WHO response to UK MHRA Statement of Non-Compliance with GMP on Micro Labs Hosur (Unit 03) manufacturing facility situated at Hosur (Tamil Nadu, India)[1]

A Good Manufacturing Practice (GMP) inspection of Micro Labs Hosur (Unit 03) was carried out by the United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA) on 15 November 2018. The inspection identified significant deficiencies in relation to cross-contamination controls which led to the issue of a Statement of Non-Compliance with GMP on 24 January 2019.[2]

Consequently, the company suspended manufacturing and supply of non-critical finished pharmaceutical products manufactured at this facility to the EU market, while this issue is being addressed.

WHO action and advice

WHO has prequalified several medicinal products, the production of which was ensured by the Micro Labs Hosur (Unit 3) facility. Their prequalification status remains current.

WHO has contacted Micro Labs Ltd. to obtain further information as well as its risk mitigation strategy for WHO-prequalified products that have already been distributed to the market; and for ensuring the quality and supply of FPPs manufactured at this site. WHO is currently assessing the information submitted by Micro Labs and the extent to which the deficiencies identified by the UK MHRA have an impact on prequalified products. In addition, WHO is in contact and exchanges information with the UK MHRA on the progress of the corrective and preventive actions undertaken by Micro Labs to ensure that the site re-establishes the necessary level of GMP compliance and that all batches of medicinal products manufactured on site, are of adequate quality.

In close collaboration with the UK MHRA and Micro Labs Ltd and based on the evidence that was reviewed up to date, a recall of WHO prequalified medicinal products is not considered to be necessary. Until WHO confirms that all matters have been resolved, it is recommended that procurers and distributors contact the company to determine the level of risk associated with specific products and consider alternative suppliers of these medicines, where appropriate. Procurers and distributors of finished pharmaceutical product (FPP) manufactured by Micro Labs Hosur (Unit 03) may contact WHO for further information.

[1] The full address of the Micro Labs Hosur manufacturing facility is: Micro Labs Ltd, Unit 03, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India.
[2] EudraGMDP; Report No : ***UK GMP 22481 Insp GMP 22481/117371-0004 NCR***

The following prequalified products have been manufactured at the Micro Labs Hosur (Unit 03) site:

- **TB171 Pyrazinamide Tablet 400 mg**
- **TB172 Pyrazinamide Tablet 500 mg**
- **TB173 Isoniazid Tablet 100 mg**
- **TB174 Isoniazid Tablet 300 mg**
- **TB237 Levofloxacin Tablet, Film-Coated 250 mg**
- **TB238 Levofloxacin Tablet, Film-Coated 500 mg**
- **TB239 Protionamide Tablet, Film-Coated 250 mg**
- **TB242 Ethionamide Tablet, Film-Coated 250 mg**
- **TB263 Moxifloxacin (hydrochloride) Tablet, coated 400mg**
- **TB331 Ethionamide Tablet, Film-coated 125 mg**
- **TB349 Moxifloxacin (hydrochloride) Tablet, Dispersible 100mg**

Further information:

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