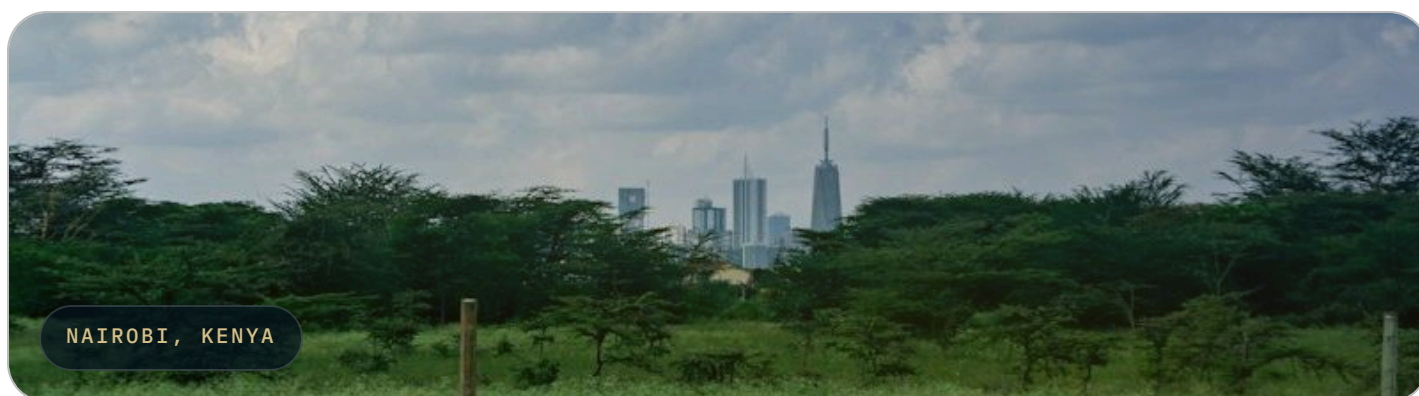


Navigating Kenya's pharmaceutical regulatory landscape

Kenya is the largest pharmaceutical hub in East Africa, importing most of its medicines and serving as a gateway into the wider East African Community. Foreign entrants must align with Pharmacy and Poisons Board requirements to ensure smooth market access and long-term compliance.



1. Regulatory authorities & framework

The **Pharmacy and Poisons Board (PPB)** regulates medicines, medical devices, cosmetics, supplements, and herbal products. Its mandate includes product registration, GMP inspections, import and export permits, pharmacovigilance, and post-market surveillance.

Foreign manufacturers must appoint a **Local Technical Representative (LTR)** in Kenya. The LTR acts as the official point of contact with PPB and is responsible for regulatory submissions, communication, and ensuring compliance obligations are met. Importers and distributors handle logistics and distribution but rely on the LTR for the regulatory interface.

2. Product registration pathways & fees

Foreign entrants must register each product before importation and sale. The pathway and fee depend on how the product is classified.

Category	Pathway	Regulatory fee
Medicines	CTD dossier, supported by GMP evidence and a Certificate of Pharmaceutical Product (CPP)	USD 1,000
Supplements / nutraceuticals	PPB nutraceutical pathway, where no medicinal claims are made	USD 500
Cosmetics	Classified separately, depending on whether therapeutic claims are made	USD 1,000
Herbals	PPB herbal category, requiring evidence of safety, quality, and traditional use	USD 1,000
Medical devices / IVDs	Classified by risk category A–D, submitted under the Common Submission Dossier Template (CSDT)	Class-dependent — higher classes attract higher fees

Applications are submitted through **PRIMS**, PPB’s online Pharmaceutical Registration and Information Management System.



Confirm product classification early. Misclassification is one of the most common causes of dossier rejection, and it is discovered after you have already paid and queued.

3. Marketing authorization

Marketing Authorizations (MAs) are valid for **five years**. Once a product is registered, it must be retained annually to remain active in the PPB database.

Retention requires the MAH or LTR to confirm product details, submit any required updates, and pay the annual retention fee of **USD 300**. Failure to retain a product means you will not be able to import, distribute, or sell it until retention is completed.

Renewal applications must be submitted before expiry to maintain continuous authorization and prevent deregistration. Renewal is therefore a mandatory compliance obligation, ensuring that all registered products remain valid and traceable in Kenya’s regulatory system.



Retention and renewal are different obligations with different consequences. [Read the full comparison](#) before building your compliance calendar.

4. GMP inspections

PPB requires compliance with GMP for manufacturing facilities. Foreign sites must undergo a GMP inspection or provide evidence of compliance. The regulatory fee is **USD 4,000**.

Importers must also comply with **GSDP** for distribution, storage, and cold-chain management. Our [GMP/GSDP Verification Guide](#) sets out what is assessed on both sides.

5. The importer–MAH–LTR relationship

MAH

Marketing Authorization Holder. Holds responsibility for product authorization and compliance.

LTR

Local Technical Representative. Acts as the regulatory liaison with PPB, ensuring submissions, renewals, and retention are handled correctly.

Importer / Distributor

Manages logistics, warehousing, and distribution.

Strong collaboration among all three parties ensures smooth market entry and sustained compliance. Where responsibilities are assumed rather than assigned, obligations fall through the gaps — usually at retention time.

6. Practical tips for market entry

- ◆ Confirm product classification early to avoid dossier rejection.
- ◆ Registration timelines depend on product category and are highlighted in PPB's official Service Charter.
- ◆ Appoint a reliable LTR to manage regulatory communication.

- ◆ Build strong partnerships with Kenyan importers for logistics and compliance.
- ◆ Prepare for deficiency queries during PPB review.
- ◆ Monitor regulatory intelligence to anticipate competitor activity and PPB updates.

7. Conclusion & next steps

Foreign entrants succeed in Kenya by mastering PPB registration, ensuring annual retention, embedding QA practices, and appointing a strong LTR to manage regulatory communication. With structured preparation and local partnerships, Kenya offers a transparent pathway into East Africa's largest pharmaceutical market.

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