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A KEY APPROACH TO CARE PHARMACEUTICAL PRODUCTS AND RECALLS

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ABSTRACT

A Firm's inventory as well as reputation largely depends on whether a complaint is made about its market product. Any flaws in the product can cost serious denigration of the manufacturing company that has earned a good reputation till time. When a product is introduced into a market, post marketing surveillance is a crucial factor for monitoring its harmful effects on population. The source of complaint can be anything i.e. Transportation, production and packing. Any failure in any of these stages can lead to a serious problem. So handling of market complaints must be of primacy task. The market complaints are handled with proper procedures. In case of genuine complaint a root cause analysis should be done to emend the problem and the products should be withdrawn from the market. Recall system should be that much efficient that can remove the product from market within as specific period of time. The following review depicts typical procedure for handling of market complaints and product recalls.

Keywords: Customer, Returned Goods, Market Complaint, Recall, Handling.

INTRODUCTION

'Complaint" is defined as a statement that something is wrong or not good enough. Generally in pharmaceutical sector, complaints are regarding the quality of the drug product. The condition when a market complaint is made about is a serious condition, which almost all of the time causes inventory loss as recall The severity of such incidences will indicate improper manufacturing& handling of pharmaceutical products, a negative impact on the brand image of the firm. It should be of the greater concern of all of the firms to avoid such events by following cGMP, and the complaints should be under investigation. Whenever the market complaints are made about, thorough revision of those complaints and other information related to the batches affected must come into action and the reasons behind complaints must have to be investigated and corrective action should be taken immediately. Handling of complaints provides the company to improve the quality of the product. It also maintains committed relationship between the company and the customer. Whatever it is about, a complaint shows customer dissatisfaction about a product and, consequently, about a company [1]. Complaint is any communication, written or verbal, received directly from any customer, retailer, distributor, or representative of contract giver, regarding the quality attributes, labeling defects or any other matter such complaints shall be considered as market complaint [2]. Proper management of the market complaints should be assigned to a dedicated department led by a supervisor, who should be empowered with proper authority to investigate the complaints, along with a satisfactory number of subordinates to support him or her. For the case of potential product defects, an efficient inquiry has to be done.

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The personnel charge should predict the actions to be taken to rectify the issue, through appropriate written procedures Any batches that may also be affected along with the complained batches, are also examined for such defective similarities [3]. If the complaint is found to be not factitious, then special consideration are required in that case and the recall of products should be done from the market within specific period of time .In such case, all investigation reports, follow up actions taken should be noted down carefully. Have to keep it in mind that any non chalet act in this field will be pernicious for the product. All the documents relating to market complaints and recalls should be referenced to corresponding batches and archived. These archives are regularly reviewed to look over the sign of specific and repetitive complaints that require attention.

Procedure for handling of market complaints [4]:

1. Product promotion department / marketing department will receive the complaint from complainer and forwards it to Quality Assurance department (QAD).
2. QAD will file the complaint in register with reference number.
3. Executive of QAD under the supervision of QAD head will perform investigation by root cause analysis.

The following figure 1 depicts the procedure for root cause analysis of market complaints.

4. This total time frame for sending replay to customer should be maximum of 15 days.

5. All the yearly complaints are reviewed for evaluation of out of trends by annual review of market complaints.

Figure 1: Procedure for root cause analysis of market complaints

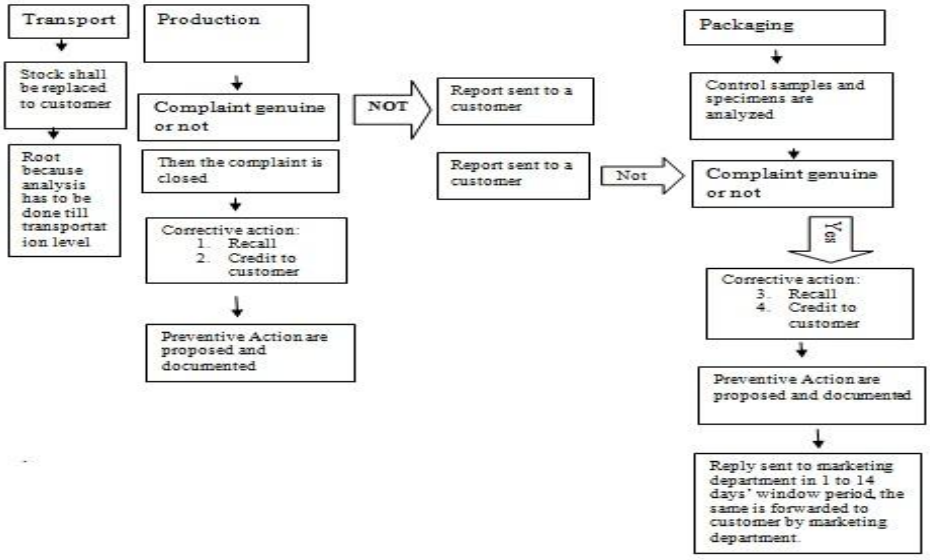

Table 1. Market complaint investigation form [5]

Product complaint details	
Product:	**Product code:**
Batch no.:	**Date of manufacture:**
Packaging:	**Date of expiry:**
Supplier / manufacturer / brand:	**Quality affected:**
Sample quantity:	**Complaint date:**
Details of the complainer **Name of the complainer: Address:** **Mode of complaint: Contact no.: Contact person:**	

Nature of the complaint	
☐ **Quality related complaint**	☐ **Physical related complaint**
☐ **Clinical related complaint**	☐ **Packing related complaint**
☐ **Label related complaint**	☐ **Process related complaint**
☐ **General complaint**	
Product management comment: **Sign & date**	
Market complaint received by QAD (comments if any)	**QAD: enter in market complaint register** **QAD: file the complaint in market complaint register** **Sign & Date**
Date of complaint forwarding to respective department:	

INVESTIGATION DETAILS		
Batch no.:	**Test conducted**	**Observation**
Batch 1		
Batch 2		
Batch 3		

Description of manufacturing process:

Root cause analysis:

Corrective action and implementation date: Preventive action and implementation date: Advises (if any): Follow up records – remarks (if any): Conclusion:

Name / designation: **Sign & date:**	**Investigation report submitted to management on:**
Date on which final action completed for replay to be sent to the complainer:	
Approved date:	**Decision date:**
Reply sent to customer on:	**Sent by sign & date:**
Enclosure of reply documents:	
Issue closed: **Sign & date:**	**Kept open for:** **Sign & date:**

Product recalls: [6]

1. Principle.

There should be a system to recall from the market, promptly and effectively, products known or suspected to be defective.

2. The authorized person should be responsible for the execution and coordination of recalls. He/she should have sufficient staff to handle all aspects of the recalls with the appropriate degree of urgency.

3. There should be established written procedures, which are regularly reviewed and updated, for the organization of any recall activity. Recall operations should be capable of being initiated promptly down to the required level in the distribution chain.

4. An instruction should be included in the written procedures to store recalled products in a secure segregated area while their fate is decided.

5. All competent authorities of all countries to which a given product has been distributed should be promptly informed of any intention to recall the product because it is, or is suspected of being, defective.

6. The distribution records should be readily available to the authorized person, and they should contain sufficient information on wholesalers and directly supplied customers (including, for exported products, those who have received samples for clinical tests and medical samples) to permit an effective recall.

7. The progress of the recall process should be monitored and recorded. Records should include the disposition of the product. A final report should be issued, including a reconciliation between the delivered and recovered quantities of the products.

8. The effectiveness of the arrangements for recalls should be tested and evaluated from time to time.

Returned goods:

Products returned from the market should be destroyed unless it is certain that their quality is satisfactory; in such cases they may be considered for resale or relabelling, or alternative action taken only after they have been critically assessed by the quality control function in accordance with a written procedure. The nature of the product, any special storage conditions it requires, its condition and history, and the time elapsed since it was issued should all be taken into account in this assessment. Where any doubt arises over the quality of the product, it should not be considered suitable for reissue or reuse.

Any action taken should be appropriately recorded

Recall Classification scheme [7]

• Class I Recall –

A situation in which there is a reasonable probability that use of, or exposure to, a violate product will cause serious adverse health consequences or death.

• Class II Recall –

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

• Class III Recall –

A situation in which use of, or exposure to, a violate product is not likely to cause adverse health consequences.

Thus, the aim of this article is to discuss the main steps of a good complaint handling procedure that can be readily implemented in pharmaceutical industries. The proposed handling system is in compliance with the GMP Guidelines of EU, USA, Brazil (ANVISA) and is presented in four steps: receiving complaints; technical investigation; corrective and preventive actions (CAPA)/feedback to customers; and monthly reports/trend analysis[1].all of which are represented below and summarized in the Flowchart 1.

Product Recall System:

industry have to have an efficient recalling system to remove unwanted material efficaciously and with celerity form the market. It can be achieved by assigning responsibilities for implementation once the decision of recall has been made. [8]

Procedure for product recall:

A product recall coordination committee has to be appointed for execution of recalls. The members of product recall coordination committee should be:

i. Managing director
ii. Quality assurance head iii. Production head
iv. Marketing department head

The managing director will make the ultimate decision regarding recalls.

Classification of complaints [2]

1. A-Type Complaints

Critical complaints in which product is required to be withdrawn from the market. Such as

• Adverse Drug Reaction.
• Major health hazard causing permanent deficiency or death.
• Purity & Safety.
• Potency.
• Product Stability

2. B-Type Complaints

Major complaints such as

• Problem with primary packaging of the product.
• b. Chemical / Physical attributes of the product.
• c. Extraneous contamination, mix-ups, etc.

3. C-Type Complaints
Minor complaints such as
a. Problem related to labelling / coding of batch details.
b. Shortages
c. Secondary packaging material problem, etc.
Responsibility [2]
1. Production Head
2. Quality Assurance Head
3. Unit Head

Criteria for recall: [9]

Recall coordination committee on order by regulatory agencies, recalls the product. The recall process must initiated within 48 hours, and has to be completed within 14 days of initiation. The product should be recalled from the market at different levels, i.e., vendor, distributor, retail or wholesaler, and user level by advertising and informing the supply chain. The recalled product must be destroyed in presence of authorized personnel and documented. The personnel will be authorized by recall coordination committee to destroy the recalls at site of manufacture.

The product should have to be withdrawn from the market at different levels, i.e., buyer, distributor ,retailer, wholesaler, and user level by advertising and bringing it under notice of the supply chain. The recalled product must be expunged under the presence of authorized personnel .The staff will be empowered by recall coordination committee to destroy the recalls at the site where manufacturing is done. The destruction of recalled products should be documented using following format of table 2.

Table 2. Documentation of destroying of recalled product [5]

Product name:	**Date of manufacture:**
Brand:	**Date of expiration:**
Batch size:	**Quantity destroyed:**
Recall completed emblem	

Personnel and Organization: [10]

1.In the case of handling complaint and quality defect investigation and for taking decisions over the measures to be taken to manage any potential risk(s) occurred by those issues including recalls properly trained and experienced personnel should take up all those responsibilities. These staffs should be given independence of the sales and marketing organization unless otherwise justified. These staffs appoint qualified persons in recalling process in order to handle whole process quite easily. If qualified Persons are not included in the certification for release of the concerned batch or batches, the latter should be made formally aware of any investigations, any risk-reducing actions and any recall operations, in a timely manner.

2.Adequate amount of well trained personnel and resources should be made forthcoming for managing, appraisement, inquisition and inspection of complaints and quality defects and for implementation of any risk-reducing actions. A good number of trained personnel and resources should also be available for the handling of interactions with competent authorities.

3.The utilization of inter-disciplinary teams should be considered, including appropriately trained Quality Management personnel.

4.Stages of centrally management of complaint and quality defect handling within an organization, proper documentation about the relative roles and responsibilities of the concerned parties should be made. Any delays must not be resulted in the investigation and management of the issue from Central management.

Procedures for handling and investigating complaints including possible quality defects: [10]

1.Written procedures involving the proper actions to be taken upon the reception of a complaint have to be introduced. Noting down all complaints and assessments to establish if they carry out a potential quality defect or other issue should be done.

2.To establish whether a complaint or suspected quality defect relates to falsification Special contemplation should be given.

3.Procedures in order to simplify a request to inspect the quality of a bunch of a medicinal product for corroborating an investigation into a reported suspected adverse event must come into application.

When a quality defect investigation is initiated, following procedures should addressed:

i. written document about the reported quality defect.

ii. Figuring out of the extent of the quality defect. The supervision or testing of referred samples should be under consideration as a part of this, and in certain cases, the performance of a review of the batch production record, the batch certification record and the batch distribution records (especially for temperature-sensitive products) should be done.

iii. The need to request a sample, or the return of the defective product from the complainant and, where a sample is provided, the need for an appropriate evaluation to be carried out.

iv. The risk(s)assessment exerted by the quality defect, depended on the intensity and extent of the quality defect.

v. The decision-making procedure that is to be utilized concerning the primal need for risk- degrading activities to be implemented in the distribution network, such as batch or product recalls, or other actions.

vi. The appraisement of the influence that any recall action may have on the availability of the medicinal product to patients/animals in any affected market, and the need to alert the relevant authorities of such impact.

vii. The communications including both internal and external should be made in relation to a deficit in quality and its investigation.

viii. The derivation of the primary root cause(s) of the quality defect.

ix. Requirement for proper Corrective and Preventative Actions (CAPAs) to be identified and introduced for the case, and for the appraisement of the efficiency of those CAPAs.

Investigation and Decision-making [10]

1.The information related to the possible quality failures have to be noted down, which includes all the original details. The propagation of all noted quality defects should be documented and appraised according to the Quality Risk Management principles in order to robust decisions regarding the degree of investigation and action taken.

2.When a quality defect is discovered or suspected in a batch, strong look should be provided to check other batches and in some cases other products, to determine whether they are also affected. Investigation must be carried on if defects are found on other batches or defective components

4.Quality defect investigations should include a review of previous quality defect reports or any other relevant information for any indication of specific or recurring problems requiring attention and possibly further regulatory action.

5.During the Quality defect investigations many decisions are made. Those decisions should be reflection of level of risk that is presented by the quality defect as well as the seriousness of any non-compliance with respect to the requirements of the marketing authorization/product specification file or GMP. Those decisions should be made timely in order to ensure no harm can occur to patient and animal.

6.In most of the cases comprehensive information on the nature and extent of the quality defect may not always be available at the early stages of an investigation; the decision-making processes should still ensure that appropriate risk-reducing actions are taken at an appropriate time- point during such investigations.

7.Reports based on Quality defects should be created in a timely basis by the manufacturing section to the marketing authorization holder/sponsor and all concerned Competent Authorities in order to withdrawal of the product with an effective manner.

Root Cause Analysis and Corrective and Preventative Actions [10]

1.A proper level of root cause analysis work should be applied during the investigation of quality defects. For the cases where the actual root cause(s) of the quality defect cannot be determined, consideration should be given to identifying the most likely root cause(s).

2.Quality defect can be caused by human defect. Product quality faults sometimes are overlooked. Appropriate care should be exercised so as to ensure that process, procedural or system-based errors or problems are not overlooked, if present.

3. In accordance to a quality defect, appropriate CAPAs should be identified and taken. The efficiency of such actions should also be monitored.

4.Widely known written procedures, regularly reviewed and updated have to be introduced when necessary, so that one can undertake any recall activity or implement any other risk-reducing actions

5.When a product is made available in a market any deliverance of it from the distribution network as a result of a quality defect should be regarded and managed as a recall.

6.Public or animal health should be the first priority of a recall operation rather than the root cause(s) and full extent of the quality defect. For that Recall operations should be capable of being initiated promptly and at any time.

7.The batch/product distribution records should contain sufficient information on wholesalers and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those medical samples and should be readily available to the persons responsible for recalls.

8.To investigate medicinal products, all sites where trials are made should be perceived and the countries to be destined should be mentioned. For an investigational medicinal product the manufacturer of the product should, in coordinating with the sponsor, inform the authorization which holds the marketing section of any quality defect that authorized medicinal product could hold. For the rapid unbinding of blinded products, the sponsor should implement a procedure where this is necessary for a prompt recall. Confirmation should be given by the sponsor about the procedure that discloses the identity of the blinded product as far as is necessary.

9.It's important to consult with the concerned Competent Authorities about the extension of the recall action into the distribution network, accounting the main risks to public or animal health and any impact that the proposed recall action may possess.

10.In case of products that have to be recalled all concerned Competent Authorities should be informed in advance. For the issues that are thought to be very serious (i.e. those with the potential to seriously impact upon patient or animal health) rapid risk-reducing actions (such as a product recall) should be under performance prior to notifying the Competent Authorities.

11.Propoundedrecall action may be of variance for different markets, and if this is the case, appropriate market-specific risk-reducing actions should be under development and discussion with the concerned competent authorities. Accounting its therapeutic use, the risk of shortage of a medicinal product which has no authorized alternative should be considered before taking decision on a risk-reducing action such as a recall. Not every decision to execute a risk-reducing action which would otherwise be required should be agreed with the competent authority in advance.

12.It is necessary to identify the recalled product and store it separately in a secure area until a decision is made about their further use. Formal disposition of all recalled batches is one of the most effective ways and it should be documented. The rationale for any decision to reuse recalled products should be documented and discussed with the relevant competent authority. The duration of shelf- life remaining for any reworked batches that are under consideration whether they would be placed onto the market should also be under judgment.

13.It's better to record the progression of any recall process until the end and preparation of the final report, including unification between the delivered and recovered quantities of the concerned products/batches.

14.The usefulness of the arrangements in place for recalls should be assessed in a periodic interval to make sure that they stay sturdy and fit when it is used. Such assessment should be extended to both situations, within office hours and as well as out-of-office hours and, when such evaluations are under performance, special monitoring should be done to whether mock-recall actions to be performed or not. This evaluation should be documented and justified.

15.Besides recalls, different other potential risk-reducing actions may occur which may deserve proper attention in order to manage the risks offered by quality defect which may include the issuance of cautionary interactions to healthcare professionals in relation to their use of a batch that is potentially defective. These should be considered on a case- by-case basis and proper discussion should be made about this issue with the concerned competent authorities.

CONCLUSION

Product recalls are widely spread across various industries from medicines to food products to automobile to household gadgets. The recalls often indicate poor product design and quality assurance failure in company when processes go occasionally out of control or in some situation recalls can take place when some outsourced vendor makes mistakes or product was not tested enough by company and launched in market .As market complaints and product recalls will decrease the brand image of the firm ,it should be properly addressed, with pre-determined working procedures All these incidents should be documented using specified formats and archived for future reference.

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CONFLICT OF INTEREST:

The authors declare that they have no conflicts of interest.

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