**NATIONAL DRUG AUTHORITY LICENCES**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **License** | **Fees** | **Other fees** | **Requirements** |
| 1. **Registration of drugs and preparations/ Retention/Notification/Amendments**
 |  | * 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.
 |
| **First registration** |
| (i) | Registration of imported human and veterinary drugs andpreparations | USD 1250 | N/A |
| (ii) | Registration of locally manufactured drugs by a large scalemanufacturer | USD 200 | N/A |
| (iii) | Registration of locally manufactured drugs by a small scalemanufacturer | 150,000 Ugx | N/A |
| (iv) | Registration of imported drugs and preparations which arerepackaged in Uganda | USD 300 | N/A |
| **Annual retention of registration of drugs and preparations on register** |
| (i) | Retention of human and veterinary drugs and preparationson the register | USD 500 | N/A |
| (ii) | Retention of foreign herbal medicines on the register | USD 250 | N/A |
| (iii) | Retention of locally manufactured drugs by a large scalemanufacturer | USD 100 | N/A |
| (iv) | Retention of locally manufactured drugs by small scalemanufacturer | USD 100 | N/A |
| **Notification of registration of herbal medicine** |
| (i) | Notification of local traditional medicine | 10,000 Ugx | N/A |
| (ii) | Notification of imported traditional medicine | USD 250 | N/A |
| **Amendment of application for registration of drugs ( human and veterinary)** |
| (i) | Major amendment of application | USD 700 | N/A |
| (ii) | Minor amendment of application | USD 400 | N/A |
| **Amendment of notification for imported herbal medicine** |
| (i) | Major amendment of notification for imported herbal medicine | USD 350 | N/A |
| (ii) | Minor amendment of notification for imported herbal medicine | USD 200 | N/A |
| 1. **A Licensed seller**
 | **New Application for a licence** | **Application for renewal of licence** |  | * 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 Ugx | 90,000 Ugx | 67,500 Ugx | 75,000 Ugx | 52,500 Ugx | 45,000 Ugx | N/A |
| (ii) | Application for a licence | 120,000 Ugx | 75,000 Ugx | 45,000 Ugx | 120,000Ugx | 75,000 Ugx | 45,000 Ugx | N/A |
| 1. **(a) Retail Pharmacies (within Kampala)**
 | **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 Ugx  | 645,000 Ugx | 660,000 Ugx | 420,000 Ugx | N/A |
| (ii) | Application for a licence | 600,000 Ugx | 300,000 Ugx | 600,000 Ugx | 375,000 Ugx | N/A |
| **(b)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 Ugx | 276,000 Ugx | 156,000 Ugx | 156,000 Ugx | N/A |
| (ii) | Application for a licence | 120,000 Ugx | 120,000 Ugx | 120,000 Ugx | 120,000 Ugx | N/A |
| 1. **(a) Wholesale Pharmacies (within Kampala)**
 | **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 Ugx | 652,500 Ugx | 570,000 Ugx | 352,500 Ugx | N/A |
| (ii) | Application for a licence | 850,000 Ugx | 450,000 Ugx | 850,000 Ugx | 450,000 Ugx | N/A |
|  **(b) 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 Ugx | 282,000 Ugx | 162,000 Ugx | 162,000 Ugx | N/A |
| (ii) | Application for a licence | 250,000 Ugx | 250,000 Ugx | 250,000 Ugx | 250,000 Ugx | N/A |
| 1. **Pharmaceutical Manufacturing Licence (Local manufacturers)**
 | **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 Ugx | 350,000 Ugx | 350,000 Ugx | 350,000 Ugx | Inspection of facilities -130,000 UgxAmendment- 250,000 UgxRe-inspection-500,000 Ugx |
| (ii) | Licence to manufactureexternal preparationsand oral preparation | 480,000 Ugx | 400,000 Ugx | 400,000 Ugx | 400,000 Ugx | Inspection of facilities -130,000 UgxAmendment- 250,000 UgxRe-inspection-500,000 Ugx |
| (iii) | Licence to manufacturesterile preparations, thepreparations in paragraphs(i), (ii) and othertypes of dosage forms | 700,000 Ugx | 700,000 Ugx | 600,000 Ugx | 600,000 Ugx | Inspection of facilities -130,000 UgxAmendment- 250,000 UgxRe-inspection-500,000 Ugx |
| (iv) | Approval of primarypackaging for the local manufacturer | 350,000 Ugx | 300,000 Ugx | 300,000 Ugx | 300,000 Ugx | Inspection of facilities -70,000 UgxAmendment- 150,000 UgxRe-inspection-200,000 Ugx |  |
| (v) | Approval of secondarypackaging for the localmanufacturer | 300,000 Ugx | 250,000 Ugx | 250,000 Ugx | 250,000 Ugx | Inspection of facilities -70,000 UgxAmendment- 150,000 UgxRe-inspection-200,000 Ugx |
| 1. **Import or Export permit**
 |  | * 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 Ugx | N/A |
| (ii) | Provisional import or export permit (per consignment) | 100,000 Ugx | N/A |
| (iii) | Verification fees for commercial consignments and donations to commercial organisations and government ministries, departments, projects, programs and institutions | 2% of FOB price | N/A |
| (iv) | Verification fees for donations to non-profit making charitable NGOs  | N/A |
| Donations up to $1000 | 100,000 Ugx |
| Donations between $1001 - $5000 | 200,000 Ugx |
| Donations over $5000 | 300,000 Ugx |
| (v) | Verification fees for consignments for disasters, outbreaks, vaccines and law materials. | Exempted | N/A |
| (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.  | USD 1000 | N/A |
| 1. **Certificate of analysis**
 |  | * Import license
 |
| (i) | Routine drug analysis of one batch in the NDA lab | USD 300 | N/A |
| (ii) | Male latex condoms per batch at the request of the owner or importer | USD 280 | N/A |
| (iii) | Mosquito nets per batch of size up to 30,000 nets and every 30,000 nets at the request of owner or importer | USD 200 | N/A |
| (iv) | Samples analysed at laboratories outside NDA | Cost of testing + 10% of service charge | N/A |
| (v) | Re-analysis of a sample at owner’s or importer’s request | USD 1000 | N/A |
| (vi) | Detailed certificate of analysis at the request of the manufacturer or the importer | USD 100 | N/A |
| (vii) | Analysis of gloves | USD 150 | N/A |
| (viii) | Analysis of more than three batches | 100,000 Ugx per batch | N/A |
| 1. **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/Newzealand/Australia** |  | * Appropriately qualified and trained personnel.
* Adequate premises and space.
* Suitable equipment and services.
* Correct materials, containers and labels.
* Approved procedures and instructions.
* Suitable storage and transport.
* Adequate personnel, laboratories, and equipment for in-process controls under the responsibility of the production management.
 |
| (i) | Site with all processes at one site for 5 product lines | USD 3000 | USD 400 | USD 600 | N/A |
| (ii) | Any additional production line | USD 1000 per line | N/A |
| (iii) | For products moving through several sites, additional sites in the country as main site |  |
|  | Warehousing of raw materials up to finished bulk products | USD 1500 | USD 2000 | USD 3000 | N/A |
|  | Final packaging, quality control and final release | USD 1000 | USD 1500 | USD 2000 | N/A |
|  | Quality control and final release | USD 500 | USD 750 | USD 1000 | N/A |
|  | GMP documents evaluation (desk audits) | USD 5000 per manufacturing site | N/A | N/A | N/A |
| 1. **Clinical trials (Human)**
 |
| (i) | Application to undertake clinical trial for a registered drug | USD 2500 | N/A | * An application for authorisation to conduct a clinical trial shall be made by a sponsor who shall be the holder of the patent of the drug, a licensed person, the manufacturer of the drug or an agent of the holder of the patent or the manufacturer, of the drug.
* Where an application for authorisation to conduct a clinical trial is made by an agent, the agent shall submit a power of attorney attesting to the appointment as an agent or a letter of authorisation.
* Clinical trial protocol.
* Evidence of approval of the clinical trial by the Uganda National Council of Science and Technology or an institution approved by the Uganda National Council for Science and Technology
* The investigator’s brochure or prescribing information data sheet.
* A declaration by the principal investigator.
* A declaration by the monitor
* The financial declaration by the sponsor and the principal

Investigator.* The information to be provided to the subjects and the written

consent forms of the subjects.* Valid evidence of the insurance of the subjects.
* Pharmaceutical data on the dosage form of the investigational medicinal product.
* Capacity building plans for the training of the staff to be

involved in the clinical trial* Any other requirement as may be determined by the Authority.
 |
| (ii) | Application to undertake clinical trial for un registered drug | USD 4000 | N/A |
| (iii) | Application to amend clinical trial application | USD 200 | N/A |
| 1. **Ectoparasiticides field trials**
* 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 | USD 1000 | N/A |  |
| 1. **Changes in particulars registered with the authority**
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| (i) | Application for change of name, ownership or management of a pharmacy | 500,000 Ugx | N/A | * Evidence of sell i.e sale agreement between the dealer and the buyer.
* Updated copies or articles and memorandum of understanding.
 |
| (ii) | Application for change of name, ownership or management of a drug shop | 100,000 Ugx | N/A |
| (iii) | Application for change of pharmacist or in-charge person during the licensing period | 100,000 Ugx | N/A |
| (iv) | Application for change in professional auxiliary staff | 50,000 Ugx | N/A |
| (v) | Application for change of person in charge of a drug shop during licensing period  | 50,000 Ugx | N/A |
| 1. **Destruction certificate**
 |  | * Approval from NEMA
 |
| (i) | Supervision of destruction of drugs | 100,000 Ugx per hour | N/A |
| 1. **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 promotion materials per language | N/A | * 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. |
| (i) | Written materials | 200,000 Ugx | N/A |
| (ii) | Audio, video and written scripts | 200,000 Ugx | N/A |
| (iii) | Posters or bill boards on any medium including internet | 200,000 Ugx | N/A |
| (iv) | Posters on vehicles | 200,000 Ugx | N/A |
| (v) | T-shirts | 200,000 Ugx | N/A |
| (vi) | Other materials including caps, wall clocks, watches, umbrellas and bags | 200,000 Ugx  | N/A |