

# Common Quality Issues - complaints and recalls

Day 3 – Session 10

29<sup>th</sup> November 2023

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## Agenda

### ➤ Quality Complaint Handling

- Process Flow

#### Contraceptives

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

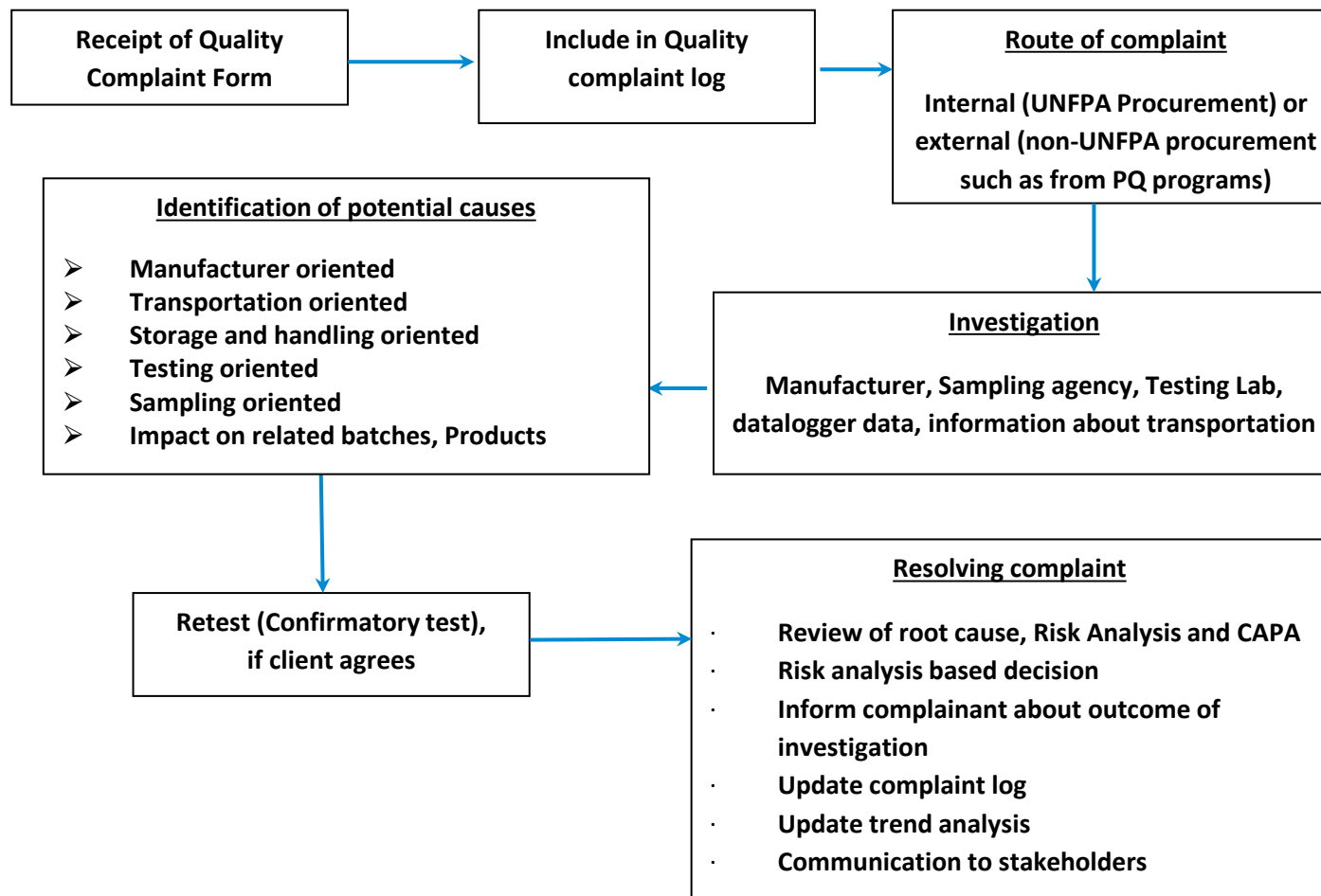
#### Pharmaceutical and Medical Devices

- Complaints Trend and Mitigation Actions

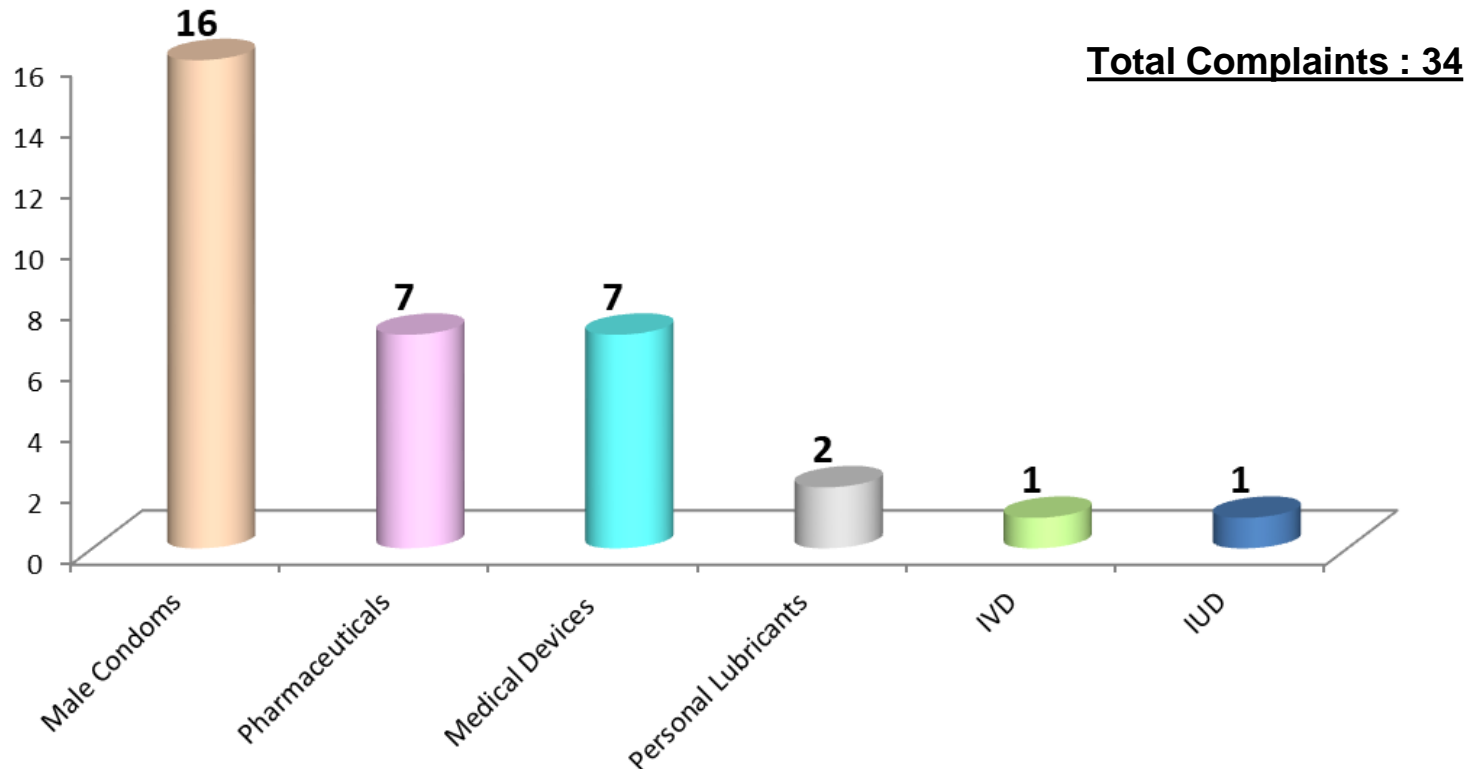
### ➤ Recall

- Process Flow
- 2023 Recall

## Process Flow

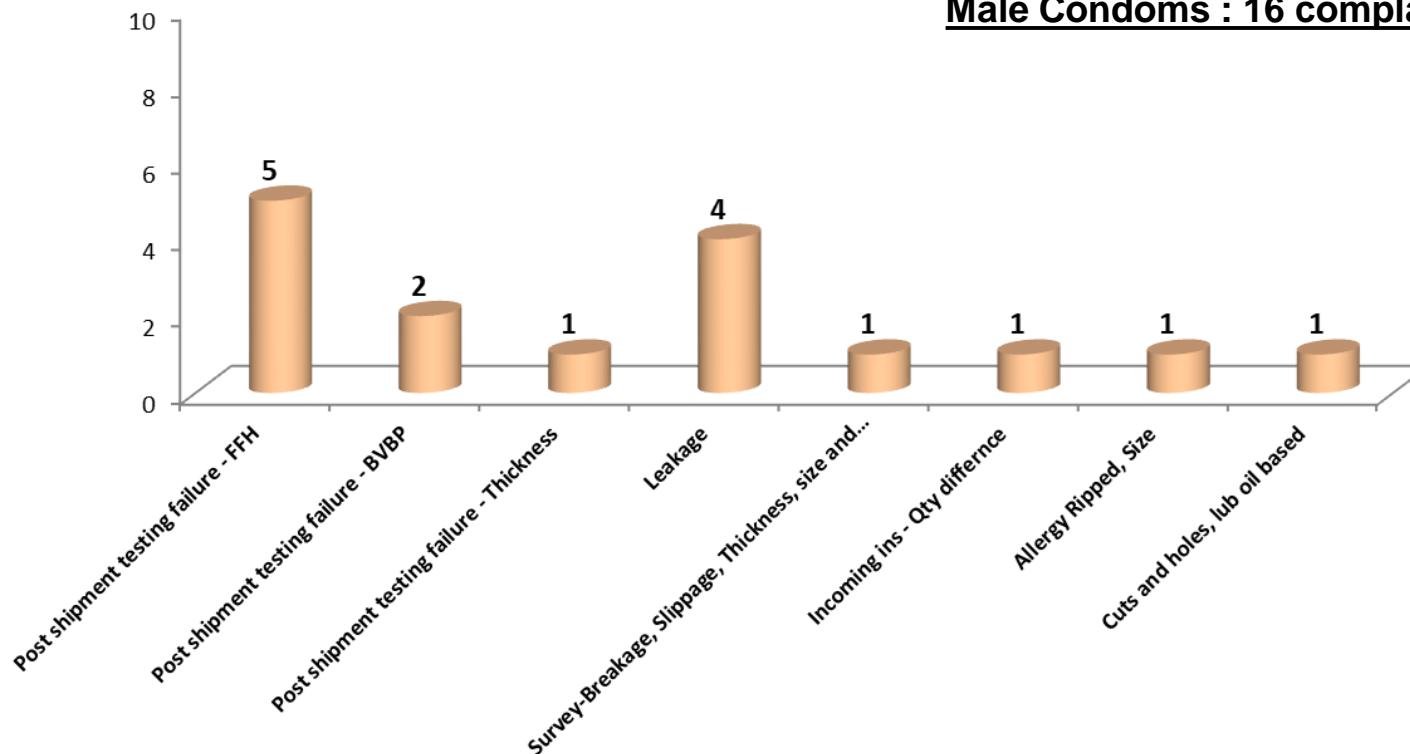


## No. of Customer Complaints Productwise From 2019 to 2023 (Upto Nov 2023)

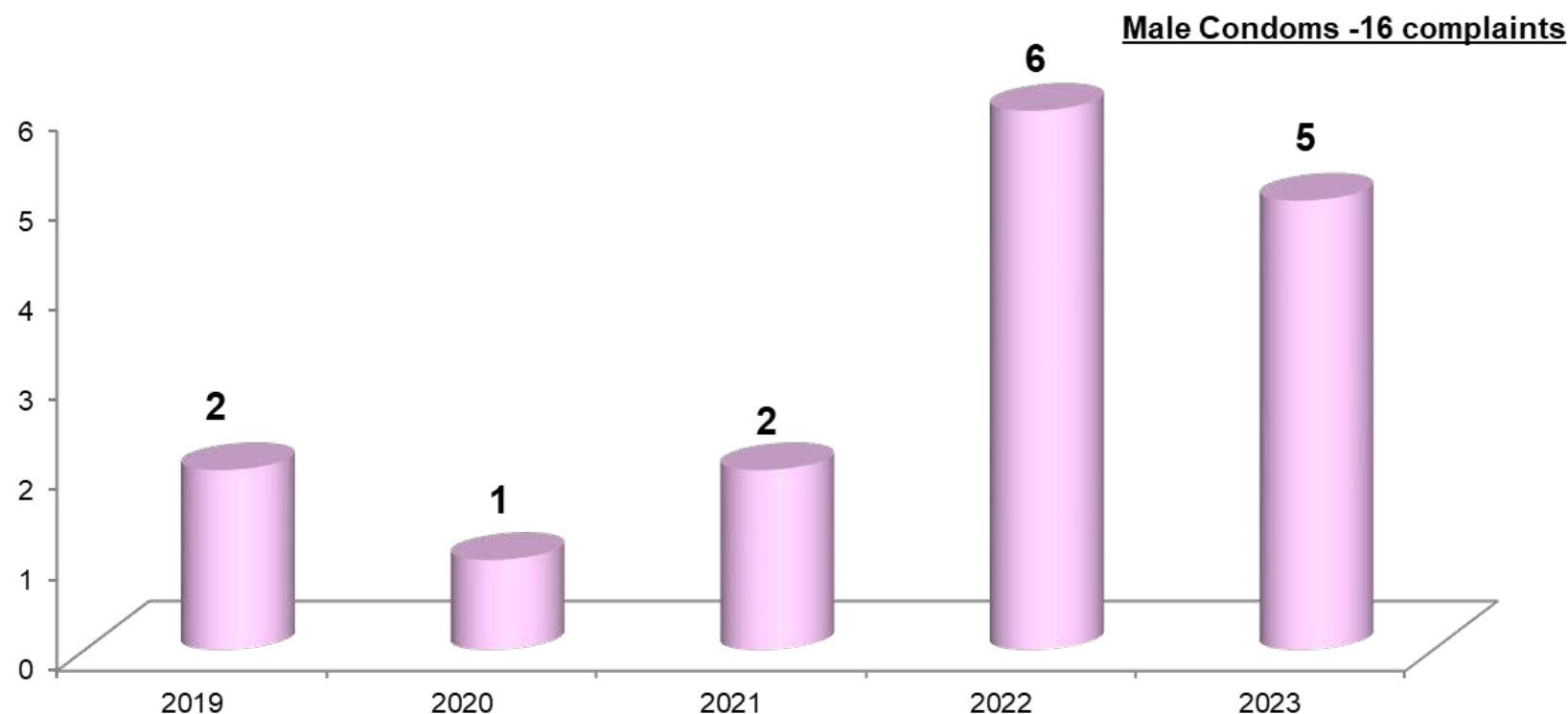


## Number of complaints - Nature of complaintwise From 2019 to 2023 (Upto Nov 2023)

Male Condoms : 16 complaints

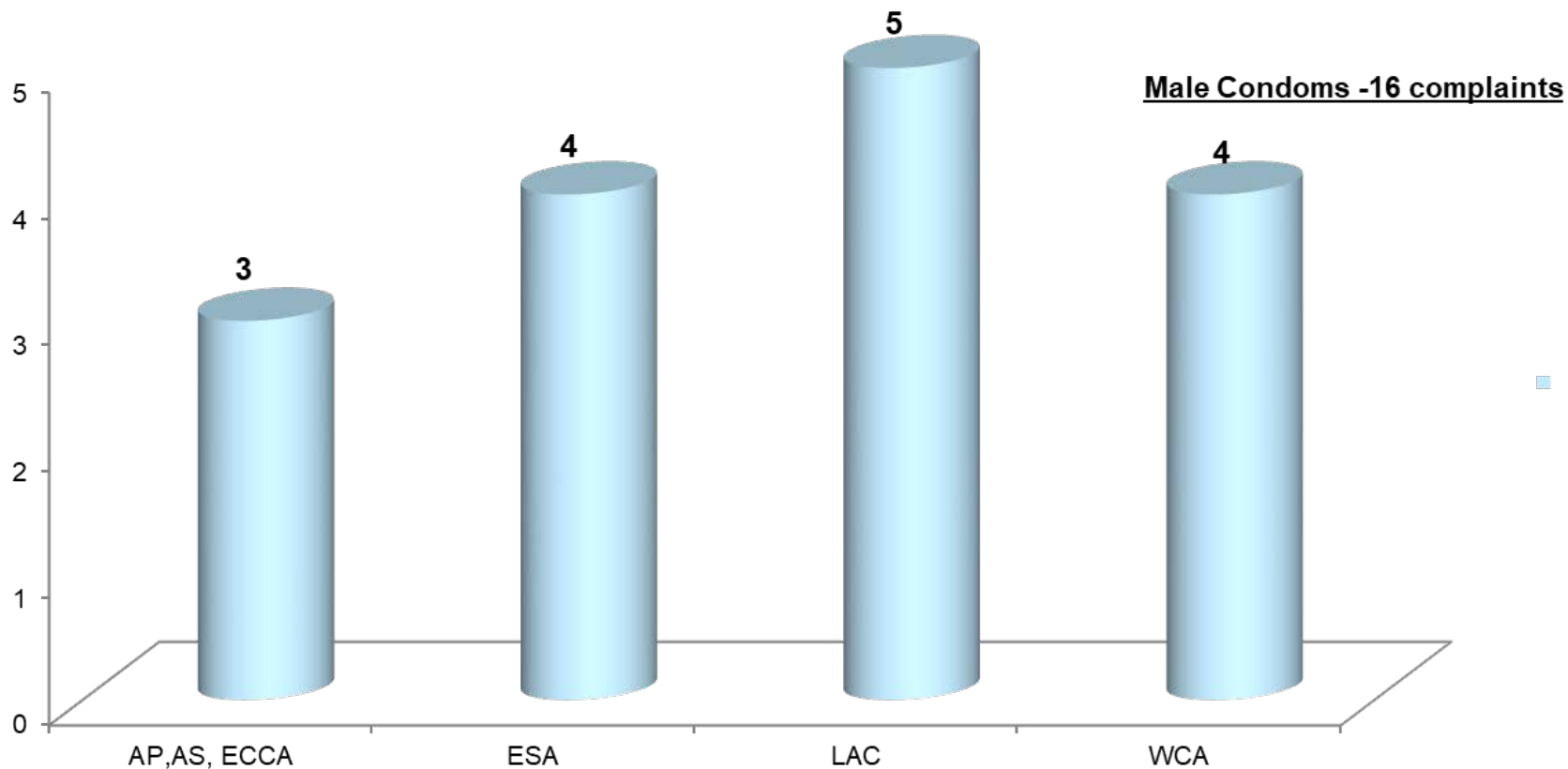


## Number of Complaints - Yearwise From 2019 to 2023 (Upto Nov'23)

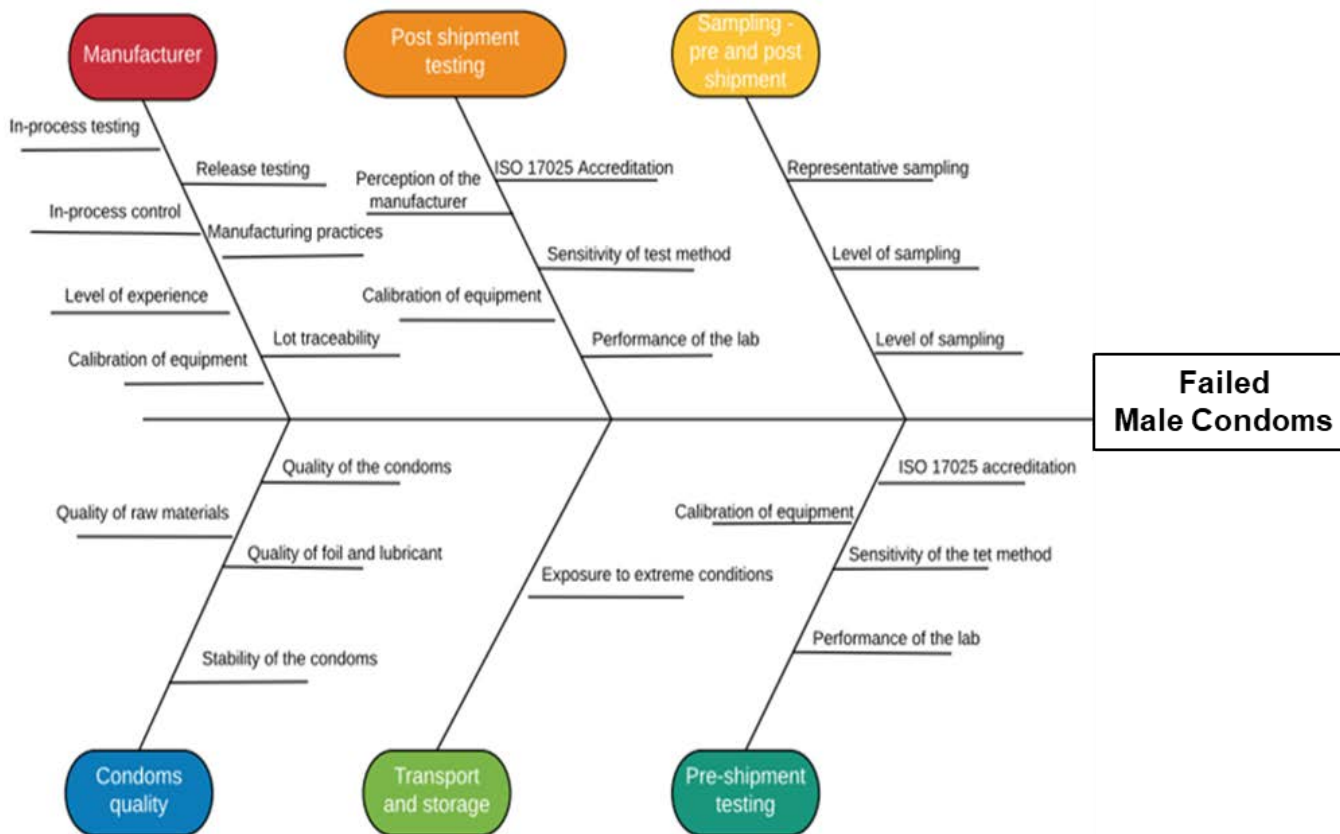


## Number of complaints -Regionwise

From 2019 to 2023 (Upto Nov'23)



## Causes and Effect Diagram





## Challenges – Male Condom Complaints

### Post Shipment Testing

Clients  
not  
aligned

Clients resist  
to accept  
confirmatory  
test results

### Post Shipment Receiving inspection

Leakage

### 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 :

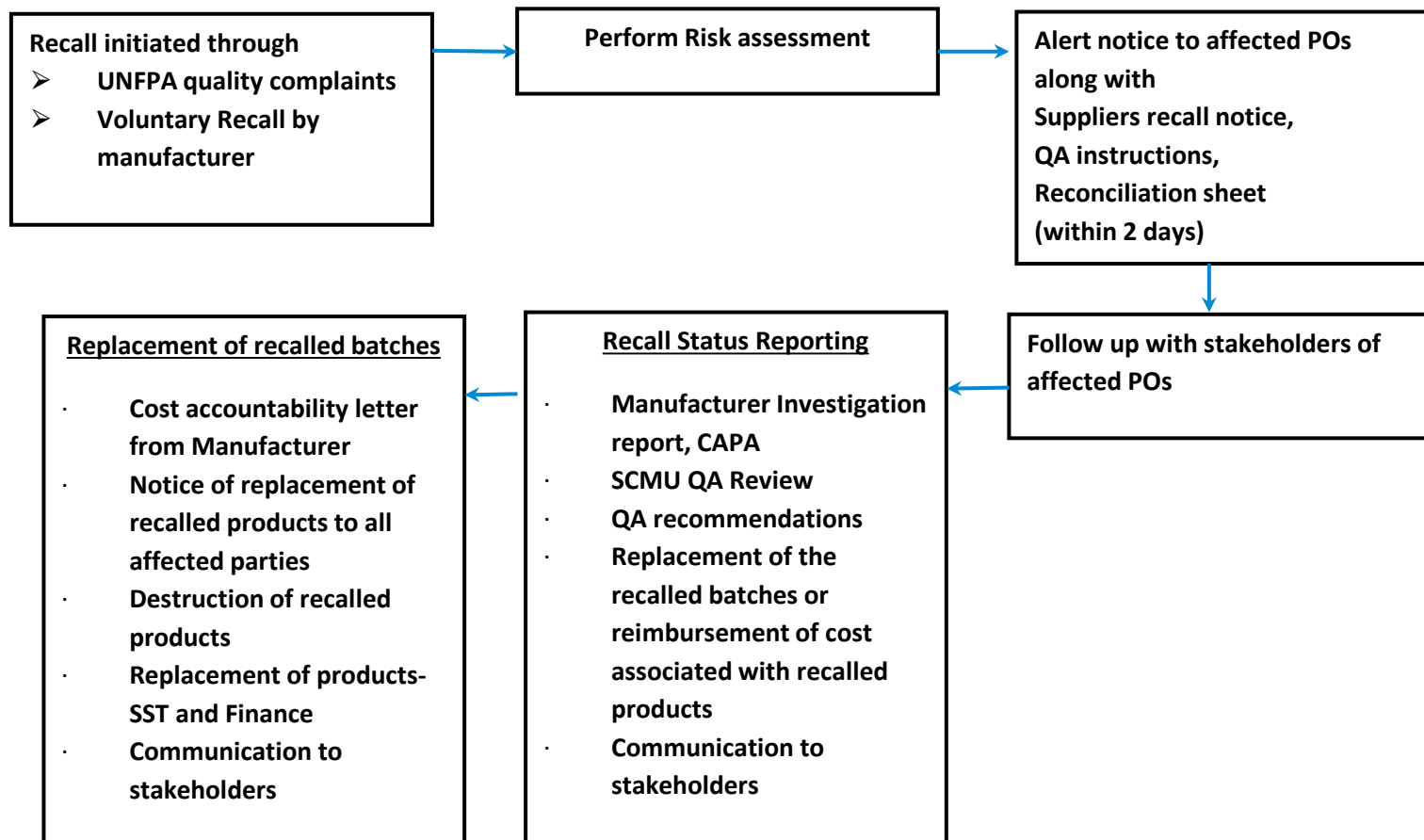
(From 2019 to 2023 (Upto Nov'23))

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

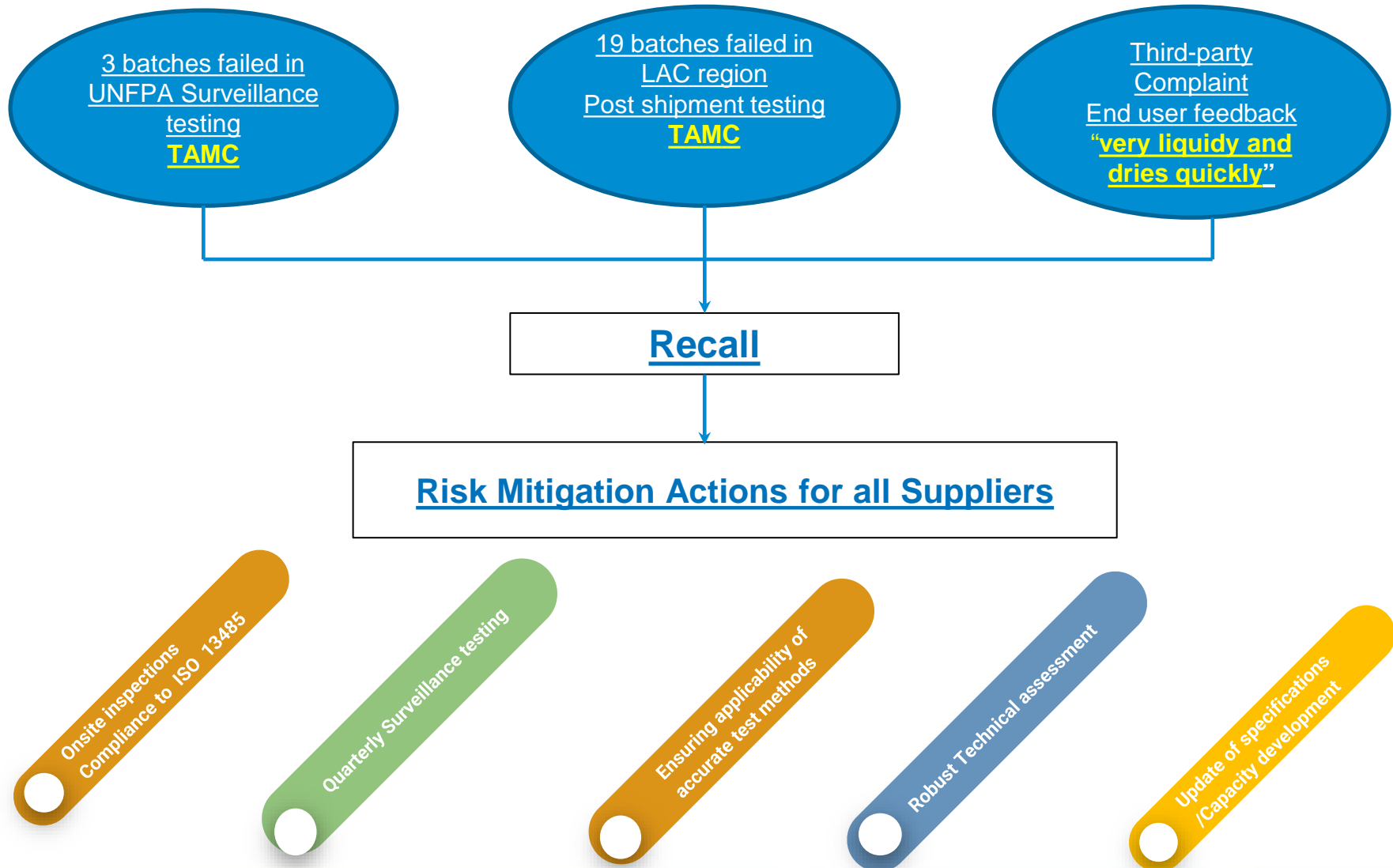
### Mitigation Action :

- 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.

## Process Flow



# Personal Lubricant Recall - 2023



**Thank you**

**Any questions?**