

Information note

19 June 2019

**PRODUCT RECALL – MOXIFLOXACIN 100 MG DISPERSIBLE TABLETS (TB342):
BATCH BMC5801A**

On 28 May 2019, Macleods Pharmaceutical Ltd. notified WHO PQT: Medicines that an out-of-specification test result had been obtained on a product that was prequalified by WHO PQT: Medicines, TB342 Moxifloxacin Hydrochloride Dispersible Tablets 100 mg, batch No. BMC5801A.¹ The dissolution test results failed to meet the acceptance criteria of NLT 80 (Q) for 15 minutes at the S3 stage when stored under the condition of 30°C/75%RH (real time) for one of the commercial batches of TB342 Moxifloxacin Hydrochloride Dispersible Tablets 100 mg i.e. batch No. BMC5801A, manufactured on September 2018 (Expiry date: August 2020, Blister, Alu/Alu 10x10).

On 1 June 2019, Macleods Pharmaceutical Ltd. initiated a voluntary recall for this product. A health hazard assessment was performed by the company which established that there are no safety issues associated to the use of this product and that the therapeutic activity of Moxifloxacin dispersible tablets 100 mg was unlikely to be affected.

WHO action and advice

WHO has contacted Macleods Pharmaceutical Ltd. to obtain further information as well as its risk mitigation strategy for other batches of the Moxifloxacin product.

WHO recommends that, while the company is working on the resolution of the remaining issues, procurers and distributors should stop the procurement and distribution of this specific batch of Moxifloxacin dispersible tablets 100 mg (TB342) Batch No. BMC5801A while Pharmacies and healthcare facilities that have the specific batch of product in stock, should contact Macleods Pharmaceutical Ltd. or their procurement agency for instructions for return of the recalled product.

As this product is indicated for the treatment of tuberculosis in paediatric patients, parents of patients should contact their doctor for further guidance before their child stops taking this drug product.

Further information:

Dr. Joey Gouws, Inspection Services Group Lead, WHO Prequalification Team — Email: gouwsj@who.int; Tel: +41 22 791 2255.

1. <https://extranet.who.int/prequal/medicine/4175>