



Kigali on ..18.. / ..01.. / ..2023

Ref. N°: FDISM/PVSM/251/FDA/2023

RMS branches (All)  
Central medical stores (All)  
Pharmaceutical Wholesalers (All)  
Importers (All)  
Retail Pharmacies (All)  
Public and private Health facilities (All)  
General Public

**Title: Recall for batches of Hyoscine Butylbromide Tablets BP 10mg and Aminophylline Tablets USP 100mg due to quality issues**

**Type of the recall: Statutory**

**Class of the recall: Class II**

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority especially in its article 8 paragraph 2 and 13. Reference is also made to regulation No.: CBD/TRG/019 Rev\_1 governing the Recall, Treatment and Disposal of Unfit regulated products in its article 6

Further reference is made to the investigations conducted by Rwanda FDA including laboratory quality control analysis. Laboratory tests results revealed that Hyoscine Butylbromide Tablets BP 10mg with batch number 22HB01 and Aminophylline Tablets USP 100mg with batch number 22AP01 do not comply with quality standards.

It is with the above background that the Authority recalls from the market these medicines with below description:

DESCRIPTION	BATCH	Mfg.date	Exp.date	Manufacturer	Quality issue
Hyoscine Butylbromide Tablets BP 10mg	22HB01	04/2022	03/2025	MORKASH PHARMACEUTICALS PVT LTD/India	Presence of cracks on the surface of tablet
Aminophylline Tablets USP 100mg	22AP01	04/2022	03/2025	MORKASH PHARMACEUTICALS PVT LTD/India	Presence of mottling on the surface of tablet

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**Action to be taken**

- Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesalers, all RMS branches, retailers, Public and Private Health Facilities to stop the distribution of the above recalled medicines and return them to the suppliers for suitable management.
- The importers and suppliers of recalled medicines are requested to report to Rwanda FDA within 10 days from the date of the recall based on recall classification. The report should include the quantities imported, quantities distributed, quantities returned and final stock on hand.

**Note:** For more information or to report any suspected poor quality products; please call 0789193529 or 9707 or send email to: [pv\\_sm@rwandafda.gov.rw](mailto:pv_sm@rwandafda.gov.rw)

Sincerely,

*E. Bienvenu*  
18/1/2023

**Dr. Emile BIENVENU**  
**Director General**

