Quality Assurance (QA) for Health Products
QA Information Notice

IN № 2019-06
Version: 19/06/2019

VOLUNTARY RECALL INITIATED BY Macleods FOR
Moxifloxacin Dispersible tablets 100mg, - Batch No
BMC5801A

Addressees

• Any person having products in stock, in transmit or under custom clearance

• Any procurers, buyers with a pending order

Purpose

The GF QA is issuing this information notice to provide information that was transmitted by Macleods regarding a voluntary recall initiated on 01 June 2019 for the following product.

Identification of the product(s) and manufacturer

<table>
<thead>
<tr>
<th>Name of Manufacturer</th>
<th>Macleods</th>
</tr>
</thead>
<tbody>
<tr>
<td>INN Name</td>
<td>Moxifloxacin (hydrochloride)</td>
</tr>
<tr>
<td>Commercial Name(s)</td>
<td>Moxifloxacin hydrochloride Dispersible tablets, 100mg</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>Dispersible tablets</td>
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<tr>
<td>Strength</td>
<td>100 mg</td>
</tr>
<tr>
<td>Packaging &amp; Pack size</td>
<td>Blister, Alu/Alu 10x10</td>
</tr>
<tr>
<td>Batch(es)</td>
<td>BMC5801A</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>August 2020</td>
</tr>
</tbody>
</table>

Background

During ongoing stability studies organized by the manufacturer Macleods, out of specifications were identified regarding the results of the dissolution test. Following investigations, Macleods finally confirmed the non-compliance and decided to perform a voluntary recall of the above-mentioned Batch.

Nature of defect(s)

| Details of defect or problem. | Non-compliant results founded for dissolution testing |

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Is there any evidence or suspicion of a risk to public health?

| Diminished availability of the active ingredient in the systemic circulation, diminished efficacy, potential increase of drug resistance, no immediate serious health related risk |

Extent of the problem (eg. how many batches).

| 1 batch: BMC5801A |
| 655 packs of 10x10 = 65500 tablets |

Extent of distribution of the product / batch(es).

| Worldwide distribution was foreseen but limited number of countries got impacted |

Number of patients potentially impacted

| No impacted patients known |

**Action/Investigations taken**

- Procurement agent have been informed by the manufacturer and should forward the information regarding this recall to all impacted countries
- No Country supported by Global Fund Grants and using the GDF Stop-TB procurement mechanism could be identified
- GF to investigate if any direct procurement occurred

**Next Steps**

Based on the information available to date and until further notice, the following actions are recommended by GF QA:

- To put under quarantine the available stock of the impacted batches at regional and central level (class III-Wholesaler stage).
- To put under quarantine the impacted batches at port of entry and in transit, if applicable
- To report to the manufacturer/procurers (IDA) the available stock that was put under quarantine

**Contacts**

This IN does not require specific written response from PR. PRs should copy GF QA Team of any correspondence regarding the matter for follow-up.

Please direct the respective answers and any questions about this matter to the technical contacts listed below

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Name / Function</th>
<th>E-mail address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Fund</td>
<td>Amelie Darmon, QA Ass. Specialist</td>
<td><a href="mailto:Amelie.Darmon@theglobalfund.org">Amelie.Darmon@theglobalfund.org</a></td>
</tr>
<tr>
<td>Global Drug Facility</td>
<td>Nigorsultan Muzafarova, Product Quality Officer</td>
<td><a href="mailto:nigorsultonm@stoptb.org">nigorsultonm@stoptb.org</a></td>
</tr>
</tbody>
</table>
URGENT DRUG RECALL

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Expiry Date</th>
<th>Lot[s]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin Hydrochloride Dispersible Tablets 100 mg</td>
<td>Aug 2020</td>
<td>BMCS801A</td>
</tr>
</tbody>
</table>

Dear Customer,

Macleods Pharmaceutical is initiating a voluntary wholesaler level recall on Moxifloxacin Hydrochloride Dispersible Tablets 100 mg.

This recall is based upon Macleods determination of out of specification results reported during stability study analysis. On the basis of medical and professional review, adverse safety or health hazard concerns are unlikely. Hence we are initiating Class III level recall.

Macleods Pharmaceutical requests that you immediately take the following actions:

- Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

- In the event you have Recall product, please withhold the further distribution and notify to Macleods Pharmaceuticals Limited.

This action applies only to Moxifloxacin Hydrochloride Dispersible Tablets 100 mg Batch No. BMCS801A listed above. Only product from this lot will be accepted under the terms of this recall.

1. If you have any questions regarding this recall, please contact Macleods Pharmaceuticals Limited.

   G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East), Mumbai - 400093, INDIA, Phone: + 91 22 61132900, Fax: 91 22 28304641

We regret any inconvenience and appreciate your immediate cooperation.

Signature

For Macleods Pharmaceuticals Limited.

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Macleods Pharmaceuticals Limited

Regd. Office:

Atlanta Arcade, Church Road,
Near Leela Hotel, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Phone: 91-22-66742800
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