International Journal of PharmTech Research
CODEN (USA): IJPRIF, ISSN: 0974-4304
Vol.7, No.3, pp 502-506, 2014-2015

Handling of Market Complaints and Recalls

Kotha Arun Kumar, N. Vishal Gupta*

Department of Pharmaceutics, JSS college of Pharmacy, JSS University, Sri Shivarathreeshwara Nagara, Mysuru – 570015, Karnataka, India

Abstract: Market complaints are serious issues which will cost the firm's inventory as well as reputation. After a product get into market, post marketing surveillance will be done to monitor the adverse effects on population. The complaint origin can be anything, i.e. transportation, production and packing. So the market complaints are handled on higher priority. The market complaints are handled with well-defined procedures. If the complaint seems to be genuine, then a root cause analysis should be performed to rectify the problem and the products should be recalled from the market. The recall system should be efficient enough to remove the product from market within a specified period of time. The following review depicts a typical procedure for handling of market complaints and product recalls.
Key words: market complaint, recall, handling.

Introduction:

The incidence of market complaint is a serious issue, which may lead to inventory loss as recall. The occurrence of such incidences will indicate inappropriate manufacturing & maintaining of pharmaceutical products, by which the brand image of the firm will be affected. Such events should be avoided by following cGMP, and the complaints should be investigated. Whenever the market complaints occurs, those complaints and other information related to the batches affected should be thoroughly reviewed, the cause for complaint has to be investigated and corrective action should be taken immediately.

The handling of market complaints should be assigned to a dedicated department led by a supervisor, who has the authority to investigate the complaints, along with adequate subordinates to support him or her. In case of potential product defects, inquiry has to be done, considering the need to recall, if necessary. The authorized personnel should determine the actions to be taken to rectify the issue, through appropriate written procedures. Any complaint should be scrutinized, documented along with the original documents of those particular batches. Any batches that may also be affected along with the complained batches, are also examined for such defective similarities [1].

In case if the complaint is found to be genuine, then the products should be recalled from the market with in specified period of time. In such case, all investigation reports, follow up actions taken should be documented. All the documents related 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:[2]

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.

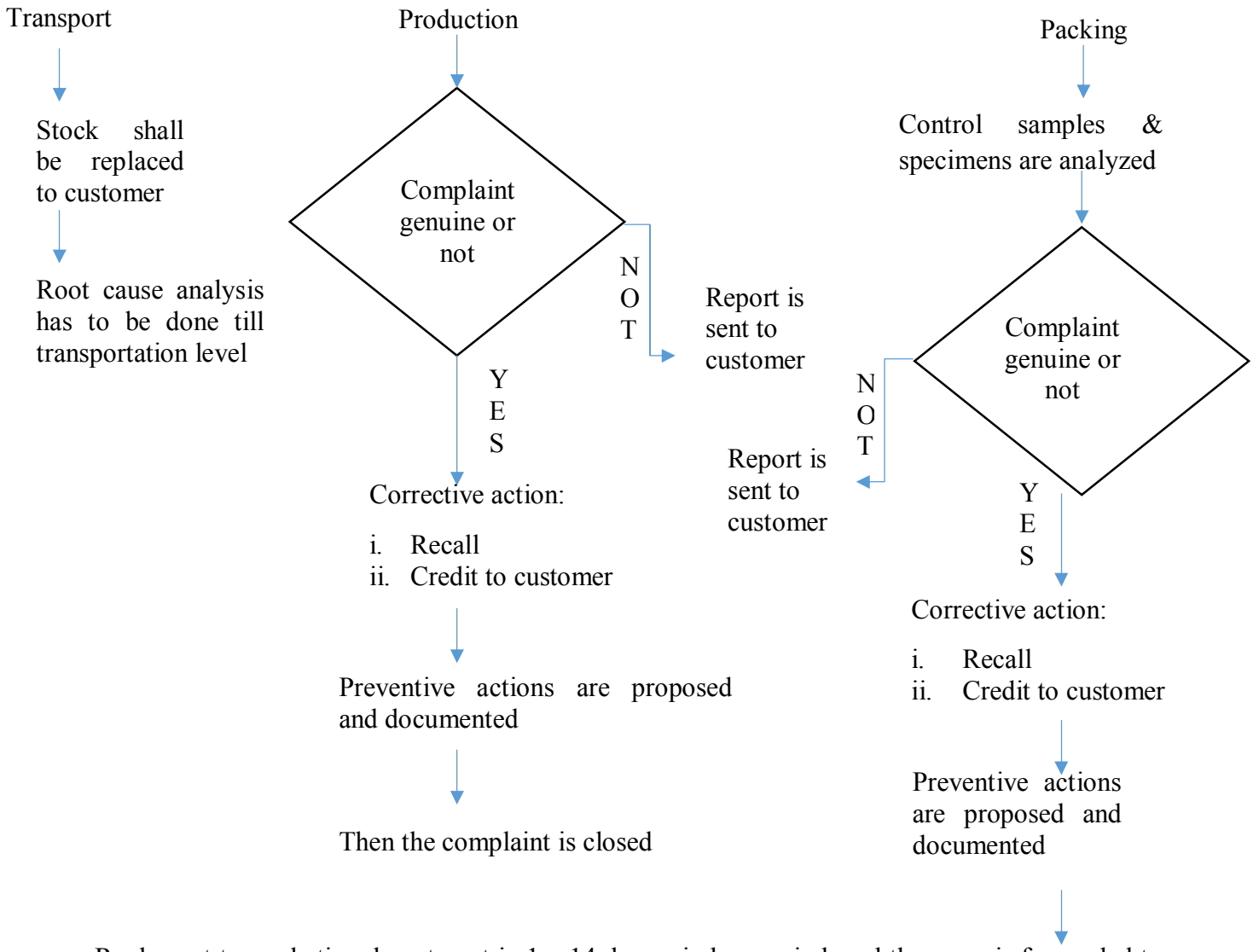

Figure 1: Procedure for root cause analysis of market complaints

The following table 1 is a typical protocol format that can be utilized for investigating market complaints.

Table 1: Market complaint investigation form

Product complaint details	
Product:	**Product code:**
Batch no.:	**Date of manufacture:**
Packaging:	**Date of expiry:**
Supplier / manufacturer / brand:	**Quality affected:**
Sample quantity:	**Complaint date:**

<table>
<tr><td colspan="4">Details of the complainer
Name of the complainer:
Address:
Mode of complaint:
Contact no.:
Contact person:</td></tr>
<tr><td colspan="4">Nature of the complaint</td></tr>
<tr><td colspan="2">☐ Quality related complaint</td><td colspan="2">☐ Physical related complaint</td></tr>
<tr><td colspan="2">☐ Clinical related complaint</td><td colspan="2">☐ Packing related complaint</td></tr>
<tr><td colspan="2">☐ Label related complaint</td><td colspan="2">☐ Process related complaint</td></tr>
<tr><td colspan="4">☐ General complaint</td></tr>
<tr><td colspan="4">Product management comment:

Sign & date</td></tr>
<tr><td colspan="2">Market complaint received by QAD (comments if any)</td><td colspan="2">QAD: enter in market complaint register
QAD: file the complaint in market complaint register

Sign & Date</td></tr>
<tr><td colspan="4">Date of complaint forwarding to respective department:</td></tr>
<tr><td colspan="4">INVESTIGATION DETAILS</td></tr>
<tr><td>Batch no.:</td><td colspan="2">Test conducted</td><td>Observation</td></tr>
<tr><td>Batch 1</td><td colspan="2"></td><td></td></tr>
<tr><td>Batch 2</td><td colspan="2"></td><td></td></tr>
<tr><td>Batch 3</td><td colspan="2"></td><td></td></tr>
<tr><td colspan="4">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:</td></tr>
</table>

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 Recall System

An industry should have an efficient recalling system to ensure speedy and efficient removal of unsatisfactory material form the market. It can be achieved by assigning responsibilities for implementation once the decision of recall has been made. [3]

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.

Criteria for recall:[4]

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, retailor, 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 destruction of recalled products should be documented using following format of table 2.

Table 2: Documentation of destroying of recalled product

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

Conclusion:

As market complaints and product recalls will decrease the brand image of the firm, it should be properly addressed, with predetermined working procedures. All these incidences should be documented using specified formats and are archived for future reference.

References:

1. S Vedanabhatla, NV Gupta, A review on audits and compliance management, Asian J Pharm Clin Res, 2013; 6(2): 43-45
2. http://www.pharmaguideline.com/2011/08/sop-for-handling-of-market complaints.html, accessed on 15th December, 2014.
3. http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm (recall fda guideline), accessed on 22nd December, 2014.
4. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=7&showFR=1 (CFR guidelines on recalls), accessed on 2nd January, 2015.

*****