



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Pharmaceutical Care Department		
Document:	Multidisciplinary Policy And Procedure (MPP)		
Title:	Handling Recalled Medications		
Applies To:	Pharmacists, Physicians & Nurses		
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1. PURPOSE:

- 1.1 To provide guidelines to medical, pharmacy, and nursing staff for the proper implementation of drug recalls, if a drug was declared to be below standard thus rendering the treatment ineffective, or may cause harm to patient's health and well-being.

2. DEFINITONS:

- 2.1 1 Drug Recall Shall mean a process by which medication has been noticed or declared contaminated, mislabelled, or dangerous by a manufacturer or a National International Drug Control Body or the hospital itself, is retrieved from various storage and dispensing areas of the Hospital; and ambulatory patient care areas.

3. POLICY:

- 3.1 When a recall notice is received, the head of pharmacy shall be immediately informed and the drug[s] in question is immediately removed from all storage areas to ensure that the drug[s] is not available for use.
- 3.2 The pharmacy will notify prescribers and individuals involved in prescribing, dispensing and administration of recalled, damaged, and discontinued medications.
- 3.3 Out-patient prescriptions are checked to determine if any prescription has been dispensed with the lot number in question and patients are informed that their medication has been recalled or discontinued for safety reason.

4. PROCEDURE:

- 4.1 Check and retrieve the Recalled, discontinued, or damaged drug, if available, from all storage and dispensing areas of the hospital (Pharmacist)
 - 4.1.1 If a drug is recalled by a memorandum from Saudi FDA, MOH Health Directorate or the Medical Supply, the drug for patient safety will be immediately halted from dispensing.
 - 4.1.2 The areas inspected shall include mainly the pharmacy store room and all other pharmacy dispensing areas (Inpatient or satellite pharmacies, outpatient pharmacy, ER pharmacy, etc).
 - 4.1.3 If the drug is on a floor stock list, then appropriate nursing stations are to be checked accordingly by designated pharmacy staff.
 - 4.1.4 Designated Pharmacy Staff will determine if any in-patients are currently receiving the recalled medication; check the individual unit dose bin and/or refrigerator on the nursing station of the area where it has been determined that a patient is receiving the recalled medication.
- 4.2 If it is possible to identify patients who received the recalled drug (Pharmacist).
 - 4.2.1 The affected patients are to be contacted through the Patient Services Department and informed to get their medications replaced by contacting the Pharmacy Department As Soon As Possible
- 4.3 Judge the severity of the Recall and if deemed necessary. All Recalled drugs will be classified according as follows:

- 4.3.1 Class I: A situation in which the use of, or exposure to a violated health product may cause permanent or irreversible adverse health consequences.
- 4.3.2 Class II: A situation in which the use of, or exposure to a violated health product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse consequences is remote.
- 4.3.3 Class III: A situation in which the use of, or exposure to a violated product is not likely to cause adverse health consequences
 - 4.3.3.1 In case that the medication has been proven to be ineffective and might pose a risk to patients, the return or destruction of the recalled product shall be handled according to instructions given by MOH - Medical Supply.
- 4.4 Isolate all quantities of the recalled drug in a secured area for processing as per instructions which should be explicitly contained in the department Recall notice (Pharmacist in-charge, supplies and inventory management).
 - 4.4.1 The Pharmacy store room is the designated area for storing all recalled drugs .
 - 4.4.2 All recalled drugs must be labelled "RECALLED" to ensure that they will not be inadvertently used
- 4.5 Maintain a file which contains information concerning each Drug Recall.
 - 4.5.1 The record should contain the generic and trade name, the company and lot number, the manufacturing and expiration dates, and quantities of the drug if available.
 - 4.5.2 The supervisor or his/her designee performing the check should sign and date the form.
- 4.6 Inform the proper authority (MOH) of the actual cases of product Recall.
 - 4.6.1 The department head is to report to MOH through proper administration channels of the product recall

5. EQUIPMENT/MATERIALS:

N/A

6. RESPONSIBILITIES:

- 6.1 The Pharmacy Director is responsible for assigning personnel to visit and check each area of the hospital that is known to stock the recalled drug.
- 6.2 The Hospital Management: is responsible for sending a letter to MOH Medical Supply to ask their advice for a drug recall

8. REFERENCES:

- 8.1 [Drug Recalls | FDA](#)

9. APPROVALS:

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