Quality Medicines for Malawi

PUBLIC SAFETY ALERT

IMMEDIATE NATIONWIDE RECALL OF ALL BATCHES OF METMIN (METFORMIN HYDROCHLORIDE) 500MG TABLETS

The Pharmacy and Medicines Regulatory Authority (PMRA) wishes to notify pharmaceutical stakeholders and the general public that it has formally directed Dawa Life Sciences Limited, located in Nairobi, Kenya, in collaboration with its authorized local distributor in Malawi, UNICHEM (2005) Company, to effect an immediate nationwide recall of all batches of Metmin (Metformin Hydrochloride 500mg Tablets) manufactured by Dawa Life Sciences Limited.

All healthcare facilities, distributors and pharmaceutical outlets are required to remove the product from circulation, regardless of batch number or expiry date.

Product details:

Product Name	Metmin (Metformin Hydrochloride) 500mg Tablets BP
PMRA Registration Number	PMRA/ PL12/138
Pack Size	10 x 10's
Affected Batches	All batches (regardless of batch number or expiry date)
Recall Classification	**Class II:** Indicates that the product may cause mistreatment through inadequate therapeutic effect, as bioequivalence has not been demonstrated.
Recall Type Depth	**Type B:** Covers wholesale, retail, and user facility levels (including hospitals, clinics, retail pharmacies, and dispensaries).
Product reference picture	

Reason for recall:

The PMRA established that the bioequivalence (BE) study report submitted in support of the registration of Metmin 500mg Tablets was falsified. Consequently, PMRA has

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revoked the product's marketing authorization.

Bioequivalence testing demonstrates that a generic pharmaceutical product releases its active ingredient into the bloodstream at the same rate and extent as the reference innovator(original) product.

Following the revocation of its marketing authorization, Metmin (Metformin Hydrochloride) 500mg Tablets will no longer be sold, distributed, or supplied anywhere within Malawi.

Actions required:

1. Stop selling, supplying and dispensing Metmin tablets immediately.
2. Check all stock locations and quarantine all units of the product.
3. Clearly label the quarantined products "RECALLED- NOT FOR SALE OR USE"
4. Return all stock to UNICHEM (2005) Company or Pharmamed (2011) Company.
5. Full credit will be given for all stock returned. For logistical arrangements regarding stock returns or further inquiries, please contact +265(0)999 640 740 or email: unichemmw@gmail.com.
6. Patients currently taking Metmin should immediately visit their nearest clinic to transition them to an alternative metformin product duly registered by the PMRA. Patients exhibiting poor glycaemic control should be referred to a prescriber for clinical review.

The Authority further reminds pharmaceutical importers, retailers, healthcare workers, and consumers to always be vigilant and report any suspected poor-quality medicines or adverse drug reactions to the nearest healthcare facility and to the PMRA via Medsafe 360 by dialing *360# for free on TNM and Airtel networks.

For more information and/ or clarification regarding this safety alert notice please contact PMRA on +265 899 567 365 or email at info@pmra.mw.

Charles Chimenya
DIRECTOR GENERAL
24th November, 2026