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To: MHL Healthcare Ltd, India

Date: January 31, 2020

Ref: **Notice of Suspension from the WHO/UNFPA Prequalification Programme for male latex condoms – MHL Healthcare Ltd**

Dear Puneet Manocha

As notified in our letter of the 23rd of December, 2019, there have been some quality complaints against male latex condoms manufactured in March and April 2019 by MHL Healthcare Ltd, and distributed to Uganda. As a result, MHL Healthcare Ltd, 3rd Km. Budhana Road, MuzaffarNagar - 251002 (U.P.), India, has been suspended from the list of prequalified manufacturers. The condoms concerned were tested by an ISO 17025 accredited laboratory, and failed to meet the performance requirements specified in ISO 4074:2015. The test reports show non-conformances recorded for airburst and freedom from holes test parameters. UNFPA has initiated an investigation on the possible causes for these non-conformances Additionally, MHL Healthcare has ongoing CAPA to address the failure of Lot no.17120103, recorded at prequalification product testing.

The results reviewed on the six lots that failed, two further lots manufactured at the same time and three lots manufactured in December 2017 that were subjected to prequalification testing, indicate that the quality of condoms manufactured by MHL Healthcare are of marginal quality with respect to both burst properties and freedom from holes. This conclusion is based on results from independent ISO 17025 accredited laboratories that undertook pre-shipment, prequalification and referee testing. It would only take a small deterioration in condom quality during storage and/or shipment or minor differences in test procedures and/or equipment calibration to cause lots that had previously been accepted at pre-shipment testing to fail when retested in - country.

Results that have been submitted for product tested after a reported change in the manufacturing process are encouraging but more data from longer term running on plant and stability studies are required to confirm this. Suspension of the prequalification status will remain effective until the relevant data has been provided. The manufacturer's full cooperation with UNFPA on the investigation is appreciated.

The Notice of suspension will remain on the UNFPA website until this issue is resolved to give notice to all stakeholders who consider the outcomes of WHO/UNFPA Prequalification Programmes in their procurement and regulatory procedures.

Please do not hesitate to contact us at psb.prequalification@unfpa.org for any clarifications.

Thank you,

Seloi Mogatle
Technical Specialist