

QA Information Notice

IN N° 2018-06 Version: 16/11/2018	Unlawfully displayed ACTm logo on boxes of Lesanto Laboratories
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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 pharmaceutical product bearing the name of the manufacturer Lesanto Laboratories.

Identification of the product(s) and manufacturer

Manufacturer	Lesanto Laboratories
INN Name	Artemether + Lumefantrine
Commercial Name(s)	Ibumartem
Pharmaceutical form	Tablets
Strength	20 mg + 120 mg
Packaging & Pack size	all four pack sizes, 6x1, 6x2, 6x3, 6x4
Batch(es)	Lo75004
Manufacturing Date	
Expiry Date	July 2021

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 medicines distributed in Nigeria.

The ACTm Logo has been found on products distributed in Nigeria, bearing the name of the manufacturer Lesanto Laboratories.

Nature of defect(s)

Details of defect or problem.	Products may not be of assured quality
Is there any evidence or suspicion of a risk to public health?	Lack of efficacy
Extent of the problem (eg. how many batches).	One batch identified L075004
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
- WHO Medical Product Rapid Alert system informed

Next Steps

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

- To stop use of the products by end users;
- 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 put under quarantine the impacted batch at port of entry and in transit;
- To report to QA Team within one month the available stock that was quarantined and/or disposed.

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
Global Fund	Amelie Darmon, Ass. QA Specialist	Amelie.Darmon@theglobalfund.org