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To: All Stakeholders
From: WHO/UNFPA Prequalification of Male Condoms
Date: March 15, 2019
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 Prequalification Team 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 Prequalification Team 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 Prequalification Team 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 Prequalification Team when procuring the condoms manufactured from this site while the investigation is on-going. Once the investigation is complete UNFPA Prequalification Team 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 implement risk mitigation steps such as higher level of sample size for the performance parameters of the condoms. In principle the following actions will be taken:

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,



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for use in official UN documents

Seloi Mogatle
Technical Specialist