IRISH MEDICINES BOARD

Case Studies

Feedback

Camden Court Hotel, 29.03.2012

Case Study 1

DOCUMENTATION AND RECORDS

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Case study 1 Documentation and records

- **Objective**
  - To analyse current systems to ensure cosmetic compliance at ‘goods in’.
  - To recognise the value of having a system for supplier approval.

- **Outputs**
  - Recommendations for key items to be included as part of goods in checklist
  - A proposed template for supplier agreement or technical agreement

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Question 1: Expired Products

- **You are a distributor** of cosmetic products and receive a shipment of cosmetics from the Responsible Person for these products. Products are **stored in your warehouse facility**. After three months you are carrying out an inventory check and **identify that certain products in the storage facility have expired**. After checking the database you realise some of the **batches have been dispatched**.

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Question 1: Expired Products

- **How can you ensure that expired product is not accepted into your warehouse as part of 'goods in' checks?**

- Goods in Checks
  - RP name and address
  - Language requirements
  - Ingredient list
  - Expiry date and
  - Batch number
  - In accordance with Article 19 (1) (a), (e), (g), Article 19 (3) and Article 19 (4) of 1223/2009.

- Operate the FIFO system

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Question 1: Expired Products

- Carry out in-house stock checks
  - FIFO system working
- Technical agreement
  - E.G. Minimum durability remaining of > 9 months
  - Expired product is not placed on the market
  - How quickly stock turns over
- Goods out checks to include expiry date check

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Question 1: Expired Products

- **What measures should you take on identifying this expired product?**

- Records retained for duration of three years following delivery of last batch

- Readily retrievable in accordance with the legal requirements of (Art. 7) Regulation 1223/2009/EC.

- Identify from records the units and batches
  - Batch number recording is best practise, not a legal requirement

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Question 1: Expired Products

- Identify chain of distribution
  - Retailers
  - Pharmacies
  - Distributors

- Inform these retailers, pharmacies and other distributors of the issue

- Identify actions to be taken
  - Product withdrawal
  - Replacement
  - Communicate this to retailers

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Question 2: Missing information

- You are a Distributor of cosmetic products and you receive a phone call from a retailer about some products. An Environmental Health Officer (EHO) has been on inspection to the outlet and noticed that the **ingredient list for a lipstick product is missing**, and is not on display in the premises. The EHO advised the retailer to follow up with their distributor on the issue. You realise the ingredient list **was never despatched** with the product and has been thrown away by mistake.

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Question 2: Missing information

- How can you ensure that any additional packaging material, such as an information booklet containing ingredient lists, are included in future deliveries?

- Goods in checks were not robust enough

- Identify if this is the only outlet affected

- Contact the manufacturer
  - Request another set of booklets containing ingredients lists

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Question 2: Missing information

- Identify how this can be avoided in future
  - Goods in and goods out checks to include inventory checklist.
  - Goods out checklist
    - record list of retailers or distributors to whom the product is supplied

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Question 3: Technical Agreement

- You are making improvements to your business as a distributor of cosmetic products and as part of your supplier approval system, you decide to put a **Technical Agreement** in place with the manufacturer (RP) of the products.

- Complete the Technical Agreement template

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Question 3: Technical Agreement

- Persons entering contract and contact details, including out of hours contacts in case of emergency. Duration of contract

- List of products and product codes concerned

- Documentation requirements
  - Batch numbers and
  - Expiry dates to be included on invoices,
  - Certificate of analysis

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Question 3: Technical Agreement

- Responsibilities of each party;
  - Who is the RP
  - RP role to be specified

- Responsibility for investigating
  - Complaints
  - Timelines involved

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Question 3: Technical Agreement

- Responsibility for reporting SUEs – The Distributor must notify the IMB and the RP of any SUE that has been made known to him without delay

- Roles and responsibilities
  - Recall
  - Withdrawal
  - Timelines involved

- Any major regulatory issues
  - Notified to the manufacturer within certain timelines

- Detail access to Product Information File

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Question 3: Technical Agreement

- Agreement on remaining shelf-life per product
  - E.G. Specify that product must have > 9 month shelf life at time of delivery
- What checks are made at delivery
- Supplier audit agreements
- Quality checks to be carried out
- Storage and transportation conditions

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Case Study 2

WHEN THINGS GO WRONG

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Case study 2 - When Things Go Wrong

- **Objective**
  - To establish a process for investigating Serious Undesirable Effects (SUE) and
  - To raise awareness to the RAPEX product safety alert mechanism.

- **Outputs**
  - A SUE template form and
  - Subscription to the NCA weekly alerts.

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Question 1 – Serious Undesirable Effect

Incident involving a cosmetic product which you supplied.

Product Description: Children's Face paint; batch number BN1111.

Incident Details:

Hospitalisation = Serious → Complete SUE form A

Reported by Consumer

Child aged 7

Product applied to the face and neck

Time to onset = 5 minutes

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Question 1 – Serious Undesirable Effect

What actions would you take as a result of this reported incident?

1. Gather further information
   - Similar complaints?
   - End user contact details
   - Additional information –
     - medical reports,
     - other products also being used etc.

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Question 1 – Serious Undesirable Effect

What actions would you take as a result of this reported incident?

2. Inform the Responsible Person and the IMB without delay.

3. Await instruction from Responsible Person and/or IMB.

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Question 1 – Serious Undesirable Effect

What actions would you take as a result of this reported incident?

4. Market Actions – should be agreed with IMB
   - Temporary suspension of distribution while the product is being investigated.
   - Ensure the retailer is aware that any materials which were distributed with the product for display at retail level have been displayed.
   - Cooperate with the IMB in any market action requested

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Question 2 – RAPEX

You have signed up to the NCA's Rapex list. You received an e-mail with a list of recent notifications. A Rapex notification has been issued for a product which you are currently distributing. You have attempted to contact the Responsible Person for this product but have been unsuccessful. Discuss what actions you would take.

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Question 2 – RAPEX

Examine the product to ensure that product codes and the batch number are identical

If a different batch has been notified:

- Contact your supplier for further information on the risk or contact IMB for further advice.

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Question 2 – RAPEX

Examine the product to ensure that product codes and the batch number are identical

If the batch number is the same:

1. Quarantine any remaining stock in your warehouse;

2. Contact the IMB to advise them that product the subject of RAPEX reference XXXX/YY was distributed by you.

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Question 2 – RAPEX

Examine the product to ensure that product codes and the batch number are identical

If the batch number is the same

3. Contact your customers (other distributors and retailers) and advise them of the product issue and to quarantine any affected stock;

4. Cooperate with the IMB and EHOs involved in the investigation.

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