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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
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**EudraLex The Rules Governing
Medicinal Products in the European Union**

**Volume 4
EU Guidelines to
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use**

**Part I Chapter 8
Complaints and Product Recall**

Document History

Revision to include new Points 8.7 on requirements on counterfeit products and transferring the original Points 8.7 into a modified Point 8.8;

slight modification of Point 8.16

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Principle

All complaints and other information concerning potentially defective products must be reviewed carefully according to written procedures. In order to provide for all contingencies, and in accordance with Article 117 of Directive 2001/83/EC and Article 84 of Directive 2001/82/EC, a system should be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.

Complaints

- 8.1 A person should be designated responsible for handling the complaints and deciding the measures to be taken together with sufficient supporting staff to assist him. If this person is not the Qualified Person, the latter should be made aware of any complaint, investigation or recall.
- 8.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.
- 8.3 Any complaint concerning a product defect should be recorded with all the original details and thoroughly investigated. The person responsible for Quality Control should normally be involved in the study of such problems.
- 8.4 If a product defect is discovered or suspected in a batch, consideration should be given to checking other batches in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch should be investigated.
- 8.5 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.
- 8.6 Complaints records should be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products.
- 8.7 Special attention should be given to establishing whether a complaint was caused because of counterfeiting.
- 8.8 The competent authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, detection of counterfeiting or any other serious quality problems with a product

Recalls

- 8.9 A person should be designated as responsible for execution and co-ordination of recalls and should be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency. This responsible person should normally be independent of the sales and marketing organisation. If this person is not the Qualified Person, the latter should be made aware of any recall operation.
- 8.10 There should be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.

- 8.11 Recall operations should be capable of being initiated promptly and at any time.
- 8.12 All Competent Authorities of all countries to which products may have been distributed should be informed promptly if products are intended to be recalled because they are, or are suspected of being defective.
- 8.13 The distribution records should be readily available to the person(s) responsible for recalls, and 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 for exported products and medical samples.
- 8.14 Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate.
- 8.15 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.
- 8.16 The effectiveness of the arrangements for recalls should be evaluated regularly.