



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

User Manual Pharmacy Inventory - Product Complaint

Version	: 13th Edition
Document ID	: U. MANUAL_INV_PRODUCT COMPLAINT



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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 detail:

- Create New Product Complaints Record
- Product Complaint Investigation

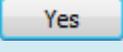
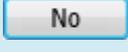
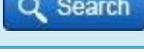
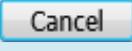
1.3 Organised Sections

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 to PhIS		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 Report From PDF file to Excel file		OK Button
	Yes Button		No Button
	Radio Button	<input type="checkbox"/>	Checkbox
	System Automatic Generate Record No.		Automatically Display/Retrieve Box
	Reset Login Screen		Show Help
	Display Home Tab		Search Record
	Cancel		Dropdown Box
	Search Icon	*	Mandatory Field
	Edit Record		Empty Text Box
	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

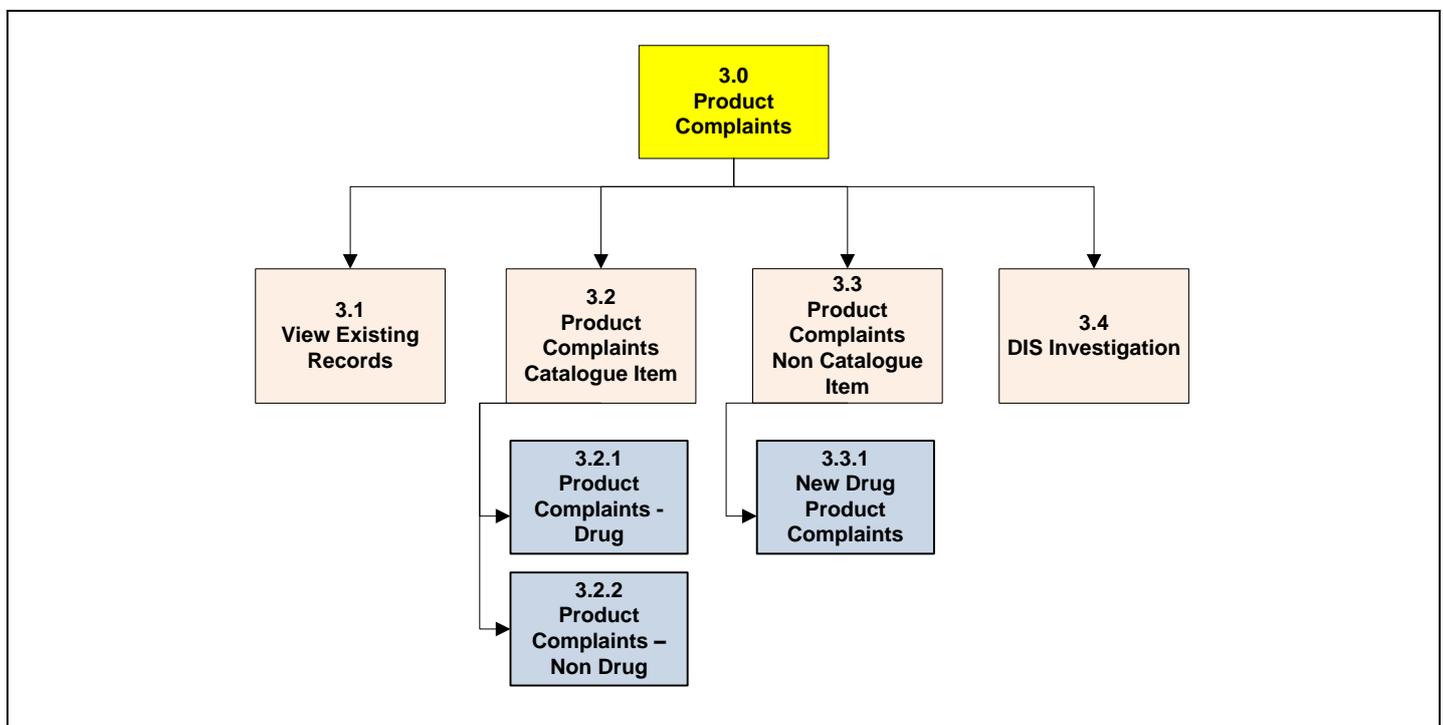


Figure 3.1

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:

The screenshot shows the 'PHARMACY INFORMATION SYSTEM' interface for 'HOSP. PAKAR SULTANAH FATIMAH'. The left-hand menu has 'Inventory' circled in red with a '1'. Under 'Inventory', 'Product Complaints' is circled in red with a '2'. The main content area has search filters for 'Complaint No.', 'Complaint Date From', 'Complaint Date To', 'Complaint Status', and 'Complaint Classification', with a 'Search' button circled in red with a '3'. Below the filters is a table with columns: Complaint No., Complaint Date, Complaint Type, Item Description, Item Code, Product Name on Label, Complaint Classification, and Complaint Status. The table contains several rows of complaint records.

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	Complaint Date From	Start date for the product complaints transaction	Format field (dd/mm/yy)
d	Complaint Date To	End date for the product complaints transaction	Format field (dd/mm/yy)
e	Complaints Status	Search by: All Investigated – Invalid Investigated – Valid Investigation – Pending Open	Able to filter and search record(s)
f	Item Description	Item Description	Able to filter by item description
g	Complaints Classification	Search by: - All - Quality	Able to filter and search record(s)

		<ul style="list-style-type: none"> - Efficacy - Label - Packaging - Others 	
--	--	--	--

Table 3.1-1

PHARMACY INFORMATION SYSTEM

HOSP. PAKAR SULTANAH FATIMAH

Product Complaints

Complaint No. Complaint Type

Complaint Date From Complaint Date To

Complaint Status Item Description

Complaint Classification (4)

Complaint No.	Complaint Date	Complaint Type	Item Description	Item Code	Product Name on Label	Complaint Classification	Complaint Status
PC21000013	23/09/2021	DRUG (5)	Betahistine Dihydrochloride 24mg Tablet	N07CA01110T1003XX.01	BETANOR 24MG TABLET	Efficacy	Investigated - Valid
PC21000012	15/08/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC21000011	12/07/2021	NON-DRUG	Catheter Foley 2 Way Ballon Size 8 Fg.5cc	B1200070009.00	-	-	Investigated - Valid
PC21000010	17/05/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC21000009	04/05/2021	NON-DRUG	Syringe, Luer Lock, Size 50ml	T2090340006.03	-	-	Investigated - Valid

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 in Figure 3.1-3

PRODUCT COMPLAINTS

🖨️
🗑️
✕

Catalogue Item Yes No

Unit Name

Complaint Status

Created By

Drug
Non Drug

+ A- PRODUCT PARTICULARS

Complaint No.

Item Description

Item Code

Name of Product On Label

Registration No. (MAL)

Type of Supply *
 APPL Product Local Purchase
 Central Contract

BATCH DETAILS

+
[1 - 1 / 1]

<< 1 / 1 >>

Batch No.	Expire Date	Manufactured Date
2102018	28/02/2024	29/02/2020

+ B-FULL COMPLAINT DETAILS

A) Complaint Classification *
 Quality Label
 Efficacy Packaging
 Others, please specify

B) Complaint Description (Please provide brief description about the complaint issue)

D) For complaint regarding EFFICACY , please fill in this section

i) Number of patient(s) having the problem

ii) Does the complaint happen after brand switching Yes No *

iii) If Yes, please state the brand (with registration no.) used before

E) Sample of product complaint attached Yes No *

i) Quantity submitted (Please specify)

ii) If not, please state reason

Figure 3.1-4 Product Complaints

Note

Click on  button to close the record.

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:

PHARMACY INFORMATION SYSTEM

HOSP. PAKAR SULTANAH FATIMAH

Home Product Complaints

PRODUCT COMPLAINTS

Complaint No. [] Complaint Type [All]

Complaint Date From [] Complaint Date To []

Complaint Status [All] Item Description []

Complaint Classification [All] [Search]

Complaint No.	Complaint Date	Complaint Type	Item Description	Item Code	Product Name on Label	Complaint Classification	Complaint Status
PC2100013	23/09/2021	DRUG	Betahistine Dihydrochloride 24mg Tablet	N07CA01110T1003XX.01	BETANOR 24MG TABLET	Efficacy	Investigated - Valid
PC2100012	15/08/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC2100011	12/07/2021	NON-DRUG	Catheter Foley 2 Way Ballon Size 8 Fg,5cc	B1200070009.00	-	-	Investigated - Valid
PC2100010	17/05/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC2100009	04/05/2021	NON-DRUG	Syringe, Luer Lock, Size 50ml	T2090340006.03	-	-	Investigated - Valid

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

PRODUCT COMPLAINTS

Catalogue Item Yes No

Unit Name [STOR FARMASI]

Complaint Status [Open]

Created By []

Drug Non Drug

A- PRODUCT PARTICULARS

B-FULL COMPLAINT DETAILS

C- COMPLAINANT PARTICULARS

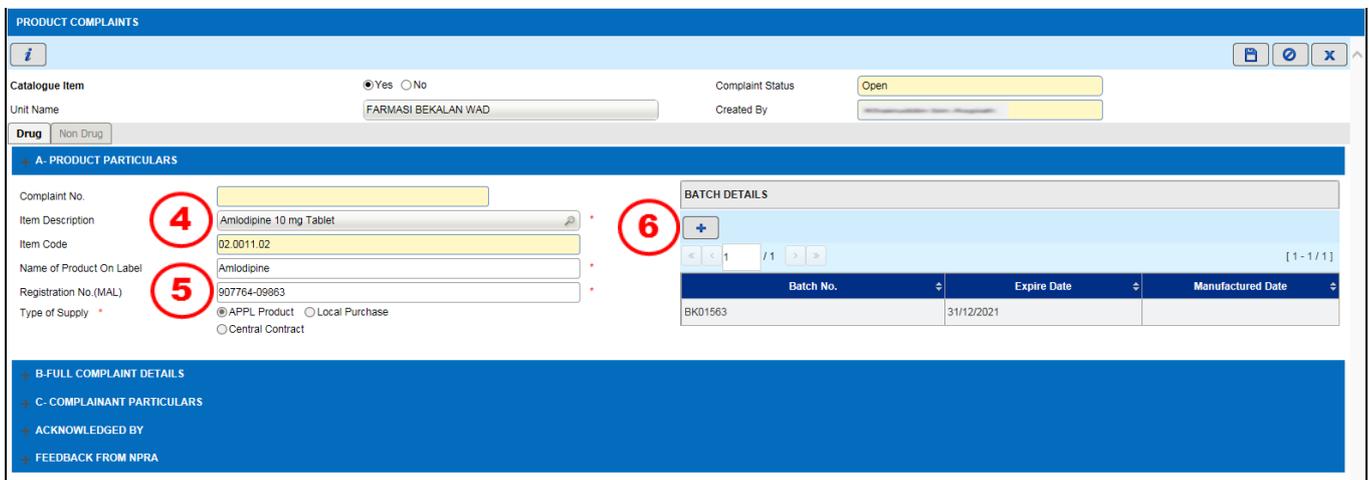
ACKNOWLEDGED BY

FEEDBACK FROM NPRA

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:
 - Product Particulars
 - Full Complaints Details
 - Complainant Particulars
- The sections can be maximized or minimized by clicking on the Header.



PRODUCT COMPLAINTS

Catalogue Item Yes No Complaint Status

Unit Name Created By

Drug Drug Non Drug

A- PRODUCT PARTICULARS

Complaint No.

Item Description **4**

Item Code

Name of Product On Label

Registration No. (MAL) **5**

Type of Supply APPL Product Local Purchase Central Contract

BATCH DETAILS

Batch No.	Expire Date	Manufactured Date
BK01563	31/12/2021	

6

B-FULL COMPLAINT DETAILS

C- COMPLAINANT PARTICULARS

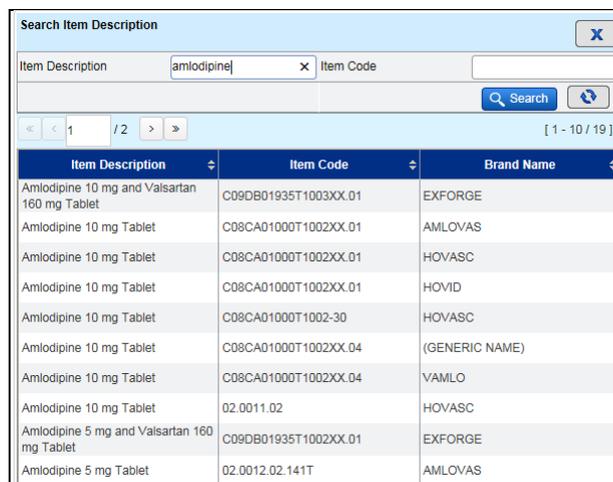
ACKNOWLEDGED BY

FEEDBACK FROM NPRA

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



Search Item Description

Item Description Item Code

[1 - 10 / 19]

Item Description	Item Code	Brand Name
Amlodipine 10 mg and Valsartan 160 mg Tablet	C09DB01935T1003XX.01	EXFORGE
Amlodipine 10 mg Tablet	C08CA01000T1002XX.01	AMLOVAS
Amlodipine 10 mg Tablet	C08CA01000T1002XX.01	HOVASC
Amlodipine 10 mg Tablet	C08CA01000T1002XX.01	HOVID
Amlodipine 10 mg Tablet	C08CA01000T1002-30	HOVASC
Amlodipine 10 mg Tablet	C08CA01000T1002XX.04	(GENERIC NAME)
Amlodipine 10 mg Tablet	C08CA01000T1002XX.04	VAMLO
Amlodipine 10 mg Tablet	02.0011.02	HOVASC
Amlodipine 5 mg and Valsartan 160 mg Tablet	C09DB01935T1002XX.01	EXFORGE
Amlodipine 5 mg Tablet	02.0012.02.141T	AMLOVAS

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  button.
- **Type of Supply** will be selected automatically 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

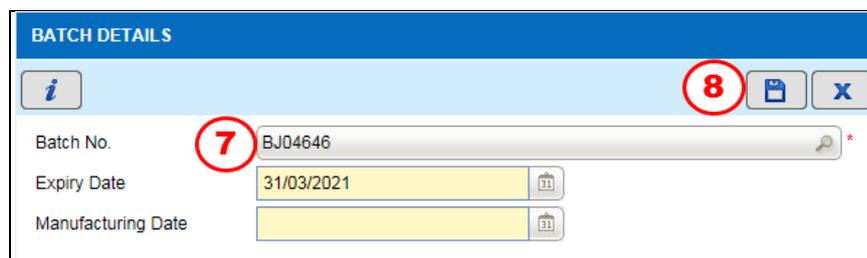


Figure 3.2.1-5 Batch Details

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

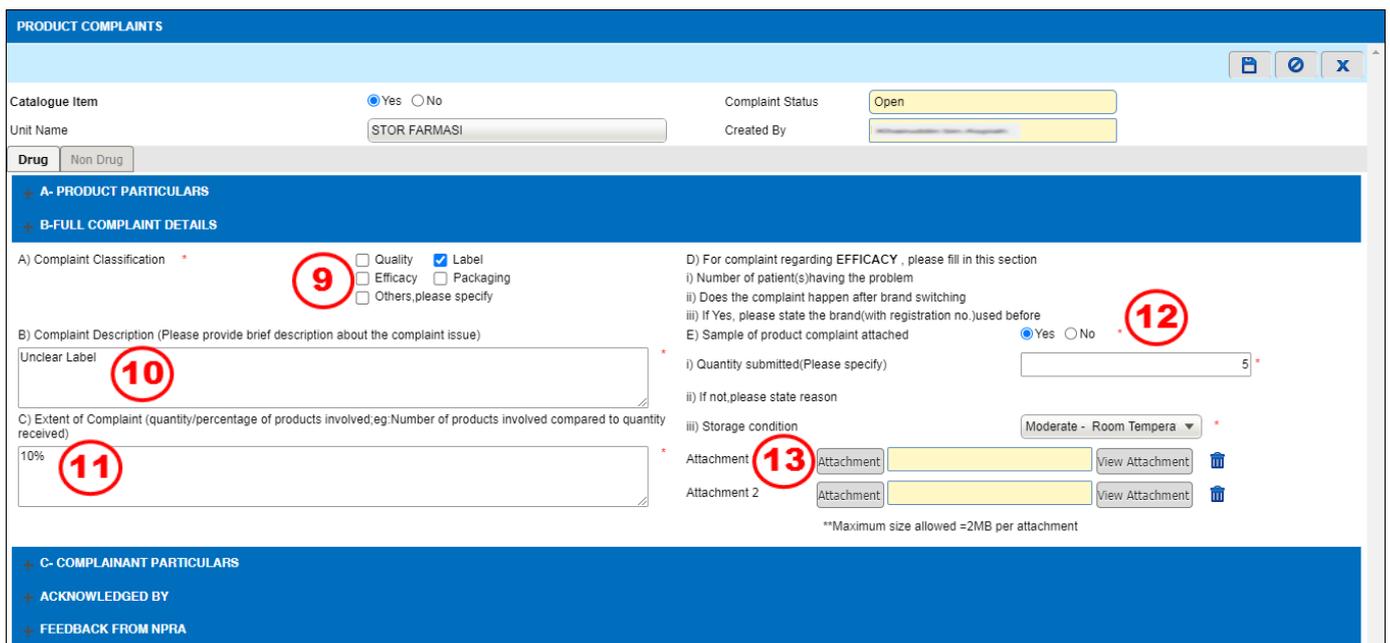


Figure 3.2.1-6 Full Complaint Details

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:
 - Number of Patient(s) having the problem.
 - 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.

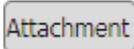
STEP 12

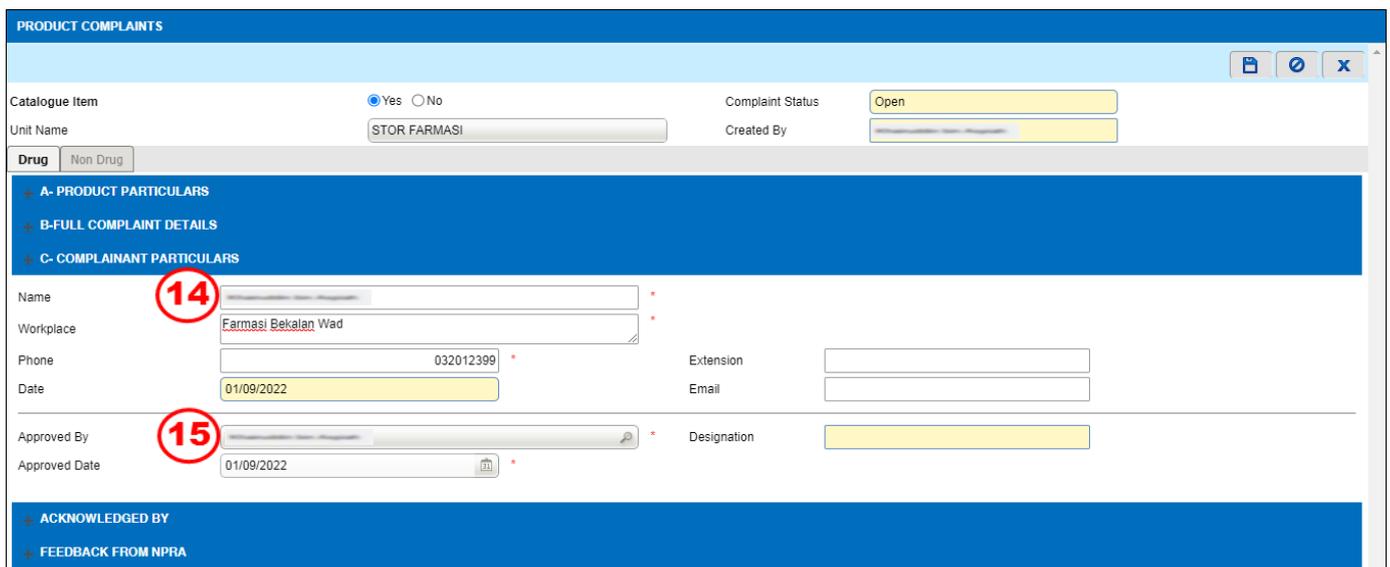
Select from the Yes/No radio button for **Sample of product Complaints attached**

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



The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top, there are fields for 'Catalogue Item' (Yes/No radio buttons), 'Complaint Status' (Open), 'Unit Name' (STOR FARMASI), and 'Created By'. Below this is a section for 'Complainant Particulars' with three expandable sub-sections: 'A- PRODUCT PARTICULARS', 'B-FULL COMPLAINT DETAILS', and 'C- COMPLAINANT PARTICULARS'. Under 'C- COMPLAINANT PARTICULARS', there are fields for Name (circled 14), Workplace (Farmasi Bekalan Wad), Phone (032012399), Date (01/09/2022), Approved By (circled 15), and Approved Date (01/09/2022). There are also fields for Extension and Email. At the bottom, there are sections for 'ACKNOWLEDGED BY' and 'FEEDBACK FROM NPRA'.

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

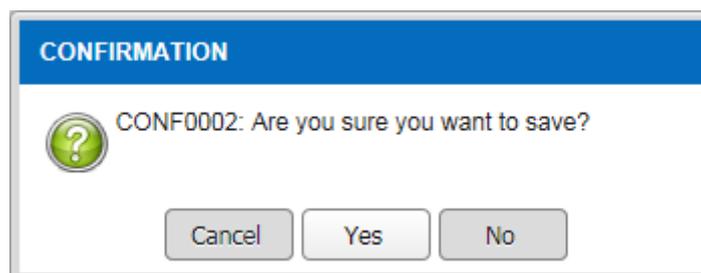


Figure 3.2.1-9 Confirmation Message

- Click on the button.

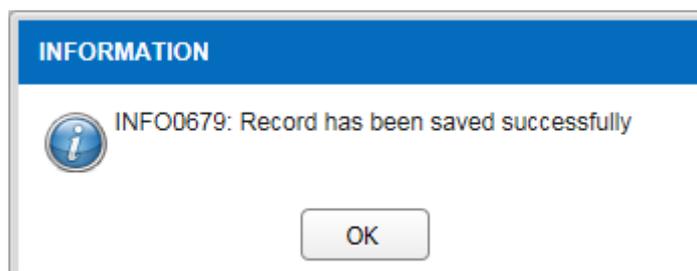
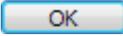


Figure 3.2.1-10 Information Message

- Click on the  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 from 000001 at the beginning of every calendar year.

Table 3.2.1-1

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

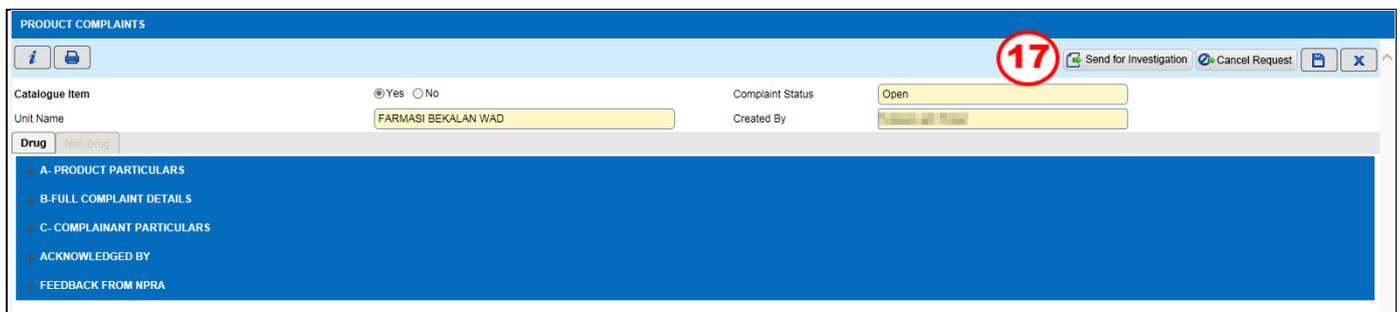


Figure 3.2.1-11 Product Complaints

Note

User is allowed to modify the information before send for investigation

STEP 17

Click on the  button to send the record for investigation

Note

User is allowed to cancel the request by click on the  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.

TASK LIST						
Transaction Type: Product Complaint		<input type="button" value="Search"/>				
<input type="button" value="Previous"/> <input type="button" value="Next"/> 1 / 1 <input type="button" value="Refresh"/>						[1 - 3 / 3]
Transaction Type	Transaction No.	Item Group	Date/Time	Task Status	From Unit/Department	From User
Product Complaint	PC17000012		22/11/2017 08:39 AM	Investigation - Pending	FARMASI NUTRISI PARENTERAL	
Product Complaint	PC18000002		11/01/2018 03:01 PM	Investigation - Pending	WAD 17 (PAED)	
Product Complaint	PC19000026	Drug	22/08/2019 01:06 PM	Investigation - Pending	FARMASI BEKALAN WAD	

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 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.

PRODUCT COMPLAINTS

Catalogue Item Yes No Complaint Status: Investigated - Valid

Unit Name: FARMASI BEKALAN WAD Created By: Suseela alp Gopal

Drug Non Drug

A- PRODUCT PARTICULARS

B-FULL COMPLAINT DETAILS

C- COMPLAINANT PARTICULARS

ACKNOWLEDGED BY

Internal Investigation Findings: valid Remarks:

Complaint Valid? Yes No Name: System Administrator

Quarantine Required? Yes No Designation: Pegawai Perubatan Pakar

Date: 22/08/2019

FEEDBACK FROM NPRA

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.

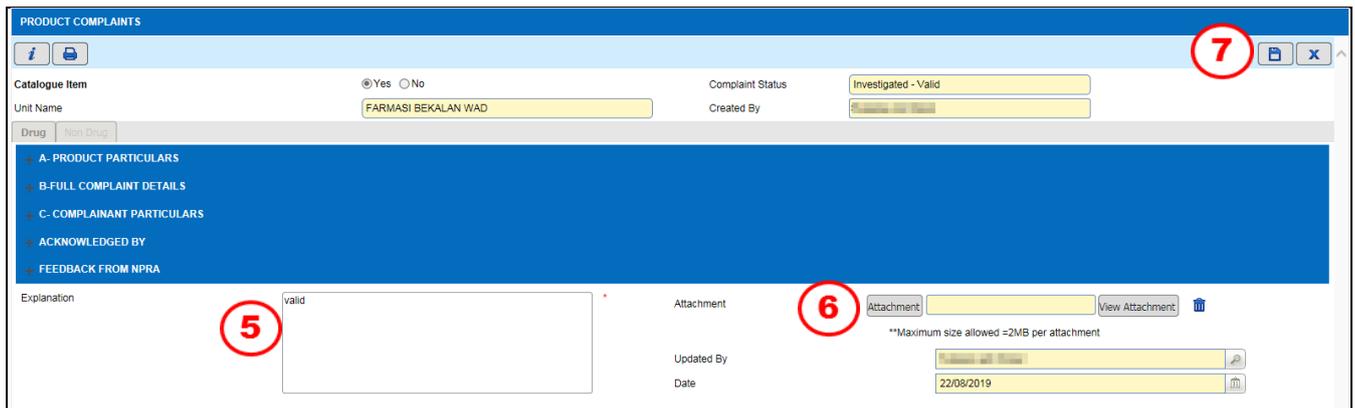


Figure 3.2.2-3 Product Complaints - Feedback From NPRA

STEP 5

Enter **Explanation**

STEP 6

Click on the  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:

PHARMACY INFORMATION SYSTEM

HOSP. PAKAR SULTANAH FATIMAH

Home Product Complaints

PRODUCT COMPLAINTS

Complaint No. [] Complaint Type: All

Complaint Date From [] Complaint Date To []

Complaint Status: All Item Description []

Complaint Classification: All [Search]

Complaint No.	Complaint Date	Complaint Type	Item Description	Item Code	Product Name on Label	Complaint Classification	Complaint Status
PC21000013	23/09/2021	DRUG	Betahistine Dihydrochloride 24mg Tablet	N07CA01110T1003XX.01	BETANOR 24MG TABLET	Efficacy	Investigated - Valid
PC21000012	15/08/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC21000011	12/07/2021	NON-DRUG	Catheter Foley 2 Way Balloon Size 8 Fg.5cc	B1200070009.00	-	-	Investigated - Valid
PC21000010	17/05/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC21000009	04/05/2021	NON-DRUG	Syringe, Luer Lock, Size 50ml	T2090340006.03	-	-	Investigated - Valid
			Epirubicin 50mg/25ml				

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

PRODUCT COMPLAINTS

Catalogue Item: Yes No

Unit Name: STOR FARMASI

Complaint Status: Open

Created By: []

Drug Non Drug **4**

- A. PRODUCT INFORMATION
- B. PROBLEM DESCRIPTION
- C. CONSEQUENCES AND HISTORY OF PROBLEM
- D. REPORTER IDENTIFICATION
- ACKNOWLEDGED BY

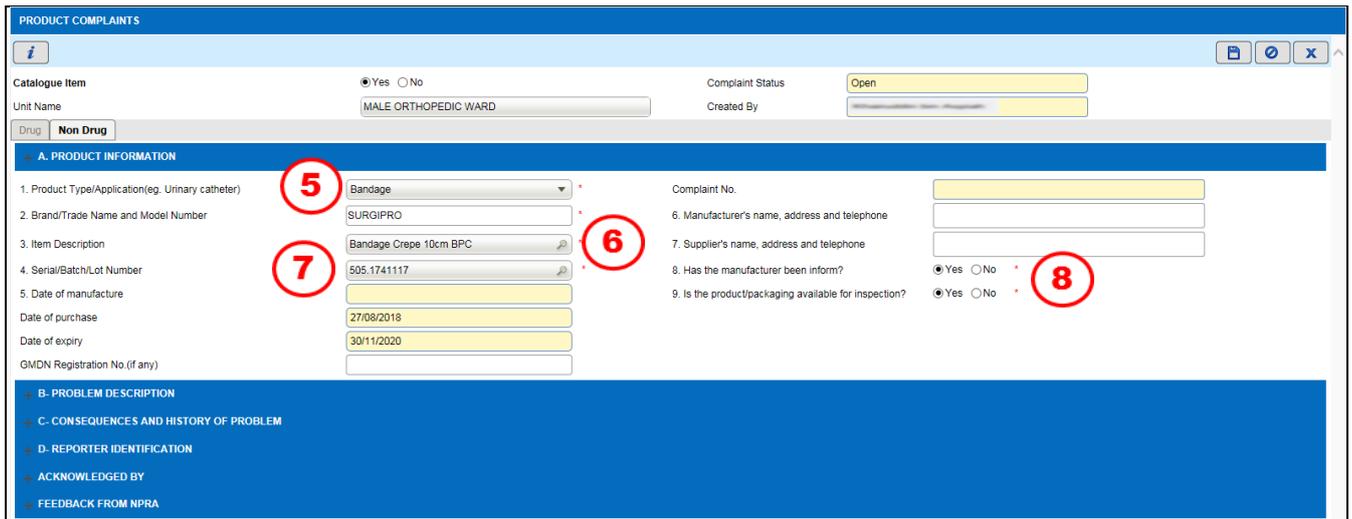
Figure 3.2.3-2 New Non Drug Product Complaints – Catalogue Item

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



The screenshot shows the 'PRODUCT COMPLAINTS' form. The 'A. PRODUCT INFORMATION' section is expanded. Fields are numbered with red circles: 5 (Product Type/Application), 6 (Manufacturer's name, address and telephone), 7 (Serial/Batch/Lot Number), and 8 (Has the manufacturer been info?).

Figure 3.2.3-3 Product Particulars

STEP 5

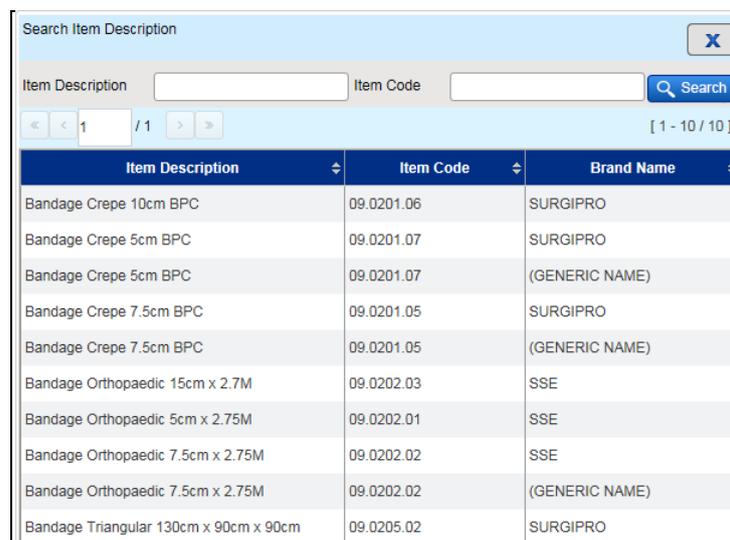
Select **Product Type/Application** (e.g. **Urinary catheter**) from dropdown menu

STEP 6

Select **Item Description**

Note

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



The screenshot shows the 'Search Item Description' window with a search bar and a table of results. The table has columns for Item Description, Item Code, and Brand Name.

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.

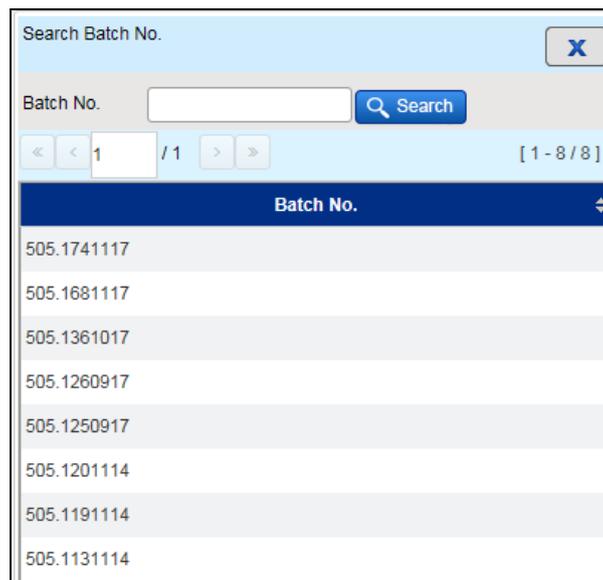


Figure 3.2.3-5 Search Batch No.

- 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

The screenshot shows the 'PRODUCT COMPLAINTS' form. At the top, there are fields for 'Catalogue Item', 'Complaint Status' (set to 'Open'), 'Unit Name' (set to 'MALE ORTHOPEDIC WARD'), and 'Created By'. Below these are tabs for 'Drug' and 'Non Drug'. The form is divided into sections: A. PRODUCT INFORMATION, B. PROBLEM DESCRIPTION, C. CONSEQUENCES AND HISTORY OF PROBLEM, D. REPORTER IDENTIFICATION, ACKNOWLEDGED BY, and FEEDBACK FROM NPRA. In section B, the 'Problem Description' field contains the text 'Broken' and is circled with a red '9'.

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

The screenshot shows the 'PRODUCT COMPLAINTS' form with the 'Reporter Identification' section expanded. It contains seven numbered fields: 1. Name (filled with 'Zuraidah'), 2. Position/Occupation (filled with 'Jururawat'), 3. Dept/Unit/Ward and Institution (filled with 'Ward 4'), 4. Address (empty), 5. Telephone (filled with '947765432'), 6. Fax (empty), and 7. Email (filled with 'z.idah@gmail.com'). A red circle '10' is placed around the 'Name' field. In the top right corner, a red circle '11' is placed around the window control buttons.

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

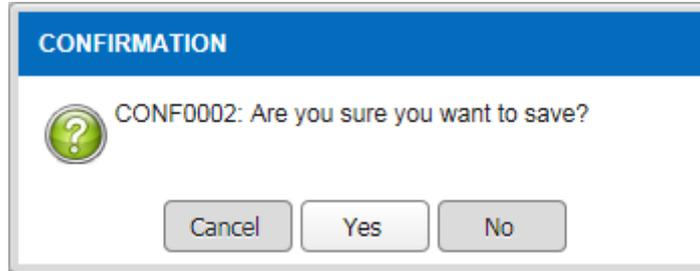
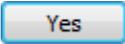


Figure 3.2.3-8 Confirmation Message

- Click on the  button.

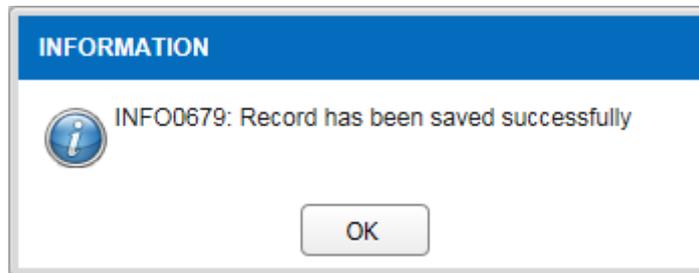
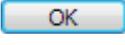


Figure 3.2.3-9 Information Message

- Click on the  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 from 000001 at the beginning of every calendar year.

Table 3.2.3-1

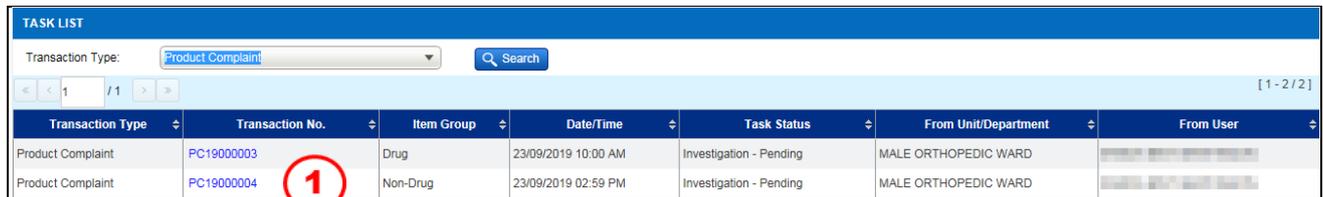
- **Send for Investigation**  **Send for Investigation** and **Cancel Request**  **Cancel Request** button will be enabled once user saves the Product Complaints record.

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

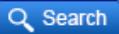
The Pharmacist will receive the 'Investigation – Pending' transaction in the Task List.



Transaction Type	Transaction No.	Item Group	Date/Time	Task Status	From Unit/Department	From User
Product Complaint	PC19000003	Drug	23/09/2019 10:00 AM	Investigation - Pending	MALE ORTHOPEDIC WARD	
Product Complaint	PC19000004	Non-Drug	23/09/2019 02:59 PM	Investigation - Pending	MALE ORTHOPEDIC WARD	

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  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.

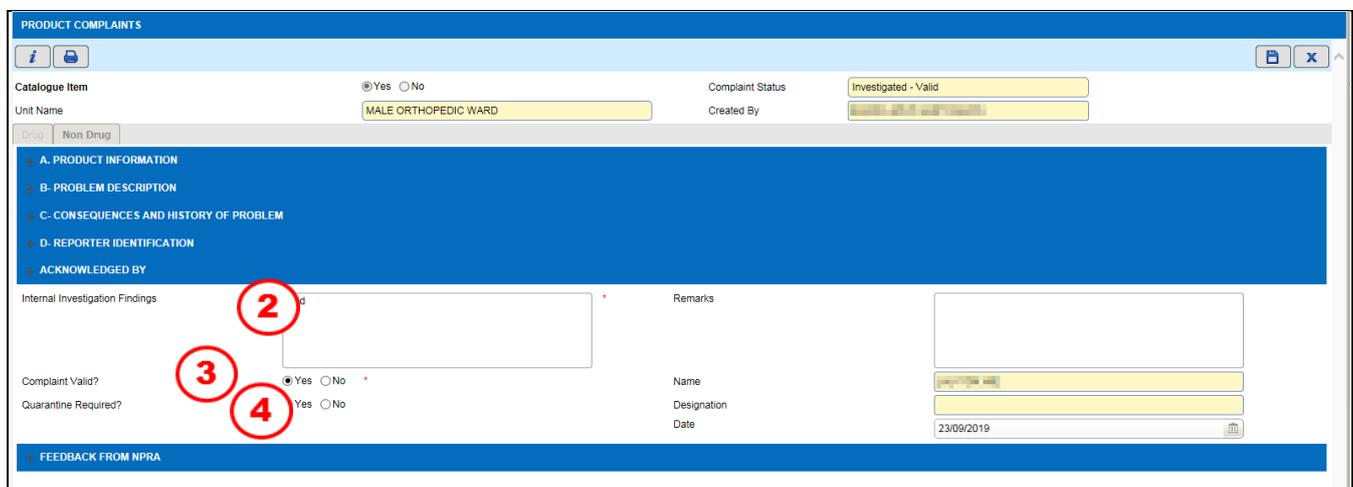


Figure 3.2.4-2 Product Complaints - Acknowledge By

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.

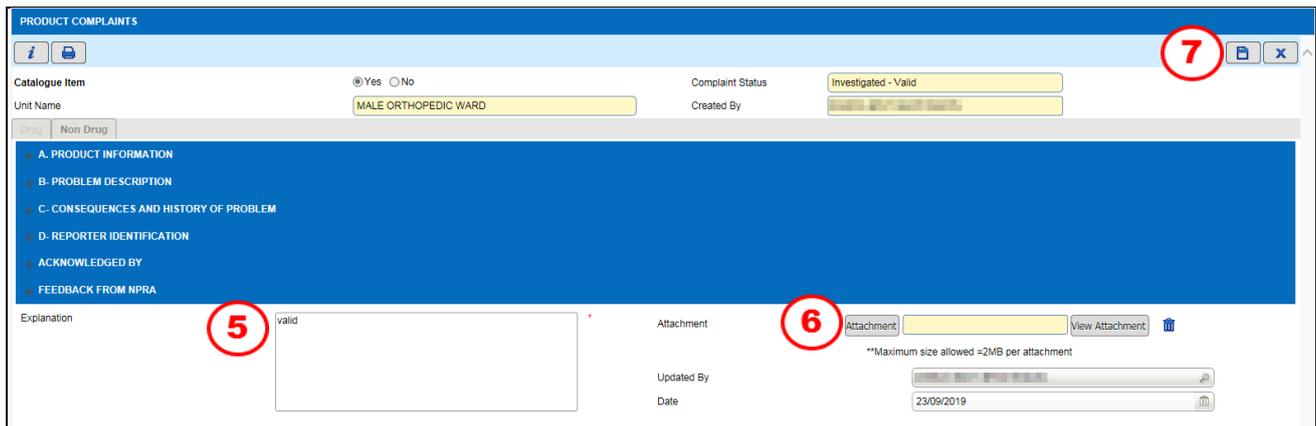


Figure 3.2.2-3 Product Complaints - Feedback From NPRA

STEP 5

Enter **Explanation**

STEP 6

Click on the  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:

Complaint No.	Complaint Date	Complaint Type	Item Description	Item Code	Product Name on Label	Complaint Classification	Complaint Status
PC2100013	23/09/2021	DRUG	Belahistine Dihydrochloride 24mg Tablet	N07CA01110T1003XX.01	BETANOR 24MG TABLET	Efficacy	Investigated - Valid
PC2100012	15/08/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC2100011	12/07/2021	NON-DRUG	Catheter Foley 2 Way Ballon Size 8 Fg.5cc	B1200070009.00	-	-	Investigated - Valid
PC2100010	17/05/2021	NON-DRUG	Mask Surgical Disposable, 3ply	10.2401.01	-	-	Investigated - Valid
PC2100009	04/05/2021	NON-DRUG	Syringe, Luer Lock, Size 50ml	T2090340006.03	-	-	Investigated - Valid
PC2100008	04/05/2021	NON-DRUG	Epirubicin 50mg/25ml	-	-	-	Investigated - Valid

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 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.

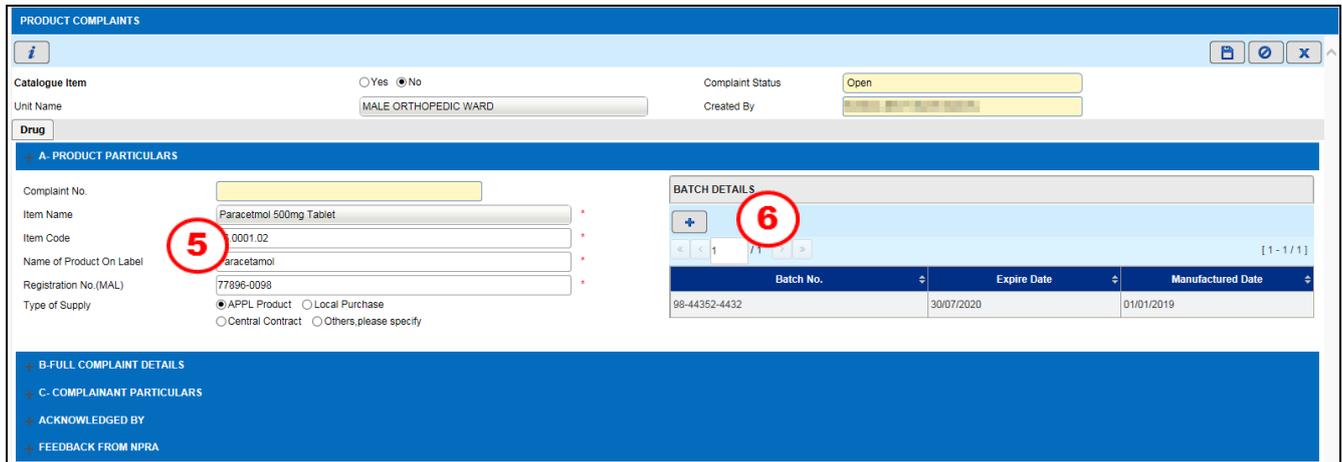


Figure 3.3.1-3 Product Particulars

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

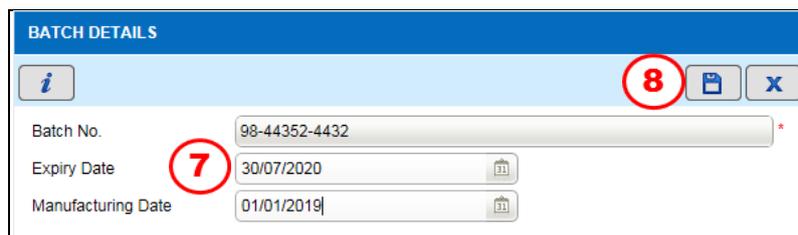


Figure 3.3.1-4 Batch Details

STEP 7

Enter following field:

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

STEP 8

Click on  the button to save the record

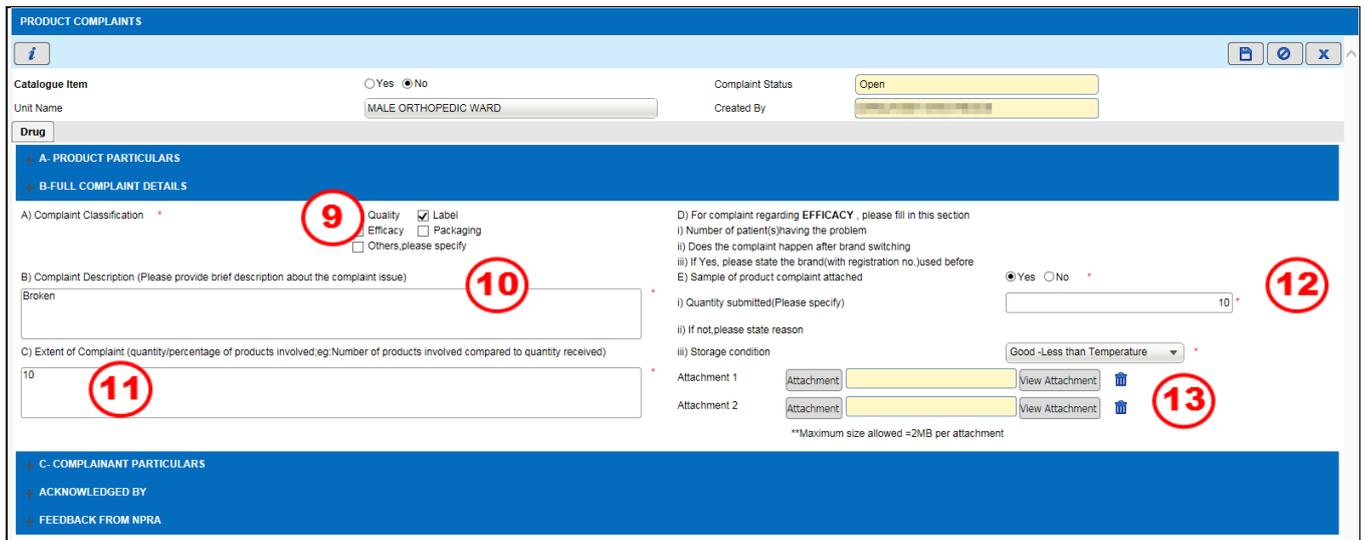


Figure 3.3.1-5 Full Complaint Details

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

The screenshot shows a web application interface for 'PRODUCT COMPLAINTS'. At the top, there are navigation buttons and a window title bar with a red circle '16' around the save button. Below this, there are dropdown menus for 'Catalogue Item' (Yes/No), 'Complaint Status' (Open), and 'Unit Name' (MALE ORTHOPEDIC WARD). The main section is titled 'A. PRODUCT PARTICULARS' and contains several input fields: 'Name' (with a red circle '14'), 'Workplace' (Farmasi Bekalan Wad), 'Phone' (067866543), 'Date' (23/09/2019), 'Approved By' (with a red circle '15' and a search icon), and 'Approved Date' (23/09/2019). There are also fields for 'Extension', 'Email', and 'Designation'. At the bottom, there are buttons for 'ACKNOWLEDGED BY' and 'FEEDBACK FROM NPRA'.

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

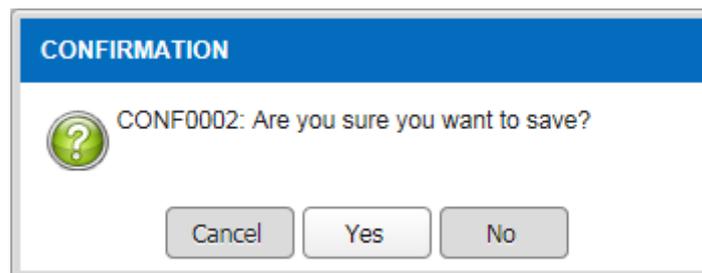


Figure 3.3.1-7 Confirmation Message

- Click on the button.

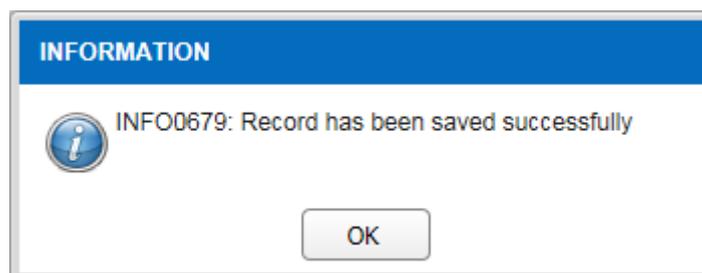
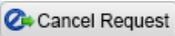


Figure 3.3.1-8 Information Message

- Click on the  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 from 000001 at the beginning of every calendar year.

Table 3.3.1-1

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

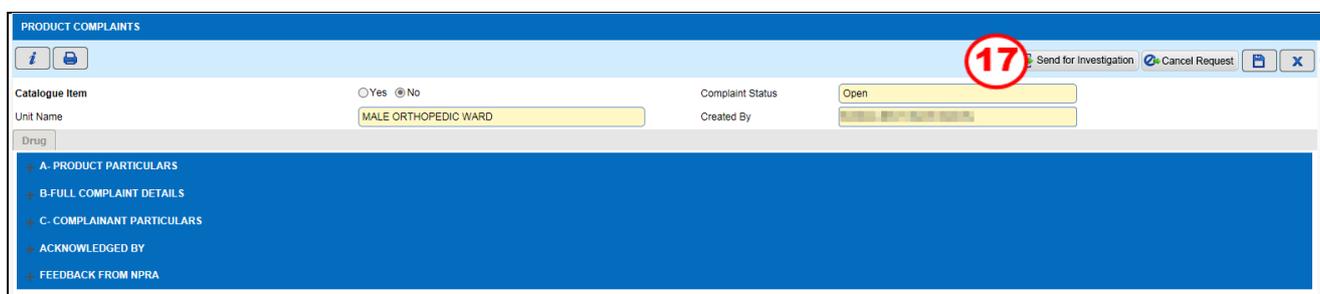


Figure 3.3.1-9 Product Complaints

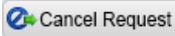
Note

User is allowed to modify the information before send for investigation

STEP 17

Click on the  button to send the record for investigation

Note

- User is allowed to cancel the request by click on the  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

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