QA Information Notice for Health Products

IN Nº 2023-02 Version - June 30, 2025	**Decision update on the procurement of water-based lubricants (sachets and tubes) manufactured by Cupid Ltd., India.**

IN Nº 2023-02 dated June 30, 2025 supersedes IN Nº 2023-02 published on May 11, 2023

Addressees

- Through Health Product Management (HPM) Specialists, all Principal Recipients (PR) reporting procurement of the affected products financed by the Global Fund.
- All procurers, buyers reporting procurement of the affected product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this updated QA Information Notice to provide information regarding the water-based lubricants (sachets and tubes) supplied by Cupid Ltd., India in the UNFPA catalogue. The procurement of lubricants from the manufacturer had been suspended since February 2023 pending effective confirmation of the instituted corrective actions by UNFPA Quality Assurance Team.

This QA Information Notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer(s)	Cupid Ltd. - 68, MIDC, MIDC Area, Malegaon, Maharashtra 422113, India
Commercial / Brand Name(s)	Cupid water-based lubricant
Packaging & Pack size & Type (catalogue number/reference number – “REF”)	Sachets: - 4ml (REF Lub-S4); - 4.3ml (REF Lub-S4.33); - 5ml (REF Lub-S5); - 10ml (REF Lub-S10); Multidose: - 20g (REF Lub-T20) - 35g (REF Lub-T30) - 118g (REF Lub-T118)

Batch(es)	Batches manufactured between June 1, 2022 and February 04, 2025
Expiry Date	Unknown

Background

In December 2022, the UNFPA Quality Assurance (QA) Team identified from the product surveillance test results that three lots of lubricants supplied by Cupid Ltd. have exceeded the total specified aerobic microbial count. Subsequently, quality complaints with similar findings were received from several UNFPA stakeholders. Independent testing of selected lots of lubricants by an ISO 17025 accredited laboratory was commissioned by UNFPA and confirmed the contamination.

The Global Fund issued QA IN (ref. IN 2023-02) on February 9, 2023, recommending the suspension of all procurement of lubricants (sachets and tubes) from the manufacturer, stopping the distribution of the impacted batches and quarantining of the remaining stocks within the regional/ central warehouses. An updated QA IN was issued on May 11, 2023 (Version 3), where quarantined stocks of batches produced from January 2022 to May 2022 were released for distribution for use, while batches manufactured after June 1, 2022 were requested to be destroyed immediately, with the suspension of all procurement of lubricants (sachets and tubes) from the manufacturer remaining effective.

As communicated by UNFPA to the Global Fund, UNFPA initiated an investigation and an onsite inspection in September 2023 to identify the most probable cause of the issue. As part of the investigation, Cupid Ltd. proposed a corrective action plan involving a formulation change to enhance lubricant preservation. Samples from four lots of products with the changed formulation were collected during the inspection and tested by the UNFPA appointed accredited laboratory, which confirmed conformity with specifications. An additional stress test was conducted by an external accredited laboratory to benchmark accelerated and real time stability studies on the products with the changed formulation provided by the manufacturer. Furthermore, according to UNFPA the manufacturer has satisfactorily addressed all the inspection findings. The UNFPA QA team recommended in February 2025 the reactivation of the water-based lubricant with changed formulation in sachets and tubes manufactured or released by Cupid Ltd., India in the UNFPA catalogue for procurement.

Nature of defect(s)

Details of defect or problem.	*Out of specification of the total aerobic microbial count for the products*
Is there any evidence or suspicion of a risk to public health?	The defect may increase the risk for the end-user to develop a bacterial infection
Extent of the problem (eg. No. of batches).	Batches manufactured between June 1, 2022 and February 04, 2025 included
Extent of distribution of the product / batch (es).	Worldwide distribution is anticipated
Number of users and / or patients potentially impacted	Unknown

Other products potentially impacted	None

Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance and Compliance Team:

Quarantine and destroy immediately stock of batches manufactured between June 1, 2022 to February 04, 2024 with the below supplier reference numbers.

Sachets:

- 4ml (REF Lub-S4)
- 4.3ml (REF Lub-S4.33)
- 5ml (REF Lub-S5)
- 10ml (REF Lub-S10)

Multidose:

- 20g (REF Lub-T20)
- 35g (REF Lub-T30)
- 118g (REF Lub-T118)

For new procurements, only the following water-based lubricant with changed formulation and supplier reference number in sachets and tubes manufactured by Cupid Ltd., India from February 05, 2025, can be considered:

Sachets:

- 4ml (REF Lub2-S4-P1000)
- 4.3ml (REF Lub2-S4.33-P1000)
- 5ml (REF Lub2-S5-P1000)
- 10ml (REF Lub2-S10-P1000)

Multidose:

- 20g (REF Lub2-T20-P100)
- 35g (REF Lub2-T30-P50)
- 118g (REF Lub2-T118-P25)

Users and /or Patients

Users and / or patients who have experienced any adverse reaction or quality problems with the use of the product shall report this to the relevant Regulatory Authorities, manufacturer and the Global Fund Health Product Management Specialist.

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the potentially affected products have been transferred. Please maintain awareness of this QA Information Notice and resulting action(s) for an appropriate period to ensure effectiveness of the recommendations.

Validity

The QA Information Notice is valid from the date of publication on the Global Fund Information Notice webpage https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice/ until it is either removed or superseded.

Contacts

This QA Information Notice does **not** require a specific written response from PR, procurers or buyers. PR, procurers or buyers should copy the Global Fund's Quality Assurance and Compliance Team on any correspondence regarding the matter for follow-up.

Please direct the respective questions about this matter to the technical contact listed below.

Organization	**Name / Function**	**E-mail address**
Global Fund	Your respective Country Team/ HPM specialist for the portfolio	County Team / HPM Specialist Email
Global Fund	Product & Supplier Quality Assurance Compliance Team Member	HealthProductQualityAssurance@theglobalfund.org