UNIT-4

PHARMACEUTICAL PRODUCT RECALL

lecture-1

What is a Pharmaceutical product recall?

As per USFDA ,

Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action.

Regulatory Requirement

FDA proposed a rule in January of 2013 that would require food manufacturers to maintain a recall plan as part of the preventive controls requirements set forth in section 103 of the FSMA(food safety modernization act). FDA's current regulations at 21 C.F.R. §§ 7.40-7.59 provide valuable guidance for manufacturers of food and other FDA-regulated products.

Regulatory Requirement:

21CFR Part 7, Subparts A and C – Recalls – General guidelines

21CFR Part 107, Subpart E –Mandatory recall of Infant formula

21 CFR Part 1270 – Human Tissue

PHS Act – 42 U.S.C. 26 – Mandatory recall of biological products

21 CFR Part 806 – Medical Device Correction

FD&C Act, 518(e) – Mandatory Device Recalls

Reasons of pharmaceutical product recall

1. Super or sub-potent formulations

One example was Actavis, which was forced to recall its digoxin tablets Digitek in 2008 because the pills were thought to have been manufactured to a double thickness.

2. Particulate contamination

Number two in our top five is contamination with particulate matter, a group which we have combined to include all cases where the contamination has come from inorganic materials such as glass, silicone and stainless steel.

3. Is poorly manufactured

Manufacturing defects related to a product's quality, purity, and potency may be to blame for a drug recall.

4. Is mislabeled or packaged poorly:

Sometimes a medicine is recalled because of confusing dosing instructions or a problem with the dosing tool provided with the drug.

5. Is not what it says:

For example, you may think you are taking a pain reliever based on the package material, when in fact what is inside the box is something else.

6. Is a health hazard:

Unfortunately, some health risks associated with certain medications are not realized until after they become widely used

OBJECTIVE OF RECALL PLAN

- Stop the distribution and sale of the affected product.
- Effectively notify management, customer and regulatory authority.
- Efficiently remove the affected product from the marketplace, warehouse and distribution area.
- Dispose and conduct a root cause analysis and report the effectiveness of the recalls.
- Impliment a corrective action plan to prevent another recall.

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Recall Stage :

1. Receipt of Pharmaceutical Product Problem Report to the Department of Health
2. Initiation of a Recall
3. Assessment of Recall
4. Recall
5. Progress of Recall and Report
6. Evaluation of the Recall

Who conducts Recall

- As per the USFDA 21CFR 7.45

Food and Drug Administration-requested recall.

- As per the USFDA 21CFR 7.46

Firm-initiated recall.

- Consumer may also request for recall

Drug recalls are classified in the USFDA 21CFR7 & European Medicines Agency (EMA):

1. Class I recalls
2. Class II recalls
3. Class III recalls

Class I Recalls

Consumption of the drug will lead to adverse health effects or death.

Recall will be required to be initiated within 72 hours after the receipt of information.

The 2008 recall of *Baxter Healthcare's* anticoagulant drug, heparin, because the FDA found contaminants in the drug that caused severe injury and death in some people.

Class II Recalls

Medically reversible health effects. medically reversible health effects.

Class II will be required to occur within 10 days of the receipt of information.

McNeil Consumer Healthcare's April 2010 recall of certain batches of over-the-counter children's drugs, including liquid Tylenol, Motrin, and Zyrtec because of possible contaminants.

Class III Recalls

Adverse health effects are not likely to occur when consuming the drug.

Class III recalls will be required to occur within 30 days of the receipt of information.

Sanofi has recalled four batches of *Combiflam* after India's Central Drugs Standard Control Organisation (CDSCO) found it was not meeting specifications for disintegration, Reuters reports.