All correspondence should be addressed to the Director General

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In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 9th September, 2025

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

MEDICAL PRODUCT ALERT NO. 4/2025: SUBSTANDARD (CONTAMINATED) FENTANILO HLB (FENTANYL CITRATE) IDENTIFIED IN THE WHO REGION OF THE AMERICAS

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 regulate, and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal use for public health protection.

Based on the above, ZAMRA wishes to alert healthcare professionals, pharmaceutical outlets and members of the public that it has been notified by the World Health Organisation (WHO) of the circulation of one batch of substandard **FENTANILO HLB** (fentanyl citrate). The substandard product has been detected in Argentina.

The substandard product was first identified in May 2025. WHO identified a fatal outbreak of bacterial infections in Argentina linked to a contaminated lot (Lot 31202) of injectable FENTANILO HLB. The contamination involved the drug-resistant bacteria: Klebsiella pneumoniae and Ralstonia Picketti.

Information now available to WHO indicates that multiple Lots of FENTANILO HLB are now considered to be contaminated and are therefore subject to recall in Argentina.

How to identify these falsified products

Product Name	FENTANILO HLB (fentanilo citrato) 0,05 mg/ml
Product registration holder	HLB PHARMA GROUP S.A.
Stated manufacturer	LABORATORIOS RAMALLO S.A
Lot	31200 31202 31244 31245 31246 3124
Identified in	Argentina

Risks

FENTANILO HLB (fentanyl citrate) is administered by injection. It may likely be given to critically ill or surgical patients. Such patients may already be vulnerable. Because of this the products sterility and quality are critical to patient safety.

The sterility of the FENTANILO HLB products identified in this WHO Medical Product Alert are considered compromised, as they may be contaminated with Klebsiella pneumoniae and or Ralstonia pickettii.

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E-mail: pharmacy@zamra.co.zm

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

These contaminated products pose significant risks to patients and can cause severe and potentially life-threatening infections, particularly in vulnerable individuals. Any use of these products poses a high risk to patients.

To protect patients, it is essential to detect and remove these substandard products from circulation.

ZAMRA wishes to notify healthcare professionals and members of the public that, while this product is not registered in Zambia and has not authorised its importation, the ZAMRA has intensified surveillance of the product on the Zambian market as it may be imported through illegal means.

In the unlikely event that you are in possession of this product, do not use it. If you suffer any adverse drug reaction/event 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 the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL