



Kigali on 27 / 01 / 2023
Ref. N°: FDISM/PVSM/419/FDA/2023

RMS Ltd (All Branches)
District Hospitals (All)
Referral Hospitals (All)
Central medical stores (All)
Pharmaceutical Wholesalers (All)
Importers (All)
Retail Pharmacies (All)
Public and private Health facilities (All)
Health professionals (All)
General public

Title: Recall for all batches and stop importation of Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) manufactured by Sparsh Bio-Tech Pvt Ltd, India

Reference is made to the **Law N° 003/2018 of 09/02/2018** establishing Rwanda Food and Drugs Authority especially in its article 8 paragraph 2 and 13.

Reference is made to the recall No. DIS/1987/FDA/2022 issued by Rwanda FDA on 29th April 2022 for 8 batches of Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) manufactured by Sparsh Bio-Tech Pvt Ltd, India;

Reference is also made to the deep investigation and laboratory quality control analysis performed by Rwanda FDA on additional reported batches of Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) which confirmed that the medicines do not meet quality standards.

It is with this background that Rwanda FDA recalls from the Rwandan market all batches of Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) manufactured by Sparsh Bio-Tech Pvt Ltd, India and stops importation of the mentioned medicines.

Action to be taken

- Rwanda Food and Drugs Authority instructs all importers, central medical stores, wholesalers, RMS Ltd branches, retailers, Public and Private Health Facilities to return the recalled Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) manufactured by Sparsh Bio-Tech Pvt Ltd, India to their suppliers for proper management.

Govt

- The importers and suppliers of Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) manufactured by Sparsh Bio-Tech Pvt Ltd, India are requested to report to Rwanda FDA within 15 working days the quantities imported, quantities distributed, quantities returned and final stock on hand.
- Rwanda FDA will communicate officially when importation of Spamox oral suspension (amoxicillin 125 mg/ 5ml and amoxicillin 250mg/ 5ml) manufactured by Sparsh Bio-Tech Pvt. Ltd, India will be permitted. This will be after the manufacturer conducts root cause analysis, implements the Corrective and Preventive Actions, and the registration process completed.

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

You will find pictures for these medicines with quality issue as attachment.

Sincerely,



Dr. Emile BIENVENU
Director General

Photo of recalled SPAMOX (Amoxicillin 125mg/5ml and Amoxicillin 250/5ml)

