REPUBLIC OF KENYA

MINISTRY OF MEDICAL SERVICES

# PHARMACY AND POISONS BOARD

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**PPB/DRG/VOL.I/035** **27TH FEBRUARY, 2012**

## ALL CLIENTS AND LOCAL TECHNICAL REPRESENTATIVES

## RE: RETENTION OF REGISTERED MEDICINES

The Pharmacy and Poisons Board would like to inform all clients and local technical representatives the requirements for retention of medicines in the market pursuant to the Pharmacy and Poisons Act (Cap 244), the Pharmacy and Poisons (Registration of Drugs) Rules.

Kindly be informed that all Marketing Authorization Holders are required to pay annual retention fee for any medicine being marketed in Kenya. The retention fee will cover a period of one calendar year with the annual retention being effective from the date of issue to the **31st December** of the retention year in which it is issued. The retention fees charged will be as follows:

| | |
|---|---|
| Imported products | USD 300 per product per year |
| Locally manufactured products | USD 150 per product per year |

The requirements for retention of a registered product are the following;

1. Proof of registration of the product either registration certificate/ re-registration letter
2. One hard and an electronic copy of the list of products to be retained using the format given in the table below. The electronic copy should be in Microsoft Office Excel document filled in a single line for each product on a CD-Rom or memory stick.
3. An electronic scanned copy of the primary (immediate) and secondary (outer) packaging of the product being retained (Please clearly label scan with the application number for each product).
4. Proof of payment of the requisite retention fee.
5. Proof of payment for GMP inspection or current valid PPB GMP certificate of the manufacturing site(s).

| NAME OF THE PRODUCT | ACTIVE INGREDIENTS PER DOSAGE UNIT | APPLICATION NO. /CERTIFICATE NO. | PACK SIZE | VISUAL DESCRIPTION OF THE PRODUCT | NAME OF THE MARKETING AUTHORISATION HOLDER | EXACT ADDRESS OF THE MANUFACTURING SITE(S) |
|---|---|---|---|---|---|---|
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**Deadline to comply: 31st March, 2012**

This Circular supersedes previous circulars, notices, letters, etc on retention, including most recently Circular Ref. No. PPB/DRG/VOL.I/032 of 6th January, 2012.

Yours faithfully,

**DR. B. K. NJUE**
**FOR: REGISTRAR**