Pharmacy Information System (PhIS)
and
Clinic Pharmacy System (CPS)

User Manual
Pharmacy Inventory - Product Complaint

Version	**: 10th EDITION**
Document ID	**: U.MANUAL_INV_PRODUCT COMPLAINT**

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Table of Contents

1.0 Introduction 1
1.1 Overview of PhIS 1
1.2 Purpose and Objectives 1
1.3 Organised Sections 1
2.0 Application Standard Features 2
2.1 PhIS Legend 2
3.0 Product Complaints 3
Overview 3
User Group 3
Functional Diagram 3
Functional Description 3
3.1 View Existing Product Complaints Record 4
3.2 Product Complaints Catalogue Item 6
3.2.1 Product Complaint – Drug 6
3.2.2 Product Complaint Investigation - Drug 12
3.2.3 Product Complaints – Non Drug 14
3.2.4 Product Complaint Investigation - Non Drug 19
3.3 Product Complaints Non Catalogue Item 21
3.3.1 Product Complaints – Drug 21
4 Acronyms 26
5.0 Links to Inventory Modules 27

1.0 Introduction

1.1 Overview of PhIS

Pharmacy Information System or better known as PhIS, is a complete and comprehensive system that integrates pharmacy related services that geared toward pharmacy excellence. PhIS implementation would transform most of current manual process to electronic system would benefit facility end user in the health care sector.

There are 12 modules to assist services delivery by the health care sector which comprises of:

1. Order Management
2. Inpatient Pharmacy
3. Outpatient Pharmacy
4. Medication Counselling
5. Ward Pharmacy
6. Pharmacy Inventory
7. Manufacturing of Cytotoxic Drug Reconstitution, Parenteral Nutrition, IV Admixture & Eye Drop, Radiopharmaceuticals and Extemporaneous
8. Adverse Drug Reaction & Drug Allergic (ADR & DAC)
9. Clinical Pharmacokinetics Services (TDM)
10. Drug Information & Consumer Education (DICE)
11. Medication Therapy Adherence Clinic (MTAC)
12. Data Mining (PhARM)

1.2 Purpose and Objectives

This user manual outlines the Product Complaints sub-module and its key features and functionalities. The primary objective is to guide user through the process of completing PhIS application process.

User will understand the following activities in details:

- Create New Product Complaints Record
- Product Complaint Investigation

1.3 Organised Sections

These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Product Complaints
- Section 4 : Acronyms

2.0 Application Standard Features

2.1 PhIS Legend

Standard Legend			
LOGIN	Login to PhIS	Logout	Logout from PhIS
	Close All Open Tabs		Refresh Screen
	Expand Menu		Collapse Menu
	Expand Module		Collapse Module
	Add/Create New Record		Save
	Close Window		Calendar Icon
	Save Transaction		Delete Record
Export to Excel	Export Report From PDF file to Excel file	OK	OK Button
Yes	Yes Button	No	No Button
	Radio Button		Checkbox
	System Automatic Generate Record No.		Automatically Display/Retrieve Box
	Reset Login Screen		Show Help
Home	Display Home Tab	Search	Search Record
	Cancel		Dropdown Box
	Search Icon	*	Mandatory Field
	Edit Record		Empty Text Box
Cancel	Cancel Button		

Note

- *To learn more about Login Information, kindly click Login Information Modules for descriptive step.*

3.0 Product Complaints

Overview

The Product Complaint module allows any user to lodge their complaints online about a product and the complaint form will be sent to the Drug Information Services Unit set by the facility. Pharmacist in charge will receive the product complaint as a message in the Task List and perform internal investigation.

User Group

This module is intended for storekeeper and pharmacists at the Pharmacy Store, Pharmacist and Assistant Pharmacist at the Sub Store; Sister and Nurse at the unit/ward.(subject to user assign by the facility)

Functional Diagram

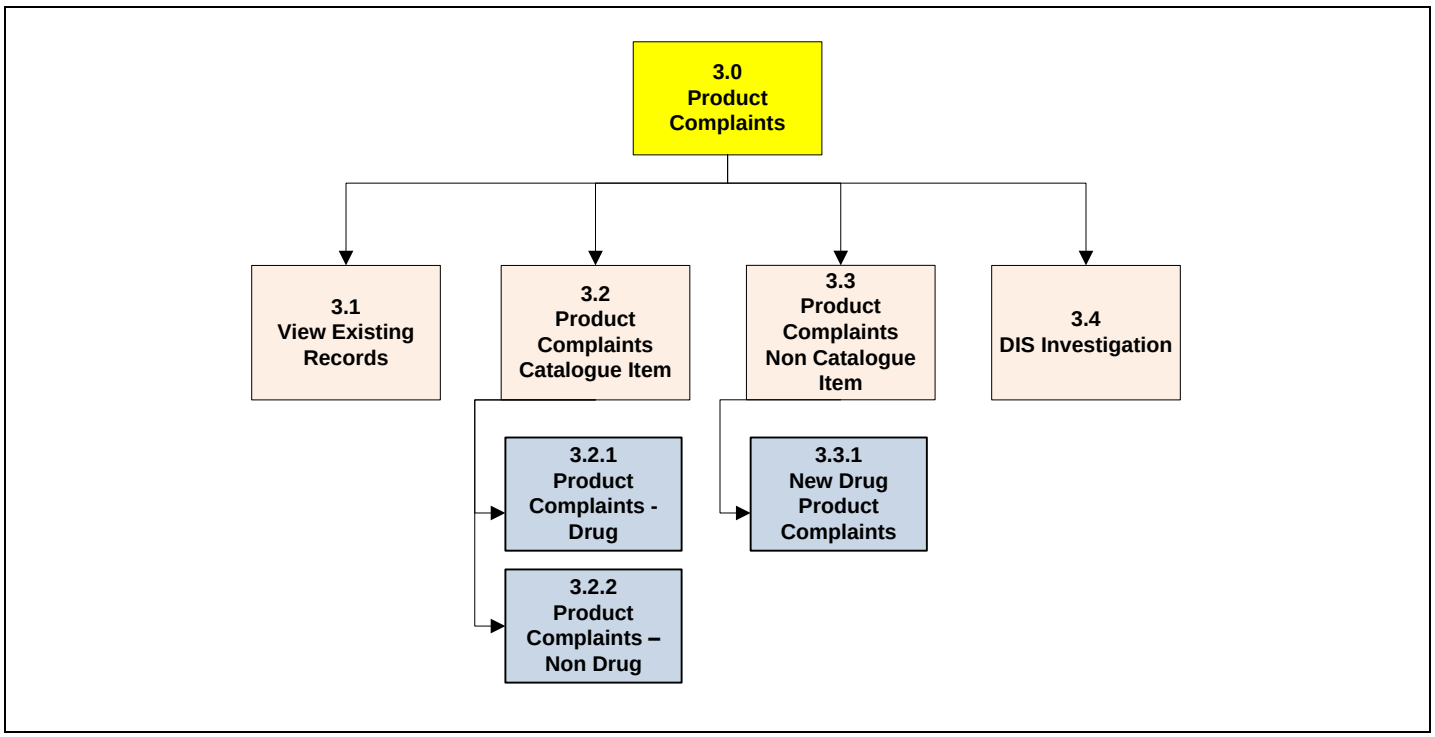


Figure 3.1

Functional Description

Product complaints comprises of four (4) main functions:

- **Product Complaints**
  This function allows user to view all existing transactions
- **Product Complaints Catalogue Item**
  This function is used to create new product complaints that are listed in the drug catalogue item
- **Product Complaints Non Catalogue Item**
  This function is used to create new product complaints that are listed in the non drug catalogue item
- **Product Complaint Investigation**
  This function allows user to receive and investigate the validity of a complaints received on a product

3.1 View Existing Product Complaints Record

To view existing Product Complaints record, perform the steps below:

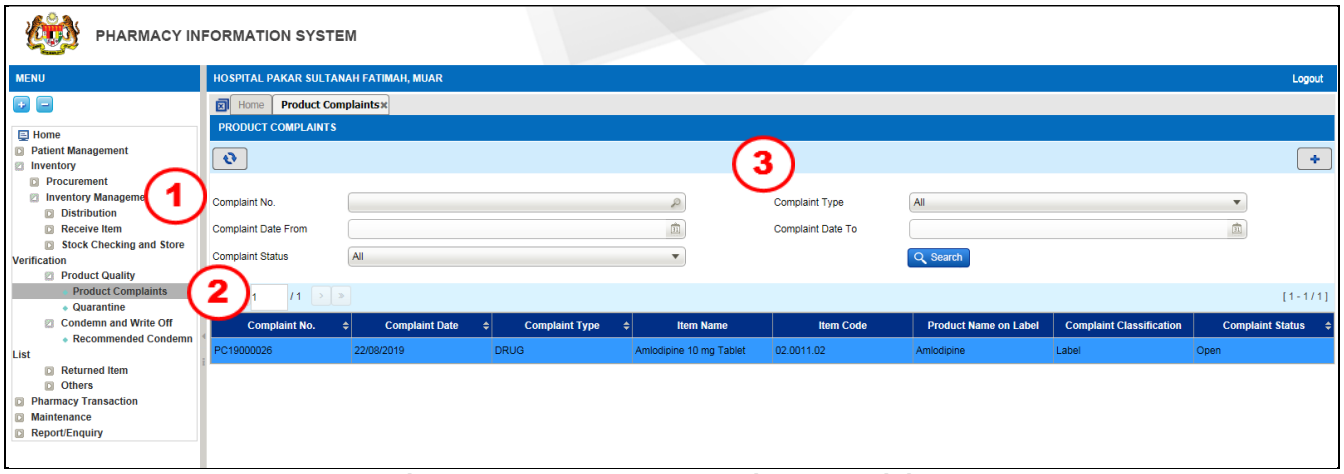


Figure 3.1-1 Create New Product Complaints

STEP 1
Click on 'Inventory' menu and click on 'Inventory Management' Sub-Menu

STEP 2
Click on 'Product Quality' and click on 'Product Complaints' Sub menu

STEP 3
To search for existing Product Complaints record(s), search by criteria as follow:

No	Field	Description	Remarks
a	Complaints No.	Product complaints Number	Display all existing Product complaints No. belongs to the requester unit
b	Complaints Type	Search by : All Drug Non Drug	Able to filter and search record(s)
c	Complaints Status	Search by: All Investigated – Invalid Investigated – Valid Investigation – Pending Open	Able to filter and search record(s)
d	Complaints Date From	Start date for the product complaints transaction	Format field (dd/mm/yy)
e	Complaints Date To	End date for the product complaints transaction	Format field (dd/mm/yy)

Table 3.1-1

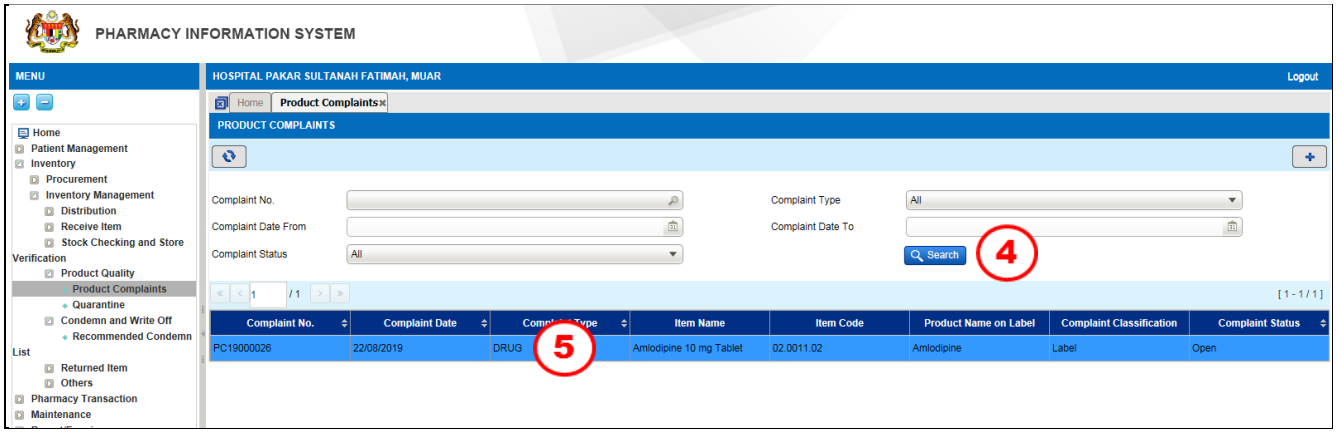


Figure 3.1-2 Create New Product Complaints

STEP 4

Click on the

button

Note

The result display will be based on the entered criteria as shown in Figure 3.1-2.

STEP 5

Double click on the selected record and the details will be displayed

3.2 Product Complaints Catalogue Item

Catalogue Items are items that are available in the facility's Catalogue. Product Complaints on Drug and Non Drug item can be logged by any user of PhIS. Pharmacist at the DIS Unit will then decide the Complaints' validity.

3.2.1 Product Complaint – Drug

To create a new Drug Product Complaints – Catalogue Item, perform the steps below:

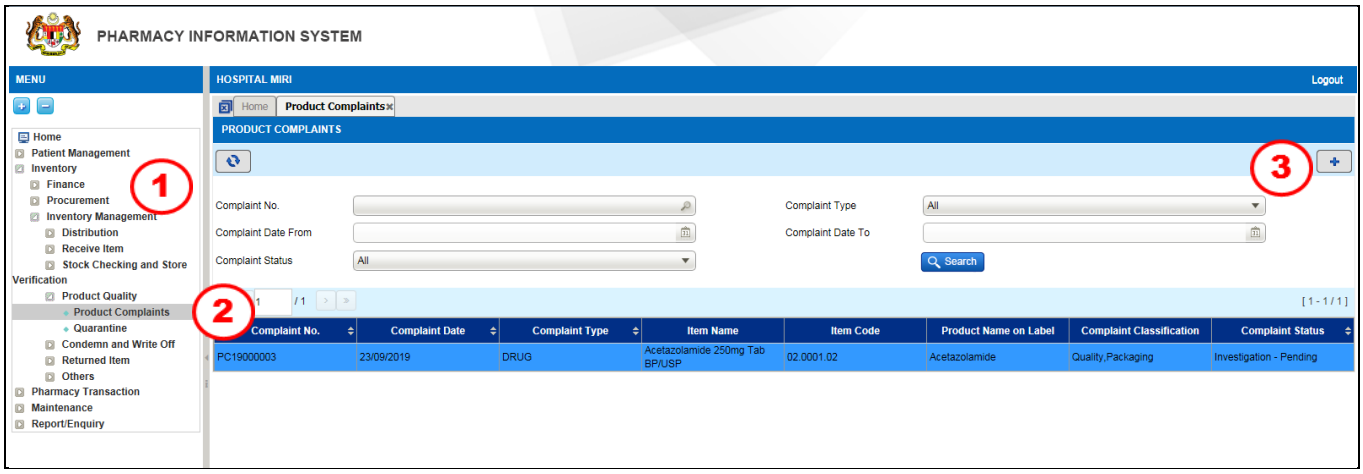


Figure 3.2.1-1 Product Complaints

STEP 1

Click on 'Inventory menu' and click on 'Inventory Management' Sub-Menu

STEP 2

Click on 'Product Quality' and click on 'Product Complaints' Sub-Menu.

STEP 3

Click on the button to record new complaints

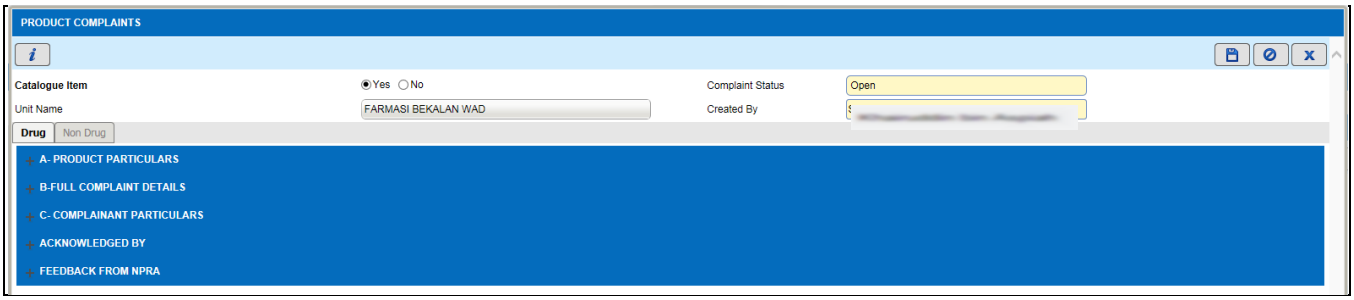


Figure 3.2.1-2 New Drug Product Complaints – Catalogue Item

Note

- *Product Complaints screen will be displayed in Figure 3.2.1-2*
- *The **Catalogue Item** radio button is default to 'Yes'. Change to 'No' if the Product Complaints item is not a catalogue item from the facility.*
- *Complaints on Drug and Non Drug item will have a different type of form. Select Non Drug tab if would like to lodge a Product Complaints on a Non Drug Item.*
- *These are the three (3) sections in a New Product Complaints form required to be filled:*

  A. Product Particulars

  B. Full Complaints Details

  C.Complainant Particulars

- *The sections can be maximized or minimized by clicking on the Header.*

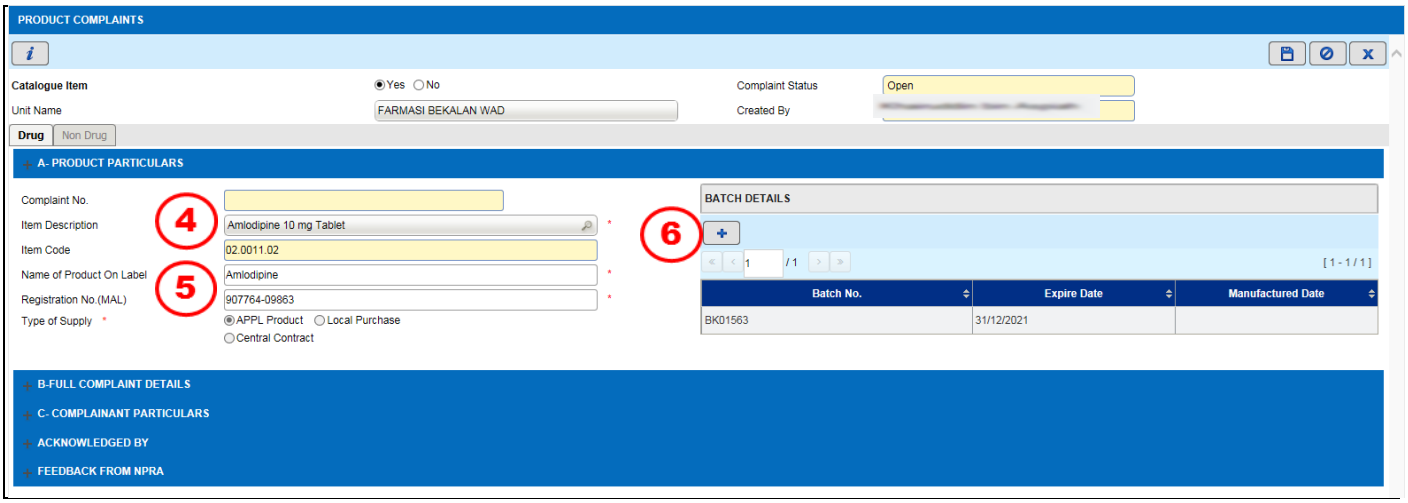


Figure 3.2.1-3 Product Particulars

STEP 4

Click on ***Item Description*** button and 'Search Item Description' window will be displayed as Figure 3.2.1-4

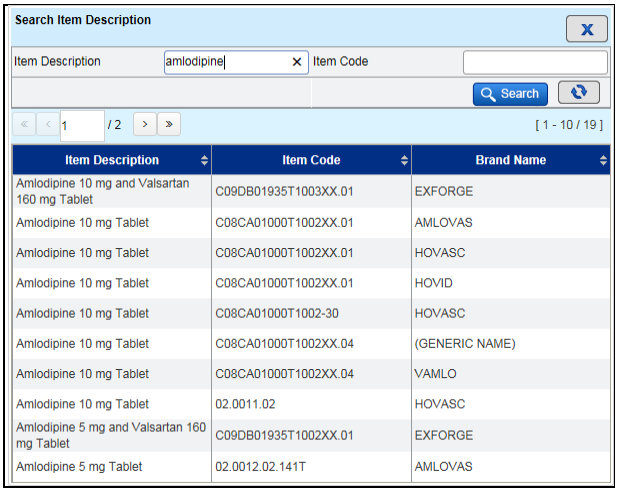


Figure 3.2.1-4 Search Item Description

Note

- ***Item Description*** *and/or* ***Item Code*** *allows to do random search based on criteria entered regardless partially and/or fully. Click on the* Search *button.*
- ***Type of Supply*** *will be selectedautomatically based on the* ***Item Description*** *selected.*

STEP 5

Enter ***Name of Product On Label*** and ***Registration No. (MAL)***

STEP 6

Click on the + ***Batch Details*** button and 'Batch Details' window will be displayed as Figure 3.2.1-5

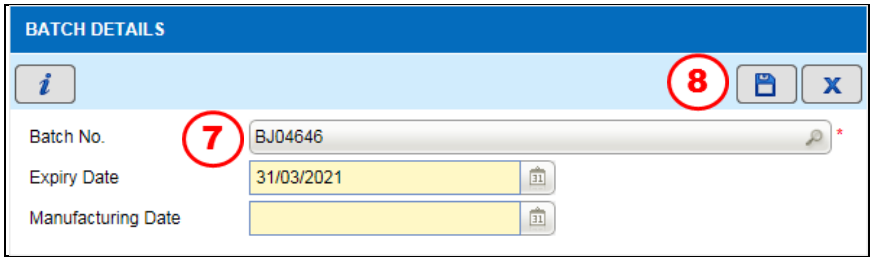


Figure 3.2.1-5 Batch Details

STEP 7

Click on ***Batch No.*** button and select batch no

Note

Expiry Date *and* ***Manufacturing Date*** *will be display based on selected* ***Batch No***

STEP 8

Click on the button to save the record

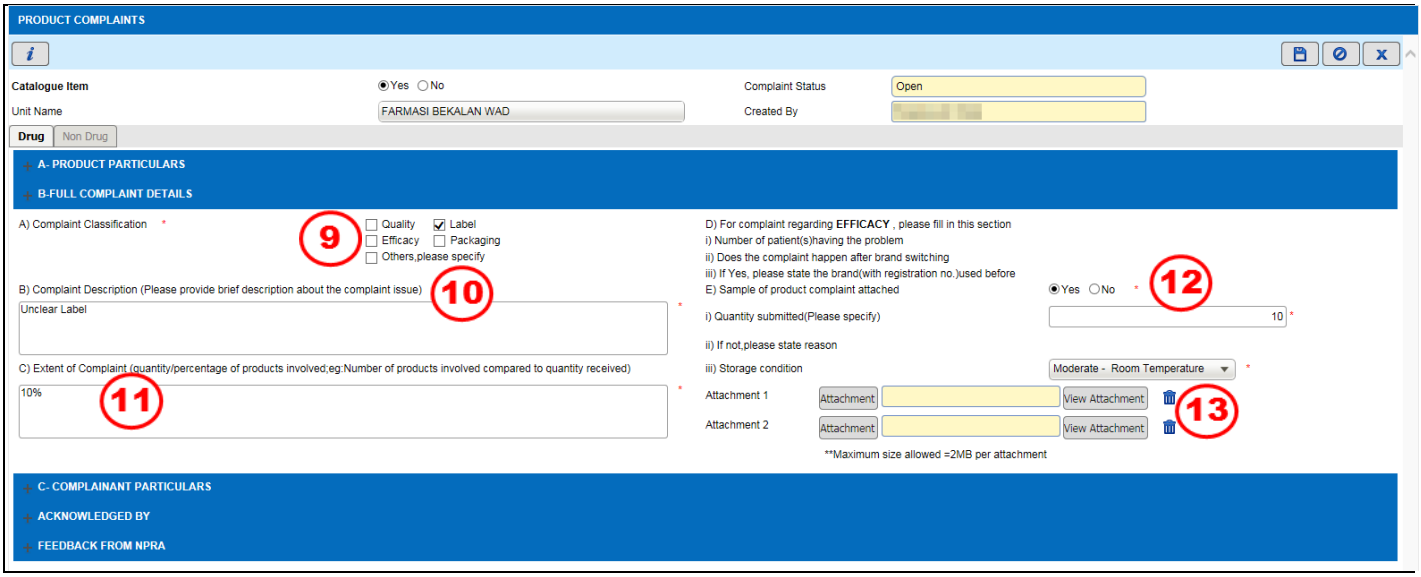


Figure 3.2.1-6 Full Complaint Details

STEP 9
Select the ***Complaints Classification*** checkbox as appropriate and user can select more than one.

- Quality
- Efficacy
- Label
- Packaging
- Others

Note
If the user selects the Complaints Classification as Others, Please Specify Field will be displayed.

STEP 10
Enter ***Complaints Description***

STEP 11
Enter ***Extent of Complaints***

Note

- *If the **Complaints Classification** is selected as Efficacy, these fields will be enabled for the user to enter/select:*
  i. Number of Patient(s) having the problem.
  ii. Does the Complaints happen after Brand switching?

- *If 'Yes' radio button is selected for 'Does the Complaints happen after brand switching', User has to state the iii) brand (with Registration No.) used before.*

STEP 12
Select from the Yes/No radio button for ***Sample of product Complaints attached***

Note

- *If 'Yes' radio button is selected, user has to state the i) Quantity submitted and the ii) Storage Condition.*

- *If 'No' radio button is selected, user has to state only the ii) Reason*

STEP 13
Click on the Attachment button to attach any document related on the complaint

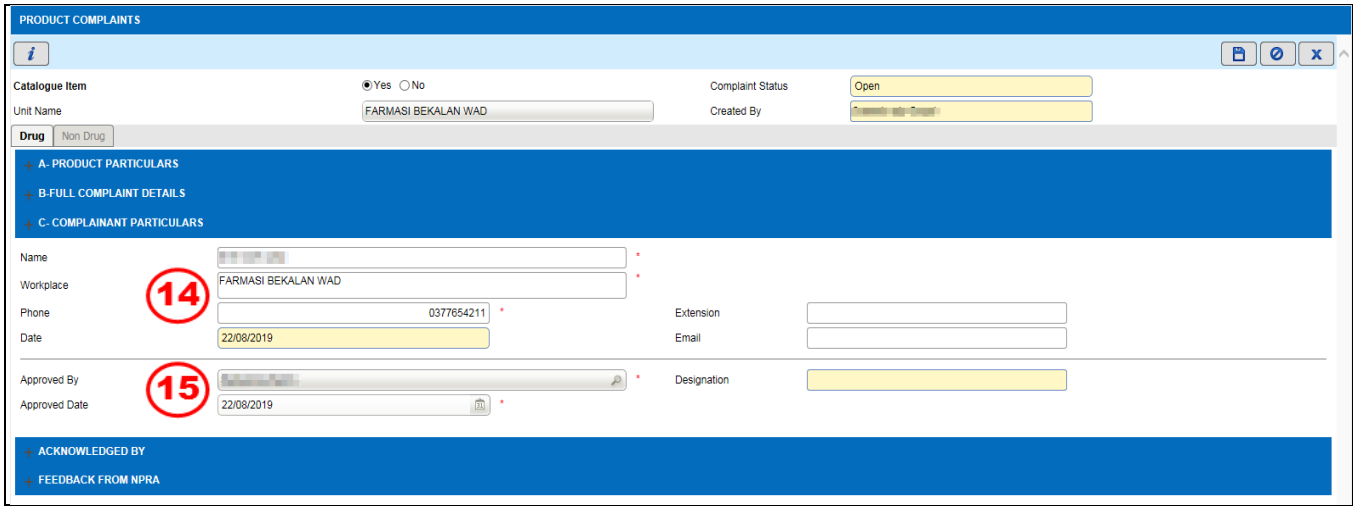


Figure 3.2.1-7 Complainant Particulars

STEP 14
Enter ***Name***, ***Workplace*** and ***Phone*** . ***Extension*** and ***Email*** is optional field

STEP 15

Select ***Approved By*** by click on the button and select ***Approved Date*** from button

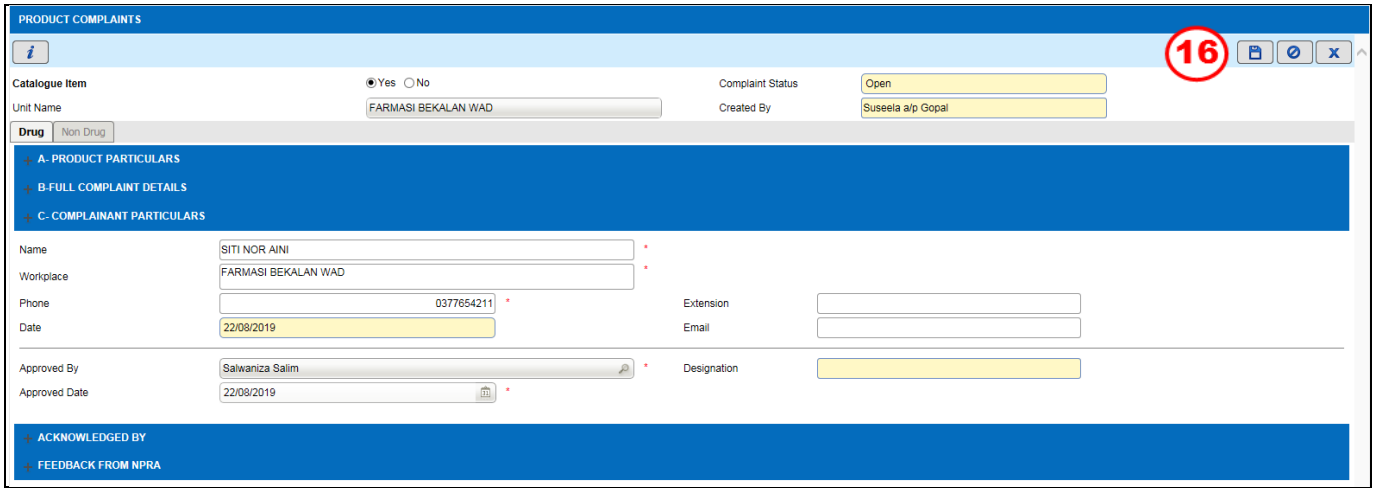


Figure 3.2.1-8 Product Complaint

STEP 16

Click on the button to save the record

Note

- *After clicking on* button, *alert message will be displayed in Figure 3.2.1-9 and Figure 3.2.1-10*

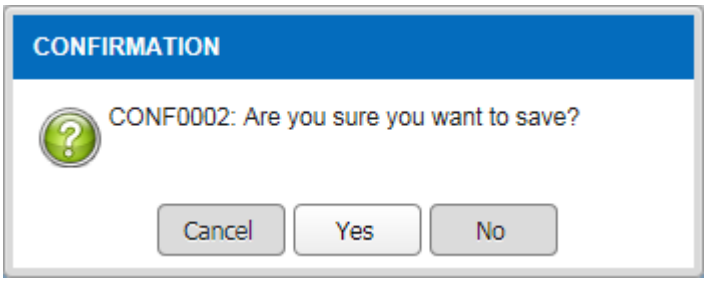


Figure 3.2.1-9 Confirmation Message

- *Click on the* Yes *button.*

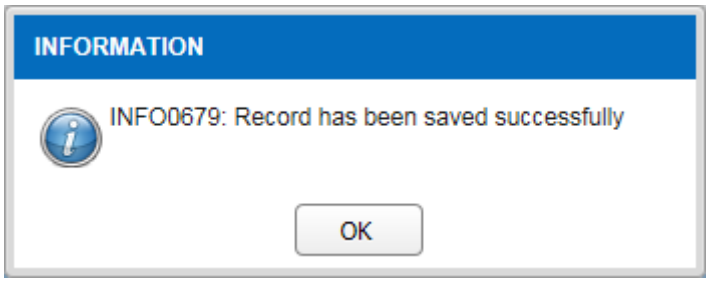


Figure 3.2.1-10 Information Message

- *Click on the* OK *button.*
- ***Complaints No*** *will be automatically generated for future reference.*

Character	Description	Value
1-2	Refer to complaint drug item	'PC'
3-4	Current Year in YY format	12
5-10	Running No	Starting from 000001. This running number will be reset to start from000001 at the beginning of every calendar year.

Table 3.2.1-1

- *Send for Investigation* Send for Investigation *and Cancel Request* Cancel Request *button will be enabled once user saves the Product Complaints record.*

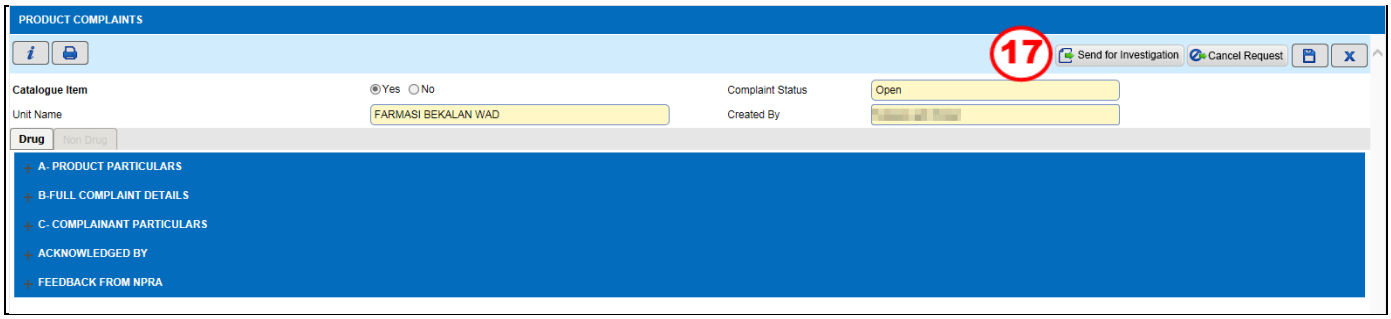


Figure 3.2.1-11 Product Complaints

Note
User is allowed to modify the information before send for investigation

STEP 17

Click on the Send for Investigation button to send the record for investigation

Note

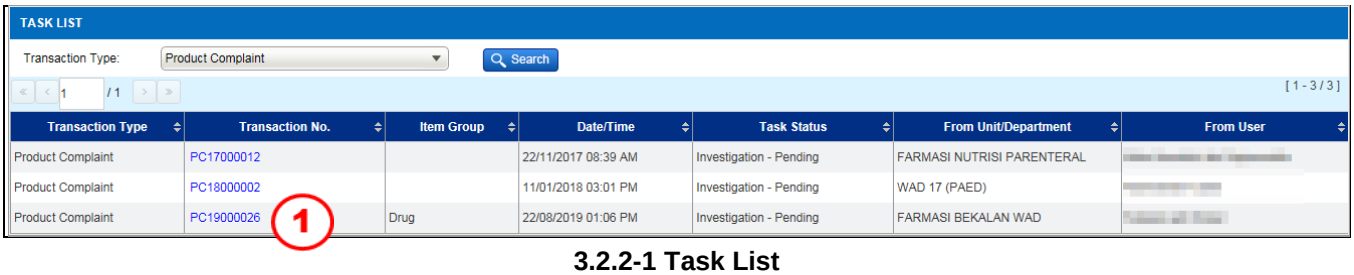
User is allowed to cancel the request by click on the Cancel Request *button*

3.2.2 Product Complaint Investigation - Drug

The pharmacist at store Pharmacy will receive notification for Investigation - Pending records to investigate the validity of a Product Complaints.

Note

The Pharmacist will receive the 'Investigation – Pending' transaction in the Task List.



3.2.2-1 Task List

Note

User can filter task list for Product Complaint record by selecting Transaction Type: Product Complaint and click on the Search *button*

STEP 1

Click on the Transaction No. hyperlink and the Product Complaints screen will be displayed as shown in the Figure 3.2.2-*2*

Note

The pharmacist is also able to refer to section [3.1 Product Complaints Listing Page](#) to search for the 'Investigation - Pending' Product Complaints record.

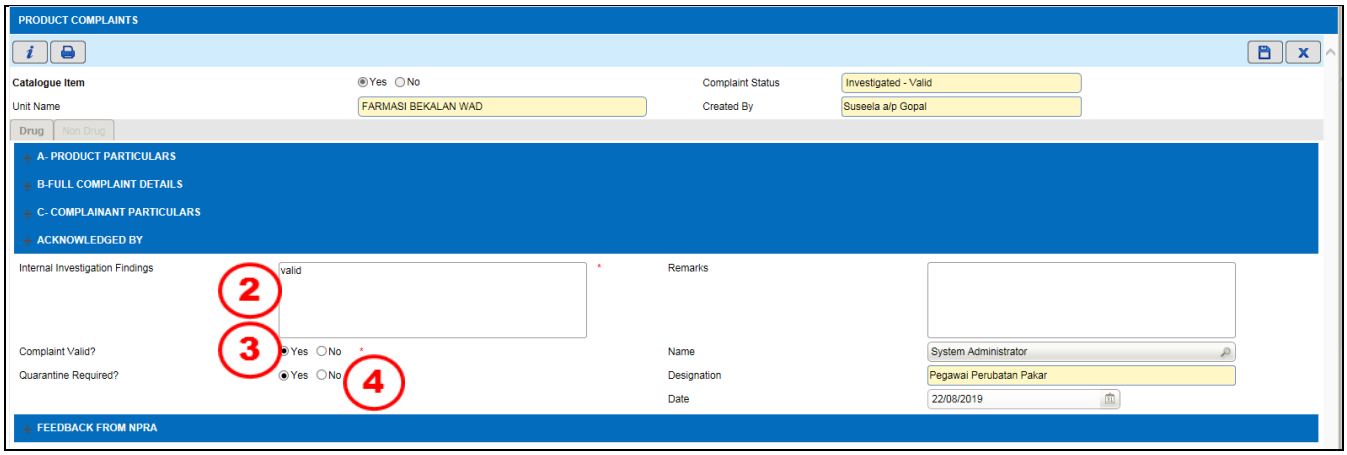


Figure 3.2.2-2 Product Complaints - Acknowledge By

STEP 2

Enter ***Internal Investigation Findings***

STEP 3

Select ***Complaint Valid?*** 'Yes' or 'No' radio button

Note

- *If 'Yes' is selected,* ***Quarantine Required?*** *'Yes' or 'No' radio button will be enabled.*
- *If 'No' is selected, user is required to enter* ***Reason.***

STEP 4
Select from the 'Yes' or 'No' for Quarantine Required? radio button

Note

- *If 'Yes' is selected, this Product Complaints No will be available in the Quarantine Module.*
- *If 'No' is selected, this Product Complaints No will not be available in the Quarantine Module.*

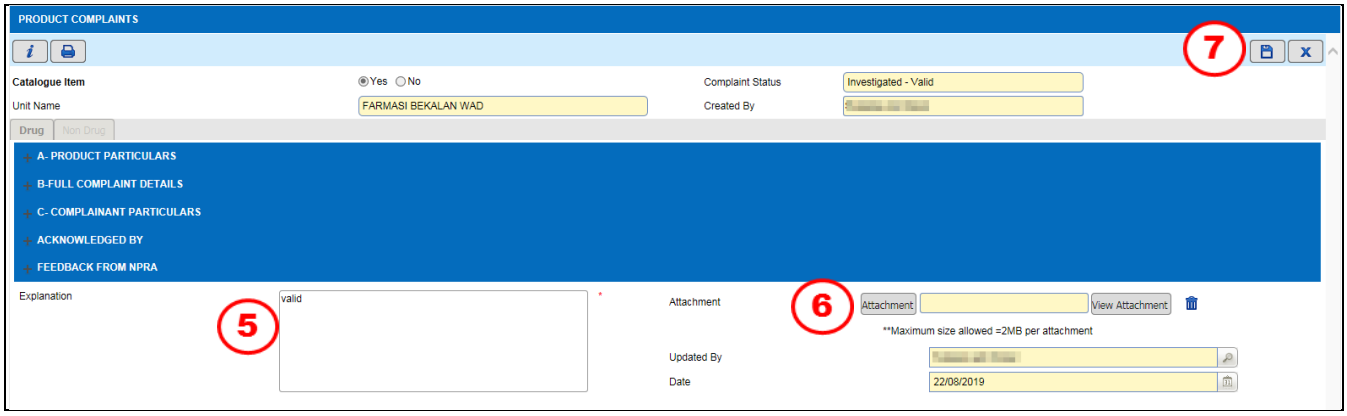


Figure 3.2.2-3 Product Complaints - Feedback From NPRA

STEP 5
Enter ***Explanation***

STEP 6
Click on the Attachment button to upload related document into the system

STEP 7
Click on the button to save the record

3.2.3 Product Complaints – Non Drug

To create a new Non Drug Product Complaints – Catalogue Item, perform the steps below:

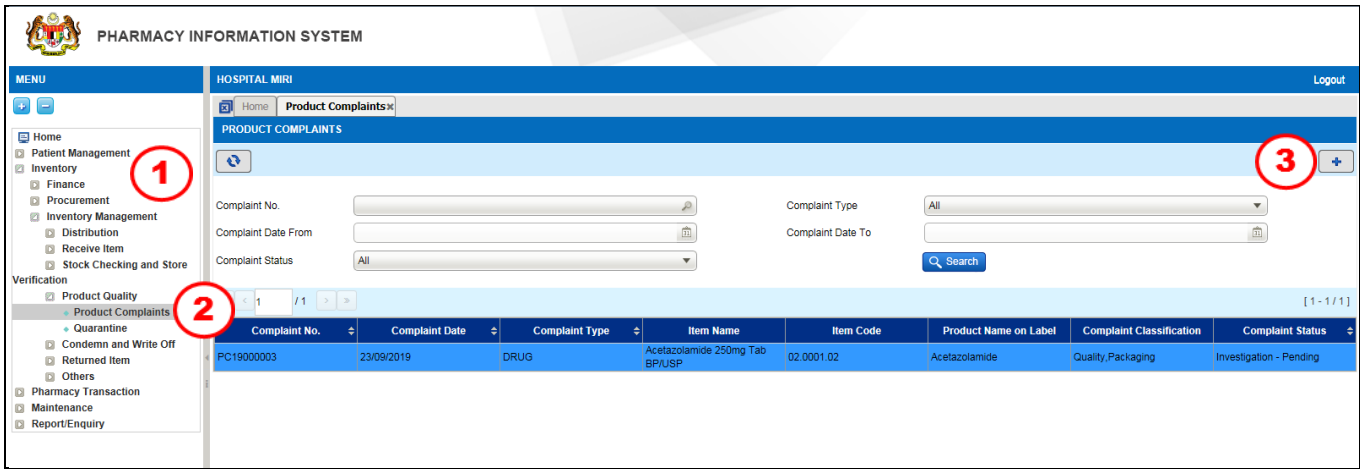


Figure 3.2.3-1 Create New Product Complaints

STEP 1
Click on 'Inventory' menu and click on 'Inventory Management' Sub-Menu.

STEP 2
Click on 'Product Quality' and click on 'Product Complaints' Sub-Menu.

STEP 3
Click on the button

Note
Product Complaints screen will be displayed in Figure 3.2.3-2

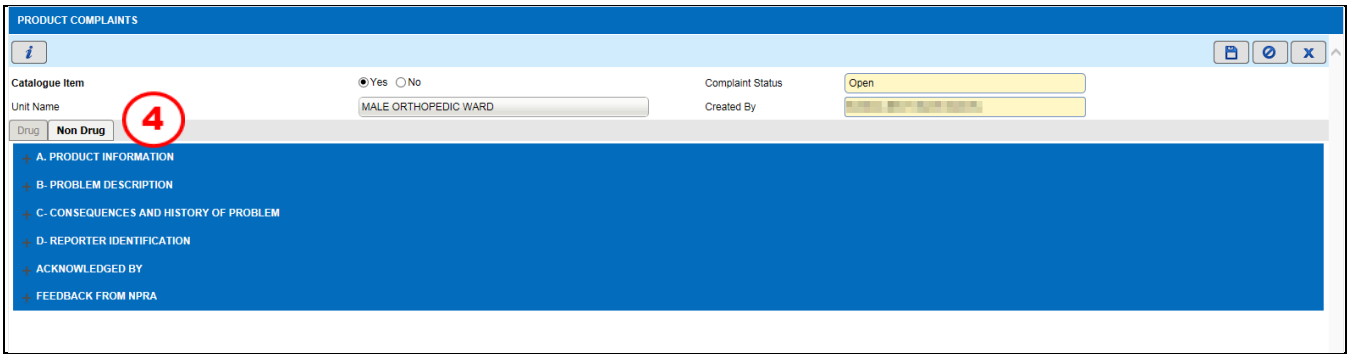


Figure 3.2.3-2 New Non Drug Product Complaints – Catalogue Item

STEP 4
Click on the ***Non Drug*** tab

Note

- *These four (4) panels in a New Product Complaints form are required to be filled:*
  - *I. Product Particulars*
  - *II. Problem Description*
  - *III. Consequences and History of Problem*
  - *IV. Reporter Identification*

- *The sections can be maximized or minimized by clicking on its Header*

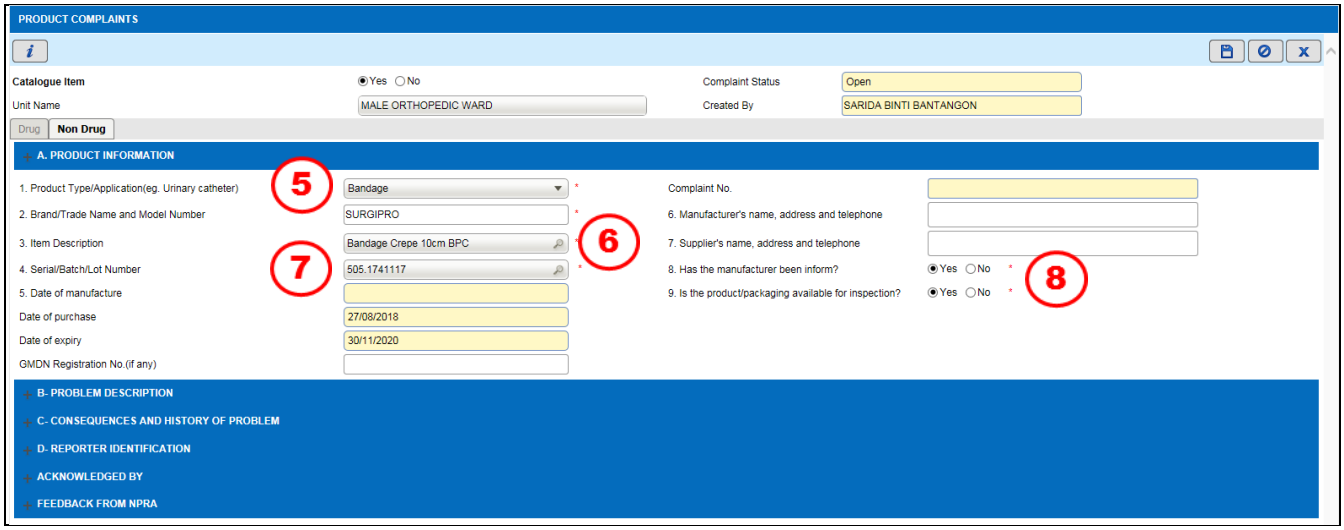


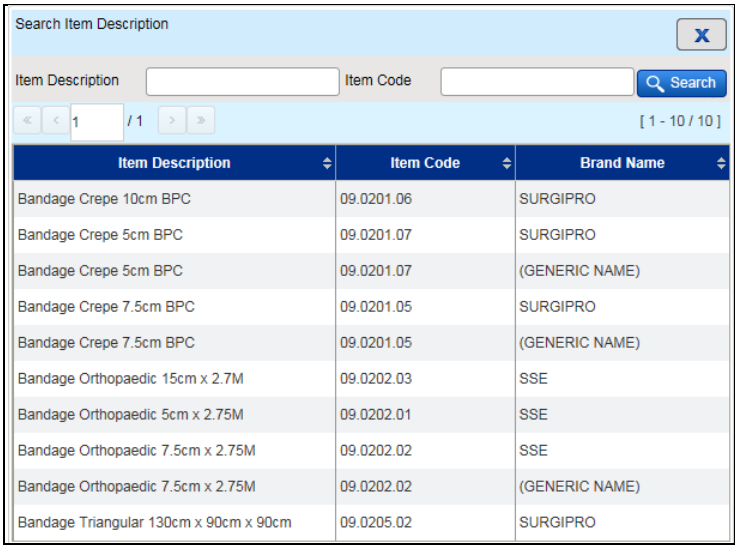
Figure 3.2.3-3 Product Particulars

STEP 5
Select ***Product Type/Application (e.g. Urinary catheter)*** from dropdown menu

STEP 6
Select ***Item Description***

Note

- *System will display Search Item Description window as Figure 3.2.3-4.*



Item Description	Item Code	Brand Name
Bandage Crepe 10cm BPC	09.0201.06	SURGIPRO
Bandage Crepe 5cm BPC	09.0201.07	SURGIPRO
Bandage Crepe 5cm BPC	09.0201.07	(GENERIC NAME)
Bandage Crepe 7.5cm BPC	09.0201.05	SURGIPRO
Bandage Crepe 7.5cm BPC	09.0201.05	(GENERIC NAME)
Bandage Orthopaedic 15cm x 2.7M	09.0202.03	SSE
Bandage Orthopaedic 5cm x 2.75M	09.0202.01	SSE
Bandage Orthopaedic 7.5cm x 2.75M	09.0202.02	SSE
Bandage Orthopaedic 7.5cm x 2.75M	09.0202.02	(GENERIC NAME)
Bandage Triangular 130cm x 90cm x 90cm	09.0205.02	SURGIPRO

Figure 3.2.3-4 Search Item Description and/or Item Code

- *Enter a partially or fully search criteria of Item Description and/or Item Code and click the*

button.

- *Select the Item Description*

STEP 7
Select ***Serial/Batch/Lot Number***

Note

- *System will display as Figure 3.2.3-5.*

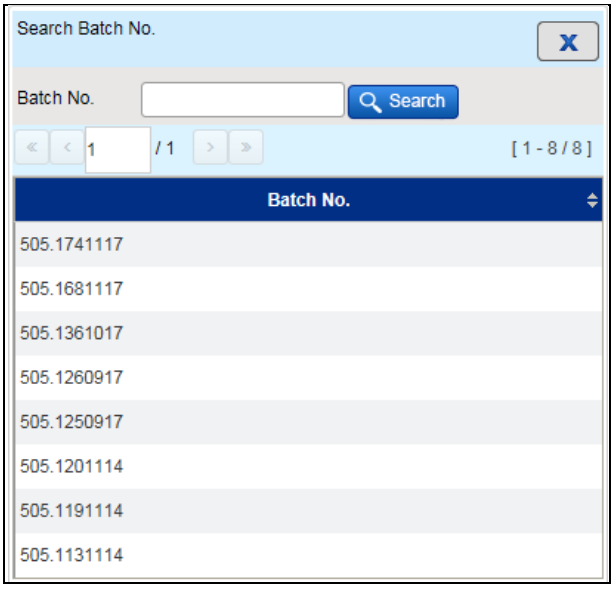


Figure 3.2.3-5 Search Batch No.

- *Only available **Batch No** in the unit will be listed in the Batch No list.*
- ***Date of Manufacture**, **Date of Purchase** and **Date of Expiry** will be displayed automatically based on the **Serial/Batch/Lot Number** selected.*

STEP 8

Select the button for question 8 & 9

Note
Optional field:

I. GMDN Registration No.(if any),
II. Manufacturer's name, address and telephone
III. Supplier's name, address and telephone

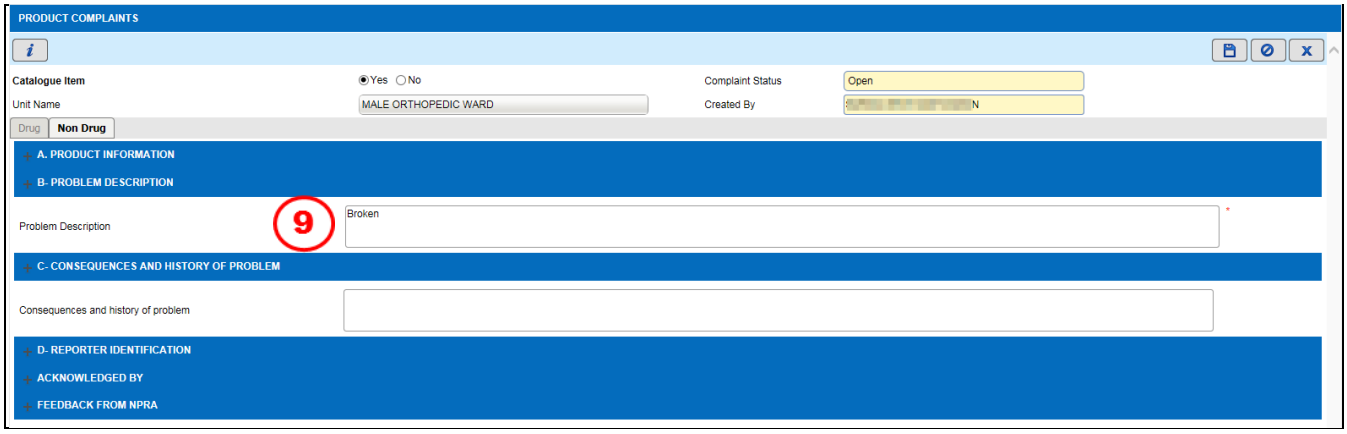


Figure 3.2.3-6 Problem Description/Consequences and History of Problem

STEP 9
Enter ***Problem Description***

Note
*Enter **Consequences and history of problem** if any*

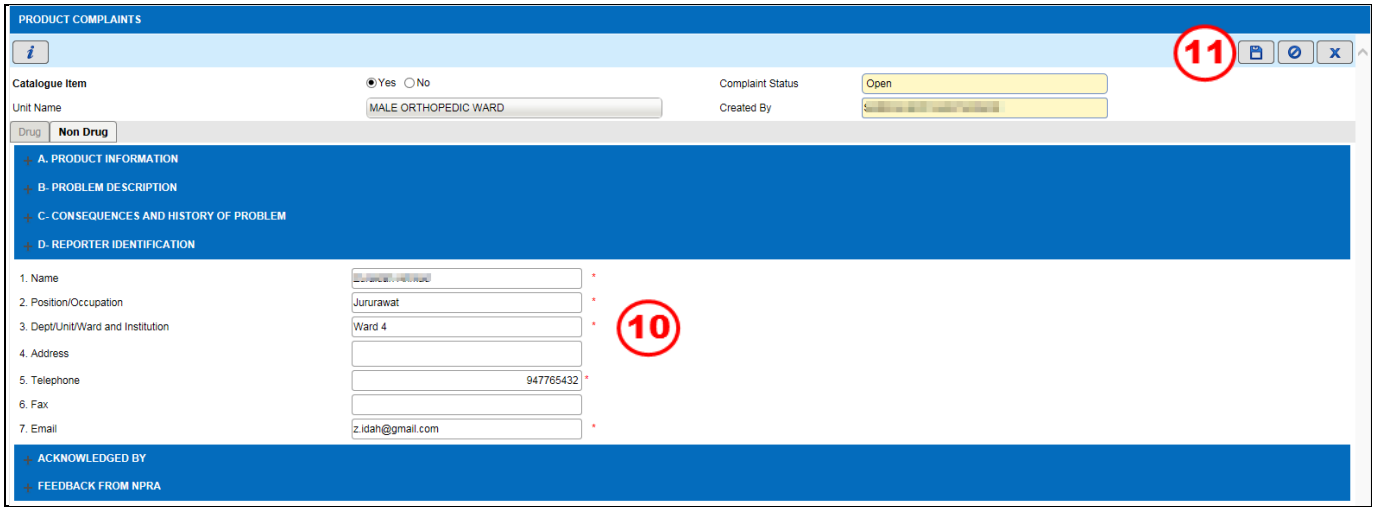


Figure 3.2.3-7 Reporter Identification

STEP 10

Enter

I. ***Name***
II. ***Position/Occupation***
III. ***Dept/Unit/Ward and Institution***
IV. ***Telephone***
V. ***Email***

Note

Optional field:

I. ***Address***
II. ***Fax***

STEP 11

Click on the the button to save the record

Note

- *After clicking on* button, *alert message will be displayed in Figure 3.2.3-8 and Figure 3.2.3-9*

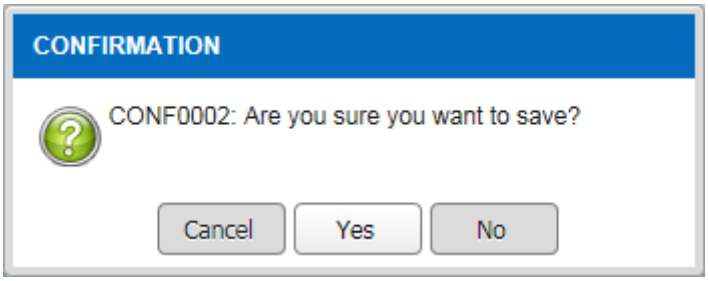
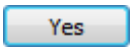


Figure 3.2.3-8 Confirmation Message

- *Click on the*  *button.*

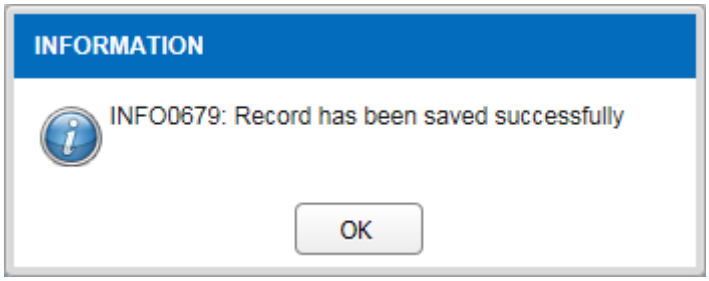


Figure 3.2.3-9 Information Message

- *Click on the* OK *button.*
- ***Complaints No*** *will be automatically generated for future reference.*

Character	Description	Value
1-2	Refer to complaint drug item	'PC'
3-4	Current Year in YY format	12
5-10	Running No	Starting from 000001. This running number will be reset to start from000001 at the beginning of every calendar year.

Table 3.2.3-1

- *Send for Investigation* Send for Investigation *and Cancel Request* Cancel Request *button will be enabled once user saves the Product Complaints record.*

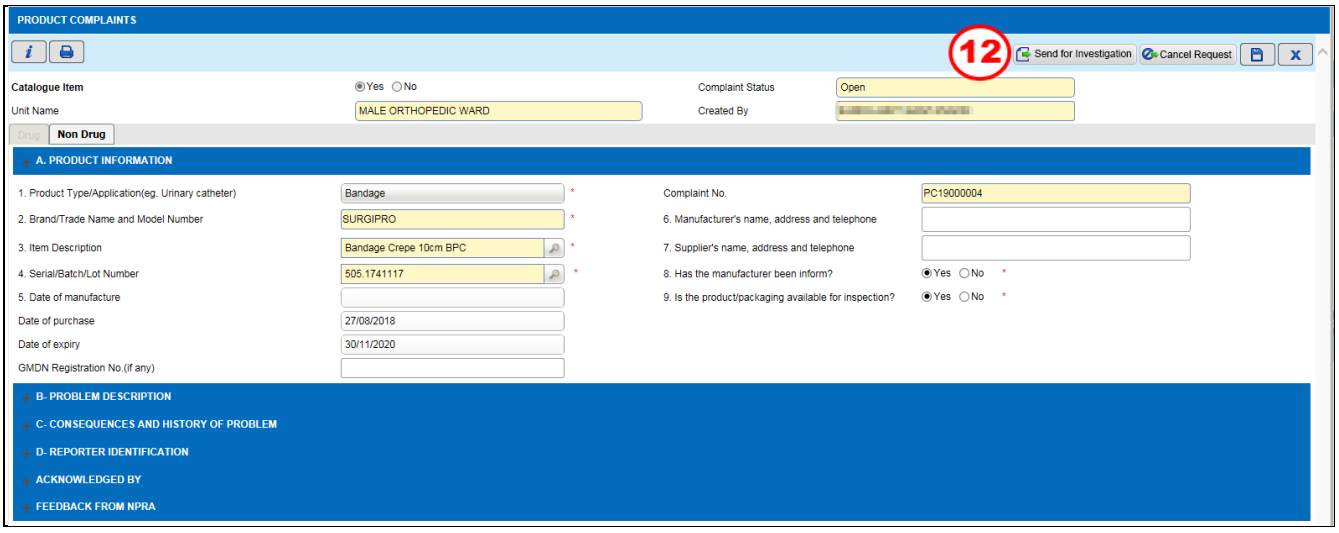


Figure 3.2.3-10 Product Complaints

Note
User is allowed to modify the information before send for investigation

STEP 12

Click on the Send for Investigation button to send the record for investigation

Note

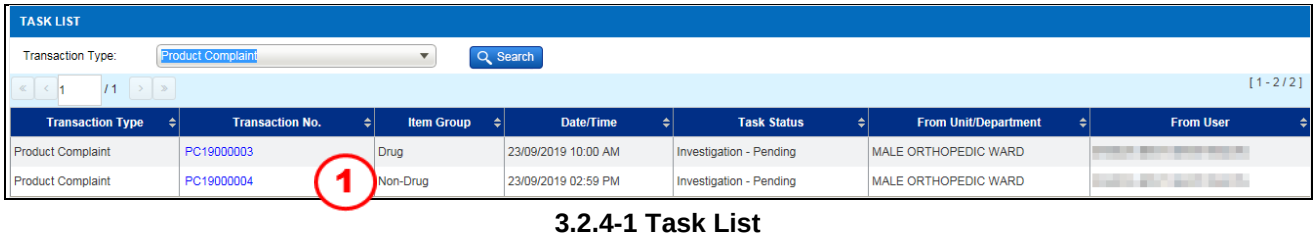
User is allowed to cancel the request by click on the Cancel Request *button*

3.2.4 Product Complaint Investigation - Non Drug

The pharmacist at Pharmacy Store will receive notification for Investigation - Pending records to investigate the validity of the Product Complaints

Note

The Pharmacist will receive the 'Investigation – Pending' transaction in the Task List.



3.2.4-1 Task List

Note

User can filter task list for Product Complaint record by selecting Transaction Type: Product Complaint and click on the Search *button*

STEP 1

Click on the Transaction No. hyperlink and the Product Complaints screen will be displayed as shown in the Figure 3.2.4-*2*

Note

The pharmacist is also able to refer to section [3.1 Product Complaints Listing Page](#) to search for the 'Investigation - Pending' Product Complaints record.

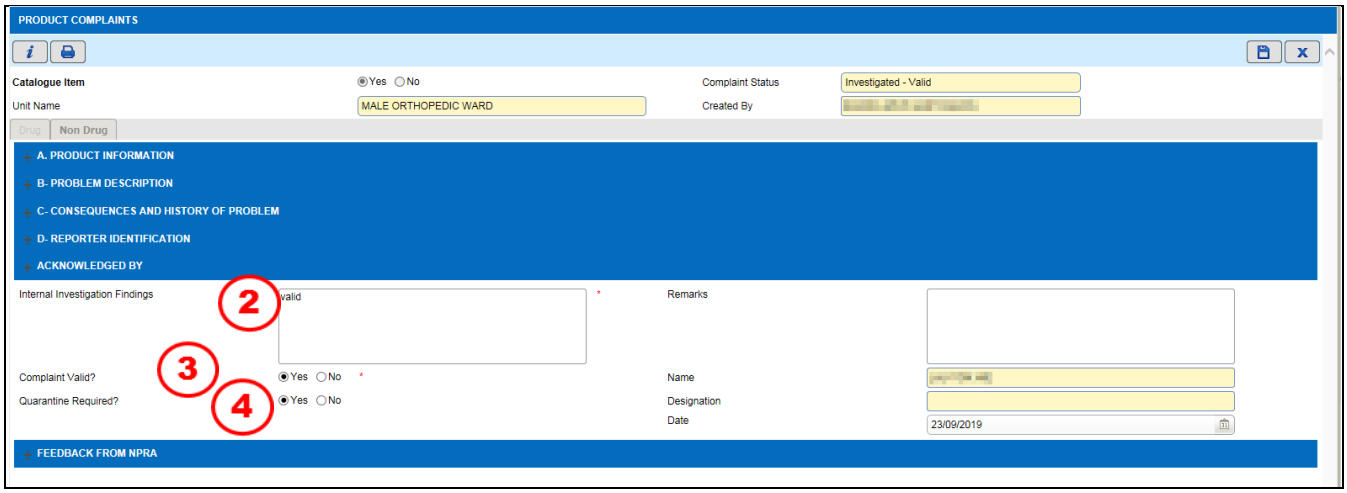


Figure 3.2.4-2 Product Complaints - Acknowledge By

STEP 2

Enter ***Internal Investigation Findings***

STEP 3

Select ***Complaint Valid?*** 'Yes' or 'No' radio button

Note

- *If 'Yes' is selected,* ***Quarantine Required?*** *'Yes' or 'No' radio button will be enabled.*
- *If 'No' is selected, user is required to enter* ***Reason.***

STEP 4
Select from the 'Yes' or 'No' for Quarantine Required? radio button

Note

- *If 'Yes' is selected, this Product Complaints No will be available in the Quarantine Module.*
- *If 'No' is selected, this Product Complaints No will not be available in the Quarantine Module.*

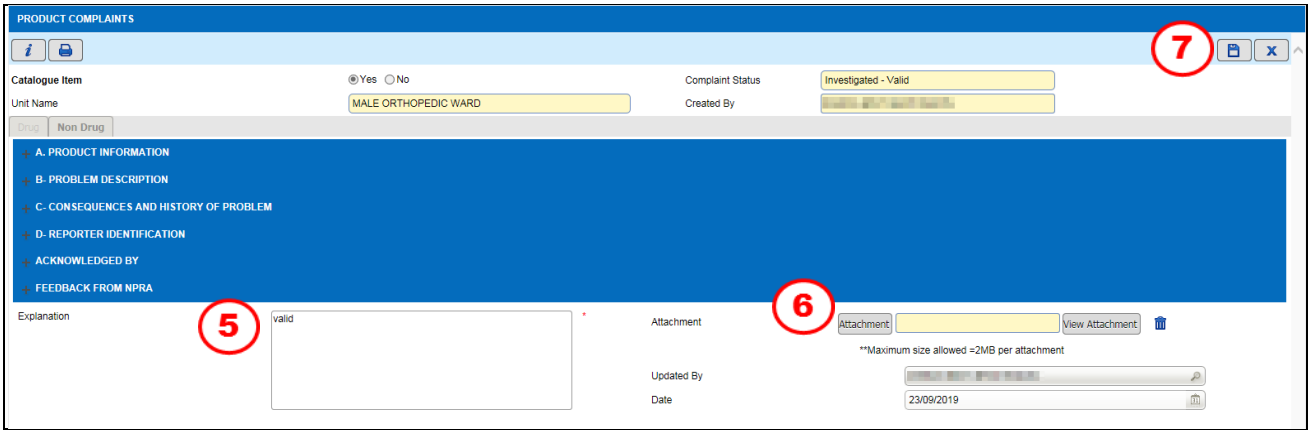


Figure 3.2.2-3 Product Complaints - Feedback From NPRA

STEP 5
Enter ***Explanation***

STEP 6
Click on the Attachment button to upload related document into the system

STEP 7
Click on the button to save the record

3.3 Product Complaints Non Catalogue Item

Non Catalogue Items are items that are not available in the facility's unit catalogue. Pharmacist at the Pharmacy Store will then decide the Complaints' validity but the Complaints will stop after the investigation results by the DIS Pharmacy.

3.3.1 Product Complaints – Drug

To create a new Drug Product Complaints – Non Catalogue item, perform the steps below:

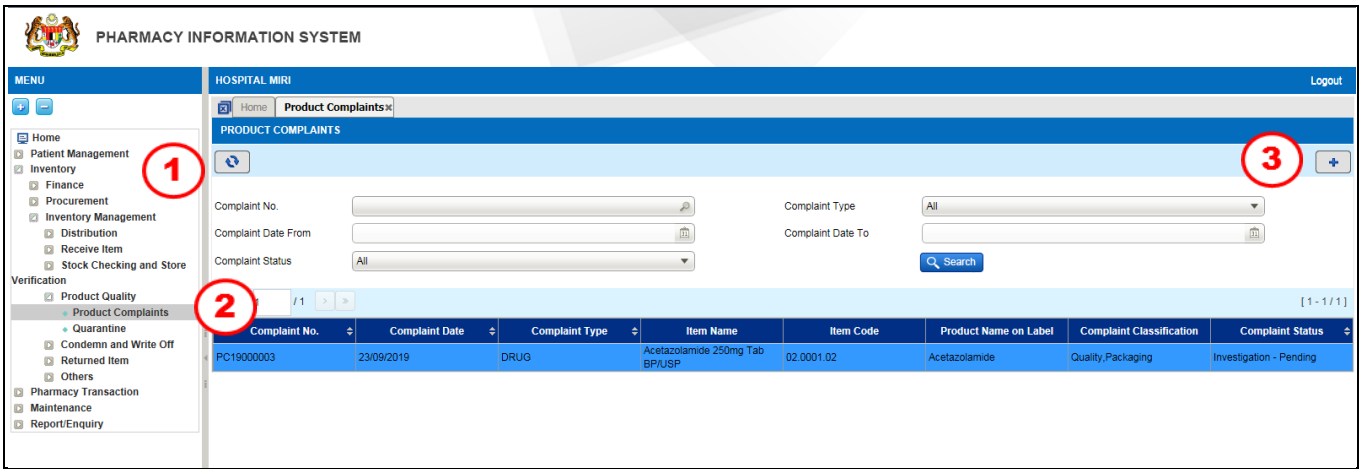


Figure 3.3.1-1 Product Complaints Listing Page

STEP 1

Click on 'Inventory' menu and click on 'Inventory Management' Sub-Menu.

STEP 2

Click on "Product Quality' and click on 'Product Complaints' Sub-Menu.

STEP 3

Click on the button

Note

Product Complaints screen will be displayed in Figure 3.3.1-2

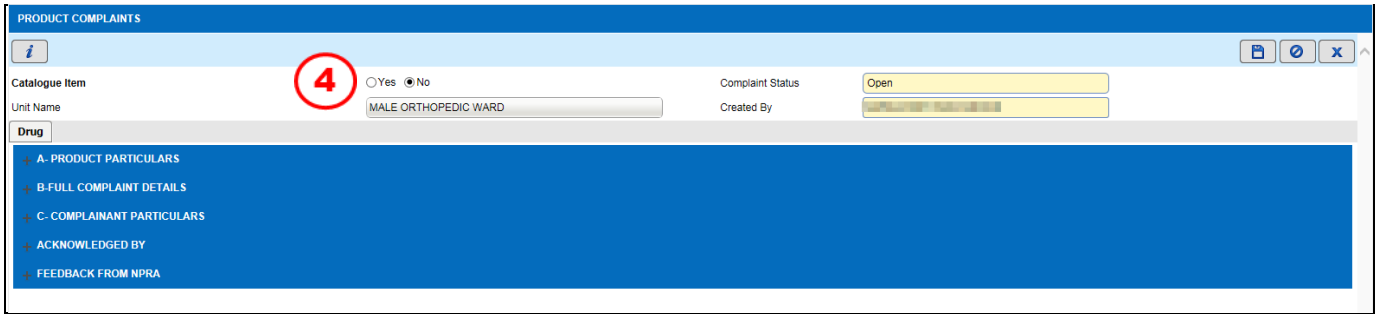


Figure 3.3.1-2 Product Complaint - Non Catalogue Item

STEP 4

Click No on the Catalogue Item

Note

- *These three (3) in a New Product Complaints form are required to be filled:*
  - *I. Product Particulars*
  - *II. Full Complaints Details*
  - *III. Complainant Particulars*

- *The sections can be maximized or minimized by clicking on its Header.*

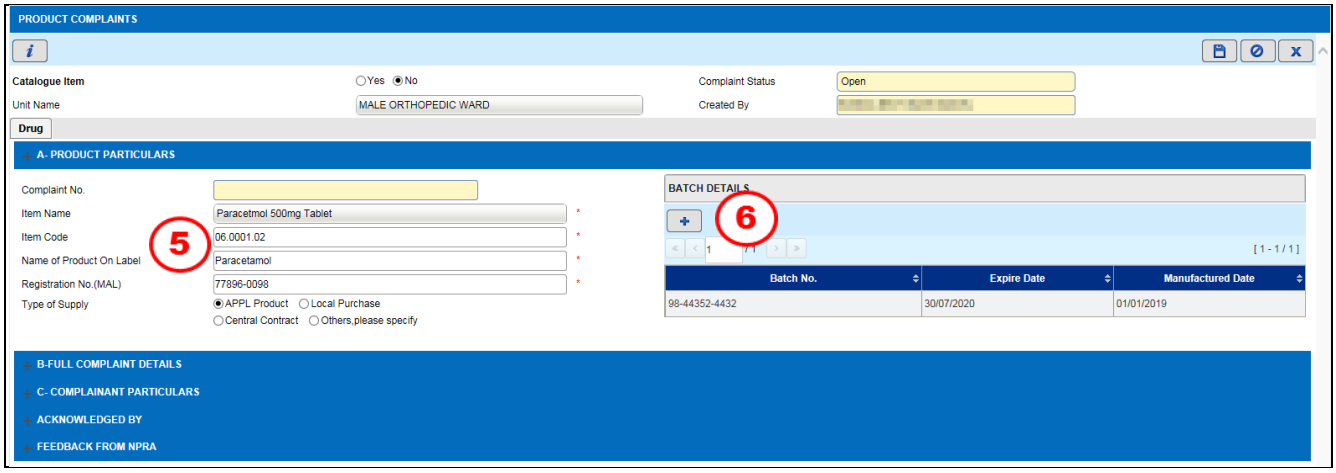


Figure 3.3.1-3 Product Particulars

STEP 5

Enter following field:

I. ***Item Name***
II. ***Item Code***
III. ***Name of Product On Label***
IV. ***Registration No(MAL)***
V. ***Type of Supply***

STEP 6

Click on the ***Batch Details*** button and 'Batch Details' window will be displayed as Figure 3.3.1-4

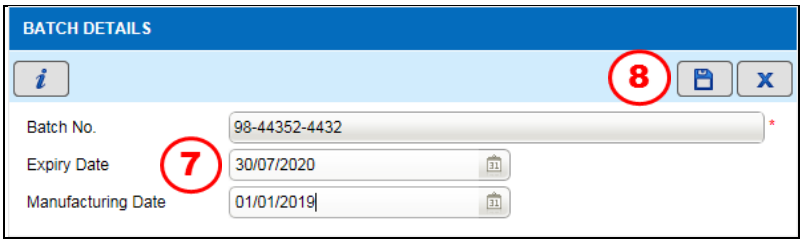


Figure 3.3.1-4 Batch Details

STEP 7

Enter following field:

I. ***Batch No***
II. ***Expiry Date***
III. ***Manufacturing Date***

STEP 8

Click on the button to save the record

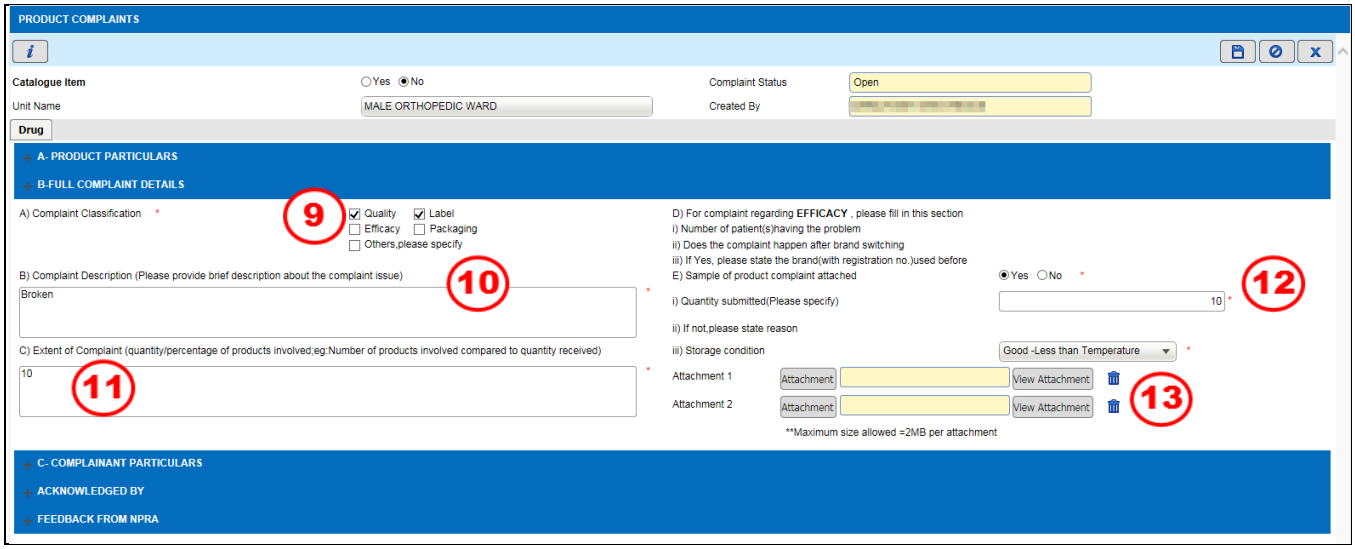


Figure 3.3.1-5 Full Complaint Details

STEP 9
Select the ***Complaints Classification*** checkbox as appropriate and user can select more than one.

- Quality
- Efficacy
- Label
- Packaging
- Others

Note
If the user selects the Complaints Classification as Others, Please Specify Field will be displayed.

STEP 10
Enter ***Complaints Description***

STEP 11
Enter ***Extent of Complaints***

Note

- *If the **Complaints Classification** is selected as Efficacy, these fields will be enabled for the user to enter/select:*
  iii. Number of Patient(s) having the problem.
  iv. Does the Complaints happen after Brand switching?

- *If 'Yes' radio button is selected for 'Does the Complaints happen after brand switching', User has to state the iii) brand (with Registration No.) used before.*

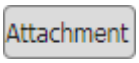
STEP 12
Select from the Yes/No radio button for ***Sample of product Complaints attached***

Note

- *If 'Yes' radio button is selected, user has to state the i) Quantity submitted and the ii) Storage Condition.*

- *If 'No' radio button is selected, user has to state only the ii) Reason*

STEP 13

Click on the 

button to attach any document related on the complaint

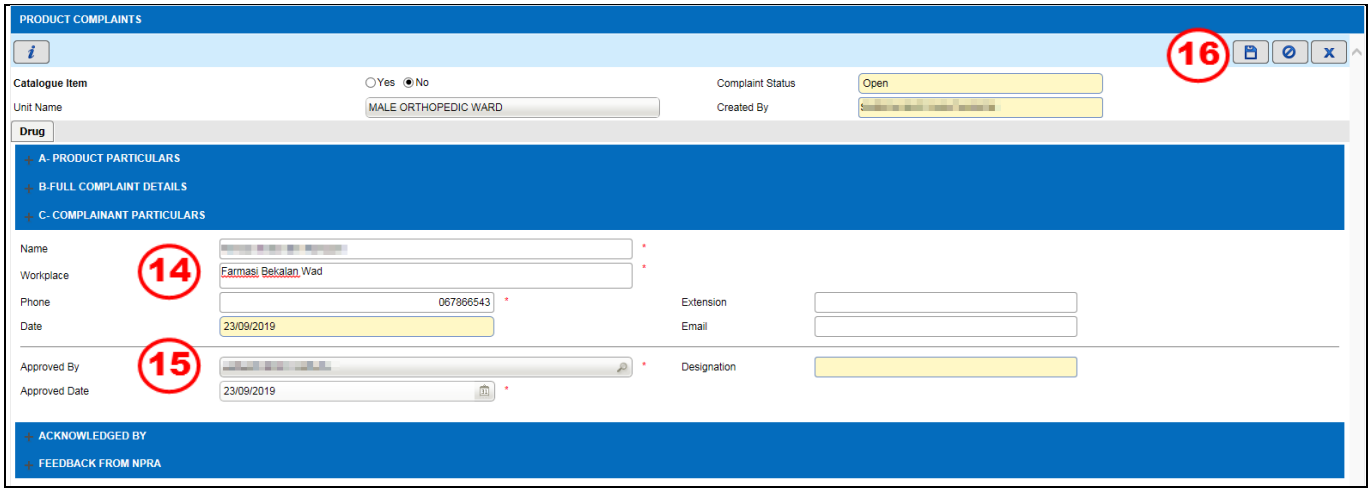


Figure 3.3.1-6 Full Complainant Particulars

STEP 14

Enter ***Name***, ***Workplace*** and ***Phone*** . ***Extension*** and ***Email*** is optional field

STEP 15

Select ***Approved By*** by click on the button and select ***Approved Date*** from button

STEP 16

Click on the button to save the record

Note

- *After clicking on* button, *alert message will be displayed in Figure 3.3.1-7 and Figure 3.3.1-8*

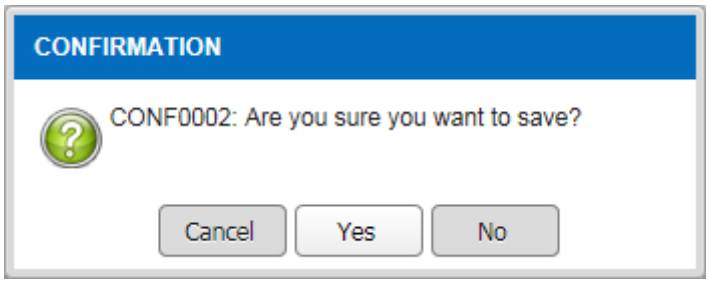


Figure 3.3.1-7 Confirmation Message

- *Click on the* Yes *button.*

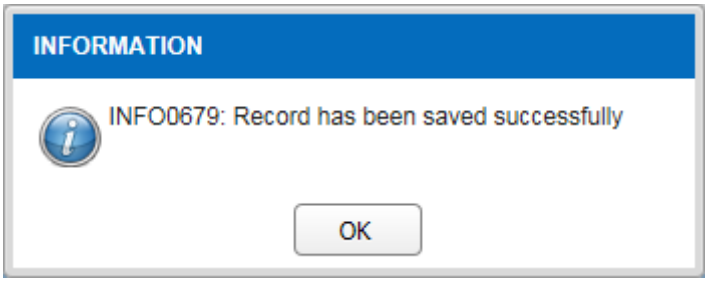


Figure 3.3.1-8 Information Message

- *Click on the* OK *button.*

- ***Complaints No*** *will be automatically generated for future reference.*

Character	Description	Value
1-2	Refer to complaint drug item	'PC'
3-4	Current Year in YY format	12
5-10	Running No	Starting from 000001. This running number will be reset to start from000001 at the beginning of every calendar year.

Table 3.3.1-1

- *Send for Investigation* Send for Investigation *and Cancel Request* Cancel Request *button will be enabled once user saves the Product Complaints record.*

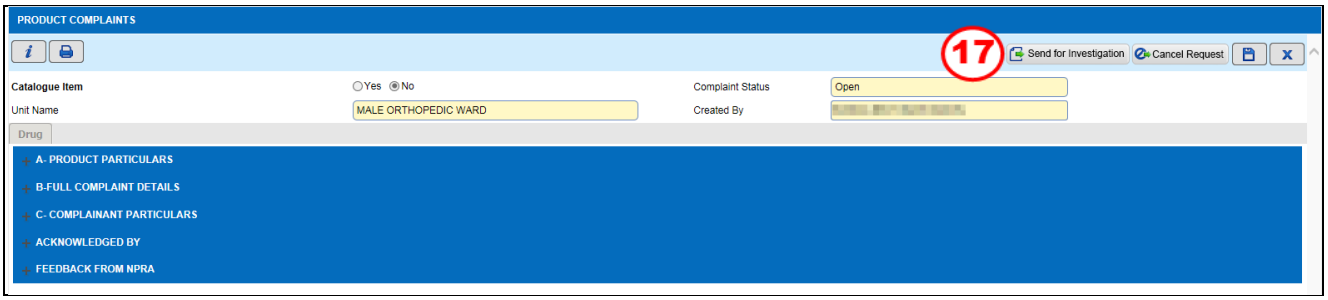


Figure 3.3.1-9 Product Complaints

Note
User is allowed to modify the information before send for investigation

STEP 17

Click on the Send for Investigation button to send the record for investigation

Note

- *User is allowed to cancel the request by click on the* Cancel Request *button*
- *To proceed with Product Complaint Investigation, refer section* [*3.2.2 Product Complaint Investigation - Drug*]

4 Acronyms

Abbreviation	Definition
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
MOH	Ministry Of Health
HQ	Headquarters
UOM	Unit Of Measure
SKU	Store Keeping Unit
PKU	Packaging Keeping Unit
RFQ	Request for Quotation

5.0 Links to Inventory Modules

No	Module	PDF Links	No	Module	PDF Links
1	Finance	Click Here	15	Internal Indent	Click Here
2	Procurement Standard APPL	Click Here	16	Issue	Click Here
3	Procurement standard LP	Click Here	17	Receive From Supplier	Click Here
4	Procurement Standard Contract	Click Here	18	Receive Inter Facility	Click Here
5	Procurement Standard Quotation	Click Here	19	Receive Intra Facility	Click Here
6	Procurement Standard (RFQ)	Click Here	20	Return to Supplier	Click Here
7	Procurement Non Standard (Requisition Order)	Click Here	21	Return to Supplying Unit	Click Here
8	Quarantine	Click Here	22	Slow Moving	Click Here
9	Product Complaint	Click Here	23	Stock Taking And Verification	Click Here
10	Recalculate Buffer Level	Click Here	24	Stock Transfer	Click Here
11	Expiration And Condemn	Click Here	25	Year End	Click Here
12	Recall Product	Click Here	26	Penalty	Click Here
13	Payment	Click Here	27	IWP Budget	Click Here
14	External Indent	Click Here	28	IWP Order Authorization	Click Here