Rwanda Food and Drugs Authority
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QMS Nº: FDISM/PVSM/FMT/034
Revision No: 0
Effective Date: 31/03/2023

RECALL NOTIFICATION

Kigali on 18 / 09 / 2023
Ref. No.: FDISM/PVSM/ 3928 /FDA/2023

Central medical stores (All)
RMS branches (All)
Pharmaceutical Wholesalers (All)
Importers (All)
Retail Pharmacies (All)
Public and private Health facilities (All)
Health professionals (All)

Title: Recall of batches (27296, 27297, 27298) of AmoxiClav-Denk 1000/125 mg Powder for oral suspension manufactured by PenCef Pharma GmbH/ Berlin

Type of the recall: Statutory

Class of the recall: Class II

Recall level: Retail / Facility level

Reference is made to the **Law Nº 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority (Rwanda FDA) especially in its article 8 paragraph 2 and 13. Reference is also made to regulation No.: CBD/TRG/019 Rev_1 governing the Recall, Treatment and Disposal of Unfit regulated products in its article 6;

Reference is also made to the recall of batches of AmoxiClav-Denk 1000/125 mg powder for oral solution issued by the medical regulatory body in Germany (BfArM; The Federal Institute for Drugs and Medical Devices) and disseminated through the WHO rapid alert system. Further reference is made to the investigations performed by Rwanda FDA which confirmed that the incriminated batches were imported into Rwanda;

It is with this background that Rwanda FDA recalls from the Rwandan market the following batches of AmoxiClav-Denk 1000/125 mg Powder for oral suspension:

Description	Batch	Manufacturing date	Expiry date	Manufacturer
AmoxiClav-Denk 1000/125 mg Powder for oral suspension	27296	06/2022	06/2025	PenCef Pharma GmbH –Berlin Breitenbachstrasse 13-14
AmoxiClav-Denk 1000/125 mg Powder for oral suspension	27297	06/2022	06/2025	PenCef Pharma GmbH –Berlin Breitenbachstrasse 13-14
AmoxiClav-Denk 1000/125 mg Powder for oral suspension	27298	06/2022	06/2025	PenCef Pharma GmbH –Berlin Breitenbachstrasse 13-14

Details of the defect / reason for the recall

Ongoing stability study and associated investigation indicated "change in appearance of individual sachets of AmoxiClav-Denk 1000/125 mg powder resulting in deviation of clavulanic acid content

Action to be taken

- Rwanda FDA instructs all importers, central medical stores, wholesalers, RMS branches, retailers, public and private health facilities to stop the distribution of above-mentioned batches of AmoxiClav-Denk 1000/125 mg Powder for oral suspension manufactured by PenCef Pharma GmbH –Berlin and return the products to their suppliers for proper management.
- The importers and suppliers of above-mentioned batches of AmoxiClav-Denk 1000/125 mg Powder for oral suspension manufactured by PenCef Pharma GmbH –Berlin are requested to report to Rwanda FDA within 10 days from the date of publication of this recall, the quantities imported, quantities distributed, quantities returned and final stock on hands.

Note: **For more information or to report any suspected poor-quality products please call toll free number 9707 or 0789193529 or send email to:** pv_sm@rwandafda.gov.rw.

Sincerely,

Digitally signed by Rwanda FDA (Director General)
Date: 2023.09.18 22:05:15 +02'00'

Dr. Emile BIENVENU
Director General

PICTURE OF RECALLED PRODUCTS: