All correspondence should be addressed to the Director General

In reply, please quote LET_LSE_PMS_0011/07/24

# ZAMBIA MEDICINES REGULATORY AUTHORITY

## PUBLIC NOTICE

Date: 30th July, 2024

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, General Public

### MEDICAL PRODUCT ALERT:

### RECALL OF FUROSEMIDE TABLETS BP 40MG BATCH NO. TFR222001 MANUFACTURED BY SKYLARK PHARMACEUTICALS PVT. LIMITED, INDIA

FOR IMMEDIATE RELEASE – The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to ensure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

On this background, the Authority wishes to notify all healthcare professionals, health facilities, pharmaceutical outlets and members of the public that it has instructed Esvee Medicare Limited to urgently **RECALL** the above-stated product due to failure to meet its Disintegration Specifications. This implies that the product takes longer to break down into smaller particles required for drug absorption.

Product details:

| S/N | Name of Product | Manufacturer | Batch Number | Mfg. Date | Expiry Date |
|---|---|---|---|---|---|
| 1. | Furosemide Tablets BP 40mg | Skylark Pharmaceuticals Ltd., India | TFR222001 | 08/2022 | 07/2025 |

### RISK

Furosemide is used alone or together with other medicines to treat fluid retention in the body (oedema) and high blood pressure (hypertension). Using a medicine that takes longer than the standard time to break down into smaller particles may lead to slow

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P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 432 350 /432 351

**Report Adverse Reactions to:**
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail: ppvu@zamra.co.zm

absorption of the required amount of the medicine and may affect the desired treatment outcome.

If you are in possession of this batch (**TFR222001**), please return it to your healthcare provider who should replace it with another batch or brand. Pharmaceutical outlets and health facilities in possession of the affected batch should quarantine the product and return it to their supplier(s), for collection and disposal by the importer.
If you suffer any adverse drug reaction having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr)
**DIRECTOR-GENERAL**