DR. PABLO O. TORRE MEMORIAL HOSPITAL
B.S. Aquino Drive, Bacolod City, Negros Occidental, 6100

Document Code:	DPOTMH-J-P22
Effective Date:	06-30-2022
Document Type:	Policy
Page Number:	1 of 3
Department/Section:	Pharmacy Division
Document Title:	**PRODUCT COMPLAINTS**

PURPOSE:

To provide a specific written procedure on processing product complaints.

LEVEL:

All Physicians, Nurse, Pharmacists, Pharmacy Inventory Control Supervisor, Logistics Division and other Healthcare Professionals

DEFINITION OF TERM:

Product Complaint- means any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, delivery, effectiveness or performance of the Product after it is released.

POLICY:

1. Retrieved product shall be evaluated by a licensed pharmacist.
2. An incident report (IR) shall be made by the licensed pharmacist after interviewing the client or user.
3. The client or user should fill up the Product Complaint Form (PCF).
4. The PCF must be signed by both the client or user and receiving pharmacist.
5. All actions taken including investigation to find the root cause, checking of retention samples and batch related files shall be gathered and documented.
6. All the eventual decision made (accept or reject refund, replacement or recall) shall also be recorded.

7. Special attention shall be given in establishing whether the product which is the subject of a complaint, genuine or is a counterfeit product.
   7.1. If a product defect is discovered or suspected in a batch, consideration shall be given to check other batches in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch shall be investigated.

8. All decisions and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records.

9. Inform the Pharmacy and Therapeutics Committee and the Food and Drug Administration (FDA) regarding serious quality problems that has potential harm to consumer.

DOCUMENTATION:

Revised Policy

DISSEMINATION:

1. Hospital Communicator
2. Conducting hospital wide continuing education to all healthcare professionals.

REFERENCE:

1. ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements 2015
2. Chapter 9- Complaints and Product Recalls.

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**MA. MADELYN N. LACSON, RPh., RN** Inpatient Pharmacy Supervisor		6/24/22
Verified:	**MIRIAM HOPE D. BRAVO, RPh.** Inpatient Pharmacy Manager		6/27/22
Reviewed by:	**DENNIS C. ESCALONA, MN, FPCHA, FPSQua** Quality Assurance Supervisor		6/28/2022
Recommending Approval:	**PRINCESS M. ABELLON, MBA** Pharmacy Division Officer		6/29/2022
	FREDERIC IVAN L. TING, MD OIC-Total Quality Division		7/27/22
Approved:	**GENESIS GOLDI D. GOLINGAN** President and CEO		8/31/22

PURPOSE:

To provide a specific written procedure on handling product complaints.

SCOPE:

All Pharmacy Division staff of Dr. Pablo O. Torre Memorial Hospital

PERSON RESPONSIBLE:

Pharmacist, Pharmacy Inventory Control Supervisor, Pharmacy Manager

GENERAL GUIDELINES:

1. All complaints shall be investigated and evaluated.
2. A written record of each complaint (including verbal complaints) shall be recorded and filed.
3. To facilitate tracking, each complaint case should be assigned with a unique number.
4. There shall be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.

PROCEDURE:

1. The Pharmacist receives the product complaint from the client.
2. The Pharmacist interviews the client regarding the reason of complaint.
3. The Pharmacist evaluates the following:
   - 3.1. Suspension- according to its consistency, ability of powder to suspend, and presence of cake
   - 3.2. Metered dose inhaler- according to its mist produced after one click
   - 3.3. Nasal spray- according to its mist produced after one click
4. The Pharmacist places the product in a transparent plastic bag.

5. The Pharmacist requests the client or user to fill out and sign the Product Complain Form (PCF). (See Annex)
6. The Pharmacist signs the PCF in the designated section.
7. The Pharmacist replaces the product with a new one.
8. The Pharmacist writes an Incident Report (IR) about the complaint and attaches it to the PCF.
9. The Pharmacist attaches the IR with the PCF to the product.
10. The Pharmacist sends it to the Inventory Control Pharmacist.
11. The Pharmacy Inventory Control Supervisor produces a photocopy of the IR and PCF and then gives it to Pharmacy Manager.
12. The Pharmacy Manager files a copy of the IR and PCF.
13. Inventory Control Pharmacist submits the product with attached IR and PCF to the Logistics Division personnel.

REFERENCE:

1. ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements – 2015 Chapter 9- Complaints and Product Recalls.

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	Document Type:	Flowchart
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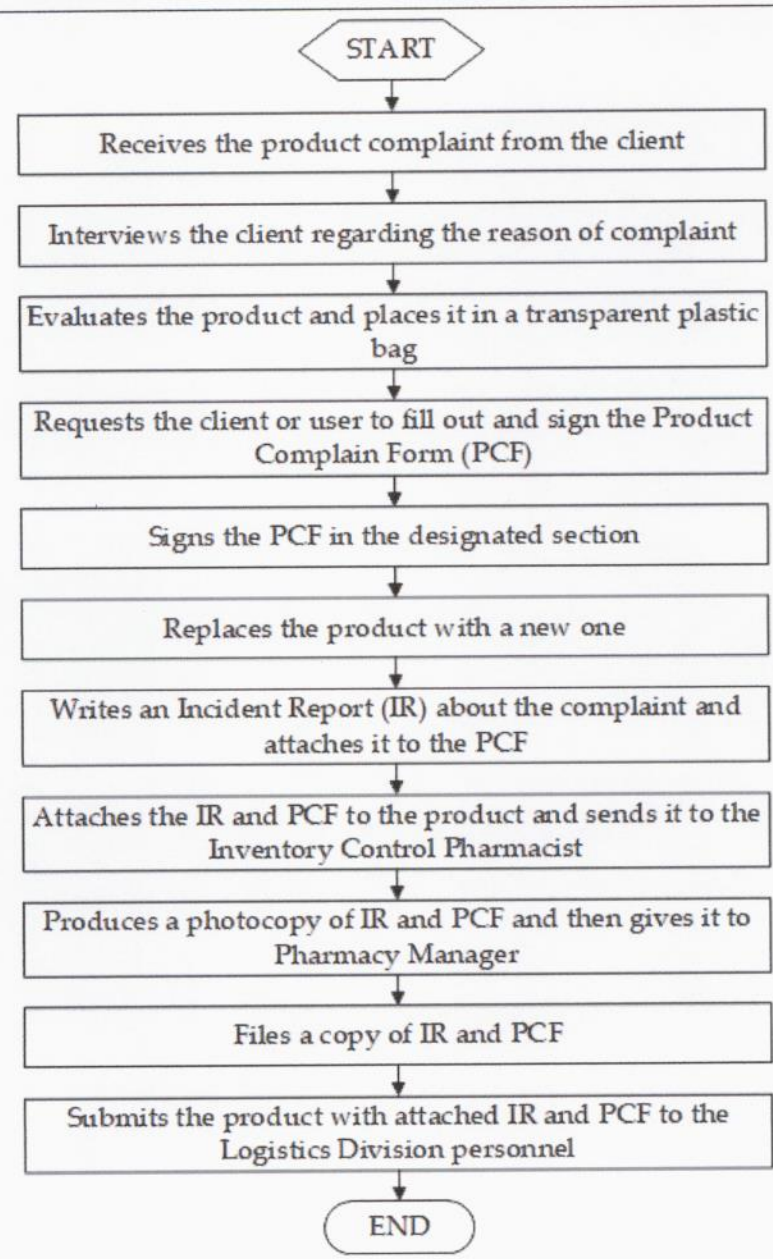
	Department/Section:	Pharmacy Division
	Document Title:	**PRODUCT COMPLAINTS**

FLOWCHART



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KEY TASKS	PERSON RESPONSIBLE
1. Receives the product complaint from the client	Pharmacist
2. Interviews the client regarding the reason of complaint	Pharmacist
3. Evaluates the product and places it in a transparent plastic bag	Pharmacist
4. Requests the client or user to fill out and sign the Product Complain Form (PCF)	Pharmacist
5. Signs the PCF in the designated section	Pharmacist
6. Replaces the product with a new one	Pharmacist
7. Writes an Incident Report (IR) about the complaint and attaches it to the PCF	Pharmacist
8. Attaches the IR and PCF to the product and sends it to the Inventory Control Pharmacist	Pharmacist
9. Produces a photocopy of the IR and PCF and then gives it to Pharmacy Manager	Pharmacy Inventory Control Supervisor
10. Files a copy of the IR and PCF	Pharmacy Inventory Control Supervisor
11. Submits the product with attached IR and PCF to the Logistics Division personnel	Pharmacy Inventory Control Supervisor

DR. PABLO O. TORRE MEMORIAL HOSPITAL B.S. Aquino Drive, Bacolod City, Negros Occidental, 6100	Document Code:	DPOTMH-J-P22-WI01
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