

Quality Assurance (QA) for Health Products

QA Information Notice

IN N° 2018-07 Version: 16/01/2019	Suspension of Dongkuk Viet Nam Co., Ltd. from the WHO/UNFPA list of prequalified male latex condom manufacturer
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Addressees

- 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 information that was transmitted by United Population Fund (UNFPA) regarding the suspension of a manufacturer of male latex condom from the WHO/UNFPA list of prequalified manufacturers.

Identification of the product(s) and manufacturer

Name of Manufacturer	Dongkuk Viet Nam Co., Ltd. No.10, Thuy Van Industrial Zone, Viet Tri city, Phu Tho Province, Viet Nam
Commercial Name(s)	All
Packaging & Pack size & Type	All (Size, Texture, Flavour , Color)
Batch(es)	All
Manufacturing Date	All

Background

UNFPA received information that some batches of male latex condoms manufactured by **Dongkuk Viet Nam Co., Ltd. No.10, Thuy Van Industrial Zone, Viet Tri city, Phu Tho Province (Viet Nam)** failed to meet the expected quality criteria. The information includes a test performed by an independent testing laboratory accredited. Results show a major issue with the condoms failing a critical performance parameter from holes' and burst properties test.

Consequently, and in the interest of public health, UNFPA has suspended the manufacturer from the WHO/UNFPA list of prequalified manufacturers of male latex condom until further notice.

Nature of defect(s)

Details of defect or problem.	Failures of the holes' and burst properties test.
Is there any evidence or suspicion of a	The failure may increase the probability of sexually

risk to public health?	transmitted infection (STIs) including HIV.
Extent of the problem (eg. nb batches).	Initially for the batches manufactured during the period of December 2015 and May 2016. While waiting for outcomes of the investigations, extended to All
Extent of distribution of the product / batch (es).	Bangladesh, Burkina-Faso, DRC, Georgia, Gambia, Guatemala, Malawi, Nicaragua, Nepal, Philippines, Togo and Uganda (based on current data) Worldwide distribution is anticipated
Number of patients potentially impacted	No impacted patients known/reported

Action/Investigations taken

- Procurement agencies have been informed directly by UNFPA on its decision regarding this manufacturer

Next Steps

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

- To suspend all procurement from this manufacturer
- To stop further distribution of the products within the supply chain
- To quarantine the remaining stock of the impacted batches at regional and central level.
- To put under quarantine the impacted batches at port of entry and in transit
- To report to the manufacturer/procurers the available stock that was quarantined, referencing the UNFPA Quality Alert

Contacts

This IN does 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 contact listed below

Organisation	Name / Function	E-mail address
Global Fund	Alain Prat, QA Specialist	Alain.Prat@theglobalfund.org

Attachement:

- QUALITY ALERT- Male Latex Condom manufacturer – Dongkuk Vietnam Co. Ltd



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To: All Stakeholders

From: WHO/UNFPA Prequalification of Male Condoms

Date: 11 December 2018

Ref: **QUALITY ALERT- Male Latex Condom manufacturer – Dongkuk Vietnam Co. Ltd**

Dear Stakeholders

UNFPA manages the Prequalification of condoms on behalf of the UN agencies. Prequalification is a procedure designed to assess the capability of a manufacturer to supply a quality product before a contract is awarded. Prequalification reduces the risk of awarding a contract to a manufacturer that is unable to meet the quality requirements defined in the WHO/UNFPA Specification. The purpose of prequalification is to protect both the buyer and the end user. Therefore, UNFPA continually monitors the quality of the condoms produced by the prequalified as well as the production of the condoms.

UNFPA received information that some batches manufactured at Dongkuk Vietnam Co. Ltd failed to meet the expected quality criteria. The information includes a test report from an independent laboratory for the mentioned batches. The independent testing laboratory is accredited for ISO 4074 test methods. Results show a major issue with the condoms failing the freedom from holes' and burst properties test. The batches were manufactured during the period of December 2015 and May 2016. The most probable cause of the failures are: weak stability studies and weak batch-to-batch homogeneity. UNFPA has launched a full investigation of the failures which will involve re-inspection of Dongkuk Vietnam Co. Ltd's premises. The manufacturer has been in communication with UNFPA and is cooperating fully with the investigation.

In the interest of public health, UNFPA has suspended the male latex condom manufacturer, Dongkuk Viet Nam Co., Ltd. No.10, Thuy Van Industrial Zone, Viet Tri city, Phu Tho Province, Viet Nam., from the WHO/UNFPA list of prequalified male latex condom manufacturers until further notice. The suspension is effective from as of the 11th December 2018.

To mitigate potential risks associated with the procurement of male condoms from Dongkuk, Vietnam's above mentioned site, procurement agencies are advised on the position of UNFPA when procuring the condoms manufactured from this site while the investigation is on-going. Once the investigation is complete UNFPA will communicate with all the relevant stakeholders.

As a precautionary step, stakeholders are advised to do a risk assessment of the condoms that were produced in the period of December 2015 to May 2016 and



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implement risk mitigation steps such as higher level of sample size for the performance parameters of the condoms.

In the meantime, the manufacturer has been requested to provide a root cause analysis, corrective and preventative actions within 30 days of the date of this letter.

Should you require any clarification please contact us at
psb.prequalification@unfpa.org.

Thank you,

A handwritten signature in blue ink, appearing to read 'Seloi Mogatle', is written over a light green rectangular stamp. The stamp contains the text 'This document is only valid for use by UNFPA documents' in a small, black, sans-serif font.

This document is only valid
for use by UNFPA documents

Seloi Mogatle
Technical Specialist