

All correspondence should be addressed to the Director General



LET_LSE_PMS_0116/24 please quote

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 25th November, 2024

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

MEDICAL PRODUCT ALERT: RECALL OF METHYLATED SPIRIT

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 assure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

The Authority wishes to notify all healthcare professionals, health facilities, pharmaceutical outlets and members of the public that as part of its post-market surveillance activities, it has initiated **RECALL** of three (3) allied substances stated below.

Reasons for the recall are that the MIMS Methylated Spirit 2.5 Litres contains lower amounts of ethanol than the recommended quantity. The Beautiful Methylated Spirit 2.5 Litres is being recalled for containing high levels of methanol, a toxic substance.

Product details:

SN	Product Name	Batch No.	Manufacturer	Expiry Date	Reason for Recall	Recall Class
1	Beautiful Methylated Spirit 2.5 Litres	2405	Not stated by (packed by Zambian Commodity Solutions Limited)	06/2028	High methanol content	I
2	MIMS Methylated Spirit 2.5 Litres	A144-24	International Drug Company Limited, Zambia	12/2027	Low ethanol content	II
3	MIMS Methylated Spirit 2.5 Litres	A132-24	International Drug Company Limited, Zambia	12/2027	Low ethanol content	II

RISK

All the three (3) products are disinfectants. Using a disinfectant with low content of API may lead to failure to disinfect the intended areas/surfaces. On the other hand, use of a

product containing high levels of methanol may lead to **methanol poisoning** through absorption through the skin during use. Symptoms of methanol toxicity includes vomiting, abdominal pain, blindness, brain damage and ultimately death.

Pharmaceutical outlets, health facilities and other retail outlets and individuals in possession of the affected products should quarantine the products and return them to their supplier(s), for collection and disposal by the respective importers.

Further, the Authority wishes to advise companies manufacturing disinfectants to register their products and ensure conformity to Good Manufacturing Practices to guarantee that the products are safe, effective and of good quality for public health protection.

Report incidents of Adverse Drug Reactions and Product Quality Problems 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