

Renewal vs retention: understanding Kenya's regulatory lifecycle

Two obligations cause more uncertainty than any others. Both are mandatory under the Pharmacy and Poisons Board, but they serve different purposes — and the consequences of missing them are not equivalent.



Misunderstanding these requirements is not limited to Marketing Authorization Holders; importers, distributors, and LTRs also struggle with clarity. This article explains the difference and consequences of each, based on PPB's official guidelines.

Annual retention

Definition: Retention is the yearly requirement to keep a registered product active in the PPB database.

Process: The MAH or Local Technical Representative confirms product details, submits updates if required, and pays the annual retention fee.

Consequence of non-compliance: Failure to retain means the product cannot be imported, distributed, or sold until retention is completed.

Purpose: Ensures PPB maintains an up-to-date record of all products on the Kenyan market.



Key point: Retention is about **continuity** — keeping the product “live” in the system year by year.

Renewal

Definition: Renewal is the five-year requirement to extend the validity of a Marketing Authorization (MA).

Process: Renewal applications must be submitted at least three months before expiry.

Consequence of non-compliance: Failure to renew leads to deregistration or removal from the PPB register, meaning the product loses its legal authorization and must undergo a fresh registration process.

Purpose: Ensures long-term compliance and that products continue to meet evolving regulatory standards.



Key point: Renewal is about **validity** — extending the legal authorization beyond its initial five-year term.

Retention vs renewal: at a glance

Requirement	Frequency	Responsibility	Consequence if missed
Annual retention	Every year	MAH / LTR	Product cannot be imported or sold until retention is completed
Renewal	Every 5 years	MAH / LTR	Deregistration or removal from PPB register; product loses authorization

Practical guidance for MAHs

- ◆ Build retention into your regulatory calendar as a yearly compliance anchor.
- ◆ Track renewal dates well in advance — start preparation at least 12 months before expiry.

- ◆ Use your LTR to manage communication with PPB and ensure submissions are timely.
- ◆ Consult PPB's Service Charter for timelines specific to your product category.

Conclusion

Retention and renewal are complementary obligations: retention keeps your product active year by year, while renewal extends its legal authorization every five years. Missing retention halts importation until resolved, but missing renewal results in deregistration — a far more disruptive outcome. Together, they form the backbone of Kenya's regulatory lifecycle, and mastering both ensures uninterrupted market access.

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