



**RWANDA FDA**  
Rwanda Food and Drugs Authority

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Kigali, 04<sup>th</sup> April, 2020

Ref N° : DIS/CRC/007/RwandaFDA/2020

**District Pharmacies (All)**

**District Hospitals (All)**

**Referral Hospitals (All)**

**Central medical stores (All)**

**Pharmaceutical Wholesalers (All)**

**Importers (All)**

**Retail Pharmacies (All)**

**Health centers (All)**

**Title: Circular on Recall of Ketoconazole (Kenazole) Cream USP 2% W/W batch 1907205**

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; Reference is also made to the spontaneous reports from retail Pharmacies, wholesale pharmacies, importers and investigation conducted by Rwanda FDA; The following batch was found with compromised seal integrity of packs and leakage of the cream which is an indication of poor quality products.

Description	Batch/Lot	Mfg.Date	Exp.date	Importer	Manufacturer
Ketoconazole(Kenazole) Cream USP 2% w/w	1907205	07/2019	06/2022	ABACUS PHARMA(A)Ltd	DAWA Ltd/KENYA

**Action to be Taken**

- Rwanda Food and Drugs Authority instructs all importers, central medical stores, wholesalers, District Pharmacies, retailers, Public and Private Health Facilities, to stop the distribution and dispensing of the above incriminated products and return them to the suppliers for suitable management.

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- The importers and suppliers of the incriminated products are requested to report to Rwanda FDA within 10 working days the quantities imported, quantities distributed, quantities returned and final stock on hand.

Sincerely,

**Dr. Charles KARANGWA**  
**Ag. Director General**

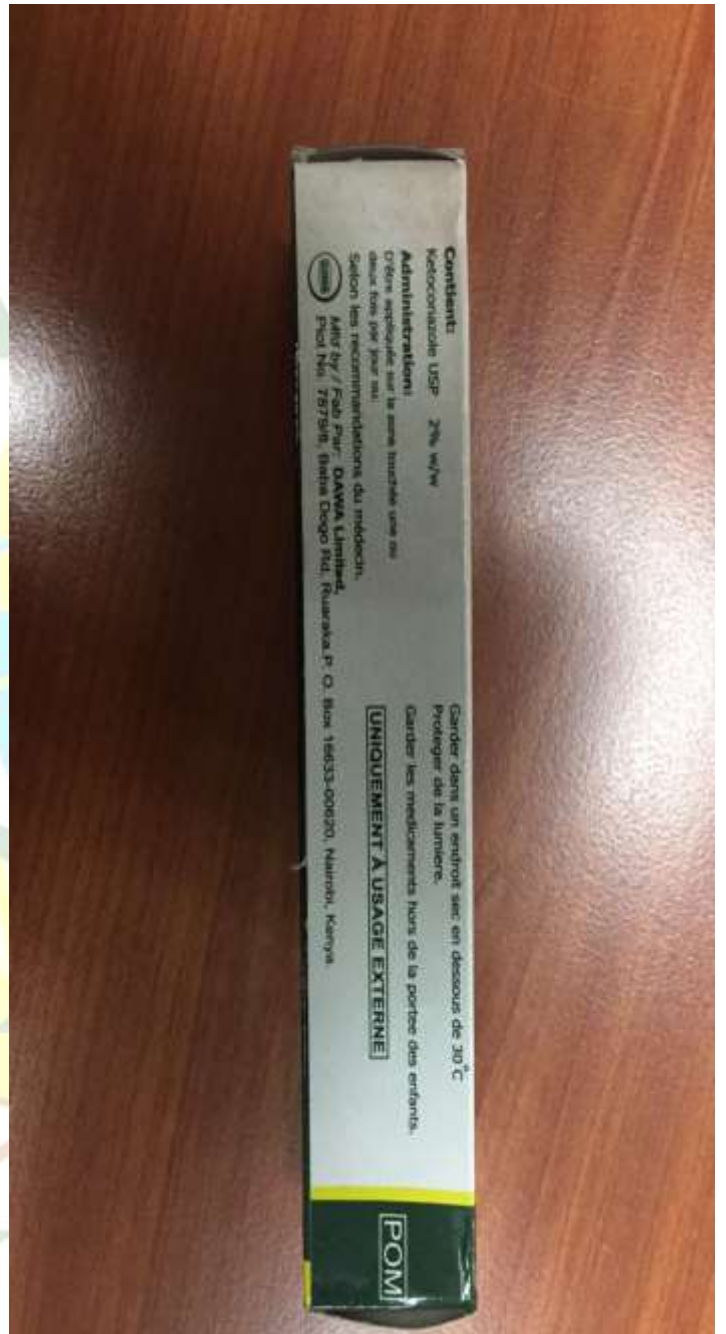


CC:

- **Hon. Minister of Health**
- **Hon. Minister of State in Charge of Primary Health Care**

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**PHOTOS OF THE RECALLED PRODUCTS**



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