Quality Assurance (QA) for Health Products

QA Notice

IN No 2023-02
Version 3 - 11/05/2023

Updated Decision: on the procurement of lubricants (sachets and tubes) manufactured by Cupid Limited, India and the request to quarantine Lubricants batches manufactured between January 2022 to date.

Addressees

• All Principal Recipients (PRs)
• Any person having products in stock, in transit or under custom clearance
• Any procurers, buyers with a pending order

Purpose

The GF QA is issuing this information notice to provide an update regarding the temporary suspension of procurement of lubricants (sachets and tubes) manufactured by Cupid Limited, India as well as the request to quarantine lubricants batches manufactured between January 2022 to date.

Identification of the product(s) and manufacturer

<table>
<thead>
<tr>
<th>Name of Manufacturer</th>
<th>Cupid Limited, -68, MIDC, MIDC Area, Malegaon, Maharashtra 422113, India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Name(s)</td>
<td>Cupid lubricant water-based</td>
</tr>
<tr>
<td>Packaging &amp; Pack size &amp; Type</td>
<td>4ml; 4.3ml; 5ml; 10ml; 20ml: pack of 10000 sachets</td>
</tr>
<tr>
<td></td>
<td>20g and 35g: pack of 25 or 50 tubes</td>
</tr>
<tr>
<td>Batch(es)</td>
<td>See attachment (Cupid Ltd. Country and distribution information)</td>
</tr>
<tr>
<td>Manufacturing Date</td>
<td>Between January 2022 to date</td>
</tr>
</tbody>
</table>

Background

UNFPA received information that three batches of water-based lubricants packed in sachets manufactured by Cupid Limited, -68, MIDC, MIDC Area, Malegaon, Maharashtra 422113, India failed to meet the total aerobic microbial count specification parameter. A review of the test results and further complaints received indicate that the quality of some batches may have been compromised.
February 2023

Consequently, to protect public health while awaiting the results of the ongoing investigation UNFPA had requested to take following precautionary risk mitigation measures:

- To quarantine all batches of personal lubricant (packed in sachets and in tubes) from Cupid Limited manufactured from January 2022 to date.
- To stop the procurement of lubricants (sachets and tubes) from Cupid Limited until further notice.

May 2023: update on the Decision and way forward

After issuing the ‘Quarantine notice’, independent testing has been performed for lubricants manufactured by Cupid Limited. Review of Corrective and preventive Actions (CAPAs), test results as well as stability studies data have also been undertaken. Outcomes of these reviews have resulted in the below conclusions and way forward (see below table and Next Steps):

### Nature of defect(s)

<table>
<thead>
<tr>
<th>Details of defect or problem.</th>
<th>Out of Specification for the parameter total aerobic microbial count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there any evidence or suspicion of a risk to public health?</td>
<td>The failure may increase the risk for the end-user to develop a bacterial infection</td>
</tr>
<tr>
<td>Extent of the problem (eg. nb batches).</td>
<td>Batches manufactured between June 2022 and today.</td>
</tr>
<tr>
<td><strong>Content updated</strong></td>
<td>For details on batch numbers, please refer to Attachment 2</td>
</tr>
<tr>
<td>Extent of distribution of the product / batch (es).</td>
<td>For PPM Orders: Belize, Cuba, Comoros, El Salvador, Honduras, Kazakhstan, Kyrgyzstan, Mauritania, Sao tome and Principe, Surinam</td>
</tr>
<tr>
<td><strong>Content updated</strong></td>
<td>Worldwide distribution is anticipated</td>
</tr>
<tr>
<td>Number of patients potentially impacted</td>
<td>No impacted patients known/reported</td>
</tr>
</tbody>
</table>

### Action/Investigations taken

- To align internally to anticipate any procurement decisions.

### Next Steps

1. **Decision on procured batches manufactured from January 2022 to May 2022.**
   Quarantined stock of batches produced from January 2022 to May 2022 are to be released and distributed for use.

2. **Decision on procured batches manufactured from June 2022 to date.**
   Quarantined stock of batches produced from June 2022 to date are to be destroyed IMMEDIATELY and to be replaced by another Supplier.
   Note: All cost associated with the recall and replacement will be borne by Cupid Limited, India. (see attachment 2).
For PPM procurement only:
- Share with nalini@unfpa.org copying serwaa@unfpa.org:
  - the certificate of destruction of the batches listed in attachment 2.
  - evidence of induced costs associated with the recall and destruction.

For Non-PPM Procurement:
- To report to the Global Fund QA Team (see below email) the available stock of batches manufactured from June 2022 to date, that were quarantined.
- Share with Amelie.darmon@theglobalfund.org:
  - the certificate of destruction
  - evidence of induced costs associated with the recall and destruction.

3. Decision on new procurement
Based on the reviews performed, the Supplier is still to address some issues relating to overall quality of lubricant packed in sachets and tubes. Any new procurement to be halted until the manufacturer has been reactivated in UNFPA’s catalogue.

Contacts
Please direct the respective answers and any questions about this matter to the technical contact 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>Amélie Darmon, Quality Assurance Specialist</td>
<td><a href="mailto:Amelie.darmon@theglobalfund.org">Amelie.darmon@theglobalfund.org</a></td>
</tr>
<tr>
<td>UNFPA</td>
<td>Linda Serwaa, Head, Product Quality Assurance</td>
<td><a href="mailto:serwaa@unfpa.org">serwaa@unfpa.org</a></td>
</tr>
<tr>
<td>UNFPA</td>
<td>N Nalini, Product Quality Assurance</td>
<td><a href="mailto:nalini@unfpa.org">nalini@unfpa.org</a></td>
</tr>
</tbody>
</table>

Attachments:
1. UNFPA Product QA Team letter: Update to Quality alert relating to water-based personal lubricant manufactured by Cupid Limited, India
2. Cost Accountability letter for recall of water-based lubricants from Cupid – 3rd May 2023
To: All Stakeholders
Date: May 1st, 2023
Status: Update to Quality alert relating to water-based personal lubricant manufactured by Cupid Limited, A-68, M.I.D.C. (Malegaon), Sinnar, Nashik – 422113, Maharashtra, India.

Dear Client,

UNFPA would like to provide an update on the status of the quality alert investigation carried out for lubricant supplied by Cupid Limited. After issuing the ‘Quarantine notice’, independent testing has been performed for lubricant manufactured by Cupid Limited. Review of Corrective and preventive Actions (CAPAs), test results as well as stability studies data have also been undertaken. Outcomes of these reviews have resulted in the below.

UNFPA has concluded as follows:

1. Quarantined stock of batches produced from January 2022 to May 2022 are to be released and distributed for use.

2. Quarantined stock of batches produced from June 2022 to date are to be destroyed and replaced by another Supplier.

3. Based on the reviews performed, the Supplier is still to address some issues relating to overall quality of lubricant packed in sachets and tubes. Any new procurement to be halted until the manufacturer has been reactivated in the UNFPA catalogue.

The following actions are to be undertaken to facilitate the process of replacement of recalled batches.

**Actions:**

➢ All quarantine batches produced from June 2022 to date are to be destroyed IMMEDIATELY.

➢ Share the certificate of destruction with nalini@unfpa.org copying serwaa@unfpa.org.

➢ Share evidence of induced costs associated with the recall and destruction.

➢ UNFPA will engage with your office to facilitate the process of product replacement.

All affected batches (produced from June 2022 to date) will be replaced by another approved lubricant manufacturer. All cost associated with the recall and replacement would also be borne by Cupid Limited.

Please contact the UNFPA Product Quality Assurance Team at scmu.qa@unfpa.org if you need further clarification.

Thank you.

[Signature]

Linda Serwaa
Head, Product Quality Assurance
Date: May 03, 2023

United Nations Population Fund (UNFPA)
Supply Chain Management Unit
Marnovej 51, 2100 Copenhagen
Denmark

Sub: Cost Accountability for Recall of water-based lubricants manufactured by Cupid from June 2022 - till date

This serves to confirm that all cost related to the recall of water-based lubricants manufactured from June 2022 to till date listed in our Recall Notice dated 01st Feb 2023 will be on Cupid’s account. The following costs to support the recall process for attached Annexure 1 which would be on our account are as detailed below:

1. Transport / Logistics cost for the replacement’s batches from origin to destination warehouses which includes sea / air freight charges.
2. Import custom clearance costs for the replacement batches at destination / in-Country.
3. Destruction of unused lubricant batches in sachets / tubes at destination warehouses and the logistics to move the batches to be destroyed as designated by local authorities in respective countries.
4. Recalled batches of lubricants in sachets / tubes to be destroyed and replaced by an appointed supplier(s) by UNFPA and Cupid to reimburse UNFPA or supplier for the replacements.

Thank you for your kind attention.

Signature

Durgesh Garg
Chief Operating Officer
Cupid Limited
### Annexure 1

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>PO Number</th>
<th>Country</th>
<th>No. of batches</th>
<th>Batch Numbers</th>
<th>Mfg</th>
<th>Exp</th>
<th>QTY</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>47438</td>
<td>CUBA</td>
<td>1</td>
<td>LBF2201</td>
<td>2022-06</td>
<td>2025-05</td>
<td>10000</td>
<td>4ml</td>
</tr>
<tr>
<td>2</td>
<td>47253</td>
<td>El Salvador</td>
<td>19</td>
<td>LBF2202-LBF2220</td>
<td>2022-06</td>
<td>2025-05</td>
<td>440000</td>
<td>4ml</td>
</tr>
<tr>
<td>3</td>
<td>47612</td>
<td>BELIZE</td>
<td>1</td>
<td>LBF2222</td>
<td>2022-06</td>
<td>2025-05</td>
<td>225000</td>
<td>4ml</td>
</tr>
<tr>
<td>4</td>
<td>47432</td>
<td>SURINAME</td>
<td>3</td>
<td>LBF2223-LBF2225</td>
<td>2022-06</td>
<td>2025-05</td>
<td>255000</td>
<td>10ml</td>
</tr>
<tr>
<td>5</td>
<td>47556</td>
<td>Cuba</td>
<td>5</td>
<td>LBF2227-LBF2231</td>
<td>2022-06</td>
<td>2025-05</td>
<td>103200</td>
<td>4ml</td>
</tr>
<tr>
<td>6</td>
<td>47695</td>
<td>Kazakhstan</td>
<td>9</td>
<td>LBG2208-LBG2216</td>
<td>2022-07</td>
<td>2025-06</td>
<td>179800</td>
<td>4.3ml</td>
</tr>
<tr>
<td>7</td>
<td>48265</td>
<td>Kyrgyzstan</td>
<td>6</td>
<td>LBI2201-LBI2206</td>
<td>2022-09</td>
<td>2025-08</td>
<td>150000</td>
<td>20ML</td>
</tr>
<tr>
<td>8</td>
<td>48817</td>
<td>Honduras</td>
<td>5</td>
<td>LBJ2201-LBJ2205</td>
<td>2022-10</td>
<td>2025-09</td>
<td>389000</td>
<td>10ml</td>
</tr>
<tr>
<td>9</td>
<td>48834</td>
<td>Comoros</td>
<td>1</td>
<td>LBJJ2206</td>
<td>2022-10</td>
<td>2025-09</td>
<td>150000</td>
<td>5ml</td>
</tr>
<tr>
<td>10</td>
<td>49172</td>
<td>Mauritania</td>
<td>7</td>
<td>LBK2208-LBK2214</td>
<td>2022-11</td>
<td>2025-10</td>
<td>151700</td>
<td>4.3ml</td>
</tr>
<tr>
<td>11</td>
<td>49728</td>
<td>Sao Tome</td>
<td>1</td>
<td>LBL22121</td>
<td>2022-12</td>
<td>2025-11</td>
<td>4000</td>
<td>5ml</td>
</tr>
</tbody>
</table>