COMPLAINTS & RECALLS

B Pharm VI Sem

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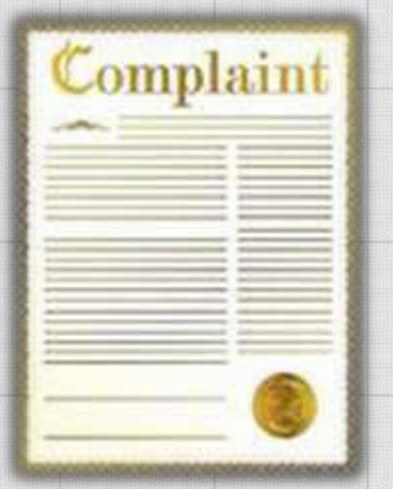
COMPLAINT

Statement that is something wrong or not good enough, which shows customer dissatisfaction about the company and the product

Example: Complaint about packaging materials, Concerning about the product etc.



Reasons

- It gives the company an opportunity to improve the quality of the product
- It is helpful to maintain cGMP
- It maintains committed relationship between the customer and company
- It is the regulatory obligation.
- Aid in implementing solutions to these quality problems
- Reduce costs and improve production schedules
- Reduce employee confusion
- Improve the safety and performance of devices

- Identify poor performance in the overall quality system, particularly faulty design of devices, and faulty manufacturing processes
- Verify confidence in, and improve the performance of the quality system
- Reduce medical device reporting
- Improve customer relations by reducing the frequency of problems, complaints, and recalls; and,
- Assure compliance with device regulations and consensus standards.

Types of Complaint

- **Quality complaints:** Originate at consumer level and concern with physical, chemical and biological properties or condition of labeling and /or packaging of the product.

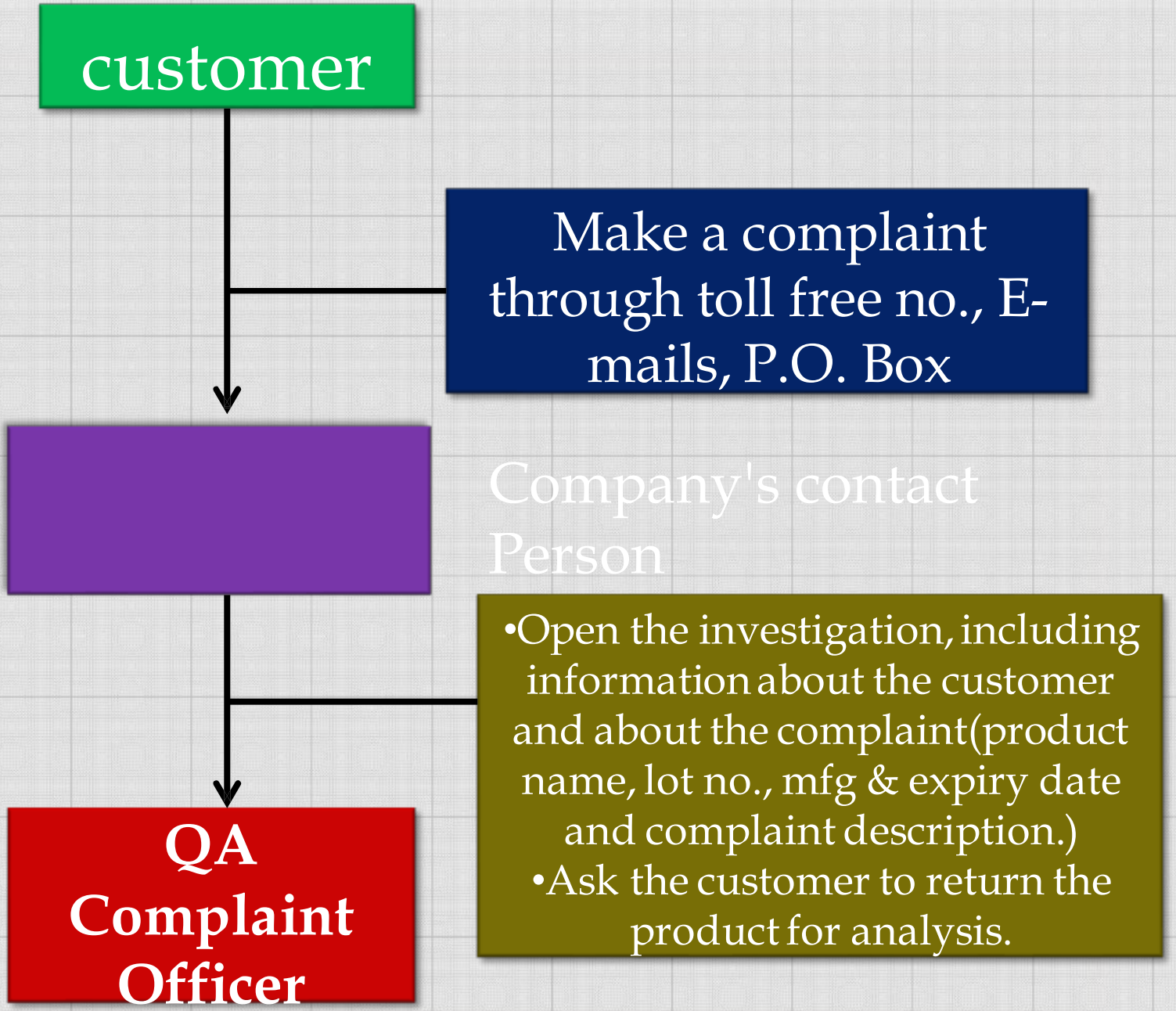
- **Adverse reaction complaints:** Due to allergic reactions of any other untoward reaction or fatal reaction or near fatal reaction.

- **Other medically related complaints:** Include complaints such as lack of efficacy or clinical response.

Steps Involved in Handling of Complaints

- **Step 1**: Receiving Complaints

It is important to have open channels with customers in order to receive their suggestions, doubts and complaints. Generally, these channels are toll-free numbers, e-mails, chat-rooms and P.O. boxes. Whatever the channel, it is necessary to have a person in charge of receiving the complaints and in putting them into an appropriate investigation form that shall be addressed to the Quality Assurance (QA) unit for investigation.


customer
Make a complaint through toll free no., E-mails, P.O. Box
Company's contact Person
•Open the investigation, including information about the customer and about the complaint(product name, lot no., mfg & expiry date and complaint description.)
•Ask the customer to return the product for analysis.
QA Complaint Officer

Step 2: Technical Investigation

Upon receipt of the investigation form, the QA unit is able to start the investigation, which can be divided in two phases:

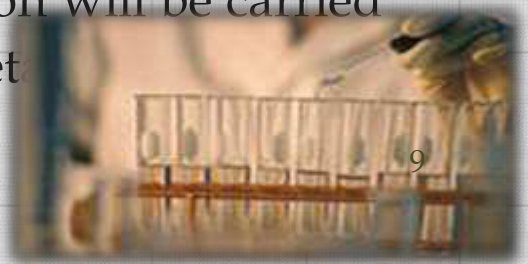
Technical investigation

Documentation-based

Checking if this complaint Occurred previously in the same lot or if any nonconformance was found in the lot during its production

Laboratory analysis phase

Requesting QC laboratory to analyze both samples (complaint & retained). If the customer did not send the complaint sample for analysis, the lab. Investigation will be carried out only with the ret



After receiving the analytical results, there are **three** possible **conclusions**, as follows:

1. Confirmed complaint - When both complaint and retained samples showed **out-of-specification** (OOS) results or when only the complaint sample showed OOS results, it is clearly a single unexplained failing product.

Example:

- *a single unexplained failure may be when one tablet is missing in the intact blister strip in the complaint sample, but no deviation was found in the retained samples or during the in-process controls and final QC analysis recorded in the batch record.*

2. Non-confirmed complaint - When both complaint and retained samples showed results in compliance with specifications or when only the complaint sample showed OOS results that cannot be considered a single unexplained failing product. OOS results in a complaint sample can be attributed to misuse or mishandling.

Example:

- *Tablets of the complaint sample show a change in their appearance that is characteristic of a light, humidity or high temperature exposure.*

3. Counterfeit / tamper suspicion - When the retained sample is within the specification but the complaint sample is clearly OOS with no reason for that, such as a counterfeit or tampered drug product.

Example:

- *when packaging material is different from the original; an example of tampering is when the color of the drug product is completely different from the original or when any foreign substance was added to the product*

Step 3: Corrective Actions and Feedback to Customers-

- Corrective actions can range from a simple and quick training to some employees to a formal **Corrective Action and Preventive Action (CAPA)** handling.

The criteria for choosing appropriate action depend on the nature of the complaint, and the complaint incidence.

If a CAPA is opened, a multidisciplinary team consisting of representatives of QA, QC, Regulatory Affairs and Production Management must be established.

- As feedback to the customer, the company must write a response letter to the complainant to explain the investigation approach taken, the results obtained and any implications, in case the quality problem was confirmed.

- The customer should be sent a free replacement product together with the response letter, since the customer returned the product (the “complaint sample”) to the company for analysis and a quality problem was found.

- Concerning non-confirmed complaints originating from misuse or inadequate handling of the drug product, even if there is no need for internal corrective actions, corrective measures should be implemented to provide orientation to the customer.

Step 4: Monthly Reports and Trend Analysis-

Monthly reports should be elaborated in order **to evaluate** the amount and the nature of the complaints received and **to perform** a trend analysis of these complaints.

The monthly reports must answer the following questions:

- How many complaints did the company receive in the period?
- How many were confirmed?
- How many were non-confirmed or were counterfeit/tamper suspicion?

Product Complaint Data Sheet

- Serial number assigned to the complaints.
- Exact nature of the complaints.
- Name of the complainants.
- Address of the complainants.
- Date of complaint received.
- If verbal, name of the person who received the complaint.
- Name of the product, strength and batch number of the product.
- Reference to analytical record number.

- Quantity involved in the complaint.
- Size of sample obtained from the complainant.
- Evaluation of complaint by QC department.
- Materials and records used to perform evaluation.
- Other possible effected materials, products and results of their investigation.
- Name and signature of the investigator(s) and date.
- Action taken by the company.
- Copy of reply sent to complainant.

Complaint Record

- Name and address of complainant;
- Name (and, where appropriate, title) and phone number of person submitting the complaint;
- Complaint nature (including name and batch number of the bulk product or Medicinal Product/Drug);
- Date complaint is received;
- Action initially taken (including dates and identity of person taking the action);
- Any follow-up action taken;
- Response provided to the originator of complaint (including date response sent); and
- Final decision on bulk product or Medicinal Product/Drug batch or lot.

Customer Complaint Record Book

Report no.	Date received	Product name	Received by	Product lot no.	Date investigation started	Date investigation ended

Regulatory Guidelines

- A SOP should be available giving full details about how to handle products complaints and necessary records about complaints handled should be maintained.

- A person should be designated for handling the complaints and deciding the measures to be taken together with sufficient supporting staff to assist him. This person should normally be from quality management department, with sufficient knowledge and experience in related work.

- If product defect is suspected in a batch, other batches should also be checked in order to determine whether they are also affected. In particular, other batches which may contain rework of the defective batch should be investigated.

- All decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

- A file regarding such drug products complaints shall be maintained at the factory site, where the drug product involved was manufactured, processed or packed.

- Written records involving a drug product shall be maintained until atleast 1 year after the expiration date of the drug product or 1 year after the date that the complaint was received, whichever is longer.

Incase of certain OTC products where expiration date is not given the records should be maintained for atleast for 3 years after the complete distribution of the drug product.

- Complaint records shall be regularly reviewed for any indication of specific recurring problems requiring attention and possibly the recall of the marketed product

- All decisions and measures taken as a result of a complaint should be recorded and referenced in the corresponding batch records.

- Trend analysis should be performed in an event to identify possible recurrent causes leading to a negative effect on a product.

SOP on Complaint Handling

1.0 OBJECTIVE:

To lay out the procedure for investigation and reporting the market complaints.

2.0 RESPONSIBILITY:

The quality assurance manager along with manager of the complaint related department.

3.0 ACCOUNTABILITY:

The Head, Q.A / Q.C / Regulatory shall review the investigation report, suggest corrective actions and approve the complaint report.

4.0 PROCEDURE:

4.1 Market complaint may be received from any of the following sources:
Physicians , Pharmacist , Warehouse, Patients, Regional Offices, Hospitals
Regulatory affairs, Wholesale Traders, Actual users

4.2 Complaints shall be classified in following categories to facilitate investigation:

-Product quality complaints (non therapeutic).

-Packaging complaints (shortages and packaging error).

-Medical complaints (therapeutic problems).

3.As a company policy even verbal complaints shall be formalized and investigated.

4.All written and oral complaints to be forwarded to Head,
QA/QC/Regulatory or his nominee for investigation

5.All the Product Quality Complaints shall be investigated jointly with QA/F and D/Manufacturing within 5 days of the receipt of the complaint.

6.Medical complaint investigations shall be carried out jointly by Medical department, QA, Production, F and D and Marketing Department within 3 days of receipt of complaint

7.Packaging complaints and Quality complaints shall be jointly investigated by QA, F and D and Manufacturing department within 10 days of receipt of complaint.

8.The investigator shall investigate the complaint by referring to the Batch Manufacturing Record, SOP, machine log tables, retain samples, reconciliation of materials, storage conditions used and prepare the Product Complaint Report (PCR)

9.The PCR **(Annexure I)** shall include the product details, details of the complainant, quantity involved, enclosed complaint sample (if any), details of investigation actions taken and recommended corrective actions to prevent such recurrences in future. Each PCR shall be approved by Head/QA/QC/Regulatory or his nominee.

10.Incase of the Head/QA/QC/Regulatory finds that investigation is not necessary, such written records shall be maintained including reasons for not conducting the investigation.

11.Each report shall be assigned a specific PCR number, which will be a 3 digit number starting with “001”in continuous sequence prefixed with “PCR” and suffixed with the last two digits of the year. For example, the first market complaint for 2006 shall have the number PCR/001/006

12.If product defect is established or suspended in a batch, Head/QA/QC/Regulatory will decide for checking other batches in order to determine weather they are also affected.

13.Incase of medical complaints, if Head, /QA /QC /Regulatory and Medical Advisor feels that the product will put the public at risk, he shall advise immediate recall of the batch. The depth of recall is dependent on the seriousness of the complaint.

4.14 Complaint Record shall be maintained at least one year after expiration date of medicine.

15.Complaint Record shall be reviewed and a monthly summary shall be prepared for the management.

16.A Register is maintained having the complete details of complaint for future reference.

ABBREVIATIONS: QA/QC : Quality Assurance/ Quality Control PCR : Product Control Report

F and D : Formulation and Development

REFERENCES: NIL

ANNEXURE – 1

PRODUCT COMPLAINT REPORT

Product Name:			Complaint Category: Packaging / Quality / Medical
Batch no.	Mfg. Date	Expiry Date	Packaging Details:
Name/ Address Of Complainant:			Reference No./ Date
Complaint Reported Through:			Reference No./ Date
Complaint Sample Enclosed: Yes/ No Quantity Of Sample Enclosed:			Total Quantity Involved
Details Of Product Complaint:			
Investigation Report (Additional Sheets To Be Attached If Necessary)			PCR Received By On : Investigation Done By :
Action Taken			Conclusion : Confirmed / Not Confirmed PCR No.: PCR Approved By :
Recommended Corrective Actions			

RECALL

Recall

- **Recall is an action taken to withdraw/remove the drugs from distribution or use including corrective action for which deficiencies are reported in quality, efficacy or safety.**
- Recalls also include drugs prohibited under the Provisions of Drugs & Cosmetics Act and also those products for which product licenses are suspended/cancelled

Recalled Products

- **Products which are already distributed or sold, may require at times to be recalled from market for various reasons.**
- e.g. - substandard quality detected after the product was distributed
  - damage of goods during transit.
- Such recalled products should be clearly identified and stored separately in a secure area until a decision is taken on their force.
- Such decision should be made as soon as possible.
- Recall applies a;

Total ban or Permanent removal
Temporary ban or Temporary removal

Reasons

- FDA authorities may order a recall for **substandard quality** of the finished product or for any other justified reasons

- Manufacturer himself may find problems with the product such as:
  - substandard quality
  - problems related to the stability of the product
  - based on the market complaint received from a customer or physician

- **Accidental damage** of the consignment may also happen during transportation

In such case product quality may not be questionable, but packages may get damaged and cannot be sold or distributed as such in the market, and hence required to be recalled.

Types of Recall

Compulsory Product Recall

- Industries do not take the responsibility of recalling the product voluntarily.
- Commission conducts a "Compulsory Product Recall"

Voluntary Product Recall

- Industries voluntarily recall the products in consultation with ICCC
- Encouraged by the commission where suppliers recall a product as soon as a defect is found that makes a product hazardous or unsafe for use or consumption.

Recall Classification

CLASS I RECALLS

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause **serious adverse health consequences or death**.

- **Examples of Class I Recalls**

- *Pathogens in ready-to-eat food: Salmonella, Listeria monocytogenes, E. coli, Clostridium*
- *High levels of sulfites*
- *High levels of heavy metals*
- *Choking hazards for susceptible populations*

Reference: www.fda.gov

CLASS II RECALLS

Class II is a situation in which use of, or exposure to, a violative product may cause **temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote**.

- **Examples of Class II Recalls**
- *Foreign objects that pose a physical hazard*
- *Pathogens: Shigella, hepatitis A, Cyclospora, Cryptosporidium*

CLASS III RECALLS

Class III is a situation in which use of, or exposure to, a violative product is **not likely to cause adverse health consequences**.

- **Example of Class III Recalls**

An example might be bottles of aspirin that contains 90 tablets instead of the 100 stated on the label.

Time Lines For Effective Recall System & Rapid Alert

- Based on the category of risks involved, a time line of :
  - Within 24 hours up to a maximum of 72 hours for Class I recall
  - For Class II recall up to a maximum of 10 days and
  - For Class III recall up to a maximum of 30 days is allowed.

Level of Recalls

WHOLESALE PRODUCT RECALL (Distributor)
wholesale, distribution Centre's and importers

RETAIL PRODUCT RECALL (Dealer)
supermarkets, stores, hospitals, restaurants and major retail outlets

INDIVIDUAL CONSUMER RECALL
individual consumer

How to Recall the Product?

1.Product Recall Process

Product is likely to cause injury/adverse health effect to a person, the Supplier should identify & take the necessary steps required to recall the product, control the risk and coordinate the recall process.

2.Level of Recall

A product can be recalled at 3 levels; wholesale, retail, individual consumer or combination of any two or three levels.

Determination of the level of recall is dependent of how far the product has penetrated the market from the supplier.

3. Recall Strategy

Supplier should develop recall strategies for various levels of recall as specified.

Supplier should consider the following:

- Notification mechanism to stop distribution and sale of product.
- How to effectively and efficiently remove potentially unsafe product from market place
- Isolation and safe storage of recovered product
- Disposal of product or return of product to market
- Availability of resources for remedial action.

4. Product Recovery, Storage and Disposal

- Methods of product recovery: product may be recovered by being returned to the supplier, supermarkets, wholesellers or retailers.
- Methods of product storage: recovered products must be stored in an area that is isolated and separated from any other products.
- Methods of corrective actions or product disposal:

Food products– destroyed by burial, denatured through retort and incinerated under supervision by the relevant or appointed officers
Product for general or consumer use– returned to the manufacturers or destroyed through the appropriate industrial practices.

5. Remedial Actions by the Supplier

The Supplier's notification to its distribution chain and clients should include advice on how to settle for the returned products at the wholesale, retail and consumer level.

The notification should be clear and concise to ensure no distribution chain and client business operations are affected severely.

6. Monitoring the Effectiveness of the Product Recall

The measurement standard is the total number of products recovered against the total number of products being issued.

Supplier must have a scale of measurement for measuring the effectiveness of the recall.

7. Post Recall Reporting

One month after the termination of recall process, the Supplier is required to furnish the recall coordination unit with a final report on the recall.

The report should contain the following information with details;

a. Copy of letter to customers
b. Circumstance leading to the recall
c. Actions taken by the supplier including copies of media statement
d. Method of disposal
e. Proposed action to avoid future recurrence
f. Difficulties experienced in conducting the recall
g. Forms of assistance from government agencies and industries.

How To Notify The Consumers?

- Public Notification

Through media coverage system
The media coverage system covers radio broadcast, television, newspapers, TV news and current affairs programs.

- Media Release

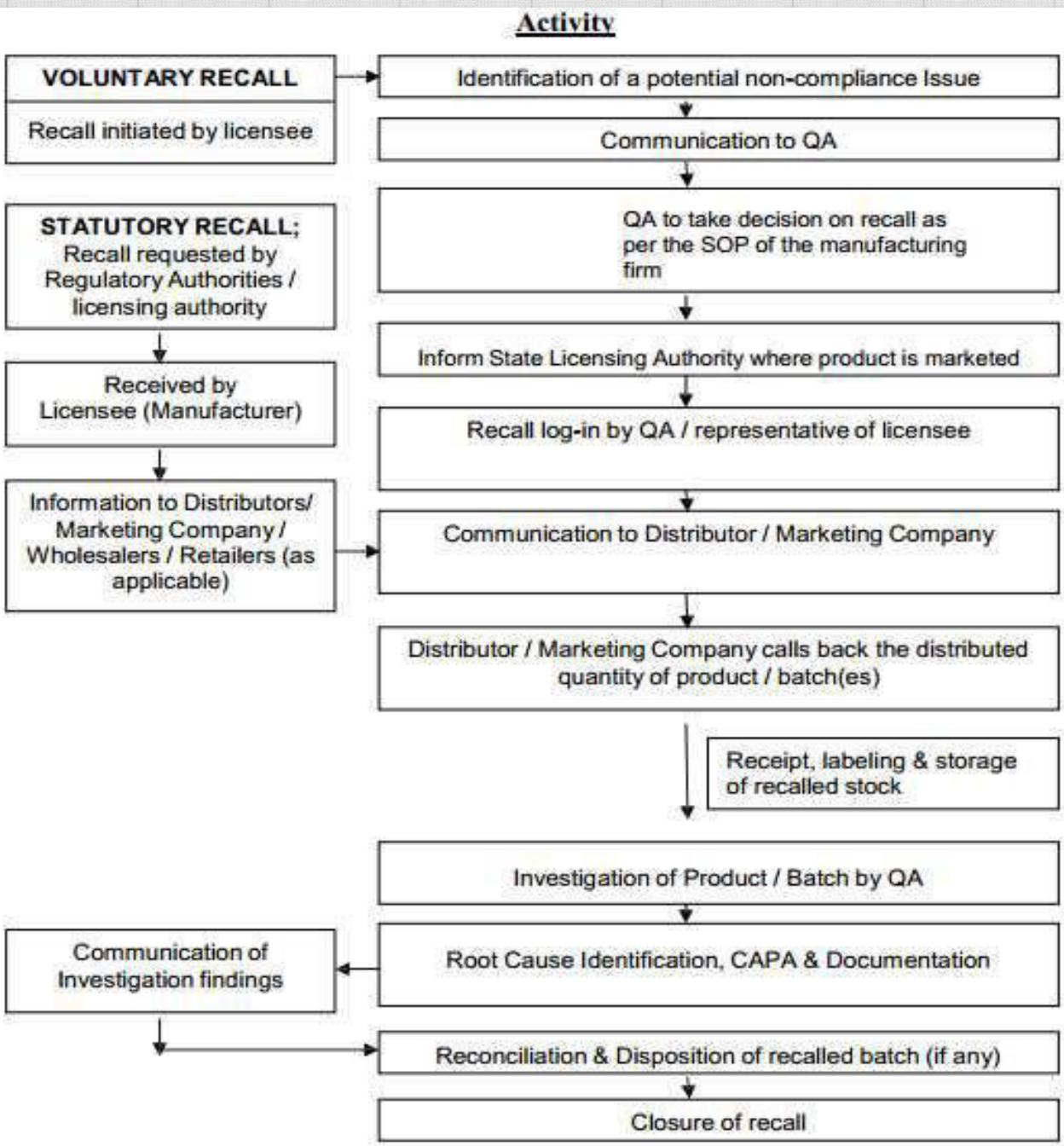
Short, concise, clear and written in simple language.

Should contain the product recall detail, problem or hazard, actions to take, remedial action, names, address, phone numbers and email address of people.

Publicity Material

a. Product information
b. Clear identification of supplier
c. Statement of hazard and associated risk
d. Actions consumers should take to avoid injury
e. Contact telephone numbers
f. Advice that the recall is at the expense of the supplier

Overview of Process Flow Rapid Alert & Recall System:



Regulatory Guidelines

- A **detailed SOP** should be available and **records of recall** should be maintained by the manufacturer.

- A **person** should be designated as responsible for **execution and coordination** and should be **supported by sufficient staff** to handle all aspects of the recall with the appropriate degree of urgency. This person should normally be independent of the sales and marketing organisation.

- Recall procedure should be capable of being **initiated promptly** and at **any time**.

- All competent authorities of the countries to which the product might have been distributed should be **informed promptly** if products are intended to be recalled because these are being defective (or suspected of).

- The distribution records should be **readily available** to the person responsible for recalls, and should contain, sufficient information on wholesellers and directly supplied customers, including those for exported products and medical samples.

- Recalled products should be **identified and stored separately** in a secured area while awaiting decision on its fate.

- The program of the **recall process** should be **recorded** and a final report issued including a reconciliation between the delivered and recovered quantities of the product.

- The effectiveness of the **recall procedure** should be **evaluated** from time to time by a dummy recall.

- A detailed **check-list** may be designed by the manufacturer to recall a product.

SOP on Product Recall

1.0 OBJECTIVE:

To specify a method of operation that will ensure the prompt and effective removal of any medicines for which XYZ Pharmaceuticals Ltd. Is the manufacturer and which may represent a health hazard to the consumer or user from the market.

2.0 RESPONSIBILITY

1. General manager (QA/QC, Regulatory): General Manager (Manufacturing):
2. In case of adverse event a committee evaluates the crisis. It consists of following individuals:
   - GM/QA/QC, Regulatory
   - GM Manufacturing
   - GM, Formulation and Development
   - Medical advisor
   - V.P-Marketing
   - V.P – International Marketing
   - V.P – Technical Operations

All available members of the crisis committee shall review the crisis and take appropriate action.

3.0 ACCOUNTABILITY

Vice President

4.1 DEFINATION

4.1.1 "Violation Medicine" means any medicine for which XYZ Pharmaceuticals Ltd is the manufacturer and,

2.which is reported to be causing serious adverse health reactions-not include in the package insert and/or

3.With regard to which reports of serious adverse health reactions described in the package insert are being received with unacceptable frequency, and/ or

4.which has a material formulation error, or other errors, and/ or,

5.Which has a material labelling error, or other errors, and/or,

6.Which has a result of on going stability studies, is found not to comply with the release specifications.

4.2 PROCEDURE

4.2.1 Any employee of XYZ Pharmaceutical Ltd becoming aware of "Violative medicine" immediately notifies the GM, QA/QC/Regulatory or in his absence GM, Manufacturing.

2.If the GM, QA/QC/Regulatory or GM, Manufacturing, is of opinion that the violation is of a sufficiently serious nature to possibly warrant a medicine recall, he shall immediately quarantine existing in-house stocks of the relevant medicines and obtain the following information :

a) The product name, strength, packs size, batch number, Manufacturing Date and Expiry Date.
b) The total number of units released for sale.
c) The Date on which distribution commenced.
d) The total number of units distributed.
e) The number of units still in stock in factory and with stockiest(s) through the Market.
f) The nature of reported violation.

The above information is recorded on the attached document "**Medicine Recall Control document**" under "**Product Information**" (Annexure- 2)

3.In the light of above information GM-(QA/QC/Regulatory) or GM-(Manufacturing) or GM-(Formulation and Development) evaluates the health hazard presented by the medicine and documents this evaluation on the attached document "**Medicine Recall Control Document**" under **Health Hazard Evaluation** (Annexure-3).

4.Taking into consideration the available information as well as the health hazard evaluation the GM-(QA/QC/Regulatory) formulates a proposed recall strategy. The recall strategy specifies the nature of communication to be used (phone, fax, telegram, letters, telemail, etc.) as well as the level in the distribution chain to which recall is extended.(wholesalers, retailers, general public, etc.)

5.The GM-(QA/QC/Regulatory) or GM-(Manufacturing) informs concerned Regulatory Authorities in India and other countries as appropriate to the distribution of the medicine. Relevant records shall be submitted to Regulatory Authorities together with proposed plan of action.

4.2.6 If the proposed plan of action meets with the Regulatory Official's approval, or if a modified recall strategy has been decided upon in conjunction with the Regulatory Official's, the GM-(QA/QC/Regulatory) or GM-(Manufacturing) documents the recall strategy on the attached document "**Medicine Recall Control Document**" under **Recall Strategy** (Annexure 4).

7.The GM-(QA/QC Regulatory) or GM-(Manufacturing) implements recall without delay.

8.The GM-(QA/QC Regulatory) or GM-(Manufacturing) prepares an interim reconciliation report after 30 days and submit a copy to concerned Regulatory Official's.

9.The GM-(QA/QC Regulatory) or GM-(Manufacturing) prepares a final reconciliation report after 90 days and submits a copy thereof to the concerned Regulatory officials for information as a final reconciliation and verification of the success of recall (Annexure-5). Relevant records shall be filed.

4.2.10 Prior to termination or completion of Medicine Recall the following points shall be given due consideration:

- Method of destruction of the product in field.
- A designed area to receive returned medicines.
- Inventory of the returned medicine.
- Destruction authorization.

11.The Medicine Recall will be terminated when the GM, QA/QC Regulatory or GM Manufacturing are assured that recall has been reasonably completed and a "**medicine recall status report**" (Annexure-6) is completed.

12.Export Products : Recall notifications related to exported products to relevant Regulatory Authorities, Applicants, Agents and Distributors loaded in the importing countries shall be informed. GM-(QA/QC/Regulatory) or GM-(Manufacturing) shall be responsible for passing on this information.

4.2.13 GM-(QA/QC/Regulatory) or GM-(Manufacturing) shall prepare a " Standardized recall letters" and "Press Statement" as given in (Annexure-7) and (Annexure-8) respectively.

4.2.14 After the authorization by GM-(QA/QC Regulatory) or GM-(Manufacturing), the recalled material along with stock in hand shall be destroyed. The same shall be indicated in the final reconciliation report (Annexure-5) with action initiated to avoid recurrence and shall be forwarded to concerned Regulatory Authorities.

ABBREVIATIONS: NIL

REFERENCES: NIL

Drugs Recalled in 2013

Date	Brand Name	Product Description	Reason/ Problem	Company
30 June 2013	Nexus, APP	Benztropine Mesylate Injection	Glass particles	Fresenius Kabi USA
19 June 2013	Rugby	Enteric Coated Aspirin Tablets,81 mg	May Contain Acetaminophen 500 mg tablets	Advance Pharmaceutical Inc.
13 June 2013	Sagent Pharmaceuticals, Inc.	Vecuronium Bromide for Injection	Due to elevated impurity levels	Sagent Pharmaceuticals, Inc.
11 June 2013	Bethel	Weight Loss Pills	Contains Undeclared Drug Ingredient	Bethel Nutritional Consulting, Inc.
10 June 2013	ZyGenerics	Warfarin 2 mg Tablets	Oversized tablet	Zydus Pharmaceuticals USA Inc.
25 May 2013	Fresenius Kabi USA	Magnesium Sulfate Injection USP	Glass Particles	Fresenius Kabi USA

Drugs Recalled in 2014

Date	Brand Name	Product Description	Reason/ Problem	Company
03 October 2014	Cadolac	Ketorolac Tromethamine Injection	Due to labelling the product with incorect expiration date	Cadila Healthcare Limited
13 August 2014	Idarubicine	Idarubicine Injection	Discovery of red precipitation	Teva UK Limited
28 July 2014	Buccolam	Midazolam hydrochloride oromucosal soln	Chemical contamination	ViroPharma SPRL
19 June 2014	Fybogel	Isapghula husk	Potential risk of contamination with metal particles	Reckitt Benckiser Healthcare
06 March 2014	Viread	Tinofovir disoproxil fumarate (245mg film coated tablet)	Presence of silicone rubber	Gilead sciences limited
17 Feb 2014	COSOPT Preservative-Free	Dorzolamide/ Timolol eye drops solution	Increase in the number of adverse events & product complaints relating to difficulty in administration	Merc sharp & Dohme limited

Reference

- cGMP of Pharmaceuticals – Manohar A. Potdar
- How to practice GMP‟s by P.P Sharma
- www.gmp-compliance.org
- Ec.europa.eu
- www.fda.gov/Safety/Recalls/ucm165546.htm
- Guidelines on Recall

THANK YOU