



Rwanda Food and Drugs Authority

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QMS N°: FDISM/PVSM/FMT/034

Revision No: 0

Effective Date: 31/03/2023

RECALL NOTIFICATION

Kigali on 11 / 03 /2024

Ref. No.: FDISM/PVSM/1250/FDA/2024

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

Title: Recall of Batch No. I13612 of Phytomenadione Injection BP 10 mg -1 ml Ampoule (10x 1 ml) manufactured by Merit Organics Ltd, India

Type of the recall: Voluntary

Class of the recall: Class II

Recall Level: Facility level

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 also made to regulation No.: CBD/TRG/019 Rev_1 governing the Recall, Treatment, and Disposal of Unfit regulated products in its article 6 and 13;

Reference is also made to the letter dated March 4th, 2024 received from Merit Organics Ltd / India, the manufacturer & supplier of pharmaceutical product, recalling Phytomenadione Injection BP 10 mg -1 ml Ampoule with Batch No. I13612 manufactured in Jan 2023 and expiring in Dec 2025 due to the variation in pH.

It is with this background that Rwanda FDA recalls from the market the following products:

| Description | Batch | Mfg. date | exp. date | Manufacturer | Quality issue |
|------------------------------------------------------------|--------|-----------|-----------|----------------------------------------------------------------------------------------------------------------|-----------------|
| Phytomenadione Injection BP 10 mg -1 ml Ampoule (10x 1 ml) | I13612 | Jan 2023 | Dec 2025 | Merit Organics Ltd, Address: Plot No 2104/2/A , G.I.D.C. City Sarigam , Dist: Valsad , Gujarat State ,India | Variation in pH |

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Action to be taken

- Rwanda FDA instructs all importers, central medical stores, wholesalers, RMS branches, retailers, and public and private health facilities to stop the distribution and dispensing of batch No. **I13612** of Phytomenadione Injection BP 10 mg -1 ml Ampoule manufactured by Merit Organics Ltd
- The importers and suppliers of batch No. **I13612** of Phytomenadione Injection BP 10 mg -1 ml Ampoule manufactured by Merit Organics Ltd are requested to report to Rwanda FDA within 10 days from the date of publication of this recall, the report should include quantities imported, quantities distributed, quantities returned, and final stock on hand.

Note: For more information or to report any suspected poor-quality products please call 0788771663 or 9707 or send email to: pv_sm@rwandafda.gov.rw

Sincerely,



Digitally signed by Rwanda
FDA (Director General)
Date: 2024.03.09 20:35:55
+02'00'

Prof. Emile BIENVENU
Director General

PICTURE OF RECALLED PRODUCT

