 300,000/= | Inspection of facilities -70,000/=Amendment- 150,000/=Re-inspection-200,000/= |  |
| (v) | Approval of secondarypackaging for the localmanufacturer | 300,000/= | 250,000/= | 250,000/= | 250,000/= | Inspection of facilities -70,000/=Amendment- 150,000/=Re-inspection-200,000/= |  |
| **Import or Export permit** Importation license is provided for under regulation3 (1) of The National Drug Policy And Authority (Importation And Exportation Of Drugs)Regulations 2014 with a purpose of prohibiting importation and exportation of un authorised drugs into or out of the country. Application shall be made using form 23 in the schedule To The National Drug Policy And Authority (Licensing ) Regulations 2014 These Regulations |  | * Licence of the licenced person
* Verification certificate
* Certificate of registration,
* Certificate of analysis
* Certificate of conformity or

the test report, relating to the specific batch or lot of drugs to be exported.* Certificate of donation in case of donated drugs.
 |
| (i) | Annual import or export permit | 300,000/= |  |  |
| (ii) | Provisional import or export permit (per consignment) | 100,000/= |  |  |
| (iii) | Verification fees for commercial consignments and donations to commercial organisations and government ministries, departments, projects, programs and institutions | 2% of FOB price |  |  |
| (iv) | Verification fees for donations to non-profit making charitable NGOs  | Donations up to $1000 – 100,000/=Donations between $1001 - $5000 – 200,000/=Donations over $5000 – 300,000/= |  |  |
| (v) | Verification fees for consignments for disasters, outbreaks, vaccines and law materials. | Exempted |  |  |
| (vi) | Fees for a consignment of drugs imported without prior authorization by the authority which consignment arrives at the port of entry before the product is registered or amendments are applied for and approved.  | $1000 |  |  |
| **Certificate of analysis** |  |
| (i) | Routine drug analysis of one batch in the NDA lab | $300 |  |  |
| (ii) | Male latex condoms per batch at the request of the owner or importer | $280 |  |  |
| (iii) | Mosquito nets per batch of size up to 30,000 nets and every 30,000 nets at the request of owner or importer | $200 |  |  |
| (iv) | Samples analysed at laboratories outside NDA | Cost of testing + 10% of service charge |  |  |
| (v) | Re-analysis of a sample at owner’s or importer’s request | $1000 |  |  |
| (vi) | Detailed certificate of analysis at the request of the manufacturer or the importer | $100 |  |  |
| (vii) | Analysis of gloves | $150 |  |  |
| (viii) | Analysis of more than three batches | 100,000/= per batch |  |  |
| **Inspection for Good Manufacturing Practices for foreign plants** |
|  | Processes at the site | Within East Africa | Within the rest of Africa | Outside Africa (Asia/Europe/America/New Zealand /Australia |  |  |
| (i) | Site with all processes at one site for 5 product lines | $3000 | $400$ | $600 |  |  |
| (ii) | Any additional production line | $1000 per line |  |  |
| (iii) | For products moving through several sites, additional sites in the country as main site |
|  | Warehousing of raw materials up to finished bulk products | $1500 | $2000 | $3000 |  |  |
|  | Final packaging, quality control and final release | $1000 | $1500 | $2000 |  |  |
|  | Quality control and final release | $500 | $750 | $1000 |  |  |
|  | GMP documents evaluation (desk audits) | $5000 per manufacturing site |  |  |  |  |
| Clinical trials (Human)scientific trials on human drugs certificateThis license is provided for under s.4o of The National Drug Policy And Authority Act Cap 206 for the purpose of carrying out clinical trialsIn respect of a particular drug. i.e it is issued to regulate clinical trials* The applicant must be , a licensed person ,a manufacturer ,patent holder or agent of manufacturer or patent holder
* Power of attorney or letter of authorisation in case of an agent
* Evidence of clinical trial by Uganda National Council for Science and Technology.
* The investigator’s brochure.
* Declaration by the principal investigator.
* Declaration by the monitor.
* Financial declaration by sponsor andprincipal investigator
* Valid evidence on insurance of subjects.
* Pharmaceutical data on dosage
* Capacity building plans for staff training
* Information to be provided to the subjects and the written consent forms of subjects.
 |
| (i) | Application to undertake clinical trial for a registered drug | $2500 |  |  |
| (ii) | Application to undertake clinical trial for un registered drug | $4000 |  |  |
| (iii) | Application to amend clinical trial application | $200 |  |  |
| 1. **Ectoparasiticides field trials**

**(**Trials for animal drugs certificate) an application for authorisation to conduct ectoparasiticides field trials is provided for under regulation 5 of the national drug policy and authority (conduct of ectoparasiticidesfield trials) regulations 2014an application for the above license shall be made using form 39 in schedule 1 to the national drug policy and authority (conduct of ectoparasiticidesfield trials) regulations 2014* Permanent residence in Uganda
* The sponsor may either be the holder of the patent of the ectoparasiticide, the manufacturer or an agent of the ectoparasiticide.
* Power of attorney where the application is by an agent.
* Evidence of approval of field trial by Uganda National council of Science and Technology.
* Evidence of insurance of animals to be used in the field trial and indemnity by the investigator
* Information to be provided to owners of animals and written consent forms of the owners.
* Declaration by the principal investigator
* Principal investigator’s brochure.
 |
| (i) | Application to conduct Ectoparasiticides | $1000 |  |  |
| **Changes in particulars registered with the authority** |
| (i) | Application for change of name, ownership or management of a pharmacy | 500,000/= |  |  |
| (ii) | Application for change of name, ownership or management of a drug shop | 100,000/= |  |  |
| (iii) | Application for change of pharmacist or in-charge person during the licensing period | 100,000/= |  |  |
| (iv) | Application for change in professional auxiliary staff | 50,000/= |  |  |
| (v) | Application for change of person in charge of a drug shop during licensing period  | 50,000/= |  |  |
| **Destruction certificate** |  | Approval from NEMA |
| (i) | Supervision of destruction of drugs | 100,000/= per hour |  |  |
| **Vetting drug promotional materials** |  | * The application shall be the holder of the patent of the drug, a licensed person, the manufacturer or authorised agent.
* Sample of material for which approval for publication or advertisement is sought
* Certified English translation in the intended materials are not in English.
 |
| Screening of drug promotion materials per languageAn approval of publications and advertisements is provided for under regulation 4 of The National Drug Policy And Authority (Control Of Publication And Advertisement Relating To Drugs) Regulations 2014 with a purpose of prohibiting promotion of harmful drugs to society.Application is provided for under regulation 6 (1) and (2) of The National Drug Policy And Authority (Control Of Publication And Advertisement Relating To Drugs) Regulations 2014 Using Form 45 in The Schedule To The Regulations |  | * An application for publication or advertisement shall be made by: the holder of the patent of the drug, a licensed person, the manufacturer of the drug, an agent authorised by the manufacturer or the holder of the patent of the drug.
* A sample of the material for which approval for publication or

advertisement is sought* Where the language of the materials required is not English, the materials shall be presented with certified English translations.
* Where the terms to be used in an advertisement, are not the recognised scientific terms, the terms shall be consistent with the approved scientific data sheet or other legally determined scientific basis, approved or adopted by the Authority .
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| (i) | Written materials | 200,000/= |  |  |
| (ii) | Audio, video and written scripts | 200,000/= |  |  |
| (iii) | Posters or bill boards on any medium including internet | 200,000/= |  |  |
| (iv) | Posters on vehicles | 200,000/= |  |  |
| (v) | T-shirts | 200,000/= |  |  |
| (vi) | Other materials including caps, wall clocks, watches, umbrellas and bags | 200,000/= |  |  |