



**RWANDA FDA**

Rwanda Food and Drugs Authority

P.O. Box 84 Kigali

info@rwandafda.gov.rw

[www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)

Kigali,

Ref N°

19 SEP 2019

1120/Rwanda FDA/2019

District Pharmacy (All)  
District Hospital (All)  
Referral Hospital (All)  
Pharmaceutical Wholesalers (All)  
Importers (All)  
Retail Pharmacies (All)  
Private clinics/ (All)

**Title: Call for Quarantine for some batches of Cloxacillin and Amoxycillin (AMOXIMED)**

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. The Authority takes into considerations every serious information from Partners to ensure safe and quality products.

Referring to the spontaneous reports from different Health facilities and district Pharmacies, the product was found to have issue of self-opening of capsules and leakage of powder when removed from the Jar or Box for dispensing. We regret to notify that the following batches were found with that quality issue.

DESCRIPTION	BATCH	Mfg. Date	Exp. Date	Distributer	Manufacturer
Cloxacillin BP 250 mg capsules	183132401	December 2018	December 2021	SOPHAR LTD  KIGALI SPECIAL ECONOMIC ZONE C8,  P.o.BOX 2320 KIGALI and RBC/ MPPD	REYOUNG PHARMACEUTICAL .CO.LTD/CHINA

2

Cloxacillin BP 250 mg capsules	183132400	December 2018	December 2021	SOPHAR LTD KIGALI SPECIAL ECONOMIC ZONE C8,  P.o.BOX 2320 KIGALI and RBC/MPPD	REYOUNG PHARMACEUTICAL .CO.LTD/CHINA
Cloxacillin BP 250 mg capsules	183132399	December 2018	December 2021	SOPHAR LTD KIGALI SPECIAL ECONOMIC ZONE C8,  P.o.BOX 2320 KIGALI and RBC/MPPD	REYOUNG PHARMACEUTICAL .CO.LTD/CHINA
Amoxicillin BP 250 mg capsules  (AMOXIMED)	767190217	02/2019	02/2022	BUFMAR	CSPC ZHONGNUC PHARMACEUTICAL (SHIJIAZHUANG CO.LTD ) / HEBE /CHINA

#### Action to be taken

Rwanda Food and Drug Authority instructs all importers, central medical stores, wholesalers, District Pharmacies, retailers, Public and Private Health Facilities to quarantine the above incriminated batches of cloxacillin and amoxicillin while Rwanda FDA is conducting deep investigation on the reported issue including Laboratory quality control.

Sincerely,



**Dr. Charles KARANGWA**  
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