

QA Information Notice

IN N° 2019-05 Version: 11/06/2019	Unlawfully displayed ACTm logo on boxes of Artemether + Lumefantrine 20mg + 120mg bearing various manufacturer names found in Nigeria
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Addressees

- Any person having products in stock, in transit or under custom clearance through PRs / For Action
- National Regulatory Authorities and/or Pharmacovigilance Centers through PRs/ For Action

Purpose

The Global Fund Quality Assurance Team is issuing this Information Notice to forward information regarding an unlawfully displayed ACTm logo on boxes of Artemether + Lumefantrine, 20mg+120mg, tablets bearing the name of various manufacturers.

Identification of the product(s) and manufacturer

Manufacturer	McW Healthcare (P) Ltd Jiangsu Ruinian qianjin Pharma. Co. Ltd.
INN Name	Artemether + Lumefantrine
Commercial Name(s)	Malaxit¹, Nemether Plus²
Pharmaceutical form	Tablets
Strength	20 mg + 120 mg
Packaging & Pack size	30 x 1 x 24
Batch(es)	AF55801¹, 181170²
Manufacturing Date	November 2018
Expiry Date	October 2021¹, November 2020²

Background

It has come to our attention that the ACTm logo trademarked by the Global Fund and used to identify quality-assured, subsidized ACTs through the Private Sector Co-Payment Mechanism has been unlawfully displayed on boxes of Artemether+Lumefantrine, 20mg + 120 mg, Tablets distributed in Nigeria.

The ACTm Logo has been found on various products distributed in Nigeria. Various boxes bearing different manufacturer names have been identified. Among them the name of the manufacturer McW Healthcare (P)

Ltd, Industrial Area and Sanwer Road, Indore (M.P.) India and Jiangsu Ruinian qianjin Pharma. Co. Ltd. have been found.

Nature of defect(s)

Details of defect or problem.	Products may not be of assured quality, products might be counterfeited
Is there any evidence or suspicion of a risk to public health?	Lack of efficacy
Extent of the problem (eg. how many batches).	AF55801, 181170
Extent of distribution of the product / batch (es).	Nigeria is the affected country already identified but broader distribution can be envisaged to the neighbouring countries
Number of patients potentially impacted	Not available

Action/Investigations taken

- No further investigation needed from GF Secretariat

Decisions/Next Steps

Based on the information available to date and until further notice, the following actions are recommended **for the identified boxes**:

- To stop dispensing the products to end users;
- To stop further distribution of the products within the supply chain;
- To quarantine the remaining stock at all levels of the supply chain e.g. central, regional, provincial, district up to facility level;
- To report to QA Team within one month the available stock that was quarantined and/or disposed.
- The Global Fund QA team to liaise with the National Agency for Food and Drug Administration and Control of Nigeria (NAFDAC)

GF Contacts and acknowledgement

This Information Notice requires a specific written response from PR to acknowledge receipt and commit to engage with the requested communications and actions.

PRs should copy the Global Fund QA Team in any correspondence regarding the matter for follow-up. Please direct the respective responses and any questions about this matter to the technical contacts listed below.

Organisation	Name / Function	E-mail address
Global Fund	Alain Prat, QA Team Lead	Alain.Prat@theglobalfund.org
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