TheGlobalFund

Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2021-01 **Version: 07/04/2022**	**Reinstatement of lubricating gel supplied by Karex Industries Sdn Bhd in the UNFPA catalogue for procurement**

Addressees

- Any person having products in stock,
- Any procurers, buyers

Purpose

The GF QA is issuing this information notice to provide updated information regarding the reinstatement of lubricating gel supplied by Karex Industries Sdn. Bhd. in the UNFPA catalogue.

Identification of the product(s) and manufacturer

Name of Manufacturer	**Karex Industries Sdn Bhd**
Commercial Name(s)	**All**
Packaging & Pack size & Type	**All**
Batch(es)	**N/A**
Manufacturing Date	**N/A**

Background

In May 2019, The Quality Assurance (QA) Team received a quality complaint from The Global Fund (TGF) regarding 1 batch of personal lubricants in sachets to Togo. The complaint was investigated and resolved with a replacement of the batch. In March 2020, TGF issued a complaint for additional 30 batches manufactured by Karex Industries Sdn Bhd in July 2018. In both cases the main complaint was that the lubricants were too runny compared to the previous ones that were supplied by UNFPA.

Immediately after receiving the second complaint, UNFPA initiated another investigation to identify the most probable root cause. As part of the investigation, all relevant stakeholders (complainant, UNFPA, manufacturer) agreed to independent testing of the failed batches. 16 batches out of the 30 batches of the lubricants were tested at an independent testing laboratory because 14 batches had expired. Test results showed significant drop in viscosity of the personal lubricants.

Consequently, and in the interest of public health, UNFPA temporarily suspended the manufacturer from supplying personal lubricants until investigation is completed. After issuing the 'Quality information notice, independent testing has been performed for lubricants manufactured by Karex

Industries Sdn Bhd in 2020. Review of Corrective and preventive Actions (CAPAs) as well as stability studies data have also been undertaken.

After the resolution of the complaint, the supplier modified the formulation of their lubricating gel. The stability of the new formulation has been technically assessed and found acceptable for procurement. Based on the review, the UNFPA QA team has approved for the Supplier's lubricating gel to be reactivated in the UNFPA catalogue for procurement.

Nature of defect(s)

Details of defect or problem.	**N/A**
Is there any evidence or suspicion of a risk to public health?	**N/A**
Extent of the problem (eg. No.of batches, date manufactured).	**N/A**
Extent of distribution of the product / batch (es).	**N/A**
Number of patients potentially impacted	**N/A**

Action/Investigations taken

- N/A

Next Steps

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

- To resume procurement of lubricant gel while maintaining current practices on registration and reporting of any adverse event/reaction or quality issue.

Contacts

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 contact listed below

Organisation	**Name / Function**	**E-mail address**
Global Fund	Alain Prat, QA Specialist	Alain.Prat@theglobalfund.org
UNFPA	Linda Serwaa, QA Specialist	serwaa@unfpa.org