Pharmaceuticals Export Promotion Council of India

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

REGULATORY & MARKET PROFILE OF KENYA

Demography

SL. No	Parameter	Description
1	Region	Easte Africa
2	Country	Republic of Kenya
3	Capital	Nairobi
4	Population	47,615,739(July 2017 est)
5	Population growth rate (%)	1.69%(2017 est)
6	GDP (purchasing power parity)	$163.5 billion (2017est.)
7	GDP - real growth rate (%)	5.1 % (2017 est.)
8	GDP - per capita (PPP)	$3,500 (2017 est.)
9	Epidemiology	HIV/AIDS Diarrheal diseases Respiratory infections Ischemic heart disease Cardiovascular diseases Tuberculosis
10	Population below poverty line	36.1% (As per 2016, No update)
11	Age structure (%)	0-14 years: 40.02%
		15-24 Years: 19.15%
		25-54 years 33.91%
		55-64 years: 3.92%
		65 years & over: 3%
Source: CIA World Fact Book updated to july 2017		

Introduction

The East African Community (EAC), made up of Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda, represents one the smaller sub-regions in SSA in value terms, both economically and from a pharmaceutical viewpoint. The total value of EAC's pharmaceutical market in 2017 was just USD2.1bn, which corresponds to 17% of SSA's total medicine expenditure that year. Forecasts show that the market would nearly double to yield a market size of USD4.1bn by 2027, at which point the EAC will still represent a relatively minor proportion of SSA's pharmaceutical market (19%).

Pharmaceutical Expenditure

In 2017 market was of the size $ 959 million and is forecasted to grow by 9.9% and touch $ 1.054 billion.

Key trends

- Achieving universal health coverage is increasingly being prioritised by African governments. This makes up President Uhuru Kenyatta's third key objective as part of the 'Big Four Agenda' for 2022. While this development highlights greater political will to improve healthcare coverage in Kenya, critics feel this target to be highly ambitious over the coming five years, with a number of persisting challenges limiting its implementation. According to our Country Risk team, implementing each of the four objectives will likely be slowed by structural challenges.
- In order to expand affordable healthcare coverage in Kenya, President Kenyatta has vowed to increase cooperation between the National Hospital Insurance Fund (NHIF) and private insurance providers, as well as to change laws regarding such providers. As of yet, little progress has been made on such measures. Success of these goals will likely depend on regulations of the healthcare companies, and whether these will be sufficient to attract substantial investment.
- Currently according to MOH, 36% of the population is covered under Health schemes and aims to cover the rest by 2022, indeed an ambitious target.
- In the July 2018 , the Kenya Network of Cancer Organisations drew attention to the depletion of cancer drug Herceptin's stocks at Kenyatta National Hospital. The drug, which costs in excess of KES250,000 for a single dose, is supplied free under the national insurance scheme.
- In June 2018, Kenya Association of Pharmaceutical Industry (KAPI) warned patients against buying medicines that do not have English or Kiswahili instructions, for fear that they may be fake. The proclamation was criticised by the Kenya Pharmaceutical Distribution Association (KPDA) as being alarmist, instead of recognising the legal status of such products.

Strengths:

- The largest pharmaceutical manufacturing industry in East Africa.
- Free pharmaceutical pricing environment in the private sector.
- No import tariffs on pharmaceuticals.
- Progress has been made towards establishing an East African Community (EAC)
- common medicines regulation policy, which aims to supervise the regulation,
- Procurement and quality of medicines available in EAC states.

Weaknesses

- Underdeveloped but improving pharmaceutical procurement and distribution system, plagued by financial problems.
- Limited public healthcare provision and staff shortages.

Opportunities:

- Potential base for exports across East Africa.
- Large and increasing burden of disease suggests a significant unmet demand for pharmaceuticals.
- The national health insurance scheme will improve access to medicines in the longer term.

Market

Pharma market is expected to grow at a CAGR of 85 in the next five years and reach $ 1.4 billion by 2022.

The country's rising population and increasing urbanization, as well as a growing communicable and no communicable disease burden, are the basis of the forecast. In January 2016, it was reported that The National Health Insurance Fund (NHIF) has introduced a new package that will cover patients with chronic diseases -specifically diabetes, hypertension and cancer will be catered for.

By international standards, per capita drug expenditure is extremely low; however, this compares favorably with other Sub-Saharan African markets such as Nigeria. A large proportion of Kenya's population has extremely low spending power. As this remains the case, the demand for low value medicines will dominate - limiting opportunities for multinational drugmakers whose product portfolio includes high-value, patented medicines. It’s an Opportunity for India’s Generic exporters.

Generic Drug market

The growth of Kenya's generic medicines sector will be supported mainly by increased volume consumption, pushed up by demand and by the support for measures aiming to achieve universal healthcare coverage. Additionally, although quality concerns exist regarding local generics manufacturers, the low per capita purchasing power will continue to favour cheaper products.

Most of formulation imports from India are re-exported.

Generic market was valued at $ 610 million in 2017 consisting of almost 64% of the total market. It is expected to grow by 10%.

Social health insurance scheme will encourage the use of the more affordable generic medicines. Intense competition in the sector and a strengthening shilling, which make imports attractive, should help to subdue price inflation in generics.

In June 2017, the government and Unitaid - a global health agency - announced the introduction of a new first-line generic version of the latest drug for people living with HIV/AIDS, making Kenya the first African country to do so. The drug can improve and prolong the lives of tens of thousands of people who suffer severe side effects and resistance to other treatments. A generic of Dolutegravir (DTG), first approved in the US in 2013, is being given to 20,000 patients in Kenya before being rolled out in Nigeria and Uganda later this year, with the backing of Unitaid

Pharmaceutical Trade

Imports meet the bulk of local demand for more sophisticated treatments, even though most locally made medicines are destined for domestic consumption. Over the coming years, rising demand for pharmaceuticals will push the trade balance further into the negative territory, as domestic producers lack the finances to innovate and modernise. The overall import/export figures, however, continue to be skewed by the country's role as a regional trade hub.

As with most emerging countries, Kenya continues to have a negative trade balance. Pharmaceutical imports, valued at USD648mn in 2017, will increase to USD728mn in 2018. Exports, valued at a modest USD102mn in 2017, will rise to US$143mn.

Kenya enjoys access to the regional medicinal exports market under a number of special access and duty reduction programmes related to the East African Community (EAC) and Common Market for Eastern and Southern Africa (COMESA), among others. However, difficulties in meeting international manufacturing standards mean that most of Kenya's domestic production is bound for the local market, despite its long history as a trading nation - its location makes it an ideal access point to the rest of Africa, and in particular, East Africa.

Local Companies

The country's pharmaceutical industry consists of approximately 37 manufacturers, with most located around Nairobi. Furthermore, approximately 30 of the Common Market for Eastern and Southern Africa (COMESA)'s 50 manufacturers are based in the country, including GlaxoSmithKline East Africa.

Statistics

India's Pharma exports to Kenya $ Million				
Category	2015-16	2016-17	2017-18	Gr%
Ayush	2.47	2.72	3.04	11.95
Bulk Drugs And Drug Intermediates	31.80	28.22	32.85	16.41
Drug Formulations And Biologicals	251.57	272.33	200.16	-26.50
Herbal Products	0.20	0.16	0.30	86.54
Surgicals	5.64	4.78	2.97	-37.96
Vaccines	40.78	17.21	15.30	-11.11
KENYA	**332.48**	**325.43**	**254.62**	-21.76

Top Ten Importing Partners of KENYA $ Million						
Rank	Country	2014	2015	2016	Gr%	Share%
1	India	233.42	294.85	318.90	8.16	52.92
2	Switzerland	48.81	33.62	46.62	38.67	7.74
3	Belgium	56.65	48.84	45.05	-7.76	7.48
4	United Kingdom	39.31	47.96	39.08	-18.51	6.49
5	China	38.17	35.99	35.90	-0.25	5.96
6	South Africa	20.53	16.53	19.15	15.88	3.18
7	France	17.27	14.81	16.80	13.41	2.79
8	Japan	0.56	1.85	10.92	488.84	1.81
9	Netherlands	17.47	17.48	9.09	-48.03	1.51
10	Germany	10.34	9.70	9.06	-6.60	1.50
	World	534.04	574.12	602.59	4.96	100.00

Regulatory Review

The Pharmacy and Poisons Board (PPB), established under Chapter 244 of the Pharmacy and Poisons Act (2002), is responsible for the registration of pharmaceuticals and medical devices in Kenya. The National Quality Control Laboratory is responsible for pharmaceutical testing for regulatory purposes. However, in reality it is believed to test less than 20% of samples.

Importers are expected to meet legal requirements such as the provision of drug samples to the Kenya Bureau of Standards for quality checks and registration and complying with national policy regulations adopted by the Ministry of Health. This includes an essential drugs list, using WHO guidelines, the objective of which is to promote the availability of quality pharmaceutical products at affordable prices.

Kenya is viewed as having an overly-complicated regulatory environment, despite the fact that the initial approval is relatively straightforward. The difficulties are mostly present in the procurement and supply sectors, due to the overlapping work of government initiatives, aid agencies and NGOs. For example, the semi-autonomous Kenya Medical Supplies Agency (KEMSA) - established in 2000 to replace the Medical Supplies Coordinating Unit (MSCU) - is responsible for supplying essential drugs to public facilities, but it competes with the Mission-based Medical Supply Facility (MEDS) and private wholesalers. The issue is further complicated by the lower prices offered to developing countries by some patented drug makers, resulting in a paradox whereby procuring branded generics can be more expensive than the originator brand.

REGISTRATION AND LICENSING REQUIREMENTS

➢ Regulatory Authority	:	**Pharmacy and Poisons Board (PPB)**
➢ Website of regulatory Authority	:	http://pharmacyboardkenya.org/
➢ Fees for Drug Registration	:	USD 1000
➢ Normal time taken for registration	:	12 Months
➢ Registration Requirement [Dossier Format]	:	CTD
➢ Whether plant inspection is mandatory	:	Yes
➢ Requirement of Local agent/ Subsidiary	:	Local Agent is sufficient

The Pharmacy and Poisons Board (PPB) is the Drug Regulatory Authority established under the Pharmacy and Poisons Act(2002), Chapter 244 of the Laws of Kenya.

The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons.

The Board aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the laws regulating drugs in force in Kenya.

The Core functions of the Pharmacy and Poisons Board:

- **Product Registration:**
  The Minister for Health in consultation with the Pharmacy and Poisons Board is empowered by section 44(1) of the Pharmacy and Poisons Act, Cap 244 and misc. Amendments of 2002 to make rules under which medicines may be imported, manufactured for sale or sold in Kenya.

- **Pharmacy Practice**
- **Manufacturer Services**
- **Inspectorate**

REQUIREMENTS FOR REGISTRATION:

1. Each foreign manufacturer shall have one local agent with blanket power of attorney. The local agent must be a registered whole seller of drugs in Kenya.
2. Provision of a free sale certificate from the country of origin or a certificate of a pharmaceutical product.
3. A separate application for each product
4. Dossier to be submitted as one original hard-copy and one electronic copy (in a Portable Document Format, PDF, on a CD-Rom) and **should include MS-Word document for Modules 1 and 2**, cross-referenced to the dossier by clearly indicating the title and section number of all the supporting documents.
5. The manufacturer must comply with GMP. The Board reserves the right to verify the Good Manufacturing Practices Compliance of the manufacturer at the applicant's expense.
6. Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.
7. An original Certificate of Pharmaceutical Product (WHO Format) on official papers of the issuing competent drug regulatory authority.
8. A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.
9. Nonrefundable application fee for registration of medicines in Kenya (USD 1000) and GMP inspection fees(USD 6000) for facilities not yet inspected by PPB.

The drug approval process for new pharmaceutical products, including biotechnology-derived productsfollows the following steps:

- Receipt of applications
- Market agency authorization
- Manufacturers and manufacturing sites inspection for current Good Manufacturing Practices
- National Quality Control Laboratory analysis
- Committee on Drug Registration Recommendation
- Practice Committee review
- Full board approval
- Gazetted

The drug application is considered withdrawn if queries are not adequately responded to within 6 months of the request. If a drug is declined, the applicant may appeal that decision within 2 months from the date of notification.

Fast Track registration:

An application may be fast tracked if the product is

- Locally manufactured in Kenya.
- A **Priority Medicine** i.e. the product is indicated for diseases which at the time of application have no registered alternative medicine or evidence has been submitted to show that the product has significant advantages in terms of safety and efficacy over existing products indicated for treatment or prevention of life threatening diseases.

Complete applications will be processed **within 90 working days** of receiving the application including evaluation of documentation and consideration by a committee on drug registration.

Validity of Registration:

The registration of a pharmaceutical product shall be valid for **five (5) years** unless earlier suspended or revoked by PPB or withdrawn by applicant.

FEE STRUCTURE:

For foreign manufacturers intends to export drugs to Kenya

1	Application for the Registration of a Drug product	US$ 1,000
2	Fee for GMP Inspection of Foreign facility*	US$ 6,000
3	Appeal fee	US$ 300
4	Variation Fee	US$ 200
5	Replacement of a registration Certificate	US$ 100
6	Annual Retention fee per product	US$ 300
7	Renewal of Registration certificate	US$ 500
8	Fine for late renewal	US$ 500

(Ref: http://www.businesslicense.or.ke/index.php/license/details/id/515)

Fee for analytical test by the National Quality Control laboratory along with * revised fee for GMP audit is available at http://www.rrfa.co.za/wp-content/uploads/2014/01/Kenya-Gazette-Notice-8695-161021.pdf

GUIDELINES TO SUBMISSION OF APPLICATIONS FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS

Drug registration - Guidelines to submission of applications published by the Pharmacy and Poisons Board (PPB) is available at http://pharmacyboardkenya.org/downloads

The guideline is divided into SIX Parts:

- General Information
- Module 1: Administrative information
- Module 2: Chemical, Pharmaceutical, Non-Clinical and Clinical Overviews and Summaries
- Module 3: Chemical and Pharmaceutical Documentation
- Module 4: Non-Clinical Reports for New Chemical Entities Only
- Module 5: Clinical Study Reports

GENERAL INFORMATION:

Language: All applications and supporting documents shall be in English and legible

SUBMISSION OF APPLICATION

The application should be submitted to the following address:

The Registrar, Pharmacy and Poisons Board Lenana Road,
P. O. Box 27663-00506, NAIROBI.

For purposes of submission to PPB, applications are classified into **three categories** as follows:

(1) New applications

This is an application for registration of a medicinal product that is intended to be placed on the Kenyan market for the first time.

A separate application is required for each product. Products that differ in active ingredient(s), strength, dosage forms, proprietary names though containing the same ingredients, are considered to be different products and hence require separate applications.

However, products containing the same active ingredients and the same strength made by the same manufacturer at the same manufacturing site, to the same specifications and dosage form, but differing only in packing or pack sizes require only one application.

A new application for registration shall include submission of:

i. Two dully filled application forms (Original and Duplicate) and an electronic copy (a summary of the dossier contents) in MS Word on a CD-ROM of modules 1 and 2 only including their supporting documents

ii. Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.

iii. An original Certificate of Pharmaceutical Product (WHO Format) on official papers of the issuing competent drug regulatory authority.

iv. A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.

v. Nonrefundable application fee for registration of medicines in Kenya and GMP inspection fees for facilities not yet inspected by PPB.

(2) Applications for Renewal of Registration

Applications for renewal of registration shall be made **at least 3 months b**efore the expiry of existing registration by submitting the following:

i. Dully filled in application form for renewal of registration.

ii. Batch Manufacturing Record (BMR) of a real batch manufactured within at most six months before the submission of the application.

iii. Submit Periodic Safety Update Reports (PSUR)

iv. Proof of interchangeability for generics.

v. Any other requirements that the Board may determine.

vi. Three (3) samples of the smallest commercial pack(s) from the same batch along with batch certificates of analysis.

vii. A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.

viii. Nonrefundable application fee for registration of medicines in Kenya and GMP inspection fees for facilities not inspected and approved by PPB, GMP department.

(3) Application for Variation of a registered medicinal product

All applications for variation to a registered product shall be made according to requirements stipulated in the PPB Application Guideline for Variation of Registered Medicinal Products.

If an application for renewal is made after the expiration of the period of validity of the certificate of registration the application shall be considered as a fresh application using form 1.

AN OUTLINE OF THE EVALUATION PROCESS

Evaluation process

The evaluation of applications is done on a first in first out (FIFO) basis unless the product meets the **fast track criteria** as set out in this guideline. An application may be fast tracked if the product is

- Locally manufactured in Kenya. Note that contract manufacturing outside Kenya by a Kenyan company will not render the product to be locally manufactured.

- A **Priority Medicine** i.e. the product is indicated for diseases which at the time of application have no registered alternative medicine or evidence has been submitted to show that the product has significant advantages in terms of safety and efficacy over existing products indicated for treatment or prevention of life threatening diseases.

Assessment of product dossiers involves evaluators from within or outside PPB. The evaluation report produced by the evaluator is reviewed by a second evaluator who does the quality assurance of the evaluation report and where necessary adds comments and finalizes the report and recommendations. Evaluation is done against the requirements of the guideline in accordance with the Standard Operating Procedures for Evaluation. However, the Board reserves the right to request any additional information to establish the quality, safety and efficacy of a medicine in keeping with the level of knowledge current at the time of evaluation.

During evaluation, additional data and/or samples may be requested through a query letter. Once a query has been raised and issued to the applicant, the process stops until when PPB receives a written response to the query. Conclusion of the application may only be made if responses to queries issued in the same letter are submitted in one transaction for consideration. Failure to comply with this condition or if the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected.

In the event the responses to the queries are not submitted **within six months** from the date they were issued, it will be deemed that the applicant has withdrawn the application. Thereafter, registration of the product may only be considered upon submission of a new application.

PRE-REGISTRATION LABORATORY ANALYSIS OF THE PRODUCT SAMPLE:

The samples will be analyzed for all medicines and a certificate of analysis from a recognized Quality Control Laboratory in Kenya and within the region shall be submitted with the application. Laboratory analysis of the samples will be done against the claimed in-house or pharmacopoeia specifications using the analytical method provided by the applicant.

The following Control Laboratories are recognised

- All WHO prequalified Laboratories in Kenya and within Eats African Community
- Drug Analysis Research Unit, DARU, of the School of Pharmacy, University of Nairobi

VERIFICATION OF COMPLIANCE TO CURRENT GOOD MANUFACTURING PRACTICES (CGMP)

If the new application is from a new manufacturing site, PPB will conduct inspection of the site or use other means to verify whether the facility complies with current Good Manufacturing Practices Regulations and/or guideline before a product is registered. No product shall be registered unless the plant complies with cGMP.

After the inspection, the details of the observation made will be presented in a full report which will form part of the evaluation process.

When the facility is found not to comply with current GMP, the applicant will be required to rectify the observed deficiencies and submit a compliance report within a time frame agreed during the inspection. Based on the report, the Board may either approve the facility or conduct re-inspection.

If the applicant does not rectify and request for re-inspection within the 12 months or if after re-inspection the facility is found not to comply with cGMP, it will be deemed that the applicant has failed to rectify the deficiencies and has therefore withdrawn the respective application(s). The application will be rejected and thereafter registration of the product will only be considered upon submission of a new application.

Inspection of a facility for the purposes of considering applications for renewal of registration shall be done and if the facility is found not to comply with cGMP, registration of all products manufactured by the facility shall be withdrawn.

CONSIDERATION BY COMMITTEE ON DRUG REGISTRATION

A summary of recommendations of evaluation, laboratory analysis and GMP status reports will be presented before the Committee on Drug Registration for consideration and making final recommendations for granting or rejecting registration of the product.

However, if there are unresolved safety, quality or efficacy issues the Committee may defer approval pending resolution of the issues. Should the applicant fail to provide the required data within six months, the product will be disqualified and the application will be rejected.

Registration will be granted by the board subject to the product complying with criteria prescribed under CAP 244, Pharmacy and Poisons Act. A certificate of marketing authorization together with applicable conditions shall be issued.

TIMELINES

The Board will implement the following timelines in processing applications for marketing authorization of pharmaceutical products.

Fast-tracked registration (Locally manufactured and Priority Medicines only), Post Approval Variation and Renewal of registration

Complete applications will be processed within 90 working days of receiving the application including evaluation of documentation and consideration by a committee on drug registration.

Evaluation of new applications

Complete new applications will be processed within 12 months of receipt of the application. The applicant will be required to provide any requested additional data within 6 months. In case additional time is required, a formal request must be submitted.

WITHDRAWAL OF AN APPLICATION

When the applicant fails to submit written responses to queries within 6 months from the date of their issuance, it will be deemed that the applicant has withdrawn the application or if the queries have been reissued for a second time and the applicant provides unsatisfactory responses, the product will be disqualified and the application will be rejected. The applicant will be required to apply afresh.

VALIDITY OF REGISTRATION

The registration of a pharmaceutical product shall be valid for five (5) years unless earlier suspended or revoked by PPB or withdrawn by applicant. The Board will give reasons in writing when it suspends or revokes, or amends conditions of registration. Likewise the applicant shall also give reasons for terminating registration of a product.

APPEALS

Any person aggrieved by a decision of PPB in relation to any application for marketing authorization of a pharmaceutical product may within two (2) months from the date of notice of the decision, make representations in writing to the Board and pay the requisite appeal fee and submitting additional data to support their representations.

MODULE 1: ADMINISTRATIVE INFORMATION

1.1 Applicant:

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

- The License/patent holder
- The manufacturer
- An authorized Local Technical Representative (LTR) of the manufacturer or License/patent holder

1.2 Trade/Proprietary name
1.3 Approved / INN / generic name in relation to a drug
1.4 Strength of the product
1.5 Dosage form of the product
1.6 Packing/Pack size of the product
1.7 Visual Description of the drug
1.8 Proposed Shelf life of the product

1.9 Pharmacotherapeutic group and ATC code:

The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of drugs. The classification system divides drugs into different groups according to the organ or system on which they act and/or their therapeutic and chemical characteristics

Reference: *WHO Collaborating Centre for Drug Statistics Methodology: About the ATC/DDD system*

1.10 Legal Category

Indicate the proposed dispensing category/classification:

- Products subject to medical prescription or not subject to medical prescription
  - The product will be dispensed from Non-pharmacy outlets and pharmacies
  - The product will be dispensed from Pharmacies Only

- Products subject to medical prescription:
  - Controlled Drug Substance
  - Prescription Only Medicine, POM

1.11 Country of Origin

1.12 Product Marketing Authorization in the country of origin and other countries

1.13 Pre-registration analysis of the product:

1.14 Name and complete address(es)of the manufacturer(s) of the FPP

1.15 GMP status of the Manufacturer and GCP/GLP status of the Clinical Research Organisation/ Laboratory

1.16 Local Technical Representative

1.17 Summary Product Characteristics (SPC)

1.17.1 Product information for Health Professionals (For All Products subject to Medical Prescription)

Proposed Summary of product Characteristics aimed at Medical practitioners and other health practitioners and approved by competent authority at the time of licensing. The SPC is an essential part of registration and can only be changed with the consent of PPB

Reference: ―*Guideline on summary of Product Characteristics – Notice to applicants*‖, *European commission, Enterprise Directorate – General, Pharmaceuticals and Cosmetics (Dec 1999)*

1.17.2 Patient information leaflet (For All Products not subject to Medical Prescription)

Provide copies of all package inserts and any information intended for distribution with the product to the patient. The patient information leaflet (PIL) should be in conformity with the SPC. It should be written in Kiswahili and/or English, should be legible, indelible and comprehensible.

Reference: http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm#2c

MODULE 2: CHEMICAL, PHARMACEUTICAL, NON-CLINICAL AND CLINICAL OVERVIEWS AND SUMMARIES

This section of the document (follows ICH: M4Q) and provides a harmonized structure and format for presenting CMC (Chemistry, Manufacturing and Controls) information in a registration dossier.

This section covers the chemical and pharmaceutical data including data for biological/ biotechnological products.

The table of contents includes sections on Drug Substance and Drug Product. A new section on Pharmaceutical Development has been included.

This module should be submitted as an electronic copy (MS Word on a CD-ROM) and be properly cross-referenced to the dossier by clearly indicating to volume, page number in other Modules and the title of all the supporting documents.

MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION

This part is intended to provide guidance on the format of a registration application for drug substances and their corresponding drug products as defined in the scope of the ICH Guidelines Q 6 A ("NCE") and ICH Guideline Q 6 B ("Biotech"). This format may also be appropriate for certain other categories of products though it has been modified to suit Generic drug applications.

MODULE 4: NONCLINICAL STUDY REPORTS FOR NEW CHEMICAL ENTITIES ONLY

This guideline presents the organization of the nonclinical reports in the applications that will be submitted. This guideline is not intended to indicate what studies are required. It merely indicates an appropriate format for the nonclinical data that have been acquired.

MODULE 5: CLINICAL STUDY REPORTS

This part provides guidance on the organization of the study reports, other clinical data, and references within an application for registration of a pharmaceutical product. These elements should facilitate the preparation and review of a marketing application.

This guideline recommends a specific organization for the placement of clinical study reports and related information to simplify preparation and review of dossiers and to ensure completeness. The placement of a report should be determined by the primary objective of the study. Each study report should appear in only one section. Where there are multiple objectives, the study should be cross-referenced in the various sections. An explanation such as ―not applicable‖ or ―no study conducted‖ should be provided when no report or information is available for a section or subsection.

Please refer the Guidance documents of Republic of Kenya for "**Drug registration - Guidelines to submission of applications**" available at http://pharmacyboardkenya.org/downloads

VARIATIONS:

A variation is a post-approval amendment that details the proposed change(s) to information appertaining to approved documentation for the purpose of updating of the details of the Marketing authorization licence issued by the Pharmacy and Poisons Board, the national Drug Regulatory Authority. Variations can only be implemented on receipt of a letter of acceptance from PPB.

Major variation:

Major variations are changes that could have major effects on the overall safety, efficacy and quality of the FPP.

Minor variation:

Minor variations are changes that may have minor effects on the overall safety, efficacy and quality of the FPP.

Notification:

Notifications are changes that could have minimal or no adverse effects on the overall safety, efficacy and quality of the FPP. Such notifications do not require prior acceptance, but must be notified to PPB immediately after implementation or within 12 months following implementation of the change. e.g Periodic Safety Update Reports.

Every application shall be accompanied by requisite fees at the time of application of variations. PSURs are exempted from payment of fee.

Please refer the "**Variation Guidelines**" published by the PPB available at http://pharmacyboardkenya.org/downloads for more information.

KENYA MEDICAL SUPPLIES AUTHORITY (KEMSA):

The Govt of Kenya mainly procures medicines through the Kenya Medical Supplies Authority (KEMSA). KEMSA is the sole public sector supplier of pharmaceuticals. It procures pharmaceutical products directly through an open international tender (any local and international manufacturer and/or distributor is free to participate). KEMSA has a strong national distribution coverage serving over 4,000 public sector facilities, and it has recently experienced improved efficiency in coordinating the supply system.

KEMSA is a state corporation under the Ministry of Health established under the KEMSA Act 2013 whose mandate is:

- Procure, warehouse and distribute drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals

- Establish a network of storage, packaging and distribution facilities for the provision of drugs and medical supplies to health institutions.
- Enter into partnership with or establish frameworks with County Governments for purposes of providing services in procurement, warehousing, distribution of drugs and medical supplies.
- Collect information and provide regular reports to the national and county government's on the status and cost effectiveness of procurement, the distribution and value of prescribed essential medical supplies delivered to health facilities, stock status and on any other aspects of supply system status and performance which may be required by stakeholders.
- Support County Governments to establish and maintain appropriate supply chain systems for drugs and medical supplies

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Details of importing country embassy in India: **http://kenyahicom-delhi.com/**

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

List of Local Pharma Associations:

- Kenya Pharmaceutical Association (KPA)
  PO BOX 13743 – 00100, Nairobi, Kenya.
  Ph:(+254)2733813
  info@kenyapharmassociation.org
  www.kenyapharmassociation.org