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To: All Stakeholders
From: Procurement Services Branch, United Nations Population Fund
Date: August 8, 2017
Ref: **QUALITY ALERT- Male Latex Condom manufacturer – HLL Lifecare Peroorkada**

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 prequalified manufacturers as well as the production of the condoms.

UNFPA recently received information that some batches of male latex condoms manufactured at **HLL Lifecare Limited Peroorkada** 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 a critical performance parameter, the freedom from holes test. The batches were manufactured May 2015.

The cause of the failures is currently unknown. UNFPA has launched a full investigation of the failures. The manufacturer, and the procurer have been in communication with UNFPA and are cooperating fully with the investigation.

In the interest of public health, UNFPA has suspended the male latex condom manufacturer, **HLL Lifecare Limited, Peroorkada, Thiruvananthapuram – 695 005, Kerala, India**, from the WHO/UNFPA list of prequalified male latex condom manufacturers until further notice. The suspension is effective as of the 17th of July 2017.

To mitigate potential risks associated with the procurement of male condoms from HLL'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 around May 2015 and implement risk mitigation steps such as higher level of sample size for the performance parameters of the condoms.

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

Thank you,

A handwritten signature in blue ink, appearing to read 'Seloi Mogatle', is written over a horizontal line.

Seloi Mogatle
Technical Specialist