وزارة الصناعة والتجارة والتموين

اليوبيل الفضي ١٩٩٩-٢٠٢٤

الرقم 14482/ 22/2/19

التاريخ 2024/06/10

الموافق .....

سعادة رئيس غرفة تجارة الأردن

سعادة رئيس غرفة صناعة الأردن

الموضوع: مجموعة الوثائق والمرجعيات القانونية المطلوبة عند تسجيل الدواء في مجلس الصيدلة والسموم الكيني

تجدون سعادتكم مرفقاً طيه رسالة البريد الإلكتروني الواردة من سعادة المستشار الاقتصادي الأردني في كينيا والمتضمنة مجموعة من الوثائق الهامة والمرجعيات القانونية المفهرسة والتي تتضمن القواعد والإجراءات والرسوم القانونية التي يحتاجها مصدر الدواء الأردني بالإضافة الى إجراءات المسار السريع عند تسجيل الدواء في مجلس الصيدلة والسموم Pharmacy and Poisons Board في كينيا وذلك بهدف اطلاع مصدر الدواء الأردني على المرجعيات القانونية والرسمية لجميع الإجراءات.

راجياً سعادتكم التكرم بالاطلاع والإيعاز لمن يلزم باجراء ما ترونه مناسباً بهذا الخصوص.

وتفضلوا بقبول فائق الاحترام،،،

محمود يوسف الشمالي

وزير الصناعة والتجارة والتموين

نسخة: مديرية السياسات التجارية الخارجية /كينيا

Hassan A. Alzubi

From: Amer Abu. Rumman
Sent: Friday, June 7, 12:22 2024 PM
To: Dana Al-Zoubi
Cc: Wafa Jiries; Maram Makhamreh; Hassan A. Alzubi
Subject: المرجعيات القانونية واجراءات تسجيل الدواء والرسوم التي يحتاجها مصدر الدواء الأردني
Attachments: Pharmacy and Poisons Board Report.docx; Documents.rar; Fast track 2.docx

عطوفة الأمين العام
تحية طيبة وبعد

ارجو أن أرفق لكم مجموعة من الوثائق الهامة والمرجعيات القانونية المفهرسة والتي تتضمن القواعد والإجراءات والرسوم القانونية التي يحتاجها مصدر الدواء الأردني بالإضافة الى إجراءات المسار السريع عند تسجيل الدواء في مجلس الصيدلة والسموم Pharmacy and Poisons Board في كينيا حتى يكون مصدر الدواء الأردني على اطلاع تام بالمرجعيات القانونية والرسمية لجميع الإجراءات وبهدف تصدير الدواء وزيادة حجم التصدير بإذن الله.

راجيا التكرم بالايعاز بتعميمها على اتحاد منتجي الأدوية والجهات ذات العلاقة بتصدير الدواء الأردني.

وتفضلوا عطوفتكم بقبول فائق الاحترام

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Pharmacy and Poisons Board Registration Medicines registrations Procedures

The *Pharmacy and Poisons Board* is a State Corporation under the Ministry of Health and is the Drug Regulatory Authority of the Republic of Kenya and was established by Chapter 244 of the Pharmacy and Poisons Act. The board is in charge of regulating the Practice of Pharmacy and the Manufacture and Trade of drugs and poisons in Kenya.

The board is in charge of ensuring the highest standards of safety, efficacy and quality for drugs, chemical substances and medical devices that are locally manufactured, imported, exported, distributed, sold, or used to ensure the protection of Kenyan consumers.

The Board comprises 7 individuals; Dr. Charles Githua who is the chairman of the board, Dr. Fred Siyoi who is the CEO of the board, and Dr. Richard Muthoka, Dr. Beatrice Amugune, Dr. Isha Anand, and Mr. Benard Maiyo who are board members.

The board is organized into four directories as follows:

Medical Products and Health Technologies

Concerned with the registration of medical products and health technologies, inspections and enforcement of good practices for manufacturing and distribution, post-market surveillance, clinical trials, vigilance and appropriate use of products to ensure their quality, safety, efficacy and economic value as defined in the Pharmacy and Poisons Act, CAP 244.

Pharmacy Practice

Ensures pharmacy practice meets the highest attainable standards of healthcare delivery through effective regulation of pharmacy training, practice and continuing professional development for maintenance of competence and fitness to practice.

Laboratory Services

Concerned with compliance testing of Medical Products and technologies and their respective ingredients, employing authorised methods and investigative testing of suspicious, substandard, falsified, illegal, counterfeit substances or products, submitted for examination by medicine inspectors, customs or police.

Corporate Services

Concerned with financial, human resource and administrative management functions of the Board.

Consolidates all support services needed for all operational work of the organization and increase ability of all departments to function as a best-practice, knowledge-based, lean and service-oriented using highly trained staff, technology and effective communication to create and sustain a pleasant and appreciative working environment to internal and external customers and partners.

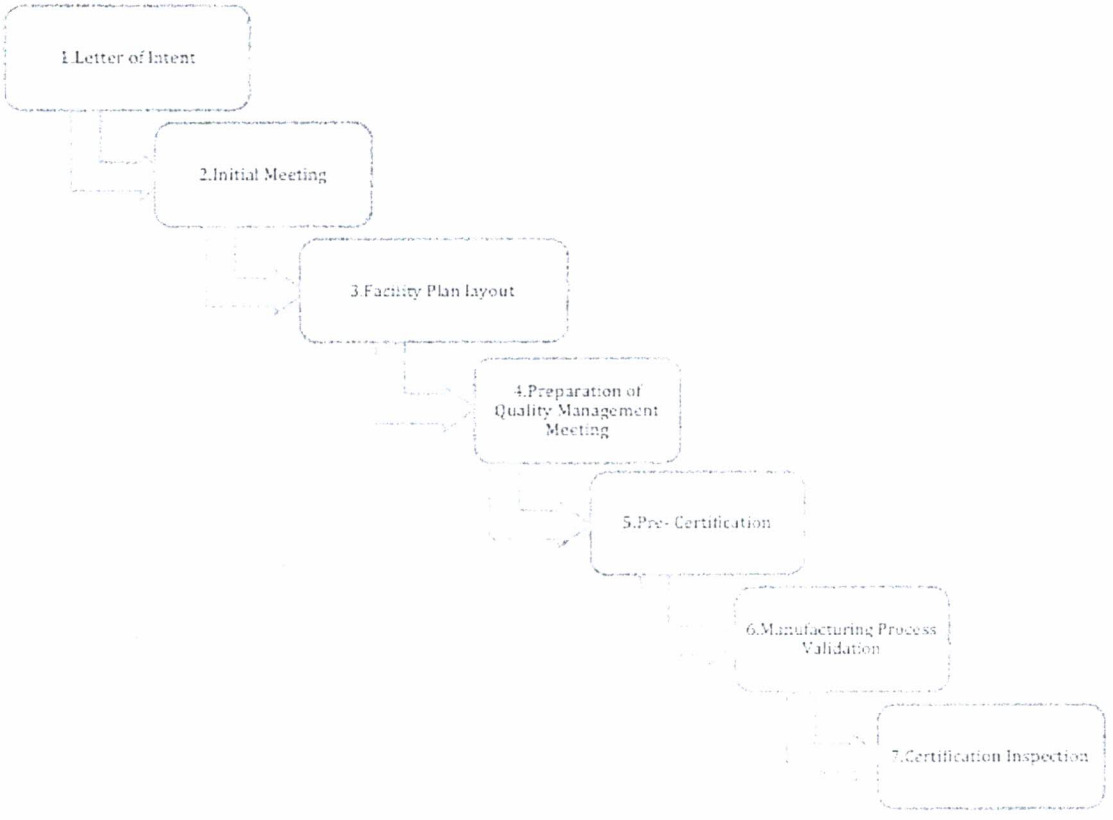
Application Procedures

Before applying for medicines evaluation and registration, you need to apply for GMP inspection (Good Manufacturing Practice Guidelines).

Good Manufacturing Practice Guidelines

1. ***Guidelines for Establishing Manufacturing Facilities for Health Products & Technologies in Kenya***

This guidance is intended to facilitate the setting up of manufacturing facilities in Kenya fit for manufacture of quality health products and technologies that meet international standards as well as protecting personnel working in these premises. This guidance is intended to guide on establishment of manufacturing facilities for health products and technologies as well as ease of doing business.



For further queries on each individual step, kindly refer to the attached *Index 1 – Guidelines for establishing Manufacturing Facilities for Health Products & Technologies in Kenya* (**Pages 15-19**) and see the below contact details:

Department:	**GMP Division**
	Pharmacy and Poisons Board of Kenya
Telephone:	**+254709770100/200/202/207**
Email:	**gmp@pharmacyboardkenya.org**

2. *Kenya Good Manufacturing Practices Guidelines*

This is relevant for manufacturers of HPTs that are importing their products into the country and applies to exporters from Jordan.

Non-technical GMP guidelines developed to guide the local manufacturing Industry and PPB GMP inspectors have been developed and published by PPB. As much as practicable, these too are developed in line with internationally recognized guidelines. Through the implementation of the guidelines in this document in regulatory oversight of GMP inspections, PPB shall better oversight manufacturers of Health Products and Technologies (HPTs) manufactured in, imported into, or exported from Kenya. It will ensure that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as require by the marketing authorization or product specification.

The Board shall reference the WHO guidelines in updating and implementing this guidance document in keeping with regulatory best practices.

The following guidelines include technical recommendations as referenced by WHO and national guidelines specific to the Republic of Kenya.

Foreign manufacturers of HPTs intending to obtain Kenyan GMP certification may also find this collection of GMP guidelines useful and as reference documents for use during the Kenya GMP inspections.

This guidance is meant to help applicants to comply with good manufacturing practices (GMP) requirements, and prepare for an inspection.

Good manufacturing practice (GMP) represents the minimum standard that a manufacturer of medicines must adhere to in their production processes.

GMP serves to ensure that the products manufactured are:

1. Consistently of high-quality;

2. Appropriate to their intended use;

3. In compliance with the requirements of the marketing authorization clinical trial authorization or product specification.

Entities subject to compliance with good manufacturing practice (GMP) include:

1. Holders of Manufacturing licenses;

2. Holders of blood establishment authorizations;

3. Overseas facilities contracted by Kenyan marketing authorization holders;

4. Overseas facilities holding or intending to hold Kenyan marketing authorization;

5. Quality Control Laboratory for Pharmaceutical Manufacturers

The Kenya Pharmacy and Poisons Board (PPB) conducts inspections to assess the adherence of manufacturing sites to GMP standards established by the

World Health Organization (https://www.who.int/teams/health-productpolicy-and-standards/standards-and-specifications/gmp).

These inspections occur as part of the application process for a manufacturer license and are periodically conducted based on risk assessments. Overseas manufacturing sites are also subject to inspections.

For guidance Manufacturers intending to market products in Kenya are expected to submit the most recent site master file in the format and content prescribed by the World Health Organization

https://www.who.int/publications/m/item/trs961-annex14

In cases where an organization manufactures both human and veterinary medicines using the same facility, the PPB may conduct inspections for both areas but evaluate GMP compliance exclusively for human medicines. The inspection and certification for GMP compliance of veterinary product manufacturing facilities does not fall under the purview of the PPB.

Types of Inspections

Marketing Authorization-Related GMP Inspections

The PPB conducts product-related routine GMP inspections when evaluating an application for a Kenyan marketing authorization. These inspections assess whether the manufacturer complies with GMP standards.

Manufacturers of products are informed in advance about these inspections.

These applications can be done through prims.pharmacyboardkenya.org/

In some instances, inspections are conducted jointly with inspectors from East African medicines regulatory agencies, as part of East Africa Joint Inspections. Under this framework, member states collaborate by deploying GMP inspectors to jointly assess the compliance of manufacturing sites with GMP principles. These sites would have applied through the East African Community pathways for the joint GMP inspections and product joint assessment for marketing authorization in respective countries.

Risk-Based Approach to Inspections

Every manufacturer is assigned a risk rating, and the Kenya Pharmacy and Poisons Board (PPB) prioritizes inspections for those with the highest risk ratings. Manufacturers are typically notified of upcoming inspections in advance. However, under the short-notice inspection program, the PPB may provide little or no advance notification. During these inspections, GMP inspectors assess the systems employed in the manufacturing of medicines. Following a GMP inspection, the inspected site's risk rating is determined based on the following factors: a) The site's compliance report. b) Internal information related to previous inspection history. c) Organizational changes Any upward revision of the risk rating is subject to peer review by a team of GMP inspectors before finalization. Manufacturers or any other inspected sites have the option to appeal the PPB risk rating, taking into consideration the risk rating report.

Before inspection, the following steps are involved:

1. **Completion of a pre-inspection form**

Before an inspection, the inspected site may be required to complete a GMP pre-inspection compliance report comprising the company's biodata and the site's compliance details.

When the completion of this form is necessary, the inspected site should submit the fully filled form in MS Word Document format to the email address provided by the Lead inspector.

2. **Schedule a GMP Inspection date**

Inspection schedules of applications are developed every six months and allocated tentative dates and inspection teams based on;

a) Type and purpose of inspection to be performed;

b) Anticipated duration of inspection based on plant size: number of

blocks, production lines and activities;

c) Location of the site;

d) Compliance history and risk rating of the site.

Inspection procedure:

PPB inspectors conduct GMP inspections to assess compliance with WHO

GMP guidelines (https://www.who.int/teams/health-product-and-policystandards/standards-and-specifications/norms-and-standards-forpharmaceuticals/guidelines/production) and any other internationally recognized GMP guidelines adopted by Kenya.

During the GMP inspection, the PPB inspection team will:

a. Interview relevant personnel.

b. Review pertinent documents.

c. Conduct on-site visits.

Site visits may encompass any facility or process involved in the production of medicines, including:

a) Manufacturing areas.

b) Quality Control (QC) laboratories.

c) Storage areas.

d) Stability study sites.

e) Utility areas.

f) Returned goods areas.

The inspection team may request additional documentation and samples for testing during the inspection. They may also adjust the inspection's focus if they suspect significant non-compliance.

In the closing meeting, the inspector will provide feedback, discuss any identified deficiencies, and establish timelines for corrective actions.

For more information, kindly reach out to PPB on gmp@pharmacyboardkenya.org.

Medicines Evaluation and Registration Procedures

To apply for MA of Medicines, you will need to meet the minimum requirements as described in the guideline (Index 3 – Compendium of Guidelines on Medicines Evaluation and Registration in Kenya).

Proceed to the online portal prims.pharmacyboardkenya.org and fill the application form provided as per the requirements in the MA Application (see Index 5 for a copy of the application form).

Before submitting an application for MA, you will need to apply for GMP inspection (please refer to the GMP inspection and Compliance procedure, link).

To apply for MA of Medicines, you will need to meet the minimum requirements as described in the guideline. Proceed to the online portal prims.pharmacyboardkenya.org and fill the application form provided as per the requirements in the Guidelines on Medicines evaluation and registration (See Index 3).

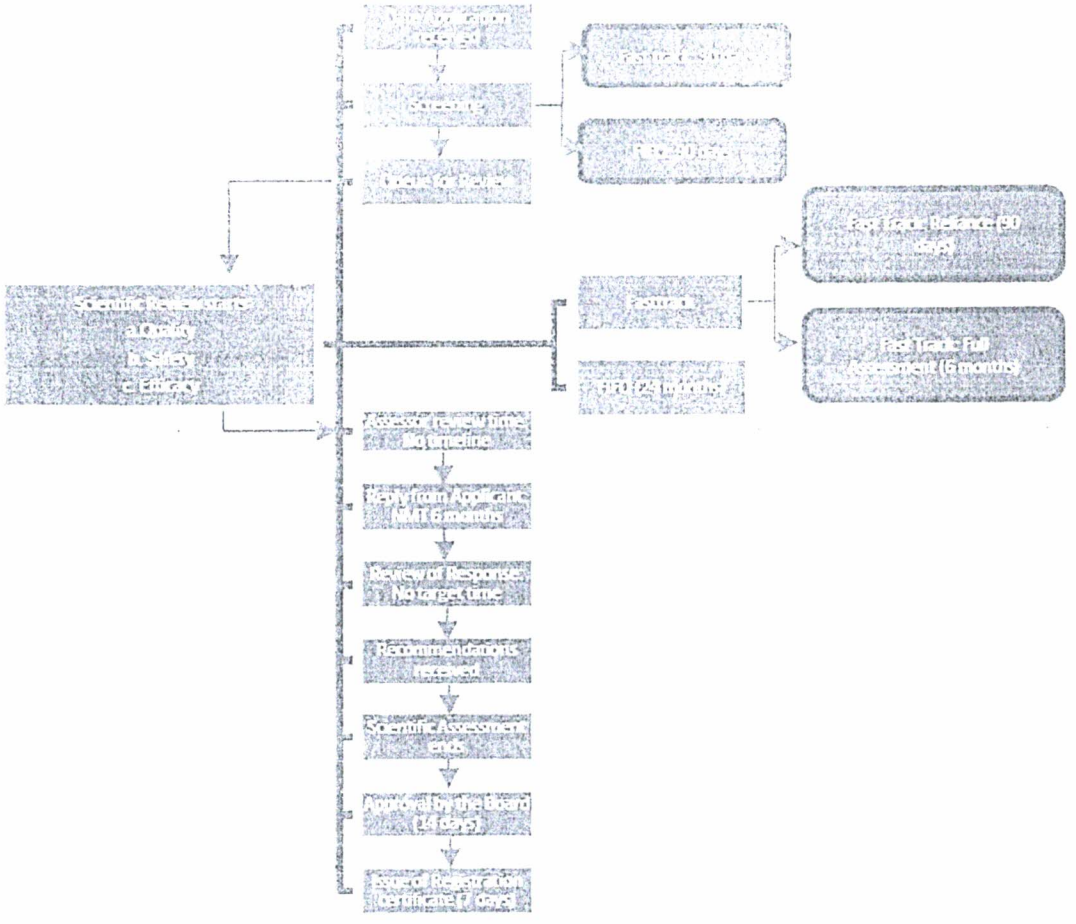
There are three pathways for submitting an application:

a. First in first out (FIFO)
b. Fast-track (full assessment and Reliance)
c. Expedited pathway (emergency use authorization).

For eligibility, please refer to Reliance guidelines on regulatory decision making in Kenya (Index 6), Guidelines for fast track review of applications for Health products and Guidelines on submission of documentation for emergency use and compassionate use authorization of health products (Index 7).

An invoice will be generated upon completion of the form after which you can make the necessary payments.

For further details regarding the necessary documentation required for the registration of



Please see Index 6 – Guidance on Reliance for Regulatory Decision Making in Kenya for this flowchart and more details pertaining to it.

PPB Current and Proposed Fees

The PPB levies fees for services rendered in executing its mandate of regulating the profession of pharmacy and ensuring the safety, quality and efficacy of medical products and health technologies. These fees are gazetted by the Cabinet Secretary for Health according to Section 44 of the Pharmacy and Poisons Act, which gazettement was last done in 2010.

For these reasons, the PPB, is in the process of revising its fees in order to keep up with the continuing increase in costs of services as well as the technology used in ensuring the provision of quality services. Further, there is need to be in line with charges across the EAC region to aid in the ongoing harmonization initiatives.

Methods of payment: Electronic payment / direct transfer. Cheques are no longer accepted as a method of payment.

Proof of electronic payment / direct transfer must be submitted in a separate and attached in the screening portal with a copy of the letter of application of the relevant submission(s).

To ensure evaluation of the relevant submission(s) a copy of proof of payment both invoice and receipts must be attached with the relevant submission documents.

Please see below all relevant fees and note that figures could vary.

	Purpose of Fees	Current Fee (USD)	Proposed Fee (USD)
2.1.1 Trade Affairs Function			
1.	Import Permit Fee	2% is the Gazetted Fee 0.75% Freight on Board (FOB) is currently charged upon execution of an out of court Deed of settlement on 17th May 2011	2% FOB

	Purpose of Fees	Current Fee (USD)	Proposed Fee (USD)
2.2.1.1 Medical Products Division			
1.	Application for registration of health products not manufactured in Kenya.	1,000	3500
2.	Application for registration of health products manufactured in Kenya.	500	1,000
3.	Application for renewal of registration of health products not manufactured in Kenya.	1,000	2,000
4.	Application for renewal of registration of health products manufactured in Kenya.	500	1,000
5.	Application for Variation: not Manufactured in Kenya- Major Variation	300	1,000
	Minor Variation	300	300

	Purpose of Fees	Current Fee (USD)	Proposed Fee (USD)
	Notification	300	300
	Safety Updates	-	300
6.	Application for Variation: not Manufactured in Kenya- (Abridged Pathway): Major Variation	300	500
	Minor Variation	300	300
	Notification	300	300
	Safety Updates	-	300
7.	Application for Variation: not Manufactured in Kenya (Locally Manufactured) Major Variation	300	500
	Minor Variation	300	300
	Notification	300	300
	Safety Updates	-	300
8.	Application for Fast tracking Evaluation of applications for Health product not manufactured in Kenya	2,000	5000
9.	Application for Fast tracking evaluation of application for health product manufactured in Kenya	2000	3000
10.	Application for donated health products	-	Exempt

28.	Application for registration of health products not manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	500	500

42.	Application for certificate of parallel importation	-	Kshs.30,000
43.	Application for renewal of certificate of parallel importation	-	Kshs.30,000
44.	Application fee for a new parallel import license	-	1000
45.	Appeal of rejected application for parallel import license	-	300
46.	Application for renewal of parallel import license	-	500

10.	Application fee for review of rescheduling of foreign manufactured products	-	1,500
11.	Application fee for review of rescheduling of locally manufactured products	-	1,000
12.	Application fee for advertising on Billboards and Television	35	100
13.	Application fee for Advertising/promotion on Immobile branded items	35	100
14.	Penalties for non-approved advertisement and promotions	-	1,000

	Purpose of Fees	**Current Fee (USD)**	**Proposed Fee (USD)**
15.	Advertisement per product per advert per media	50	100

Good Manufacturing Practice Audit per site -

a. Foreign Manufacturing Site – USD 4000
b. Local Manufacturing site – USD 1,000

	Purpose of Fees	Proposed Fee (USD) Within Kenya	Proposed Fee (USD) Within Africa	Proposed Fee (USD) Outside Africa (Asia/Europe/America/New Zealand/Australia)
2.2.3.1 Good Manufacturing Practices Division				
1.	Inspection of General products manufacturing site with all processes at one site for a maximum of 5 product lines for finished pharmaceutical products including biologicals.	2,000	6,000	8,000
2.	Inspection of Penicillin products manufacturing site with all processes at one site for a maximum of 5 product lines for finished pharmaceutical products	2,000	6,000	8,000
3.	Inspection of Cephalosporin products manufacturing site with all processes at one site for a maximum of 5 product lines for finished pharmaceutical products.	2,000	6,000	8,000
4.	Inspection of Hormone products manufacturing site with all processes at one site for a maximum of 5 product lines for finished pharmaceutical products	2,000	6,000	8,000
5.	Inspection of Cytotoxic products manufacturing site with all processes at one site for a maximum of 5 product lines for	2,000	6,000	8,000

	Purpose of Fees	Proposed Fee (USD) Within Kenya	Proposed Fee (USD) Within Africa	Proposed Fee (USD) Outside Africa (Asia/Europe/America/New Zealand/Australia)
	finished pharmaceutical products			
6.	Inspection of Blood products manufacturing site with all processes at one site for a maximum of 5 product lines for finished pharmaceutical products	2,000	6,000	8,000
7.	Inspection of any additional production line	500	1,000 per line	2,000 per line
8.	Inspection of sites for final Primary packaging, quality control and final release	1,000	2,000	4,000
9.	Inspection of sites for final Secondary packaging, quality control and final release	1,000	2,000	4,000
10.	GMP off-site inspection (Document Review Audits)	-	4,000	8,000
11.	Inspection of warehousing facility	2,000	2,000	4,000
12.	Site Variation	2,000	6,000	8,000
13.	Special Inspection/Concise Inspection	2,000	6,000	8,000
14.	Fast Track Audits	100% of nominal fee	200% of nominal fee	200% of nominal fee
15.	CRO (Contract Clinical Research Organization)	2,000	6,000	8,000

Medicines Application and Evaluation Process

Registration of locally-produced and imported medicines is overseen by the *Pharmacy and Poisons Board* (PPB) which is the Drug Regulatory Authority of the Republic of Kenya. The board is in charge of regulating the Practice of Pharmacy and the Manufacture and Trade of drugs and poisons in Kenya.

Once Good Manufacturing Practice Guidelines (GMP) inspection has been done, the next step is the application and evaluation process.

A complete application consists of documentation in hard copies and electronic copy (a summary of the dossier contents), samples and fees. The application may be delivered physically along Lenana Road, Nairobi, Kenya. An application may only be received by PPB upon payment of the application fees.

Evaluation can be done in two main ways:

- First In-First Out
- Fast Track

The First In-First Out (FIFO) is the main evaluation process. Products may go through a faster evaluation process if they meet the conditions below:

- **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.

Timelines

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.