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

Kigali, 11 OCT 2019
Ref N° 1243 /RwandaFDA/2019

District Pharmacies (All)
District Hospitals (All)
Referral Hospitals (All)
Central medical stores (All)
Pharmaceutical Wholesalers (All)
Importers (All)
Retail Pharmacies (All)
Private clinics/ (All)

Re:Recall of Ranitidine products from Rwandan Market

The role of Rwanda FDA is to protect the public health by disseminating information on quality,efficacy and safety of products regulated under the Law No 003/2018 of 09/02/2018 to health professionals and other concerned persons. Rwanda FDA also has the mandate for follow up and analyzes information on the use of pharmaceutical products that are subject to global drugs safety monitoring.

Rwanda FDA has received information from US FDA that ranitidine medicine including the brand name Zantac that contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels; NDMAis classified as a probable human carcinogen based on results from laboratory tests.

Ranitidine is a histamine-2 blocaker, indicated for treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post operative peptic ulcer and other conditions

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 incriminated products and return to suppliers while further investigation is being conducted.
- All importers, central medical stores are requested to provide a report to Rwanda FDA within 10 working days on imported Ranitidine from January 2018 up to now

Information to Healthcare professionals and Patients

- Health care professionals and Patients should report any adverse drug eventssuspected to be associated with Ranitidine to Rwanda FDA by completing the reporting form available at Rwanda FDA website **www.rwandafda.gov.rw** and send to the email: **pv_sm@rwandafda.gov.rw** or **info@rwandafda.gov.rw**

- Patients taking prescription ranitidine should talk to their healthcare providers about other treatment options.

Sincerely,

Dr KARANGWA Charles
Ag. Director General of Rwanda FDA

CC:

- **Hon. Minister of Health**
- **Hon. Minister of state in Charge of Primary Health care**
- **Permanent Secretary/MOH**
- **D.G Rwanda Biomedical Center**