

Warehousing and Distribution of Commercial Products

these records should be made available to the competent authorities in whose territory the products were distributed.

5.7.3 In order to ensure the efficacy of the emergency plan, the full distribution records for finished products should be readily available.

5.7.4 In the case of a recall, the level of recall will be determined as part of the recall strategy. It is the decision of the distribution unit as to whether a wholesaler is to contact their customers. If yes, the wholesaler may decide to contact all of their customers or only those having received the batch to be recalled. Contact should be made within the specified timescales.

5.8 Suspect Counterfeit or Counterfeit Products

Suspect counterfeit products found in the distribution network should be clearly labeled and kept apart from other products to avoid any confusion.

5.9 Disposal of Rejected, Returned, Recalled or Counterfeit Product

A formal decision should be taken on the disposal of these products and the decision should be recorded. The person responsible for the quality system of the wholesaler and, where relevant, local QA manager should be involved in the decision making process.

5.10 Self Inspections

Self-inspections should be conducted (and recorded) in order to monitor the implementation of and compliance with this guideline.