





Common Quality Issues - complaints and recalls

Day 3 – Session 10

29th November 2023

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Complaints and Recalls







Agenda

Quality Complaint Handling

Process Flow

Contraceptives

- Complaints Trend
- Cause and Effect Diagram
- Challenges and Mitigation Actions

Pharmaceutical and Medical Devices

Complaints Trend and Mitigation Actions

Recall

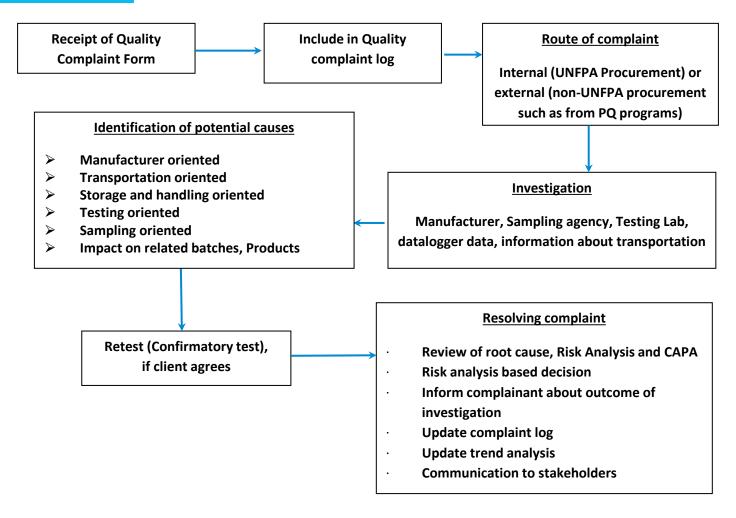
- Process Flow
- 2023 Recall







Process Flow

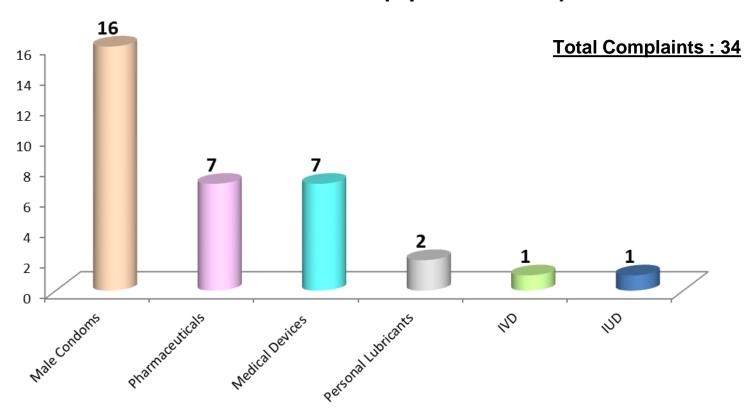








No. of Customer Complaints Productwise From 2019 to 2023 (Upto Nov 2023)

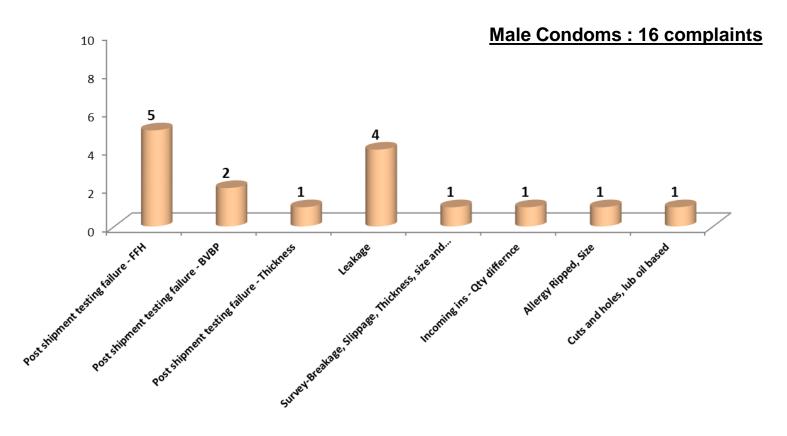








Number of complaints - Nature of complaintwise From 2019 to 2023 (Upto Nov 2023)



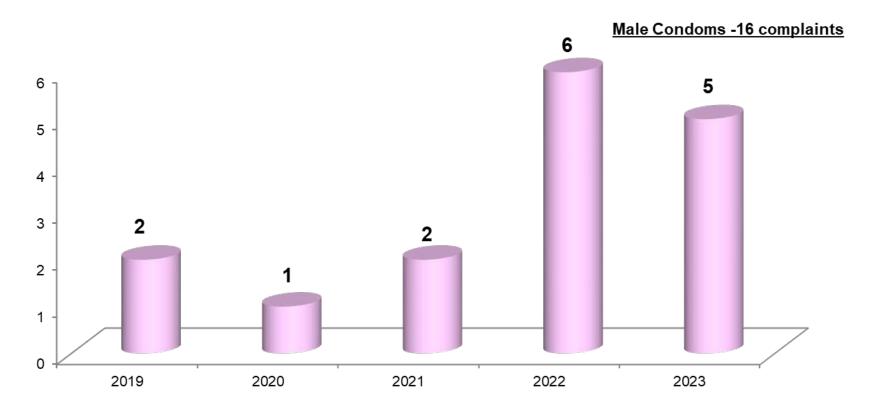






Number of Complaints - Yearwise

From 2019 to 2023 (Upto Nov'23)

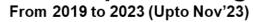


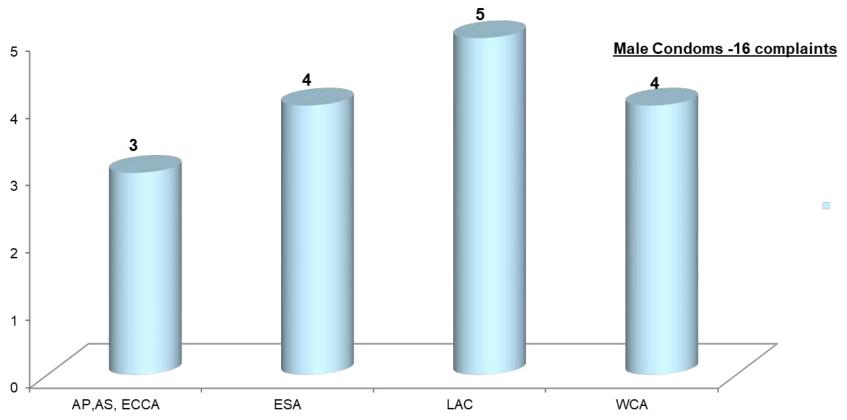






Number of complaints -Regionwise



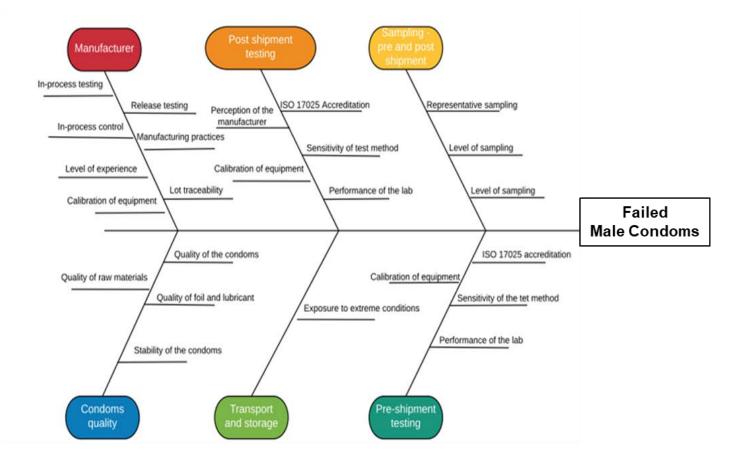








Causes and Effect Diagram









<u>Challenges – Male Condom Complaints</u>

Post Shipment Testing

Clients not aligned Clients resist to accept confirmatory test results

Post Shipment Receiving inspection



Mitigation Actions

Capacity building / development activities

In-house trend analysis of manufacturers

Mitigation Actions

Planning to include Dry Vacuum test in PST







Pharmaceuticals:

(From 2019 to 2023 (Upto Nov'23)

4 complaints out of 7 complaints were reported in the years 2020 and 2021, related to temperature deviation.

Mitigation Action:

Introduced the temperature monitoring programme (TTSHP) in September 2021 for RH product procurement.







Medical Devices:

(From 2019 to 2023 (Upto Nov'23)

Majority of the medical device complaints out of 7 complaints were related to "products not meeting specifications".

Mitigation Action:

- Manufacturers must supply medical devices in compliance with the UNFPA catalogue specifications.
- Emphasised inspection agencies to report all deviations from catalogue specification during preshipment inspections.

Joint Meeting 27 November – 1 December 2023







Process Flow

Recall initiated through

- > UNFPA quality complaints
- Voluntary Recall by manufacturer

Perform Risk assessment

Alert notice to affected POs along with Suppliers recall notice, QA instructions, Reconciliation sheet (within 2 days)

Replacement of recalled batches

- Cost accountability letter from Manufacturer
- Notice of replacement of recalled products to all affected parties
- Destruction of recalled products
- Replacement of products-SST and Finance
- Communication to stakeholders

Recall Status Reporting

- Manufacturer Investigation report, CAPA
- SCMU QA Review
- QA recommendations
- Replacement of the recalled batches or reimbursement of cost associated with recalled products
- Communication to stakeholders

Follow up with stakeholders of affected POs

Personal Lubricant Recall - 2023















Thank you

Any questions?