All correspondence should be addressed to the Director General

In reply, please quote

LET_LSE_PMS_0007/03/25

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 14th March, 2025

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

MEDICAL PRODUCT ALERT NO. 1/2025: FALSIFIED (CONTAMINATED) OXYCONTIN 80MG TABLETS IDENTIFIED IN THE WHO EUROPEAN REGION

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 falsified (contaminated) **Oxycontin** (Oxycodone hydrochloride). The falsified Oxycontin 80mg Tablets was detected in the unregulated (illegal) supply chain in Switzerland and reported to WHO by the genuine manufacturer, MUNDIPHARMA. See products details in the annex below.

Oxycontin is an opioid medicine used to treat moderate to severe pain. Laboratory analysis of the samples of the falsified product did not contain oxycodone, but contained a nitazene compound.

Nitazene derivatives are primarily used in research due to their high addiction potential and severe side-effects. Limited information is available on their risks, toxicity and long-term consequences.

How to identify this falsified product

To identify this falsified product, check for the following discrepancies:

- The placement of the batch number and expiry date on the falsified product is incorrect.
- On the falsified product the batch number and expiry date are visible on the front side of the blister strip.
- Genuine OXYCONTIN has the batch number and expiry date visible on the back of the blister strip.
- On the falsified product, the expiry date is on the left and the batch number on the right.
- Genuine OXYCONTIN has the batch number on the left and expiry date on the right.

Risk

This falsified product has been intentionally made to mimic genuine OXYCONTIN manufactured by MUNDIPHARMA. Since the product contains an undeclared nitazene

compound, it poses significant risk to end users due to the high likelihood of adverse events, even in small doses. Use of this product may be life-threatening.

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

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

Annex: Product subject of WHO Medical Product Alert No. 1/2025

Product Name	*OxyContin 80mg*
Stated manufacturer	*Mundipharma A/S*
Batch	*262174*
Expiry date	*12/2025*
Identified in	Switzerland
Available photos