


CCHE-57357 -Policy and Procedure

 مؤسسة مستشفى سرطان الأطفال - مصر Children's Cancer Hospital Foundation - Egypt		Policy Name: <h2>Medication and supplies Recall</h2>	
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1.0 Change in policy

1.1 No change

2.0 Purpose

2.1 This policy and procedure were established to ensure that all medication and supplies dispensed in the hospital are safe for patient use.

2.2 Medication and supplies recall occurs when a medication or supplies is removed from the market because it is found to be either defective or potentially harmful. Defects may be related to incorrect packaging, potential contamination, or poor manufacturing, resulting in impurities or errors in strength/potency. Sometimes, the manufacturer identifies a problem with their medication or supplies and voluntarily recall it.

3.0 Policy

3.1 Policy statement

The hospital has established and implemented a process for medication and supplies recall. This process includes receiving MOH notification, retrieving, returning and destroying recalled medication or supplies by manufacturer. The process includes also compounded medications within hospital in which product have been recalled by the manufacturer or by end user complaining request.

3.2 Scope

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3.2.1 This policy and procedure applies on all recalled medication and supplies.

3.3 Responsibilities

- 3.3.1 Pharmacy director.
- 3.3.2 Supply chain manager.
- 3.3.3 Warehouse Manager.
- 3.3.4 Stores Supervisor.
- 3.3.5 Pharmacy staff.
- 3.3.6 Nursing section head.
- 3.3.7 Nursing staff.
- 3.3.8 Store keepers.

4.0 Definitions /abbreviations:

- 4.1 **CCHE:** Children Cancer Hospital – 57357 Egypt
- 4.2 **MOH:** Ministry of Health.
- 4.3 **CPID:** Continuous Performance Improvement Department.
- 4.4 **MMU:** Medication Management & Use.
- 4.5 **DPS:** department of pharmaceutical services.
- 4.6 **Oracle fusion:** The Supply Chain information system in CCHE.
- 4.7 **PNT Committee:** Pharmacy, Nutrition and Therapeutics Committee.
- 4.8 **ROWA:** Automated storage and dispensing machine.
- 4.9 **Pyxis:** Automated unit dose dispensing machine.
- 4.10 **Pharma flow:** system of dispensing medication on ROWA.

5.0 Procedure:

- 5.1 It's the responsibility of receiving and inspection specialist to record lot number and expiry date on inspection form.
- 5.2 Technical committee review batch number and expiry date of received item
- 5.3 After inspection store keeper record batch and expiry date on oracle fusion system.
- 5.4 It is the responsibility of the pharmacy director to update lists from Ministry of health, manufacturer or any approved agencies that issue reports for recall.
- 5.5 **When the pharmacy receives recall from medication or supplies, the following procedure will be followed:**
 - 5.5.1 An official mail is sent to the supply chain manager and warehouse Manager.
 - 5.5.2 PNT must be informed with recalled medication.
 - 5.5.3 Locate and remove the entire product stocked in all areas as main store, sub stores, pharmacy and other areas contain medications or supplies.
 - 5.5.4 The director of pharmacy, supply chain manager or delegate shall ensure that all wards, floor stock, Pyxis, Rowa machine and all areas contain recalled medication or supplies were withdrawn.

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- 5.5.5 IV sterile medications and Extemporaneous compounding medications within hospital in which product have been recalled is collected by the pharmacy.
- 5.5.6 If the recall is mandated all the way to the patient level, the manufacturer or MOH is required to supply the pharmacy with all lot numbers & expiration dates of any affected product. Pharmacy records will be checked for prescriptions filled during the time period the recalled product might have been available to the pharmacy. Prior to contacting any patient, the problem will be reviewed by pharmacy and PNT committee to determine the appropriate mechanisms for contacting the patients involved (i.e., phone, letter, etc.).
- 5.5.7 Recalled medication must be isolated in specific area in the store and Clearly mark the product "Drug Recall - Do Not Use" until company withdraw recalled medication or supplies or destruction by internal committee from Inventory Control department, Storekeeper, Occupational health and Safety members after approval of upper management.
- 5.5.8 After all of the recalled product has been gathered, record the amount of each lot number involved and total amount on hand on the letter of notification, indicate date and action taken and details where and to whom the returned product was directed as documentation is mandatory. Place letter in Recall Drug File which is maintained in the hospital.
- 5.5.9 A formal mail is sent to the purchase section to formally contact the company and return the recalled medication or supplies. In case of company refused the return through an official documentation hospital dispose recalled products (refer to medication storage policy).

6.0 References:

6.1 N/A

7.0 Appendices

7.1 Related Forms:

7.1.1 N/A

7.2 Related Policy(S):

7.2.1 Medication Management Program

7.2.2 refer to medication storage policy

7.3 Related Standards:

7.3.1 JCI standards 7th edition – MMU Chapter.

7.3.2 GAHAR standards. MMS.08

7.4 Attachments

7.4.1 N/A