Quality Medicines for Malawi

PUBLIC NOTICE

MEDICAL PRODUCT ALERT N°3/2024: FALSIFIED (CONTAMINATED) OXYMORPHONE HYDROCHLORIDE 40MG TABLETS

Lilongwe, Thursday, 8th August, 2024: The Pharmacy and Medicines Regulatory Authority (PMRA) is informing stakeholders and the general public that the World Health Organisation (WHO) has issued an alert concerning one batch of falsified (contaminated) Oxymorphone Hydrochloride 40mg tablets. The falsified product was detected in the unregulated supply chain in Finland and reported to WHO in July 2024 by the Finnish Medicines Agency (FIMEA).

Oxymorphone Hydrochloride is a semi-synthetic opioid used to treat moderate to severe pain.

The falsified product imitates Oxymorphone Hydrochloride marketed by AUROLIFE PHARMA LLC., who have confirmed that the product, subject of this Alert, is falsified and was not produced by their company.

PMRA is assuring stakeholders and the general public that Oxymorphone Hydrochloride is not registered with the Authority, making it very unlikely for the falsified product to be available in the country.

However, in case anyone has the affected product, PMRA recommends that they should not use it and report to the Authority immediately.

PMRA urges pharmaceutical importers, retailers, healthcare workers, and consumers to report any suspected falsified medicines or adverse drug reactions to any healthcare facility and to the PMRA by dialing *360# for free on TNM and Airtel networks.

The Authority remains steadfast in ensuring that medicines and allied substances being used in the country are of acceptable quality, safe and efficacious in line with our mandate as provided for under the PMRA Act, 2019.

Full details of the alert are available on: Medical Product Alert N°3/2024

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