Complaints and Recalls

Sections 5 and 6

World Health Organization

Complaints and Recalls

Objectives

- To identify the key issues in product complaint and recall handling
- To understand the specific requirements for organization, procedures and resources
- To understand and develop actions to resolve current issues applicable to you

Complaints and Recalls

Complaints: Principle

"All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures and corrective action should be taken."

5.1

Complaints and Recalls

Complaints Procedure - I

- Designated responsible person:
  - *To handle complaint*
  - *Decide on measure to be taken*
  - *May be authorized person - if not, must advise authorized person of results*
  - *Sufficient support staff*
  - *Access to records*

- Written procedure (SOP):
  - *Describes action to be taken*
  - *Includes need to consider a recall (e.g. possible product defect)*

5.2 – 5.3

Complaints and Recalls

Complaints Procedure - II

- Thorough investigation:
  - *Quality Unit (e.g. QC) involved*
  - *With special attention as to whether suspect (counterfeit) products may have been the cause*
  - *Fully record of detailed investigation*
- Due to product defect (discovered or suspected):
  - *Consider checking other batches*
  - *Batches containing reprocessed product*

5.4 – 5.6

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Complaints Procedure - III

- Investigation and evaluation should result in appropriate follow-up actions
  - ↗ *May include a "recall"*
- All decisions and measures taken should be recorded
- Referenced in batch records
- Records reviewed at regular intervals
- Also trending to be done to identify recurring problems

5.7 – 5.9

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Other actions

- Inform competent authorities in case of serious quality problems such as:
  - *Faulty manufacture*
  - *Product deterioration*
  - *Suspect product*
  - *Serious quality problems*

5.10

Complaints and Recalls

Classification of Defects

- If complaint is justified, then there has been a failure of the quality system
- Once the defect has been identified, the company should be dealing with it in an appropriate way – which may include a recall
- The definition of defects is useful
- The following system has been found in some countries (Note: this is not a WHO guideline):
  - Critical defects
  - Major defects
  - Other defects

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Critical Defects

- Those defects which can be life-threatening and require the company to take immediate action by all reasonable means, whether in or out of business hours

Examples

- *Product labelled with incorrect name or incorrect strength*
- *Counterfeit or deliberately tampered-with product*
- *Microbiological contamination of a sterile product*

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Major Defects

- Those defects which may put the patient at some risk but are not life-threatening and will require the batch recall or product withdrawal within a few days

Examples

- *Any labelling/leaflet misinformation (or lack of information) which represents a significant hazard to the patient*
- *Microbial contamination of non-sterile products with some risk for patients*
- *Non-compliance to specifications (e.g. active ingredient assay)*

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Other Defects

- Those defects which present only a minor risk to the patient — batch recall or product withdrawal would normally be initiated within a few days

Examples

- *Readily visible isolated packaging/closure faults*
- *Contamination which may cause spoilage or dirt and where there is minimal risk to the patient*

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Root Cause Analysis

- It is also an increasing practise to do root cause analysis (RCA) as part of the investigation of a complaint
- Use appropriate RCA tools to identify the reason(s) for the failure or defect.
- RCA assists in ensuring that appropriate corrective action and preventive action (CAPA) is taken

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Recalls: Principle

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

6.1

Complaints and Recalls

Reasons for Recall may include:

- Customer complaint
- Detection of GMP failure after release
- Result from the on-going stability testing
- Request by the national authorities
- Result of an inspection
- Known counterfeiting or tampering
- Adverse reaction reporting

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Definition

- Recall
  - *Removal from the market of specified batches of a product*
  - *May refer to one batch or all batches of product*

Recall Procedure - I

- Designated responsible person (should be the "authorized person")
  - *To execute and coordinate recalls*
  - *Decide on measure to be taken*

- Sufficient support staff
  - *To handle all aspects and urgency of recall*

6.2

Complaints and Recalls

SOP for Recall

- Written and authorized SOP with detailed actions to be taken
- Regularly reviewed and updated
- Capable of rapid operation to required level of distribution chain, e.g. hospital and pharmacy level
- Ensures that recalled products are kept in a secure, segregated area

6.3 – 6.4

Complaints and Recalls

Distribution Records

- Distribution records available to authorized person and contain sufficient information on:
  - *Wholesalers*
  - *Direct customers*
  - *Export locations*
  - *Batch numbers and quantities*
  - *Including for clinical tests and medical samples*

  to permit effective recall

6.6

Complaints and Recalls

Progress of recall

- Inform all competent authorities of all countries where the given product had been distributed
- Monitor and record the progress during the recall
- Final report should include reconciliation between delivered and recovered products
- Record of the disposition of the product

Effectiveness of procedure tested and evaluated from time to time! (Mock recall)

6.5, 6.7, 6.8

Complaints and Recalls

Group Session

- Collect 3 examples of complaints or recalls from your experience
- Describe the actions to be taken by the company or authority and the implications for all interested parties
- Suggest a classification of the complaint or recall into critical (life-threatening), major or other

Complaints and Recalls

Possible Issues – I

- No response to justified complaints
- Response to unjustified complaints
- Failure to recall
- Failure to correct frequent complaints
- No resources to investigate
- No senior management support
- Senior management interference

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Possible Issues – II

- No distribution information/batch records
- No access to records
- Inability to contact government during holidays/weekends
- Disagreement on severity of defect