Quality Medicines for Malawi

PUBLIC NOTICE

PRODUCT RECALL: ACTRAPID® SOLUBLE INSULIN 100IU/ML MANUFACTURED BY NOVO NORDISK

Pharmacy and Medicines Regulatory Authority (PMRA) is notifying stakeholders and the public of an immediate recall of Actrapid® Soluble Insulin 100 IU/ml batch numbers JT6R236, KS6BR28 and KL3BC30 whose labels are suspected to have been tampered with.

PMRA, through its medicine and vaccine post-market safety monitoring initiative, received a complaint from one of the public hospitals in the country that label details of some vials of insulin supplied to it by a supplier (name withheld) appeared to have been altered and concealed with new labels.

Preliminary investigations have since revealed that these falsified batches were sourced locally and supplied to Kamuzu Central Hospital (KCH), Queen Elizabeth Central Hospital (QECH), Zomba Central Hospital, Malamulo and Mulanje Mission hospitals. These facilities have since been informed to quarantine the concerned batches.

At this stage, the Authority is not ruling out possibility of a mix-up between insulin with authentic batch details and the one whose batch details are suspected to have been tampered with.

The Authority is, therefore, urging all facilities supplied with insulin bearing the above batch numbers to immediately recall the insulin from all user points including patients. All patients in possession of insulin with above details are advised to immediately stop using it and consult their respective health practitioners for replacement.

The manufacturer, Novo Nordisk of France has since been notified of the development and is cooperating with the Authority's on-going investigation on the matter.

Meanwhile, PMRA inspectors are working with law enforcement agencies to get to the bottom of the matter and ensure that all those involved in the supply chain of the affected insulin are prosecuted in accordance with the PMRA Act and other relevant laws.

The Authority is reminding stakeholders and the public that distributing or selling of expired drugs, tampering with and/or falsifying medicine labels are serious offenses

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which upon conviction attract up to K10 million fine and 10-years imprisonment.

The Authority remains steadfast in ensuring that medicines, allied substances and vaccines being used in the country are of acceptable quality, safe and efficacious in line with our mandate as provided for under the PMRA Act No. 9 of 2019.

For further information, please contact PMRA on +265 212 755 165 / +265 212 750 108 or email at info@pmra.mw

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About PMRA

PMRA is a statutory organization established by Act of Parliament to regulate medicines, allied substances and the practice of pharmacy in Malawi.

Charles Chimenya
ACTING DIRECTOR GENERAL
20th May, 2022