# Review of significant changes by condom manufacturers 2023

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# Introduction

Condom or IUD manufacturers prequalified by UNFPA are judged essentially at the time the PQ inspection was carried out.

However, changes will often take place at the company in the period following the PQ inspection.

These changes can take place for several reasons, for example:

## Some of the reasons for change

Continuous improvement (as required by ISO 13485 clause 8.5.1 and ISO 9001 clause 10.3).

Certifications expiring and needing renewal.

New equipment being installed & validated.

Formulation and process being changed.

Changes in raw materials (cost saving? Product improvement?).

## Other reasons for change

Customer complaints

Changes in senior management.

Changes in regulatory requirements.

Changes in site of manufacture.

And many more.

# Possible effect and evaluation of changes

These changes may well have an effect on product quality - sometimes deliberately, sometimes inadvertently; sometimes obvious, often less obvious.

For this reason, UNFPA demands that any PQ manufacturer reports any change for evaluation, together with the rationale for the change and supporting data.

The data are recorded on a template and passed to UNFPA experts for assessment and report.

## Changes reported during 2023

Changes from 31 companies were evaluated, 26 condom companies and 5 IUD manufacturers.

For 13 companies the changes were accepted.

Changes from 4 companies were accepted conditionally.

8 companies reported no changes.

Changes from 6 companies were not accepted because of lack of adequate supporting evidence.

# Follow-up actions

Generally supporting information from accepted changes will be verified at the next PQ inspection.

Where the changes have not been accepted, the additional data will be reviewed by UNFPA experts and a decision made to recommend acceptance or not.

THANK YOU FOR YOUR ATTENTION!