



RWANDA FDA
Rwanda Food and Drugs Authority
P.O. Box 84 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

Kigali, 09/12/2019
Ref N° 1722 /RwandaFDA/2019

District Pharmacies (All)
Referral Hospitals (All)
Provincial and district hospitals (All)
Private hospitals and Clinics (All)
Central medical stores (All)
Pharmaceutical Wholesalers (All)
Importers (All)
Retail Pharmacies (All)
Health centres (All)

Title: Recall for Urinalysis Reagents strips (3 Parameters) and Urinalysis Reagent Strips (10 Parameters)

The role of the Rwanda FDA is to protect the public health by disseminating information on quality and safety of products regulated under the LAW N° 003/2018 of 09/02/2018 to health professionals and to other concerned organs.

Referring to the spontaneous reports from Health facilities, district pharmacies and investigations conducted by Rwanda FDA, it was found that manufacturing date, manufacturer's name and manufacturer's address were not mentioned on both Inner and outer packages. These are key information on labelling requirements to ascertain the origin of the product. The expiry date and Batch/Lot number are displayed on the sticker which is not allowed by Rwanda FDA since the sticker can be replaced and this contravene with labelling requirements. Consequently, we regret to notify that the following batches were found with the above mentioned issues.

DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Manufacturer
Urinalysis Reagent Strips (3 Parameters) (Dry Chemical Method)	UR35111906A	Not mentioned	06-2021	Not Mentioned
Urinalysis Reagent Strips (10 Parameters) (Dry Chemical Method)	UR105111906A	Not mentioned	06-2021	Not mentioned

Action to be taken

Rwanda Food and Drugs Authority instructs all importers, central medical stores, Pharmacy wholesalers, District Pharmacies, retail pharmacies, Public and Private Health Facilities in possession

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of above incriminated products to stop their distribution and use. Therefore, they are requested to return them to their suppliers for proper disposal.

Rwanda FDA reminds all supply chain managers both in public and private institutions to check basic information on labels and organoleptic parameters to ensure preliminary quality parameters of medical products before their reception.

Sincerely,



Dr. Charles KARANGWA
Ag. Director General



CC:

- **Hon. Minister of Health**
- **Hon. Minister of state in Charge of Primary Health care**

