



RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 19-03-2020
Ref N° 495 /RwandaFDA/2020

District Pharmacies (All)
District Hospitals (All)
Referral Hospitals (All)
Central medical stores (All)
Wholesale Pharmacies (All)
Importers (All)
Retail Pharmacies (All)
Health centers (All)

Title: Recall for batches of Cloxacillin 250mg capsules

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 call for quarantine No:1120/Rwanda FDA/2019 dated 19th September 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 Cloxacillin 250 mg capsules failed to quality standards:

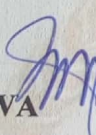
DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Manufacturer
Cloxacillin BP 250 mg capsules	183132401	December 2018	December 2021	REYOUNG PHARMACEUTICAL.CO.LTD /CHINA
Cloxacillin BP 250 mg capsules	183132400	December 2018	December 2021	REYOUNG PHARMACEUTICAL.CO.LTD /CHINA
Cloxacillin BP 250 mg capsules	183132399	December 2018	December 2021	REYOUNG PHARMACEUTICAL.CO.LTD /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,


Dr. Charles KARANGWA
Ag. Director General



CC:

- **Hon. Minister of Health**

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