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Recalls & the Role of the Wholesaler

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Content

- Quality Defect Investigations
- Recalls
- Role of the Wholesaler in Recalls
- Issuing and Receiving Recall Letters
- Recalls related to Wholesale Activities



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Recall Statistics 2009

- During 2009, 614 Quality Defect investigations were handled by the IMB.
- A Quality Defect is an unplanned attribute of a Medicinal Product, or component, which may affect the quality, safety **and/or** efficacy of the product **and/or** is not in line with the approved marketing authorisation/product registration file for that product or component.
- Market Compliance Section (MCS) investigates all Quality Defect Investigations and liaises with relevant sections in the IMB as necessary.



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Quality Defect Report

1. Initial Investigation/
Information gathering

2. Risk Based Decision

3a. No Market Action but
Corrective Actions

3b. Market Action &
Corrective Actions

4a. Investigation Report

4b. Recall or
Investigation Report

Outcomes of Quality Defect Investigations

- Availability of product on the marketplace is always considered when determining action(s) to be taken
 - Batch or Product Recall
 - Issuance of a Caution In-Use Notification / Dear Doctor Letter / Counterfeit Notification
 - Other Actions



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Recalls

- Retrieval of a batch/product (for quality defect, non-compliance or safety and/or efficacy reasons) is considered a recall once:
 - The batch has been QP released and has left the control of the manufacturer responsible for QP release
- Return of a batch/product for commercial reasons, logistical reasons or due to ordering or shipping errors is not classified as a recall (See IMB recall guidance – Section 1.1)

Recall Statistics

- 99 of the 614 Quality Defect Investigations required recall action on the Irish Market
- Only 16% of all Quality Defect investigations resulted in a recall
- 91 human medicine recalls and 8 veterinary medicine recalls



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Level of Recalls

Level of Recall	Number of Recalls in 2009
Patient Level	8
Retail/Pharmacy/Dispensing Level (including free medical samples)	51
Secondary Wholesale	5
Primary Wholesale	27
Total	91



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The role of the Wholesaler in a Recall

- Generally, the responsibility & role is dependent on where the Quality Defect (QD) occurs.
 1. If the QD which led to the recall occurs at a premises other than a wholesaling premises
 - Wholesaler will have a minor role
 2. If the QD which led to the recall occurs at a wholesaling premises
 - Wholesaler will play a greater role



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1. When the Quality Defect has occurred outside of the wholesale premises

- Role of the Primary Wholesaler
 - Recalls often channelled through the primary wholesaler
 - Quarantine stocks at hand
 - Compile customer listing for Marketing Authorisation Holder (MAH)
 - Receive and quarantine stock retrieved during recall (Wholesale & Retail)



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1. When the Quality Defect has occurred outside of the wholesale premises

- MAH may delegate the responsibility of co-ordination of the recall to the primary wholesaler
 - Issuance of recall letter(s)
 - Monitoring the progress of the recall & ensuring efficient recovery of recalled stock
 - Reconciliation of distributed & recalled stock
- MAH is responsible for the quality defect investigation and submission of recall report
 - Primary distributor may be requested to compile reconciliation section



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1. When the Quality Defect has occurred outside of the wholesale premises

- Role of the Secondary Wholesaler
 - Follow instructions as per the recall letter
 - Quarantine stocks at hand
 - Ensure that your wholesale customers are notified of the recall
 - Receive and quarantine recalled stock from customers (Wholesale & Retail)
 - Transport quarantined stock to primary distributor



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2. When the Quality Defect/Non-Compliance is Identified at a wholesale premises

- Wholesaler should inform IMB & MAH (All Wholesalers)
- Decision regarding recall action
 - IMB, MAH(s) & Wholesaler
- If no recall action required
 - Wholesaler is requested to submit investigation report (root cause & corrective actions)
- If recall action required
 - Decision regarding responsibility for recall co-ordination (MAH(s) &/or Wholesaler)



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Wholesaler Co-ordinating a Recall

- Written confirmation from MAH that IMB may liaise directly with the wholesaler concerning the recall
- Wholesaler responsible for:
 - Drafting recall letter(s) & submitting to MCS for approval (IMB show copy to MAH)
 - Issuance of recall letter(s)
 - Receipt & reconciliation of recalled stock
 - Investigation into cause of quality defect & identify corrective action(s)
 - Submission of recall report



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Recalling outside Ireland

- Where a wholesaler has supplied product which is the subject of a recall to a wholesaler outside of Ireland:
 - Notify those wholesale customers
 - Inform IMB MCS, so that it can liaise with the Competent Authority in the country to which the product has been supplied



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Exempt Medicinal Product Recall

- Regardless of where the quality defect occurs, it is the responsibility of the primary wholesaler in conjunction with the MAH, to remove the defective exempt medicinal product from the Irish marketplace, in the event that a recall is required
- If a wholesaler identifies a quality defect, or, is notified of a quality defect with an exempt medicinal product they should immediately inform IMB



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Recall Letters

- All recalls, except those to primary wholesale level are executed via the issuance of recall letter
 - Initial communication may be via telephone or fax, but, always followed with a hard copy letter
- IMB Template must be used to ensure correct content
- Approved by IMB prior to issue
- Independent check should be performed prior to submitting to IMB
- IMB included in the mailing of the signed and dated letter

On Receipt of a Recall Letter

- Please read the complete letter carefully
 - 'If you have supplied this batch (these batches) to any other wholesaler, please fax those wholesalers a copy of this recall letter, requesting that they quarantine and return any unsold quantities of this batch (these batches) to you.'
- Responsibility of the RP to ensure that recall instructions are carried out



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Recalls related to Wholesale Activities

- Of the 91 Recalls of Human Products – 35 related to unlicensed products on the Irish market
 - UK stock identified in numerous retail stores
 - UK stock distributed by primary wholesalers in error
 - Commercial stock distributed as Free Medical Samples in error
 - Joint UK/IE pack sourced from the UK for distribution here contained Australian stock approved for use in the UK by the MHRA
 - Parallel distributed Centrally Authorised Products without the required overlables



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Recommendations

- Maintain a system in place to ensure the presence of a PA /EU number and challenge that system regularly
- Regularly challenge your recall SOP
- Batch tracking is strongly advised by the IMB for all wholesalers as it can allow a targeted recall rather than a blanket recall for batch recalls
- Ensure ALL staff involved in checking of PA/EU numbers, exempt product notifications, OCABR vaccine requirements etc. understand WHY they are doing checks
- Ensure that recalled packs received back via returns are identified and segregated immediately

Information

- IMB Recall Guidance Document
 - www.imb.ie – Publications Section – Safety & Quality Guidance
'Guidance on the recall of medicinal products for human and veterinary products'
- Reporting a Quality Defect or Recall
 - recallsandqualitydefects@imb.ie
 - Phone 01 6764971
 - Kevin O'Donnell (Market Compliance Manager)
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 - Breda Gleeson (Market Compliance Inspector)
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Questions

