Information on the GMP status of Micro Labs Kumbalgodu (ML08) manufacturing facility situated at Bangalore (Karnataka, India)[1]

A Good Manufacturing Practice (GMP) inspection of Micro Labs Ltd., Kumbalgodu (ML08) was carried out by the World Health Organization 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., Kumbalgadu notified PQT: Inspections during December 2018 of its decision to undertake extensive renovations and refurbishment of its ML08 facility.

Consequently, the company voluntarily suspended manufacturing of prequalified finished pharmaceutical products 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).

WHO action and advice

WHO has prequalified several medicinal products, the production of which was ensured by the Micro Labs ML08 facility. Their prequalification status remains current. However, their manufacturing will be transferred to other manufacturing facilities of Micro Labs Ltd. pending submission and approval of variation packages to WHO PQT.

Following from communication with Micro Labs Ltd., Kumbalgodu (29 March 2019), the latest batches of prequalified medicinal products manufactured at the site, prior to the manufacturing shutdown are the following:

- **HA598**: Sulfamethoxazole and trimethoprim tablets 400mg /80mg, Batch No. TSABK00009, manufactured December 2018.
- **HA599**: Sulfamethoxazole and trimethoprim tablets 800mg /160mg, Batch No. TSBBK0069, manufactured December 2018.
- **TB335**: Pyrazinamide dispersible tablets 150mg, Batch No. PDAHK0015, manufactured February 2019 with
- **TB349**: Moxifloxacin not recently manufactured.

In addition, the following products prequalified by WHO PQT are listed to be manufactured at Micro Labs ML08 facility however to date have never been commercialised:

- **TB223**: Ethambutol/Isoniazid/Pyrazinamide/Rifampicin
- **TB323**: Linezolid

[1] The full address of the Micro Labs ML08 manufacturing facility is: Micro Labs Ltd, ML08, Plot No 15/A, 2nd Phase, Kumbalgodu Industrial Area, Bangalore, 560 074, India.

The quality of batches manufactured at Micro Labs ML08, until suspension of its manufacturing on 12 February 2019, is considered to be acceptable. Procurement agencies, distributors and regulatory authorities of Member States are welcome to contact the WHO Inspections Team for information on when manufacturing will resume.

Further information:

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