





Review of quality complaints

Mr. David Hill **UNFPA Technical Experts**







Introduction

As part of the prequalification programme, every year UNFPA request details of customer complaints from prequalified suppliers.

This presentation will give an overview of customer complaints for male and female condoms during 2021 and 2022







Methodology

Prequalified male and female condom manufacturers submit details of their customer complaints annually to UNFPA.

These are reviewed by UNFPA consultants.

The type of complaint (as logged by the manufacturer), and any corrective actions are reported.

Following review a recommendation to accept (sometimes with verification requested) or a request for more information is made.







Potential Problems

Problems are as reported by the customer, and possibly interpreted by the manufacturer. The same problem can therefore be reported in several different ways, making analysis difficult.

Some complaints are not specific - for example "customer dissatisfaction", "dots wrong size" etc.















Customer Complaints 2021/2022

Major Complaints

Breakage accounted for 28.5% of the complaints

Packaging complaints totalled 25.1%

"Other" accounted for 16.9%, but this covered a wide range of issues, and cannot easily be broken down further.

Note that the total number of complaints is a very small proportion of the condoms sold - typically less than 1 for every million condoms sold.







Customer Complaints 2021/2022

Minor Categories

Irritation 5.3%

Shortage 4.6%

Foreign body 3.9%

No lubricant 3.7%

Holes 2.5%

Odour 2.4%

Leaking foil 1.7%

Poor quality 1.2%

Low burst 0.8%

Visible defects 0.5%

Foil defects 0.2%







Review Process

Companies are asked to forward their complaints to UNFPA, together with a summary of their corrective actions and the results.

These are reviewed by UNFPA consultants, and either accepted, accepted with verification to be done at the next inspection or more details are requested from the company







Breakage

Breakage - usually in use - is the most common cause for complaint at 28.5%, presumably because it is obvious and of concern to the customer.

Condoms, when properly used, do not often break in use and it is possible that many of these complaints refer to inexperienced users. However, it is an obvious cause for concern and the reaction s of the company is important.







Breakage

The CAPA should show that the company is looking for any common factors in breakage. Are the affected condoms from the same batch? Of the same type? Made from the same latex batch? Sold into the same market? Made at the same site? etc.

The consultants will be looking to see the results of this type of follow up - if not further information will be requested.







Packaging

Packaging is the second largest category of complaint, but covers a wider range. Packaging complaints can vary from outer boxes deformed in transit to other types of damage.

Where possible packaging complaints of leaking foils, empty foils or open foils are separated out and reported separately.

Open foils are considered a serious complaint, as they expose the condom to possible degradation by external factors.







Other Complaints

The "other" category is more difficult to analyse in detail. It can cover vague complaints such as "I did not like the condom". "It did not fit".

If the complaint contains sufficient information, then the company's response can be assessed. If not more information will often be requested.







Irritation

Complaints of irritation are taken seriously. If the complaint relates to more than one incident, the consultants will look for evidence to show that the company has looked for any trends - for example in batch, compounded latex used, production records, etc.







Holes, Low Bursts

It is reassuring to see that complaints of holes and low strength/low burst properties are low, although of course these are most likely to be detected by a test laboratory rather than the user.

It shows that prequalified manufacturers seem to be controlling these stages in the production process adequately well.







Some Examples

Complaints to company 'A' included 25% of breakage and 26% of packaging. As these are the majority categories overall they are in line with the trend, but still give the company information on where they should be focussing their quality improvement programme.







Another Example

Complaints to company 'B' included a total of 57% incidences of breakage.

This is a very significant issue, and this company should be making strenuous efforts to identify and rectify the cause.







A Third Example

Packaging complaints to company 'C' were over 68% of the total.

Again, this type of information is valuable in identifying where a company should be applying corrective and preventive action.

In many of these cases the consultants have had to request further information to allow the corrective actions to be accepted. It also provides valuable information to UNFPA to guide future prequalification inspections.







Helpful Advice

It is always useful to remember these simple rules for helping to control quality.

- 1. No process without data collection
- 2. No data collection without analysis
- 3. No analysis without decision
- 4. No decision without action (which may include a decision that no action is necessary)







A Few Words in Conclusion

In this review is was noted that several manufacturers returned only one or two, or even no complaints.

There could be two reasons for this: either their product is essentially perfect, or the customer has little faith in the company to respond to a complaint.

Lack of complaints should prompt a company to carry out some customer liaison to find out why.

A complaint is an opportunity to interact with the customers and a responsible company will take advantage of the fact.







Thank you for your attention