Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2018-04

Version: 04/07/2018

REMEDICA Rapid Alert Notification CY/1/07/01

Falsified Quinine Sulphate tablets 300 mg

Addressees

- Any person having products in stock, in transit or under custom clearance through PRs / For Action
- National Regulatory Authorities and/or Pharmacovigilance Centers through PRs/ For Action

Purpose

The Global Fund Quality Assurance Team is issuing this Information Notice to forward information that was transmitted through Rapid Alert Mechanism by the Pharmaceutical Services of the Ministry of Health of Cyprus regarding a falsification of an authentic pharmaceutical product manufactured by Remedica.

Identification of the product(s) and manufacturer

<table>
<thead>
<tr>
<th>Manufacturer (for the authentic product)</th>
<th>Remedica Ltd, Limassol (Cyprus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INN Name</td>
<td>Quinine Sulphate</td>
</tr>
<tr>
<td>Commercial Name(s)</td>
<td>Quinine Sulphate Tablets BP 300mg</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>Tablets</td>
</tr>
<tr>
<td>Strength</td>
<td>300 mg</td>
</tr>
<tr>
<td>Packaging &amp; Pack size</td>
<td>Plastic container of 1000 tablets</td>
</tr>
<tr>
<td>Batch(es)</td>
<td>44680</td>
</tr>
<tr>
<td>Manufacturing Date</td>
<td>09/2017</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>10/2020</td>
</tr>
</tbody>
</table>

Background

On the 10th April 2018, Remedica received a notification/information regarding a suspicion of falsified product named “Quinine tablets” from the German Institute for Medical Mission (DIFAEM) found in Cameroon carrying Remedica’s name. Remedica initiated an investigation, performed chemical analysis of the product and the results of the returned samples confirmed that the product is counterfeit/falsified. The Pharmaceutical Service of the Ministry of Health of Cyprus and the World Health Organization (WHO) were notified by Remedica about the concerned case. A Rapid Alert Notification was issued by the Pharmaceutical Services of the Ministry of Health of Cyprus.
Nature of defect(s)

<table>
<thead>
<tr>
<th>Details of defect or problem.</th>
<th>Counterfeit/falsified products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there any evidence or suspicion of a risk to public health?</td>
<td>Lack of efficacy</td>
</tr>
<tr>
<td>Extent of the problem (eg. how many batches).</td>
<td>One batch identified No 44680</td>
</tr>
<tr>
<td>Extent of distribution of the product / batch (es).</td>
<td>Cameroon is the affected country already identified but broader distribution can be envisaged</td>
</tr>
<tr>
<td>Number of patients potentially impacted</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Action/Investigations taken

- Manufacturer confirmed the counterfeit/falsified products
- Pharmaceutical Services of Cyprus issued A Rapid Alert Notification, distributed also to WHO
- No further investigation needed from GF Secretariat

Next Steps

Based on the information available to date and until further notice, the following actions are recommended for the impacted batch:

- To stop use of the products by end users;
- To stop dispensing the products to end users;
- To stop further distribution of the products within the supply chain;
- To quarantine the remaining stock at all levels of the supply chain e.g. central, regional, provincial, district up to facility level;
- To put under quarantine the impacted batch at port of entry and in transit;
- To report to QA Team within one month the available stock that was quarantined.

GF Contacts and acknowledgement

This Information Notice requires a specific written response from PR to acknowledge receipt and commit to engage with the requested communications and actions.

PRs should copy the Global Fund QA Team in any correspondence regarding the matter for follow-up. Please direct the respective responses 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>Alain Prat, QA Team Lead</td>
<td><a href="mailto:Alain.Prat@theglobalfund.org">Alain.Prat@theglobalfund.org</a></td>
</tr>
<tr>
<td>Global Fund</td>
<td>Amelie Darmon, Ass. QA Specialist</td>
<td><a href="mailto:Amelie.Darmon@theglobalfund.org">Amelie.Darmon@theglobalfund.org</a></td>
</tr>
</tbody>
</table>
TO WHOM IT MAY CONCERN

Reference: Medicinal Rapid Alert No. CY/II/07/01: Falsified ‘Quinine Tablets’
(Batch Number: ‘44680’) found in Cameroon.

Regarding the Medicinal Rapid Alert No. CY/II/07/01 (Falsified Quinine Tablets found in Cameroon), please be informed of the following:

- On the 10th of April 2018, Remedica received a suspicion of a falsified product ‘Quinine tablets’ from the ‘German Institute for Medical Mission (DIFAEM)’ found in Cameroon.

Table 1: Suspect falsified Medicinal Product found in Cameroon:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Quinine Sulphate Tablets BP 300mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch Number</td>
<td>44680</td>
</tr>
<tr>
<td>Manufacturing Date</td>
<td>09/2017</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>10/2020</td>
</tr>
</tbody>
</table>

- Remedica Ltd immediately initiated an investigation; analysis results of the returned samples confirmed that the product is a counterfeit/falsified.
- The Pharmaceutical Services of the Ministry of Health of Cyprus and the World Health Organisation (WHO) were notified by Remedica for the concerned case and on the 25th of June 2018 a Rapid Alert was issued by the Pharmaceutical Services of the Ministry of Health of Cyprus.

You are kindly requested if any product is suspected to be counterfeit/falsified to be immediately communicated to Remedica.

For Remedica Ltd,

Andreas Vasilidiou
Head of Drug Safety Department/QPPV

Maria Michael
Chief Technical Officer / QA Manager/QP
IMPORTANT – DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

From: GMP Inspectorate, Pharmaceutical Services, Ministry of Health, Cyprus

1. To: All Rapid Alert contacts

2. Product Recall Class of Defect: I (circle one)

3. Falsification / Fraud (specify)*
   YES

4. Product:
   Quinine 300mg Tablets

5. Marketing Authorisation Number:
   N/A

6. Brand/Trade Name:
   Quinine Sulphate Tablets BP 300mg

7. INN or Generic Name: Quinine Sulphate

8. Dosage Form: Tablets

9. Strength: 300mg

10. Batch number: 44680

11. Expiry Date:
    10/2020

12. Pack size and Presentation:
    Plastic Containers of 1000 Tablets

13. Date Manufactured: 09/2017

14. Marketing Authorisation Holder: N/A (WHO Essential Drugs Program)

15. Manufacturer: Remedica Ltd (for the authentic product)

16. Recalling Firm:
    Contact Person:
    Telephone:

17. Recall Number Assigned (if available) N/A

18. Details of Defect/Reason for Recall: The Manufacturer of the authentic medicinal product (Remedica Ltd) was informed by the German Institute of Medical Mission (DIFAEM) in April about a suspected counterfeit medicinal product, found in Cameroon and carrying Remedica’s name on its label. The manufacturer performed chemical analysis of the product and it is confirmed that the product is counterfeit.

19. Information on distribution including exports. Unknown

20. Action taken by Issuing Authority: Issuance of Rapid Alert in order to protect public health


22. From (Issuing Authority):
    GMP INSPECTORATE
    PHARMACEUTICAL SERVICES
    MINISTRY OF HEALTH
    CYPRUS

23. Contact Person:
    Anna Papfitou
    apapfitou@phs.moh.gov.cy
    Telephone: +357 22608616

24. Signed: Anna Papfitou

25. Date: 25/06/2018

26. Time: 14:00