Kigali, 19-03-2020
Ref N° 494 /RwandaFDA/2020

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

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

Title: Recall for batches of Amoxicillin 250 mg capsules (AMOXIMED)

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA especially in its article 8 paragraph 2; reference is also made to the calls for quarantine with Ref No:1120/Rwanda FDA/2019, Ref No: 1592/RwandaFDA/2019 and call for quarantine with Ref No: 1447/Rwanda FDA/2019.

Reference is also made the spontaneous reports from different Health facilities, retail Pharmacies, and wholesale pharmacies where the products were found with the issue of self-opening of capsules and leakage of powder when removed from the Jar for dispensing; further reference is made to the investigation conducted by Rwanda FDA. We regret to notify that the following quarantined batches of amoxicillin 250 mg capsules failed to quality standards:

DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Manufacturer
Amoxycillin BP 250 mg capsules (AMOXIMED)	767190217	02/2019	02/2022	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG CO.LTD) / HEBEI /CHINA
Amoxycillin BP 250 mg capsules (AMOXIMED)	767190207	02/2019	02/2022	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG CO.LTD) / HEBEI /CHINA

Amoxycillin BP 250 mg capsules (AMOXIMED)	767190208	02/2019	02/2022	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG CO.LTD) / HEBEI /CHINA
Amoxycillin BP 250 mg capsules (AMOXIMED)	767190216	02/2019	02/2022	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG CO.LTD) / HEBEI /CHINA
Amoxycillin BP 250 mg capsules (AMOXIMED)	767190205	02/2019	02/2022	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG CO.LTD) / HEBEI /CHINA

Action to be taken

Rwanda Food and Drug Authority instructs all central medical stores, wholesale pharmacies, District Pharmacies, retailers, Public and Private Health Facilities in possession of the quarantined products to return them to their suppliers or importers for suitable disposal.

The importers and suppliers of the incriminated batches are requested to report to Rwanda FDA within 10 working days the final report of quantities imported per product, quantities distributed, quantities returned and final stock on hand and also reminding to apply for destruction of the incriminated products.

Sincerely,

RWANDA FOOD AND DRUGS AUTHORITY · RWANDA FDA

Dr. Charles KARANGWA
Ag. Director General

Cc:

- **Hon. Minister of Health**