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HANDLING OF MARKET COMPLAINTS AND RECALLS, REVIEW OF FDA-483 FORM

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ABSTRACT

In the pharmaceutical industry, any type of immediate response to the customer complaint can be critical because any product failure can be fatal situation for customer. Product complaint management is critical but essential component in the pharmaceutical industry from the point of view of regulatory and patient compliance. Once, the product get into market, the post marketing surveillance will start its role to monitor the adverse effect on population. The origin of complaint can be anything, like production, transportation and packing. This critical step needs uniform, single, and secured platform to manage product complaint right from initiation to the closure. Hence, the market complaints are handled with well defined procedure on higher priority. If the complaint is genuine, then a root cause analysis performed to rectify the problem and the product should be recalled from market if it is necessary. The main contributions of this paper will be to describe the concerns about the handling of market complaint, effective product recall and rule called as FDA - 483.

Key words: Transportation, patient compliance, Product complaint

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INTRODUCTION:[1]

The pharmaceutical industry introduces many therapies to the market; hence it is at an important place in medical innovations. If this industry stops working, many health problems would remain unsolved. Pharmaceutical industry can create several problems also due to topic called product complaint. Product complaint is a topic of interest for all pharmaceutical industries, consumer health care companies, medical device manufacturer, and various other Industries governed by regulatory authorities. The product should be recalled from all the above, if complaints are found to be genuine.

Product complaints are, when any party or customer has reported any adverse event or product defect of any company's marketed product. The complaints can be from various sources like external or internal, or it can be verbal or written. If these complaints found to be genuine, the product should be recalled to the company. The product recall is a procedure of retrieval or withdrawal of products known to be defective, promptly and effectively, from the market. As the pharmaceutical industry is one of the largest industry, generates enormous amount of sensitive and private information such as medical records, employee information, financial data and research data, it requires a effective Information Security Management. Information Security Management is critical in the pharmaceutical industry and it can be a very big loss to the company to not having it.

Product complaint:[1]

Product complaint is either internal or external report regarding any product defect or dissatisfaction of customer. The internal complaint can be from warehouse, quality control, production and marketing division of the company. External complaint can be from doctors, clinics, hospitals, paramedics, pharmacies, drugstores, supermarkets, and customers. It can be of two forms like verbal or written like mail, letter, etc. The written complaints are received in writing. The verbal complaints are received by oral and must be documented by appointed person.

In the pharmaceutical industry, handling of this product complaint is important issue because if there is a serious

quality problem aroused, it can harm the customer, also to the company's reputation. If product complaint received, it is necessary to identify and address the root cause of the complaint. Solution of root cause will help to prevent the recurring of complaints. Appropriately handled complaints can help to retain or get more customers and ensure customer satisfaction. If there are serious quality problems of product cause potential harm to the consumer, product recall shall be considered. The handling of complaint will take a very important place in pharmaceutical industry, as this industry directly related to the human lives. The market product complaints should be handled in an appropriate manner.

Procedure for handling of market complaints:[1]

The complaint will receive by the marketing department or product promotion department and forward it to quality assurance department (QAD).

The quality assurance department will file the complaint in register with reference number.

- Under the supervision of quality assurance department head, the executive of quality assurance department will perform investigations by root cause. The following figure shows the procedure for root cause analysis.
- The maximum time for sending reply to customer should be of 15 days.
- All the complaints are reviewed yearly for evaluation of market complaints which are out of trends by annual review procedure.

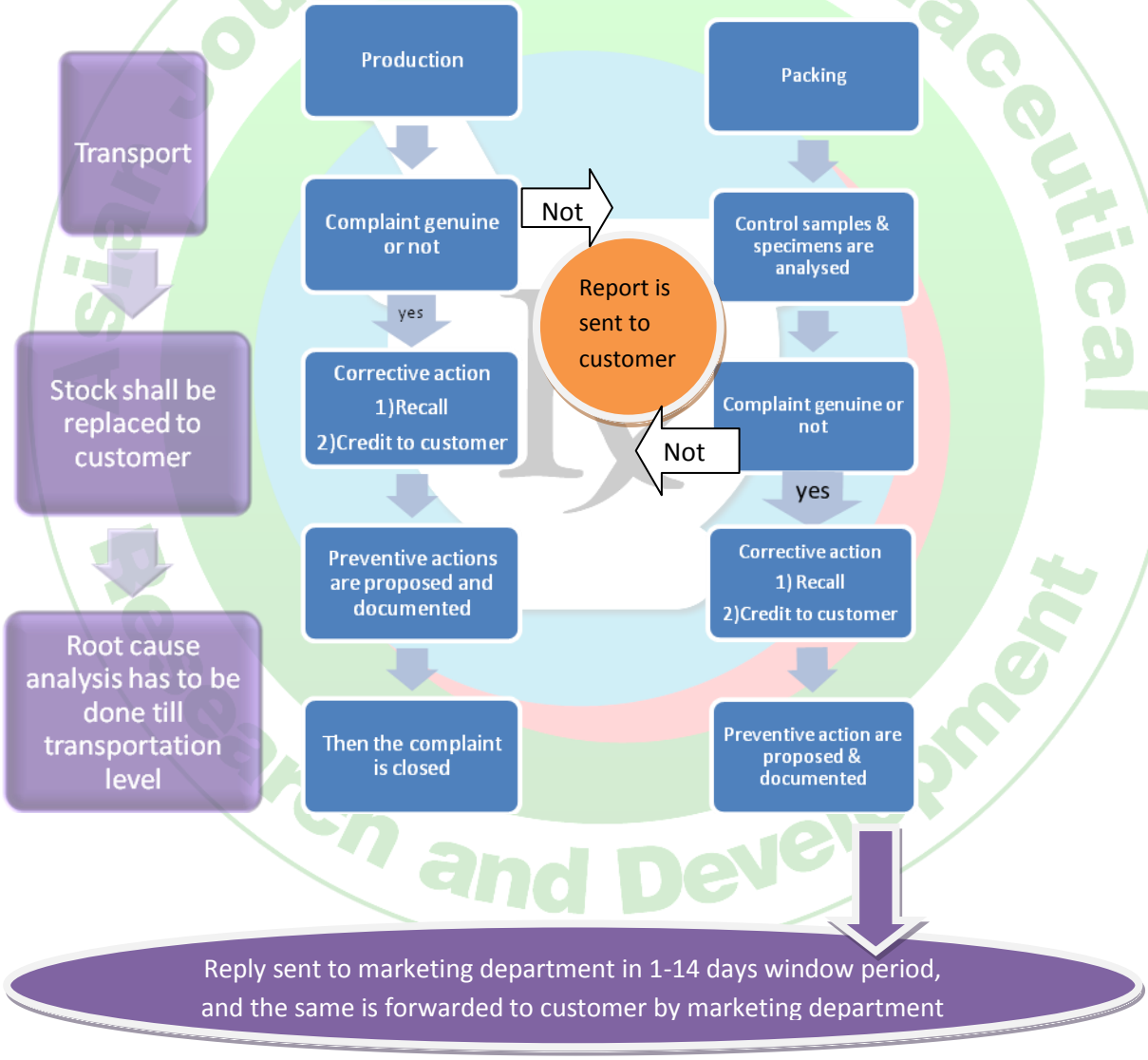
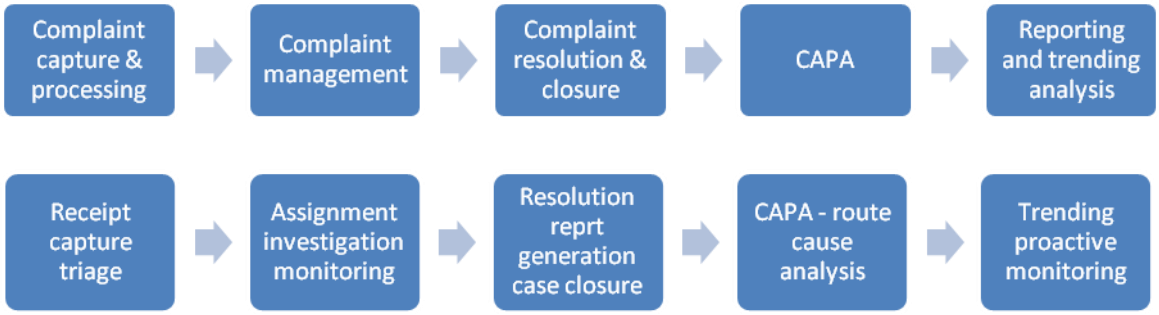


Fig. 1: Procedure for root cause analysis of market complaints

The basic workflow for product complaint handling in pharma is as



All the complaints related to quality, whether they received orally or in writing, they should be recorded and investigated according to the stated procedures.

- The complaint report should contain the following,
- Name and address of complainant
- Name and phone number of person submitting the complaint
- Complaint nature including name and batch number of the API
- Date at which complaint is received.
- Action initially taken including date and identity of person taking the action.
- Any follow up action taken
- Response provided to the complainant
- Final decision on intermediate or API batch or lot

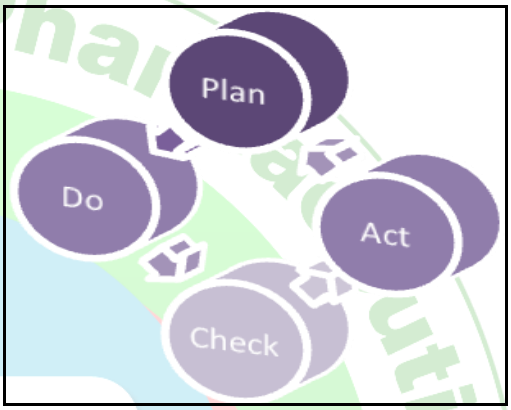
CAPA: Corrective and preventive action [2, 3, 4]

CAPA means corrective and preventive options. It usually includes a set of action under laws and regulations require an organization to take in documentation, procedures, manufacturing or systems to eliminate frequently occurring problems or non-performances. This CAPA is an improvement to the organizations process used to eliminate the cause of undesirable situations and non-conformities. The root cause analysis can help to identify the non-performance after systemic evaluation and analysis. The non-performance can be anything like failure of machinery or a quality management system, market complaint or customer complaint, or misinterpretation of written instructions to carry out the work. The CAPA must be implemented systematically and should observe for its ability to eliminate further recurrence of such non-conformation. This corrective and preventive action is designed by team that includes personnel of quality assurance department and personnel involved in actual observation of non-conformance. CAPA is a part of overall quality management system (QMS). It is a concept within good manufacturing practices (GMP).

The PDCA cycle

This PDCA (plan-do-check-act) is a four step management method used in any business like pharmaceutical for the control and improvement of processes and products. The version of this PDCA cycle is OPDCA. In this, the "O" stands for observation.

The PDCA cycle:



Product recall: [4]

The product recall is a removal of marketed product from market for the reason of deficiencies in safety, quality and efficacy, including labeling considered being in violation of laws. For the effective management of product recall, it is important to know what the product recall constitutes of.

The decision to recall drug from market can be taken by the ministry of health, manufacturer, the licensee or the import permit holder. The reason of the recall of medicinal product can be any complaint from the customer or any unexpected and serious adverse drug reaction.

Any type of industry should have an efficient recalling system for fast removal of unsatisfactory material whenever the complaint arises. Once the decision of recall made, the responsibilities should be assign to separate personnel for implementation, this can help to achieve an efficient recalling system.

Every industry should have a product recall co-ordination committee to execute the recalls.

The product recall co-ordination committee should constitute of:

- Managing director
- Quality assurance head
- Production head
- Marketing department head

The managing director will make the ultimate decision regarding recalls.

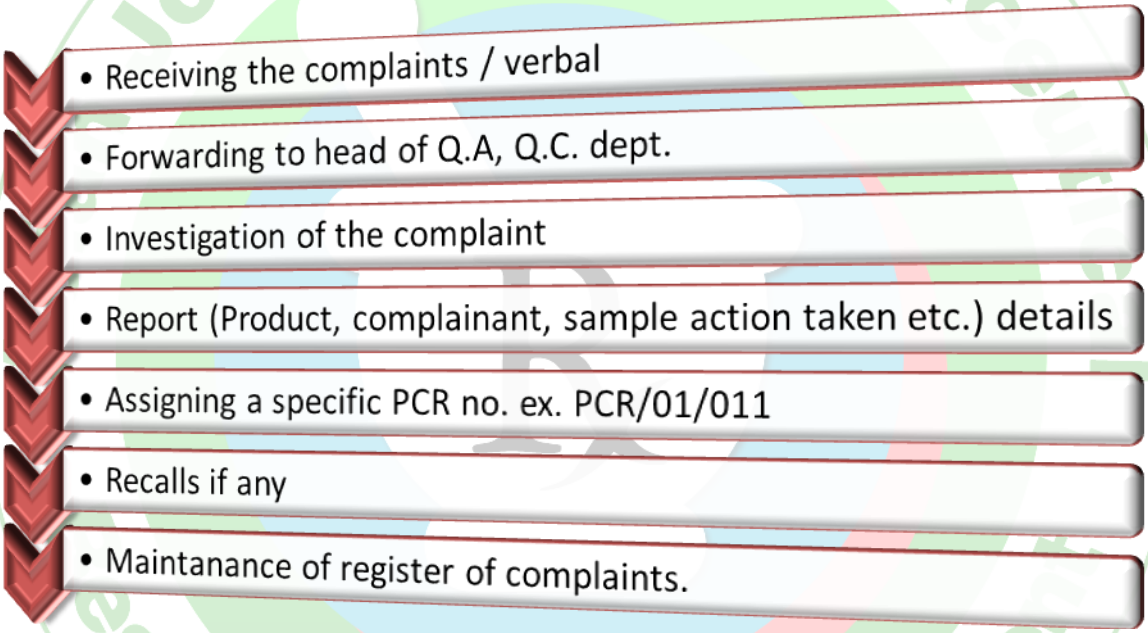
A specific criterion should be followed by the manufacturer company for recall. When regulatory agency ordered, the recall co-ordination committee should recall the product. Once complaint found to be

genuine, the recall process must initiate within 48 hours and should be completed within 14 days. This product recall procedure should be done at different level, i.e., vendor, distributor, retailer, wholesaler, and user, by informing the supply chain. As soon as the product recalled from market, the recall co-ordination committee authorize a person to destroy the recalls at the site of manufacture. The recalled product should be destroyed and documented in presence of the authorized personnel.

A product recall usually results from one or combination of several situations like company discovery, customer complaint, adverse drug reaction, or regulatory inspection. In that, customer complaint can be any major and critical defect like stained labels due to leakage, precipitation in clear syrup, off odour. The company discovery can include problems related to the running batch; a particular batch may have some problem during processing, the company carrying out an investigation might lead to the discovery of any problem with earlier batch which is not found prior to release can be included in company discovery e.g. change in viscosity. Any adverse situation reported can also lead to the product recall.

The product recall is classified into three types, class I, class II, and class III. Class I recall includes reasonable probability that the exposure or use of violative product will cause serious adverse consequences or death. The class II recalls includes a situation in which the probability of serious adverse reactions can be controlled and exposure to violative product may cause temporary medically reversible adverse reaction. The class III includes a situation in which the exposure or use of violative product is not causing a adverse reaction.

The product recall can be arising in following sequence:



The FDA-483[7, 8]

The FDA-483 is a form used by FDA investigators for inspection. It is required to officially record inspectional result at the completion of an investigation. The FDCA $704(b)[21USC$374(b)] is requires the written inspectional observations. Whenever an investigator found that the drug may be adulterated or is being packed, or processed under conditions which are not confirm to specification, then the 483 observations are made. On the last day of inspection, these forms are presented to the management. A deadline is given by the FDA for submission of response within 15 days to the firms. The agency will not review the response before issuing a warning letter, if FDA received the response after 15 working days.

Some of the non-GMP areas post marketing issues related to adverse drug reaction are observed in the FDA-483. These are reported in the descending order of significance. It also contains the observations of some objectionable practices but is not listed on FDA-483; they are verbally discussed with the firms during the inspection and are reported in the establishment inspection report (EIR).

This FDA-483 form does not contain observations related to the style of labeling, content of label, and promotional material, etc.

Impact of a significant FDA-483: [5, 6]

The FDA-483 forms gives impact on both import and export. In case of export, the FDA policy states that the certificate to foreign government (CFGs) will not give if the manufacturing facility for the product to be exported is not in compliance with the good manufacturing process.

In case of import, FDA can authorize refuse for the products that appear to be misbranded, adulterated, or unapproved without their physical examinations. The FDA has authority to issue import alerts for foreign manufacturing companies.

CONCLUSION:

From the above stated study, it is concluded that the market complaints and the product recalls will decrease the reputation and brand image of the firm. They should

be addressed in a proper way with the predetermined working procedures. All these things should be documented using specified format and should be compiled for the future references. The FDA-483 will help to record these complaints and recall procedures and their results. Also it will help in the assurance of import and the export.

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