P11
Drug Recalls

E356 – Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management

E356 Topic Tree

Pharmaceutical and Bio-chem Supply Chain

- Introduction to Pharma and Bio-chem
- Classification of Dangerous Goods
- Best Practices (GMP/GDP)
- Clinical Supply Chain
- Cold Chain Management

Import, Packaging and Distribution

- Import and Distribution of Medical Devices
- Import of Pharmaceutical and Bio-Chem Products
- Local Transportation of Pharmaceutical and Bio-Chem Products
- Packaging of Pharmaceutical DG for Air Transport
- Declaration of Pharmaceutical DG for Air Transport

Product Tracing, Recall and Disposal

- Product Tracing (anti-counterfeit technologies)
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics

Guidelines and Governing Authority

- As part of HSA's ongoing initiative to update and streamline the regulatory controls for health products, pharmaceutical products, commonly known as chemical or biologic drugs, are now regulated as "Therapeutic Products (TP)" under the Health Products Act (HPA).

- Defects in TP may occur at any point in the supply chain. Under the Health Products (Therapeutic Products) Regulations 2016, product defects that affects the safety, quality and efficacy and may cause potential harm to the patient or public health will have to be reported to the Health Sciences Authority (HSA).

- Companies (product registrants, manufacturers, importers and suppliers) are responsible for the safety, quality and efficacy of their therapeutic products and should have adequate systems and appropriate procedures in place to investigate, review and report the product defects to HSA, and if necessary, to promptly recall the affected products.

Definition by HSA

Product Defect

A suspected deficiency which may produce an impact, whether directly or indirectly, on the continuing safety, quality and efficacy of a product.

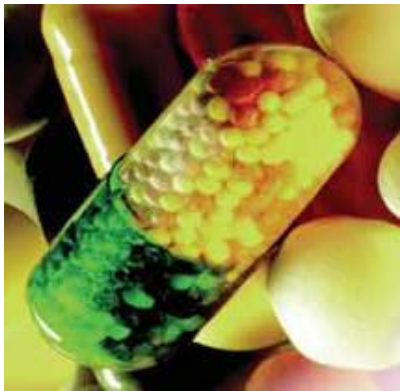
Product defect is classified as “critical defect” or “non-critical defect”.

Product Recall

A permanent removal of the affected products from the market OR a temporary removal for product correction, after which the corrected products may be returned to the market for sale.

If a defect is found in a product, HSA can suspend the sales of a product or the licences of products.

A suspended product may or may not result in a recall.



Classification of product defects

A defect is classified into either “critical defect” or “non-critical defect” according to the potential impact to public health and the risks posed to the intended user of the TP.

Critical defect

A critical defect is deemed as one that can pose a ***serious threat*** to the intended users or public health in Singapore. Notify HSA **within 48 hours**.

Non-critical defect

A non-critical defect is one which does not meet the criteria of “critical defect” but may cause illness or affect the outcome of a person’s medical treatment and/ or significantly affect the quality of a TP. Notify HSA **within 15 calendar days**.

Classification of recalls by HSA

The classification and level of recall will depend on the potential hazard of the defective product and the extent of product distribution. These are determined after consultation between the Company and HSA.

Class 1 Recall

Initiated when there is a reasonable probability that the use of or exposure to a Therapeutic Product (TP) with critical defect which may cause serious adverse health consequences or death.

Class 2 Recall

Initiated when the use of or exposure to a Therapeutic Product (TP) with non-critical defect which may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Levels of Recall

a) Recall to Consumer level includes

- Patients
- Other consumers
- Wholesale and retail levels

b) Recall to Retail level includes

- Restructured and private hospital pharmacies;
- Retail pharmacies;
- Medical, dental and other healthcare practitioners' establishments;
- Community hospitals, nursing homes and other related institutions;
- Other retail outlets, e.g. health food stores, supermarkets.

c) Recall to Wholesale level includes

- All wholesalers

Initiation of Recall

Recall Initiated by HSA

Recall may be initiated by HSA as a result of adverse drug reaction monitoring, product quality surveillance or defective reports from reputable sources.

Recall Initiated by Company

Recall may also be initiated by the Company as a result of defective reports from various sources such as those from healthcare professionals and members of the public.

Responsibilities of The Company

- Report product defects to HSA

  Every company must, upon becoming aware of any defect in the TP, report the defect to HSA in accordance with the following timelines:

  - Critical defects to be reported **within 48 hours;**
  - Non-critical defects to be reported **within 15 calendar days**.

- Maintain records of product defects

  Company must maintain records of every defect in a TP for at least 2 years after the expiry date of the TP and produce such records for inspection by HSA.

- Notify HSA concerning product recalls

  Every company who intends to recall a TP must notify HSA of, and the reasons for, the intended recall no later than 24 hours before the start of the intended recall.

Implementation of Recall

1. Company to notify HSA within 24 hours prior to initiation of the recall;
2. Justify if the level of recall should be to consumer or retail or wholesale level;
3. Refer to details of the recall process timeline (refer to the next slide);
4. Submit investigation and Corrective and Preventative Action (CAPA) report.

Details of the recall process timeline

	Class 1 recall	Class 2 recall
Description	There is a reasonable probability that the use of or exposure to a TP with **critical defect** which may cause serious adverse health consequences or death.	The use of or exposure to a TP with **non-critical defect** which may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
Notification to HSA	Company must notify HSA within 24 hours (**1 day**)* prior to the start of the intended recall.	Company must notify HSA within 24 hours (**1 day**)* prior to the start of the intended recall.
Issuance of Dear Purchaser Letter	Company is required to issue a Dear Purchaser Letter within **1 day*** of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.	Company is required to issue a Dear Purchaser Letter within **3 days*** of recall commencement, notifying of the recall action and providing the required instructions to purchasers.
Recall process *(refer to Section 7.5 for details)*	The recall process is recommended to be completed within **1 week**, unless otherwise justified. Company should submit the Product Recall Completion Form to update HSA on the completion of recall.	The recall process is recommended to be completed within **3 weeks**, unless otherwise justified. Company should submit the Product Recall Completion Form to update HSA on the completion of recall.

*Not including Sundays and public holidays.

Source: HSA- Reporting of Therapeutic Product (TP) Defects and Recall of Therapeutic Products (26 October 2016)

Maintenance of Up-to-Date Contact Details

- Contact details for the Company should be maintained up-to-date at all times.
- It is the responsibility of the Company to contact HSA proactively whenever there are any changes in the contact details, such as the person responsible, telephone number, fax number, address and email address.

Information dissemination to Distribution Channel

I. Company Particulars

- Name of Company responsible
- Name of person responsible
- Contact number(s) / hotline(s) for enquiry
- Fax number
- Address
- Signature of person responsible

II. Product Particulars

- Product name & Strength
- Active ingredient(s) & Strength
- Product licence number – if any
- Dosage form
- Pack size
- Batch number(s)
- Name of manufacturer
- Country of manufacture
- Other details for easy identification

- **III. Details of Product Defect and Treatment of Defective Products**
- Reason(s) for recall
- Nature and cause of defect
- Assessment of risk to user
- Necessity to cease sale and quarantine product(s)
- Method of recovery / collection of defective product(s) by the Company

- **IV. Other Details**
- Date of recall letter
- Other relevant details

Resources 1

Guidelines on Product Defect Reporting and Recall Procedures by HSA

https://www.hsa.gov.sg/docs/default-source/hprg/therapeutic-products/product-defect/guidance-for-industry_reporting-of-therapeutic-product-defects-and-recall-of-tps_nov2016_v1revised.pdf?sfvrsn=c267814c_0

HSA Processes for recall of Therapeutic Products

https://youtu.be/3OrHKggrjm4

Learning Outcomes

- Discuss the guidelines and governing authority involved in drug recall
- Explain the classification of product defects and recall
- Describe the level of product recall
- Explain the implementation of product recall
- Explain the initiation of recall