

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2019-04 Version: 17/05/2019	Suspension of manufacturing activities at Micro Labs Limited, Kumbalgodu, MLo8, Bangalore (India)
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Addressees

- Any person involved in the procurement of medicine to treat tuberculosis and HIV related conditions
- Any procurers, buyers with a pending order
- Partners agency and Principal recipient for information

Purpose

The Global Fund QA team is issuing this information notice to provide information regarding the voluntarily suspension of manufacturing activities at the following site : Micro Labs Ltd, MLo8, Plot No 15/A, 2nd Phase, Kumbalgodu Industrial Area, Bangalore, 560 074, India.

Identification of the product(s) and manufacturer

Name of Manufacturer	Micro Labs Ltd, MLo8, Plot No 15/A, 2nd Phase, Kumbalgodu Industrial Area, Bangalore, 560 074, India.
Product Name	Products used for treatment of tuberculosis (TB) and essential medicines for HIV related conditions as listed in Annex A
Product Code	See Annex A
Packaging & Pack size	See Annex A

Background

A Good Manufacturing Practice (GMP) inspection of Micro Labs Ltd., Kumbalgodu (MLo8) was carried out by the World Health Organization from 27-31 August 2018. As part of its corrective and preventive action plan and to expand and modernize equipment and systems on site, Micro Labs Ltd., Kumbalgodu notified WHO Prequalification Team (PQT) of its decision to undertake extensive renovations and refurbishment of its MLo8 facility.

Consequently, the company **voluntarily suspended manufacturing** of prequalified finished pharmaceutical products and ERP authorized ones at this facility from 12 February 2019 onwards, until completion of the modifications of the facility and completion of its intended corrective and preventive actions following the inspection. Therefore, the continuous manufacturing of any medicines at the site is not acceptable until the completion of the modifications of the facility, as the renovation activities will impact on its ability to comply with the standards of Good Manufacturing Practices (GMP) published by the World Health Organization (WHO).

The quality of batches manufactured at Micro Labs MLo8, until suspension of its manufacturing on 12 February 2019, is considered to be acceptable.

Nature of defect(s)

Details of defect or problem.	Voluntarily suspension of manufacturing activities at Micro Labs Ltd, MLo8, Kumbalgodu Industrial Area, Bangalore,
Is there any evidence or suspicion of a risk to public health?	NA
Extent of the problem (eg. how many batches).	NA
Extent of distribution of the product / batch (es).	NA
Number of patients potentially impacted	NA

Action/Investigations taken

- Procurement agents will be informed by Global Fund and should forward the notification of this Information Notice
- Products temporarily delisted from Global Fund list of eligible products and from WAMBO to prevent any direct procurement
- The Global Fund requested the manufacturer if any further procurement conducted by countries resulted in procurement of the affected product to take corrective and preventive actions

Decisions / Next Steps

Based on the information available to date and until further notice, The Global Fund QA has taken the decision to temporarily delist the products listed in the Annex A from its lists of eligible products.

Furthermore, The Global Fund QA recommends following actions to be taken:

- PRs to stop procuring products manufactured at this facility and should switch to the use of products from alternative sources.

Contacts

This Information Notice is for information purposes only and does not require a specific written response from the PR.

Please direct any questions about this matter to the technical contacts listed below.

Organisation	Name / Function	E-mail address
Global Fund	Amelie Darmon, Associated QA Specialist	Amelie.Darmon@theglobalfund.org
Stop TB-GDF	Nigorsulton Muzafarova, Lead Product Quality Officer	nigorsultonm@stoptb.org

Annex A : List of medicines manufactured at the Micro Labs Ltd, MLO8, Plot No 15/A, 2nd Phase, Kumbalgotu Industrial Area, Bangalore, 560 074, India.

Designation of Pharmaceutical products	TGF Quality Standards
Essential Medicines	
<ul style="list-style-type: none"> Sulfamethoxazole/Trimethoprim Tablet 400mg/80mg 	WHO-PQ
<ul style="list-style-type: none"> Sulfamethoxazole/Trimethoprim Tablet 800mg/160mg 	WHO-PQ
TB Medicines	
<ul style="list-style-type: none"> Pyrazinamide Tablet, Dispersible 150 mg 	WHO-PQ
<ul style="list-style-type: none"> Moxifloxacin (hydrochloride) Tablet, Dispersible 100mg* 	WHO-PQ
<ul style="list-style-type: none"> Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin Tablet, Film-coated 275mg/75mg/400mg/150mg 	WHO-PQ
<ul style="list-style-type: none"> Linezolid, Tablet, Film-coated 600mg 	WHO-PQ
<ul style="list-style-type: none"> Isoniazid Tablet, Dispersible 100 mg 	GF-ERP

*Moxifloxacin (hydrochloride) Tablet, Dispersible 100mg will remain eligible for procurement from the alternative manufacturing site Micro Labs Ltd, Unit 03, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India

References:

https://extranet.who.int/prequal/sites/default/files/documents/NoticeStakeholders_MicroApril2019.pdf