PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce & Industry, Govt. of India)

REGULATORY & MARKET PROFILE OF UGANDA

Demography

SL. No	Parameter	Description
1	Region	Africa
2	Country	Uganad
3	Capital	Kampala
4	Population	40,853,749 (July 2018 est.)
5	Population growth rate (%)	3.18%(July 2018 est)
6	GDP (purchasing power parity)	89.19 $ Billion(2017 est)
7	GDP - real growth rate (%)	4.8%(2017 est)
8	GDP - per capita (PPP)	2,400 $(2017 est)
9	Epidemiology	Communicable diseases majorly Infectious and parasitic diseases Malaria Tuberculosis(Multi Drug Resistant TB) Cancers
10	Population below poverty line	21.4%(2017 est)
11	Age structure (%)	0-14 years: 47.84%
		15-24 Years: 21.04%
		25-54 years26.52%
		55-64 years: 2.64%
		65 years & over: 1.96%
Source: CIA World Fact Book updated to July 2018		

UGANDA MARKET REPORT

Introduction

Fundamental barriers in Uganda's pharmaceutical and healthcare sector will limit the opportunitiesto multinational drug makers. Low affordability levels will promote low-cost generic drugs, while the government plans to localize drug production to boost medicine sustainability. While the market has brighterlong-term prospects, multinationaldrugmaker appetite will remain subdued despite the positive economicgrowth forecastover the coming years.

Market size was $ 414 Million in 2017. Percapita consumption of Medicines is put at $ 9.6.

Latest Updates

- In September 2018, the director general of external security organization in Ugandaannounced that an Indian company will invest USD10mn towards a pharmaceuticalmanufacturing facility in Uganda.
- In September 2018,Health officials in the Democratic Republic of the Congoconfirmed a caseof Ebola virus on the Ugandan border.
- In August 2018, China donated hospital supplies and medicines worth USD70,000 to theUgandan Ministry of Health, following the success of previous Chinese donations to theChina-Uganda Friendship Hospital.

Strengths

- The government's interest in developing the pharmaceutical sector.
- Further discoveries in the oil and gas industry are likely - boosting economic prosperity andgovernment financing options for industry sectors.

Weaknesses

- Acute shortage of Pharmacies & Hospitals

Opportunities

- Progress has been made towards establishing the East African Medicines and Food SafetyCommission, which would improve drug registration processes.
- Large and increasing burden of disease suggests a significant unmet demand forpharmaceuticals.
- Protection of local pharmaceutical manufacturers from foreign competition is expected toincrease.

Market

Uganda will remain a small, underfunded, and generic-dominated pharmaceutical industry. A combination of low per capita spending in a youth-dominated, highly ruralized population, will limit opportunities for innovative drug makers looking to launch patented medicines in

Uganda.Opportunities for foreign firms will be largely indirect, with potential licensing agreements with local players that are able to advance their manufacturing capabilities over the coming years.

In August 2018, Uganda-basedCipla Quality Chemicals launchedanIPOto float 657mn shares.

In 2017, pharmaceutical expenditure in Uganda reached a value of USD414mn. 76% of this value is met by private sector(out of Pocket). In 2018, estimates are that market may reach USD434mn and by 2022, the market will be valued at USD519mn, experiencing a five year CAGR of 4.7%. In 2017, per capita drug expenditure was USD10- which is extremely low by international standards. Additionally, in 2017, pharmaceutical spending is estimated to have accounted for 21.9% of total healthcare expenditure. Nevertheless, in comparison with many other African markets, Uganda offers greater commercial promise and a more stable overall business environment.

Due to low purchasing power, generic drugs comprise the majority of Uganda's pharmaceutical market. Patented drugs comprise a small market share of medicines, as low per-capita drug expenditure continues to limit the capacity of most of the population to purchase higher-priced patented drugs. Multinational pharmaceutical companies may try to increase the usage of patented products by employing tiered pricing.

Self-medication is prevalent in Uganda, making the over-the-counter (OTC) drug market an attractive prospect. Many Ugandans lack access to health facilities owing to financial reasons, or because of sparse healthcare infrastructure in rural areas. The division between prescription and OTC drugs is blurred by the prevalence of roadside kiosks selling malaria drugs and antibiotics, highlighted by a rapid growth in the number of pharmacies in both rural and urban areas.

There are challenges when it comes to the local production of medicines (including poor infrastructure). Uganda is a part of Common Market for Eastern and Southern Africa (COMESA), an increasingly influential 19-member economic bloc covering a large swathe of Africa, including South

Africa. Membership of COMESA should bolster the country's attractiveness to companies looking to manufacture products in the country.

Epidemiology

Uganda’s disease profile is similar to other less developed African countries, with communicable diseases accounting for roughly 67% of the total burden. However, economic growth will boost lifestyle diseases, increasing the demand for medicines for chronic diseases.

Uganda's communicable disease burden is dominated by infectious and parasitic diseases. Malaria is considered as the major cause of deaths in the country.

An increasing number of Ugandan patients are experiencing multi-drug resistant TB and so the Ugandan government is building a national referral TB laboratory at Butabika in Luzira to address this, according to allAfrica.

Cervical cancer is also an issue in Uganda. Annual deaths are expected to increase to 416,000 by

2035, with more than 95% of these deaths occurring in women living in low-income countries, according to the International Agency for Research on Cancer. However, national vaccination campaigns in Uganda have attempted to address this.

Statistics

India's Pharma exports to Uganda $ Million					
Category	2015-16	2016-17	2017-18	Gr%	Contbn to Region
Bulk Drugs And Drug Intermediates	13.73	12.63	9.34	-26.05	2.38
Drug Formulations And Biologicals	139.09	126.32	138.62	9.74	5.35
Ayush Herbal Products	1.19	1.16	1.71	47.77	9.62
Surgicals	0.94	1.24	1.59	27.97	3.28
Vaccines	14.29	12.22	4.56	-62.69	1.54
Total	169.24	153.57	155.82	1.47	4.66

Top Ten Importing Partners of Uganda $ Million						
Rank	Country	2015	2016	2017	Gr%	Share%
1	India	174.38	158.84	141.05	-11.20	51.53
2	Belgium	2.72	32.28	27.89	-13.60	10.19
3	China	18.51	17.95	22.66	26.29	8.28
4	Kenya	22.64	19.84	19.63	-1.05	7.17
5	Denmark	20.37	18.38	11.83	-35.66	4.32
6	Netherlands	6.09	10.75	9.09	-15.45	3.32
7	United Kingdom	3.00	4.32	7.59	75.77	2.77
8	Rep. of Korea	0.22	1.71	4.78	180.22	1.75
9	South Africa	7.69	10.13	4.16	-58.93	1.52
10	Switzerland	3.06	5.63	3.51	-37.69	1.28
	World	370.85	316.48	273.73	-13.51	100.00

REGISTRATION AND LICENSING REQUIREMENTS

➢	Regulatory Authority	:	**NATIONAL DRUG AUITHORITY (NDA)**
➢	Website of regulatory Authority	:	https://www.nda.or.ug/
➢	Fees for Drug Registration	:	USD 1250
➢	Normal time taken for registration	:	18 Months
➢	Registration Requirement [Dossier Format]	:	CTD
➢	Whether plant inspection is mandatory	:	Yes
➢	Requirement of Local agent/ Subsidiary	:	Local Agent is sufficient

NATIONAL DRUG AUITHORITY (NDA):

The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition).

The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

The functions of the Drug Authority are stated under Section 5 of the NDP/A Act, Cap. 206.

- Deal with the development and regulation of the pharmacies and drugs in the country
- Control the importation, exportation and sale of pharmaceuticals
- Control the quality of drugs
- Promote and control local production of essential drugs
- Encourage research and development of herbal medicines
- Establish and revise professional guidelines and disseminate information to the health professionals and the public

- Provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the National Drug Policy
- Perform any other function that is connected with the above or that may be accorded to it by law.
- Regulates Drug promotion /adverts

Directorates:

- Directorate of Inspectorate & Enforcement Services
- Directorate of Product Assessment and Registration
- Directorate of Public Safety
- Directorate of Corporate Services
- Directorate of Laboratory Services

Regulations:

- Pharmaceutical regulation in Uganda is governed by the Pharmacy and Drugs Act of 1970, as well as by the 1993 Act of Parliament that set up the National Drug Authority (NDA). As is the case in other
- African nations, significant issues exist in Uganda's intellectual property (IP) environment - with a major problem being the enforcement of laws.

Drugs in Uganda are classified into three major categories:

Class A - Narcotics
Class B - Restricted drugs - Prescription only drugs /medicines + pharmacy only medicines.
Class C - Over-the-counter (OTC) drugs/medicines

Importation & Exportation of Pharmaceuticals:

Drugs imported must be registered unless given special clearance by the NDA under Sec 8(4) of NDPA (National drug policy & Authority) Act. All imports must have a valid import permit issued by NDA. The import permit may be:

a) Annual-which is issued for regular imports like-retail pharmacies, wholesale premises, pharmaceutical manufacturers or any organization that regularly imports drugs and other related substances. Ministry of Health of Uganda and its affiliated units may also apply for an annual import permit.
b) Provisional import permit is issued to non-regular importers who may import drugs, for some reasons. The provisional import permit is issued per consignment, This usually applies to organizations, which receive donations, physicians or individuals who may for specified reasons need to bring limited quantities of specialized drugs that are not available in the country. The permit is valid for one month.

Import License: (Form-24)

- Eligibility to apply for import license: A licensed person (a person holding license to operate pharmacy or for manufacture drugs)
- Import license is valid for one year and is valid within the calendar year within which it is issued.
- Verification certificate: A consignment of drugs to be imported into Uganda shall before importation, be issued with a verification certificate (Form-25) by the NDA basing on the application submitted in this regard in Form-26

Procedure for Drug Importation:

a) Applications for importation of a drug shall be submitted to NDA in the prescribed form (Form-23, given below) together with the following documents.
   i. Application for verification of pro-forma invoice.
   ii. Three copies of pro-forma invoice endorsed by the pharmacist in charge of the importing pharmacy/institution and local Technical representative where applicable.
   iii. Evidence of payment of the prescribed verification fees.
   iv. Packing list includes name, strength, quantity, expiry date, name and address of manufacturers(for donations)
   v. Copy of Certificate of registration of the recipient health facility and certificate of registration for the pharmacist or medical officer in-charge (for donations)
b) Pro-forma invoice verification processing time takes 5 working days.
c) A verification certificate corresponding to the drugs to be imported is issued by NDA.
d) During the process of inspection and release of the consignment, an inspector may carryout sampling and even pick drug samples for further investigations.
e) Chemical analysis normally takes a period of 2 weeks from the time a consignment is sampled to when the results are released. The time mentioned applies only if the chemical analysis is to be done in Uganda, but when carried outside, a longer period may be required.
f) On inspection of the consignment:
   i. An authorisation or clearance may be given.
   ii. A query may arise whereby consignment may be held pending further investigations.
   iii. An outright rejection of the consignment pending re-export or destruction at owner's expense may be issued.

Re-export of Rejected Consignments:

a) Drugs rejected for quality reasons must be re-exported to the supplier in the country of export within a stipulated period of one month after receiving rejection report.
b) Drugs rejected due to being unregistered in Uganda or neutral labelling may be re-exported to a third country on special request with special clearance from the authorities of the importing country.

Re-Export procedure:

a) Application for verification is lodged in by intending exporter, accompanied by the relevant invoice and documents related to the rejection indicating also the exact point of destination.

b) Re-inspection is carried out by an inspector of drugs to confirm that the consignment is still intact, before a provisional re-export permit is issued by NDA on payment of application fee.
c) A customs or NDA official must witness loading for re-export.
d) Copies of the re-export documents stamped at exit ports must be submitted to NDA as prrof of Re-Export.

FORM 23

Regulations 4(1)

APPLICATION FOR IMPORT LICENCE FOR DRUGS

I hereby apply for an importation licence for drugs

1. Name of pharmacist-in-charge of the business .....
2. Name of the business for which application is made .....
3. File No.....
4. P.O. Box Number: ..... Tel: ..... Fax: .....
5. This is a retail pharmacy/wholesale pharmacy/manufacturer of drugs/others (Specify).....
6. Licence Number ..... (the operating licence of the Authority)
7. I hereby apply for the issue of an importation licence for (Delete what is not applicable)
   (a) Materials and ingredients for the production of drugs
   (b) Materials and ingredients for the production of veterinary drugs
   (c) Finished drugs for human use.
   (d) Finished drugs for veterinary use.

I understand that a separate verification certificate has to be obtained for each order placed and that a consignment coming into Uganda shall be issued with an authorization certificate by the Authority, at the port of entry into Uganda.

I have read and understood the regulations relating to the importation of drugs and raw materials for the manufacture of drugs into Uganda.

Signed (pharmacist-in-charge of the business of the applicant)

..... Date .....

For NDA Use only: **APPLICATION APPROVED/REJECTED**

If rejected state reasons .....

.....

.....

Licence Number..... Issued on ..... *(Date)*

Signed..... *For the Authority*

SEAL/STAMP

SHEDULE

FORMS

FORM 22

Regulation 3 (2)

IMPORT LICENCE FOR DRUGS

(Issued under sections 44 and 46 of the Act)

This is to certify that:
the applicant named .....
of address .....
TIN .....
is authorized to import into Uganda, in accordance with sections 44 and 46 of the Act, the following classified drugs and raw materials.

.....
.....
.....
.....
.....

Conditions

1. This licence does not allow the importation of narcotic and psychotropic drugs.
2. The importation shall be through authorised Customs entry points.
3. Each consignment to be imported shall be verified prior to importation, by the Authority.
4. This permit shall be displayed at the premises for which it is issued.

Permit. No. ..../IMP/..... Date dd/mm/yyy

Fee Paid Ushs .....

This permit expires on ..... (dd/mm/yyyy)

.....
For the Authority

Marketing Authorisation of a Pharmaceutical Product for Human Use

An application for registration of a product shall be made to the Authority in the prescribed Form 1 for human or veterinary drugs and preparations and Form 2 for vaccines and other immunological products. Formats of applications and the certificate of registration can be find in Drug Registration regulation document given at https://www.nda.or.ug/ndpa-act-regulations/

Application for Registration:

Application for the registration of a drug shall be made only by:

- The license/patent holder
- The manufacturer
- A distributor authorized by the manufacturer, license/patent holder
- An authorized Local Technical Representative (LTR) of the manufacturer or license/patent holder

The application shall submit the drug manufacturing license and COPP.

The application shall state—

(a) The name, physical address, email address, the telephone and faxnumber of the applicant;
(b) The proprietary name of the product;
(c) The approved generic name of the product;
(d) The particulars of the product;
(e) The strength of the product in per unit form such as mg, mL, IU/G or IU/M, where applicable;
(f) The indication of the intended use of the product;
(g) The description of the product;
(h) The packaging specifications;
(i) The studies undertaken in respect of the product, if any;
(j) The safety and efficacy properties of the product;
(k) The chemistry and pharmaceutical form and aspects of the product;
(l) The registration and licensing status of the product in other countries including the country of manufacture;
(m) The particulars relating to the toxicology and pharmacology of the product; and
(n) Any other information as may be determined by the Authority.

The application shall be in writing, in the English language and shall in addition to the above requirements be accompanied by—

(a) Two samples of the product;
(b) All the general and specific information and documents relating to the product;
(c) A complete index to the various appendices; and
(d) The prescribed fees.

Particulars and activities of manufacturer:

(1) Where the applicant is not the manufacturer of the product, the applicant shall provide in relation to the manufacturer—

(a) The name, physical address, email address, telephone and fax number of the manufacturer; and

(b) A copy of the manufacturing licence.

(2) Where different activities of manufacturing are carried out at more than one site, the applicant shall provide the particulars specified above in respect of each site, clearly specifying the activity which is carried out at each site.

(3) The applicant shall provide details of—

(a) The procedures used at the various stages of manufacture in the form of a flow diagram accompanied by a list of the equipment used at each stage; and

(b) The analytical, microbiological and other process control procedures and the frequency and sequence in which they are carried out during the manufacturing process.

(4) The applicant shall provide the characteristics of a manufacturedproduct by—

(a) Stating the details of the product including—

(i) The name, dosage form and strength of the product;

(ii) The approved generic name of the product, if any;

(iii) The visual description of the manufactured product; and

(iv) The visual description of the packaging for the product; and

(b) Stating the regulatory status of the product in other countries including the country of origin.

(5) The application shall also contain the details of the active pharmaceutical ingredient including—

(a) The nomenclature of the active pharmaceutical ingredients;

(b) The properties of the active pharmaceutical ingredients used;

(c) The site of manufacture for the active pharmaceutical ingredients;

(d) The route of synthesis of the active pharmaceutical ingredients used;

(e) The specifications of the active pharmaceutical ingredients bearing the justification for such specifications;

(f) The container closure system including the description and identification of the components;

(g) The results of the stability testing (For Zone IVb)

(6) An applicant for registration of a manufactured product shall in the application furnish the Authority with the following—

(a) A valid licence or other form of authorisation for manufacturing the product;

(b) The pharmaceutical development detailing the studies conducted in relation to the product;

(c) The formulation for a typical batch of the product;

(d) The site of manufacture, where any aspect of manufacture occurs, and the activity performed at the site;

(e) The manufacturing process giving steps of the process and showing where the respective materials are introduced in the manufacturing process;
(f) A copy of the master formula and a copy of a manufacturing record for a real batch;
(g) The documented evaluation of at least three production scale batches to provide assurance that the manufacturing process will reliably meet predetermined specifications;
(h) The manufacturing process controls of critical steps and intermediates;
(i) The manufacturing process validation and evaluation;
(j) The specifications for excipients;
(k) The control of the finished product listing the general characteristics, specific standards, tests and limits for results;
(l) The analytical procedures;
(m) The suitability of the container or closure system and other packaging used for storage and transportation; and
(n) The container labelling sample for the product.

(7) Stability testing and the design of the formal stability testing shall be based on the behavior and properties of the active pharmaceutical ingredients and the dosage form.

Raw material specifications and details of their analytical methods:

(1) The applicant shall provide the specifications of the raw material to be used and details of the analytical methods used for the raw materials.
(2) Where World Health Organisation Technical Report Series or pharmacopoeial references to specifications and analytical methods are given, photocopies of the references or monographs shall be supplied.
(3) For non-World Health Organisation Technical Report Series, nonpharmacopoeialraw materials, the following information shall be provided—
(a) A description of the active immunogenic raw materials;
(b) The pysico-chemical tests conducted;
(c) The biological activity tests conducted;
(d) Comprehensive details of the procedures involved in the various stages of the manufacture of the products;
(e) summarized specifications of the manufactured products including the acceptable limits of all the physical and other control procedures carried out to ascertain the specifications of the final product;
(f) The specifications and test methods for all dosage forms;
(g) The batch manufacturing records;
(h) Stability studies on the manufactured products; and
(i) Test samples.

Manufacture of active raw material.
(1) The applicant shall state the details of the manufacturer of the active raw material and the description of the methods of manufacture of the active raw material.

(2) It shall include—

(a) A description of the source of the raw material and the specifications and the test methods of the starting materials such as—

(i) The animal sources;

(ii) The virus sources;

(iii) The cellular sources including microbial cells, animal cells, primary cells, and cell lines;

(iv) The genetic constructs and recombinant cell lines including host cells, gene construct, vector, final gene construct and cloning and establishment of recombinant cell lines; and

(v) The cell bank system including master cell bank, working cellbank, end of production cells and characterization and testingof cell banks;

(b) A description of the growth and harvesting process includingpropagation and harvesting;

(c) The purification and downstream processing including inactivation, where appropriate, purification, where appropriate, stability processing and detoxification;

(d) The details of the manufacture of synthetic raw material including synthetic peptides and conjugates and modified active raw materials; and

(e) A description of in process control specifications and tests at each stage of manufacture of active raw materials.

Requirements for sample of packaging.

(1) The applicant shall at the time of applying for registration of a product provide a sample of the labelling and packaging for the product which shall contain—

(a) The brand name, where applicable;

(b) The international non-proprietary name or generic name of the product;

(c) The quantity of active ingredient per dosage unit;

(d) The pharmaceutical form and the quantity of active ingredient per dosage unit;

(e) The total contents of the primary, secondary and tertiary container;

(f) The date of manufacture of the product;

(g) The date of expiry of the product;

(h) The batch number of the product;

(i) The storage conditions;

(j) The product information for health professionals;

(k) The patient information and package leaflet; and

(l) The name and address of the manufacturer of the product.

(2) The name and address of the manufacturer, the date of manufacture or the conditions of storage may be omitted from the primary packaging if the primary packaging is a blister, strip pack or a vial or an ampoule of less than ten millilitres.

(3) The name of the manufacturer may be substituted with a trade mark or other symbol associated with the manufacturer.

(4) Where the name and address of the manufacturer, the date of manufacture or the conditions of storage are omitted from the primary packaging, they shall appear in full on the secondary packaging.

(5) The application shall also contain—

(a) Justification for any differences to the product in the country issuing the submitted World Health Organization Type Certificate such as a certificate issued in terms of the World Health OrganisationCertification Scheme for Pharmaceutical Products Moving in International Commerce or the Certificate of a Pharmaceutical Product;

(b) Data on the interchangeability for generic products as may bedetermined by the Authority; and

(c) A summary of the pharmacology, toxicology and efficacy of the product, when the product contains new active ingredients and new combinations of active ingredients.

(7) The Authority shall only register a product with a clear, easily legible and comprehensible label.

Therapeutic effects and indications:

The applicant shall state—

(a) The proposed therapeutic use of the product;

(b) The evidence of the potential benefit of using the product in Uganda; and

(c) The potential side effects of the product.

Information leaflet.

(1) The product packaging shall include a prescribing information leaflet in the case of prescription medicines or a patient information leaflet in the case of non-prescription medicine.

(2) The leaflet shall include the following information—

(a) The international non-proprietary or botanical name, where appropriate;

(b) A brief description of the mechanism of action and pharmacological effects;

(c) Clinical information on the product including—

(i) Not more than three indications;

(ii) The dosage regimens for the different age groups, including for children;

(iii) The contraindications;

(iv) Precautions in pregnancy;

(v) Lactation, renal and hepatic failure, if any;

(vi) The adverse reactions including their frequency;

(vii) Clinically significant drug interactions; and

(viii) The symptoms and treatment of over dosage; and

(d) Pharmaceutical information on the product including-

(i) The dosage form of the product;

(ii) The strength of the product;

(iii) The excipients of the product;

(iv) the conditions under which the product is to be stored;

(v) The shelf-life of the product;

(vi) The pack size of the product;

(vii) A description of the product and package; and
(viii) The name and physical address of the manufacturer of the product.

(3) Inappropriate claims shall not be included in the information leaflet.

Certificate of Registration:

The Authority issue a certificate of registration of a productregistered in the prescribed Form-3.

Validity:

- Thefirst registration, a certificate ofregistration which shall be valid for five years.
- The holder of a certificate of registration issued shall pay an annual retention fee prescribed by the Authority for maintaining the registered human or veterinary drug or preparation, vaccine or other immunological products or surgical instrument, on the Register.
- A certificate for renewal of registration shall be valid for one year from the date of issue.

Application for renewal of registration:

- A holder of a certificate of registration who wishes to renew the registration shall submit an application for renewal of registration, to the Authority at least 90 days before the expiry of the registration
- An application for renewal of registration shall be in writing to the Authority and shall be accompanied by—
  (a) A consolidated report of the changes, if any, whether reported to the Authority or not, which are made with respect to the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, during the validity of its registration;
  (b) A report of additional adverse drug reactions, if any, detected during the lifetime of the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be;
  (c) Five samples of the packaging of the registered drug or preparation, vaccine or other immunological products or surgical instrument, as the case may be, for which renewal of registration is sought, in the form in which it is to be marketed;
  (d) The prescribed fee.

"Guidelines on Submission of Documentation for Marketing Authorisation of a Pharmaceutical Product for Human Use"was published by the National Drug Authority on 1st mar 2018 and is can be find at https://www.nda.or.ug/human-medicine-guidelines/

- Dossier Format is : CTD

Guidelines on submission of Documentation for marketing Authorisation of a Pharmaceutical Product for Human use that is prequalified by WHO or approved by a Stringent Regulatory

Authority (SRA) can be identified at https://www.nda.or.ug/human-medicine-guidelines/ with the title of " Guidelines_ Marketing Authorization of SRO Approved Medicinal products".

As per the above guideline, National Drug Authority recognizes the scientific evaluation of drugs by SRAs and WHO. Where an applicant shares with NDA, information on a drug that has been approved by the SRA or WHO, NDA will consider a drug for registration using an abridged evaluation process.

Guideline for Variation of Registered Medicinal Products:

Individual changes normally require the submission of separate variations. Grouping of variations is acceptable only when variations are consequential to each other, e.g. introduction of a new impurity specification that requires a new analytical procedure.

For the purpose of classification, an application involving two or more types of variations will be considered as the highest risk type, e.g. a variation grouping both a minor change and a major change will be classified as a major change.

Minor variations:

1. Changes that could have minimal or no adverse effects on the overall safety, efficacy and quality of the FPP. These include:

   a) Changes for which applicants must satisfy themselves that they meet all of the prescribed conditions for the change. (M1). An M1 change should be summarized as part of the changes made throughout the year but the indicated documentation is not required to be submitted. The documentation indicated for M1 changes should be available on request or at the time of inspection. M1 changes should be submitted to NDA within 12 months of implementation of the changes

   b) Changes for which applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the notification application. (M2).

2. Changes that could have minimal effects on the overall safety, efficacy and quality of the FPP. (M3). Applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the variation application.

Major variation (Vmaj):
Major variations are changes that could have major effects on the overall safety, efficacy and quality of the FPP. The documentation required for the changes included in this reporting type should be submitted. Prior acceptance by National Drug Authority is required before the changes can be implemented. A letter of acceptance will be issued for all major variations when the variation is considered acceptable. These variations will be handled within a time period of six (6) months from the date of acknowledgement of receipt.

New applications

Certain changes are so fundamental that they alter the terms of the accepted dossier and consequently cannot be considered as changes. For these cases a new dossier must be submitted.

Labelling information:
For any change to labelling information (SmPC, PIL, labels) not covered by the variation categories described in this document, National Drug Authority must be notified and submission of the revised labelling information is expected as per the EAC Guidelines on Submission of Documentation for Registration of Human Pharmaceutical Products.

Conditions to be fulfilled
For each variation, attempts have been made to identify particular circumstances where lower reporting requirements (M1, M2 or M3) are possible. A change that does not meet all of the conditions stipulated for these specific circumstances is considered to be a major variation.

In some circumstances Vmaj categories have been specifically stated for a given variation. This has been done to indicate to applicants what documents should be considered to be provided. This is for informational purposes only. The list ofdocumentation is not intended to be comprehensive and further documentation may be required. For all changes it remains the responsibility of the applicant to provide all necessary documents to demonstrate that the change does not have a negative effect on the safety, efficacy or quality of the FPP.

Documentation required

For each variation certain documents have been identified and the change categories are organized according to CTD structure as supporting data. Regardless of the documents specified, applicants should ensure that they have provided all relevant information to support the variation:

(a) A variation application form (a template can be downloaded from the website). All sections of this form shall be completed and the document signed. Electronic versions of the application form, both as a Word document and a scanned signed PDF file, shall be provided;

(b) Replacement of the relevant sections of the dossier as per CTD format;

(c) Copies of SmPC, PIL and labels, if relevant.

Drug Fees Regulation

FEES FOR REGISTRATION OF DRUGS, RETENTION, NOTIFICATION AND AMENDMENT

Registration / Retention/Notification/Amendments	**Fees in US $ except where indicated in Shillings**
1.First registration Registration of imported human and veterinary drugs and preparations	US $1250
2. Annual retention of registration of drugs and preparations on register	
(a) Retention of human and veterinary drugs and preparations on the register	US $500

(b) Retention of foreign herbal medicines on the register	US $250
3. Fees for notification of registration of herbal medicine Notification of imported traditional medicine	US $250
4. Fees for amendment of application for registration of drugs (human and veterinary)	
(a) Major amendment of application	US $700
(b) Minor amendment of application	US $400
5. Amendment of notification for imported herbal medicine	
(a) Major amendment of notification for imported herbal medicine	US $350
(b) Minor amendment of notification for imported herbal medicine	US $200

FEES FOR IMPORTATION OF DRUGS

Description	Fees
1. Application for a general import or export permit	300,000/=
2. An application for limited import or export permit	100,000/=

FEES FOR INSPECTION FOR GOOD MANUFACTURING PRACTICES FOR FOREIGN MANUFACTURING PLANTS

a) On site GMP inspection per manufacturing site

Processes at the site	Outside Africa
Inspection of manufacturing sitewith all processes at one site for 5 product lines	US$6,000

b) Fees for inspection of sites where the manufacturing process is carried out in more than one site in the country where the main site is located

Processes at the site	Outside Africa
Inspection of warehousing of raw materials up to finished bulk product	US$3,000
Inspection of sites for final packaging, quality control and final release	US$2,000
Inspection of sites for quality control and final release	US$1,000

FEES FOR ANALYSIS OF SAMPLES IN A LABARATORY

Description	Fee
Application for routine drug analysis of one batch of drugs in the laboratory of the Authority after registration	US$300

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Details of importing country embassy in India:**https://newdelhi.mofa.go.ug/**

Contact details of Indian Embassy abroad: **https://hci.gov.in/kampala/**

List of Local Pharma Associations:

- Pharmaceutical Society of Uganda — Ph:(+)256 414 581679 / (+)256 414 348 796 / (+)256 392174280
  psupc@psu.or.ug
  www.psu.or.ug