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

User Manual
Adverse Drug Reaction (ADR) & Drug Allergy Card (DAC)

Version	**: 13th Edition**
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Reference ID : U. MANUAL_ADR & DAC-13th E

Application reference: PhIS & CPS v2.6.1

Table of Contents

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 geared towards pharmacy excellence. PhIS implementation would transform most of current manual process to electronic system to 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, lV 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 Adverse Drug Reaction (ADR) and Drug Allergy Card (DAC) 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:

- ADR Reporting
- NPRA Feedback
- Adverse Event Following Immunisation
- Print Allergy Card

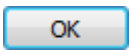
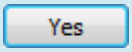
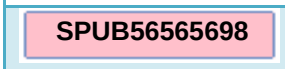
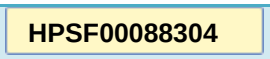
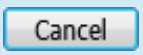
1.3 Organised Sections

These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Adverse Drug Reaction (ADR) & Drug Allergy Card (DAC)
- Section 4 : Acronyms
- Section 5 : Links to Clinical Modules

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

ADR & DAC Module Legend			
Print In Malay	Print DAC card in Malay	Causality Grading	Causality Grading Guide
Print In English	Print DAC card in English	WHO Terminology Guide	WHO Terminology Guide Hyperlink

Note

To learn more about Login Information, kindly click Login Information module for descriptive steps.

3.0 Adverse Drug Reaction & Drug Allergy Card

Overview

The Adverse Drug Reaction module converse the implementation of a safe, organised, and efficient adverse drug reaction reporting, adverse reaction after immunisation reporting and allergy card printing

User Group

This module is intended for pharmacist and prescriber. (subject to the user assigned by the facility)

Functional Diagram

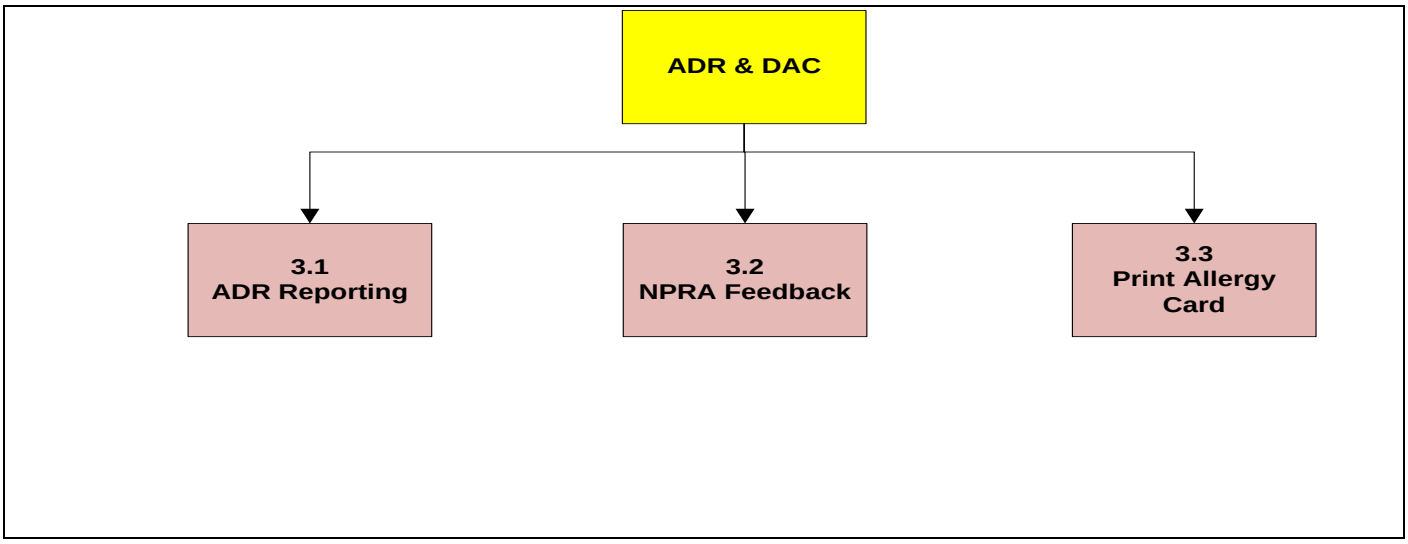


Figure 3.0

Functional Description

ADR & DAC comprises of three (3) main functions:

- **ADR Reporting**
  This process is used by prescriber and pharmacist to record any adverse drug reaction of the patient. The format is similar to the Adverse Drug Reaction Form by National Pharmaceutical Control Bureau (NPCB).

- **NPRA Feedback**
  This process is used by pharmacist to record any feedback on the ADR Reporting sent to National Pharmaceutical Regulatory Agency (NPRA)into the system.

- **Print Allergy Card**
  This process is used by pharmacist to print an allergy card for the patient. The allergy record is created based on allergy reported by prescriber.

3.1 ADR Reporting

This function is used to record any drug reaction of the patient before sending to NPRA.

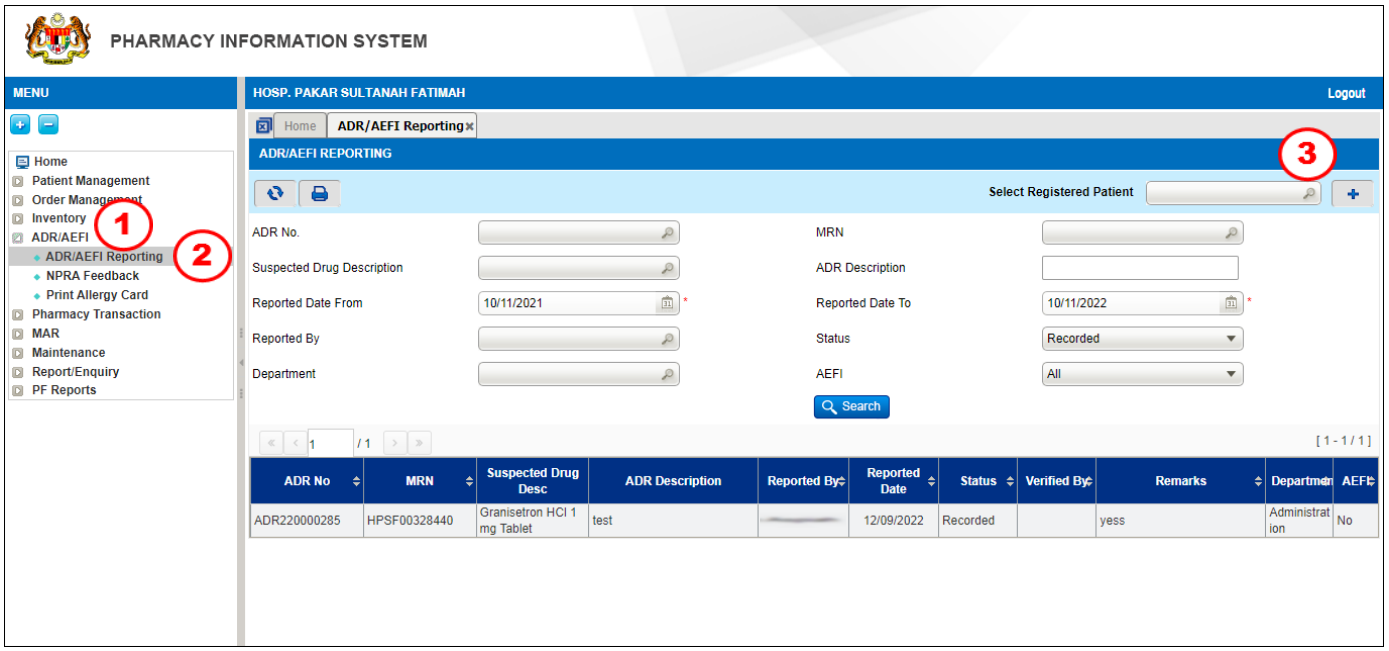


Figure 3.1-1 ADR Reporting Listing Page

Note

PhIS Screen menu/sub menu will be displayed according to user access right.

STEP 1
Click on 'ADR/AEFI' menu

STEP 2
Click on 'ADR/AEFI Reporting' sub-menu

STEP 3

Click on the  button to search for patient record

Note
Search for ADR Reporting record by below criteria: -

Basic Search			
No	**Field**	**Description**	**Remark**
a	ADR No	–	Allow to search record by full or partial ADR No
b	MRN	Patient MRN	Allow to search by patient full or partial MRN No
c	Suspected Drug Description	Drug Name	Allow to search by full or partial drug name
d	ADR Description	–	Allow to search by full or partial ADR description exp, Rash, Rashes
e	Reported Date From	–	Allow to search date before current date
f	Reported Date To	–	Allow to search date later than date on Reported Date From field
g	Reported By	User Login Name	Allow to search by full or partial User Login Name

k	Status	– Confirmed – Verified – Recorded – Cancelled – NPRA Received – Feedback Received	– Confirmed • Allow to search for records that have been confirmed – Verified • Allow to search for records that are verified but not yet confirmed – Recorded • Allow to search for records that are not yet verified and confirmed – Cancelled • Allow to search for records that are cancelled – NPRA Received • Allow to search for records that are NPRA receive but not get feedback yet – Feedback Receive • Allow to search for records that are receive feedback
l	Department	–	Allow to search by full or partial department name in facility
m	AEFI	– All – Yes – No	Allow to search and filter record for AEFI only, ADR only or both

Table 3.1

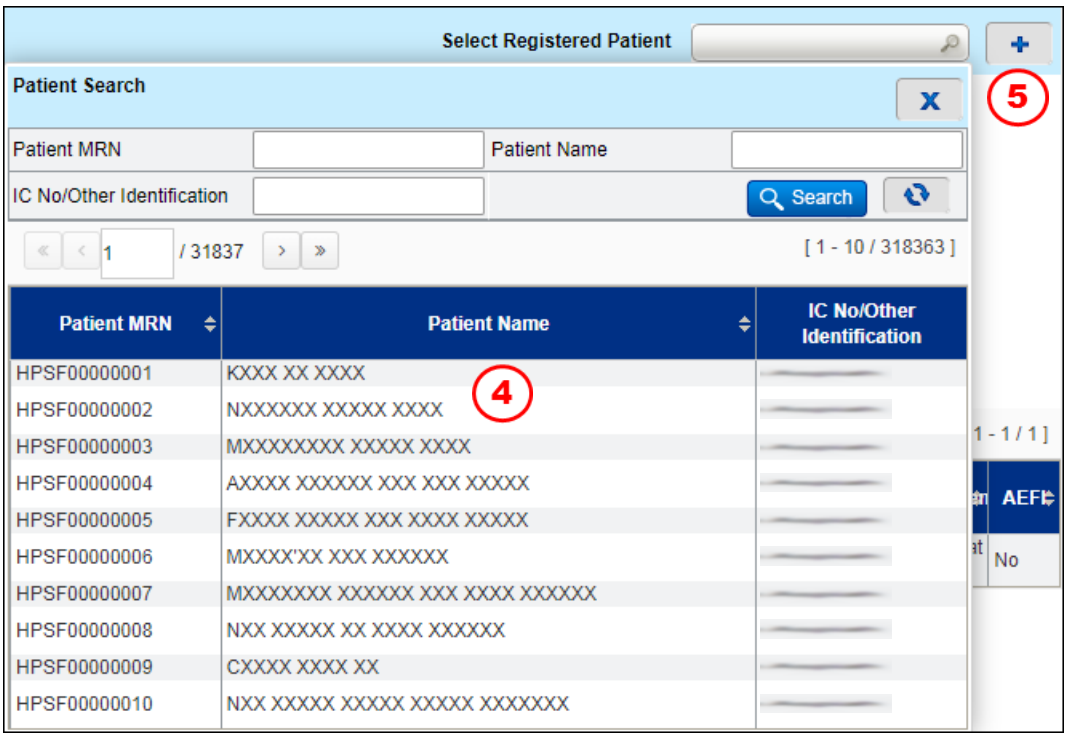


Figure 3.1-2 Enter/Select search MRN

STEP 4
Double-click on selected patient record

STEP 5

Click on the + button and system will generate '***ADR Reporting'*** screen

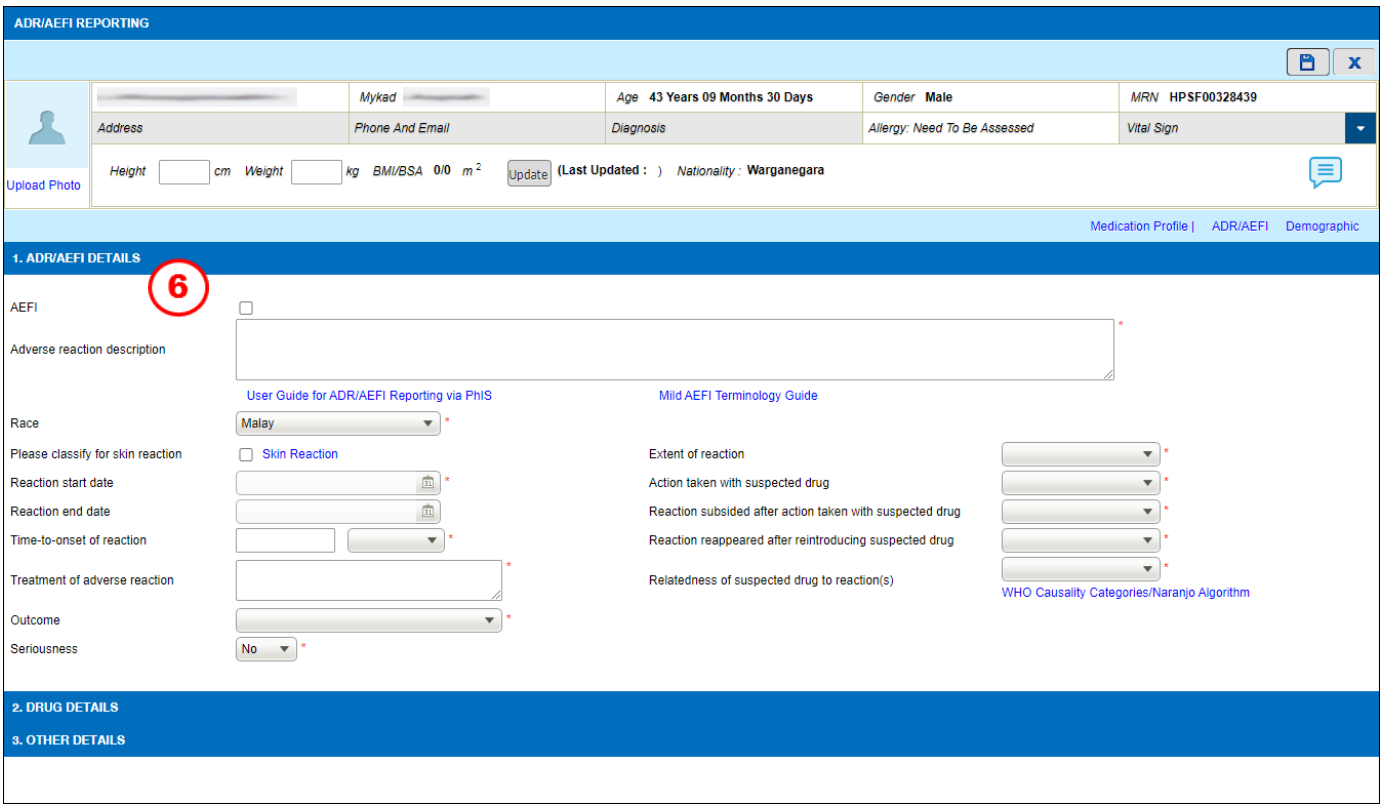


Figure 3.1-3 ADR Details Information

STEP 6
Enter the information in the ***ADR Details*** section:

a) ***Adverse Reaction Description***.
b) ***Reaction Start Date***
c) ***Reaction End Date***
d) ***Time To Onset of Reaction***
e) ***Treatment of Adverse Reaction***
f) ***Outcome***
g) ***Seriousness***
h) ***Extent of Reaction***
i) ***Action Taken With Suspected Drug***
j) ***Reaction Subsided after action taken with suspected drug***
k) ***Reaction Reappeared after reintroducing suspected drug***
l) ***Relatedness of suspected drug to reaction(s)***

Note

- *Click at the ☐ checkbox to enter **AEFI reporting***
- ***Please Classify for Skin Reaction** is an optional*
- ***Reaction end date*** is not mandatory
- *User can refer* User Guide for ADR/AEFI Reporting via PhIS *and* Mild AEFI Terminology Guide *from the link to enter the information in the field '**Adverse Reaction Description**'*
- ***Race** field is retrieved from patient registration.*
- *If "Yes" is selected for '**Seriousness'** from drop down box, another drop down box will appear with the following:*

- *Results In Death (if this is selected, another field will appear and user need to fill in the information of **Date of Birth**, **Was Autopsy Done**, **Autopsy Determined Cause of Death** and **Cause of Death**)*
- *Life Threatening*
- *Hospitalization/Prolong Hospitalization*
- *Disability/Incapacity*
- *Birth Defect*

- *Drop down box for **Reaction Subsided after action taken with suspected drug** has 4 options to select from the following:*

  - *1. Yes*
  - *2. No*
  - *3. Unknown*
  - *4. N/A (Drug continued)*

- *Drop down box for **Reaction Reappeared after reintroducing drug** has 4 options to select from the following:*

  - *1. Yes*
  - *2. No*
  - *3. Unknown*
  - *4. N/A (not introduced)*

Figure 3.1-4 Skin Reaction Screen

Note

- *If '**Please Classify for Skin Reaction'** checkbox is selected,* 

hyperlink is displayed. Click on the hyperlink, system will display as shown in Figure 3.1-4. Select the checkbox and click on the  *button to save the record.*

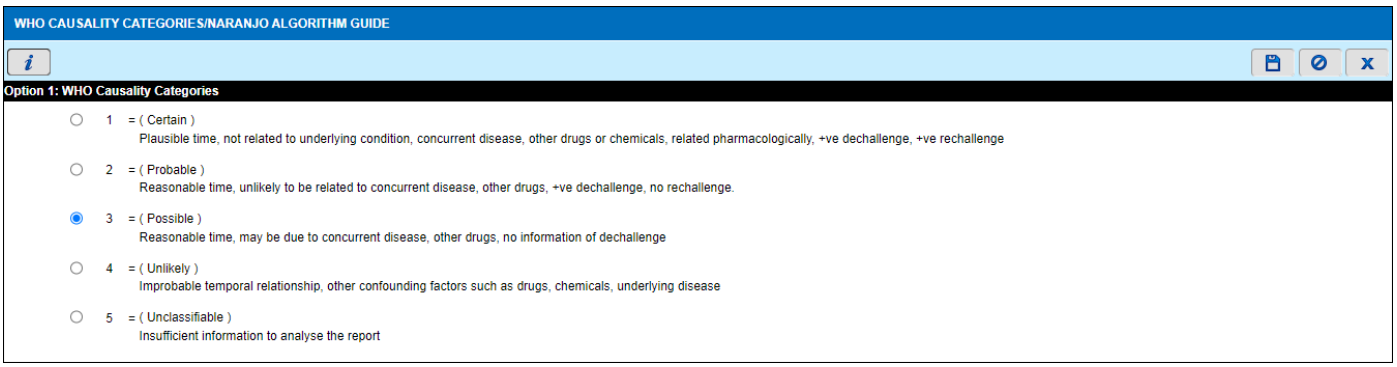


Figure 3.1-5 WHO Causality Grading

Note

- ***Drug Relationship*** *field is selected from drop down box or by clicking on the*

  WHO Causality Categories/Naranjo Algorithm *hyperlink. System will display the screen as shown in Figure 3.1-5 and Figure 3.1-6.*

- *Results selected from WHO Causality Grading will be displayed at the Drug Relationship field.*

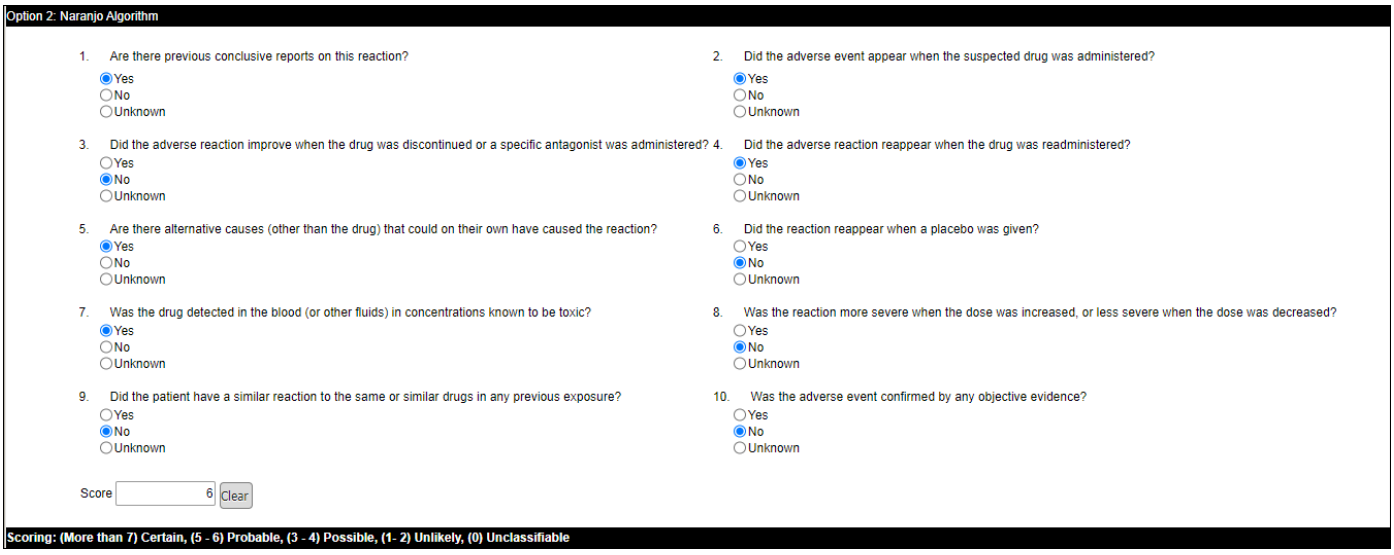


Figure 3.1-6 Naranjo Algorithm

- *Naranjo Algorithm is used as a guideline only. Results from this questionnaire will not be used as the causality grading.*
- *Select on the radio button and click on the*  *button to save the record*

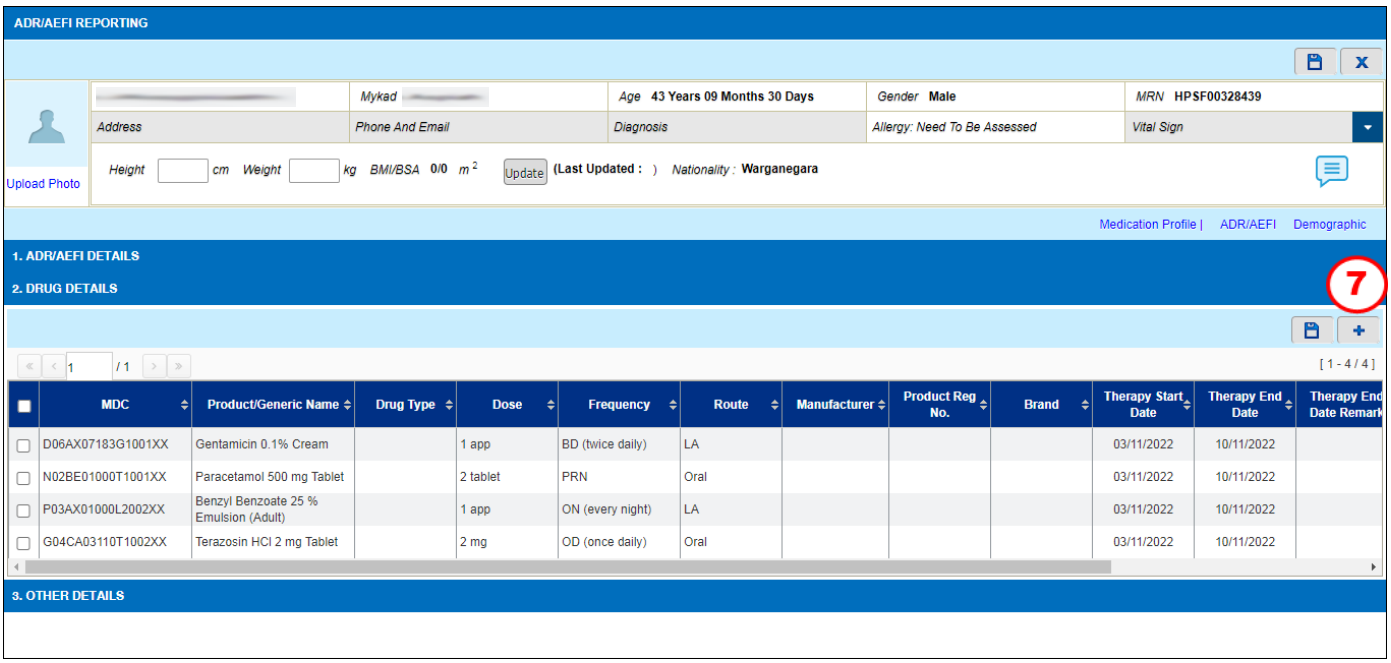


Figure 3.1-7 Drug Details

STEP 7

Click on the + button as shown in Figure 3.1-7 and '**Add Drug Detail'** screen will be displayed as shown in Figure 3.1-8

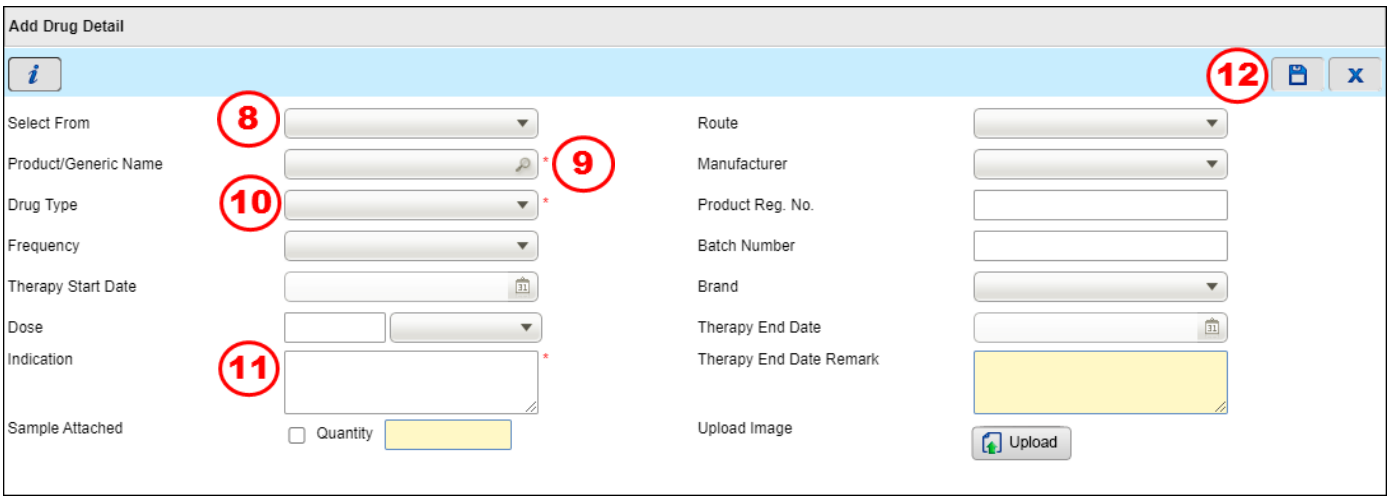


Figure 3.1-8 Add Drug Details

STEP 8

Select and enter from Select From drop down box:

- Drug Master
- Others

Note

- *Drug Master- The searching of drugs will be from the Drug Master list.*
- *Others – Free text field provided. User can record drugs which are not setup in the drug configuration file. e.g.: traditional herbs.*

STEP 9
Enter ***Product/Generic Name.*** The selection will be based on the selected criteria in the ***Select From*** field

STEP 10
Select and enter from Drug Type drop down box:
- Concomitant
- Interaction
- Suspected

STEP 11
Enter ***Indication***

Note
- *Enter the other optional field if applicable*
  a) Frequency
  b) Therapy Start Date
  c) Total daily dosage given
  d) Route
  e) Manufacturer
  f) Product Reg No
  g) Batch No
  h) Brand
  i) Therapy End Date
  j) Therapy End Date Remarks
  k) Sample Attached
  l) *Upload Image*

- ***Select From*** *field = Drug Master,* ***Frequency*** *and* ***Route*** *field is displayed as drop down box.*
- ***Select From*** *field = Other,* ***Frequency*** *and* ***Route*** *field is displayed as free text fields.*
- *Select* the checkbox ***Sample Attached*** and *enter* the quantity if sample is available from patient.
- Click on the ***Upload*** button to upload the image of the drug if available.

STEP 12

Click on the  button to save the record

Note
User is allowed to add same drug with different dosage, frequency or route

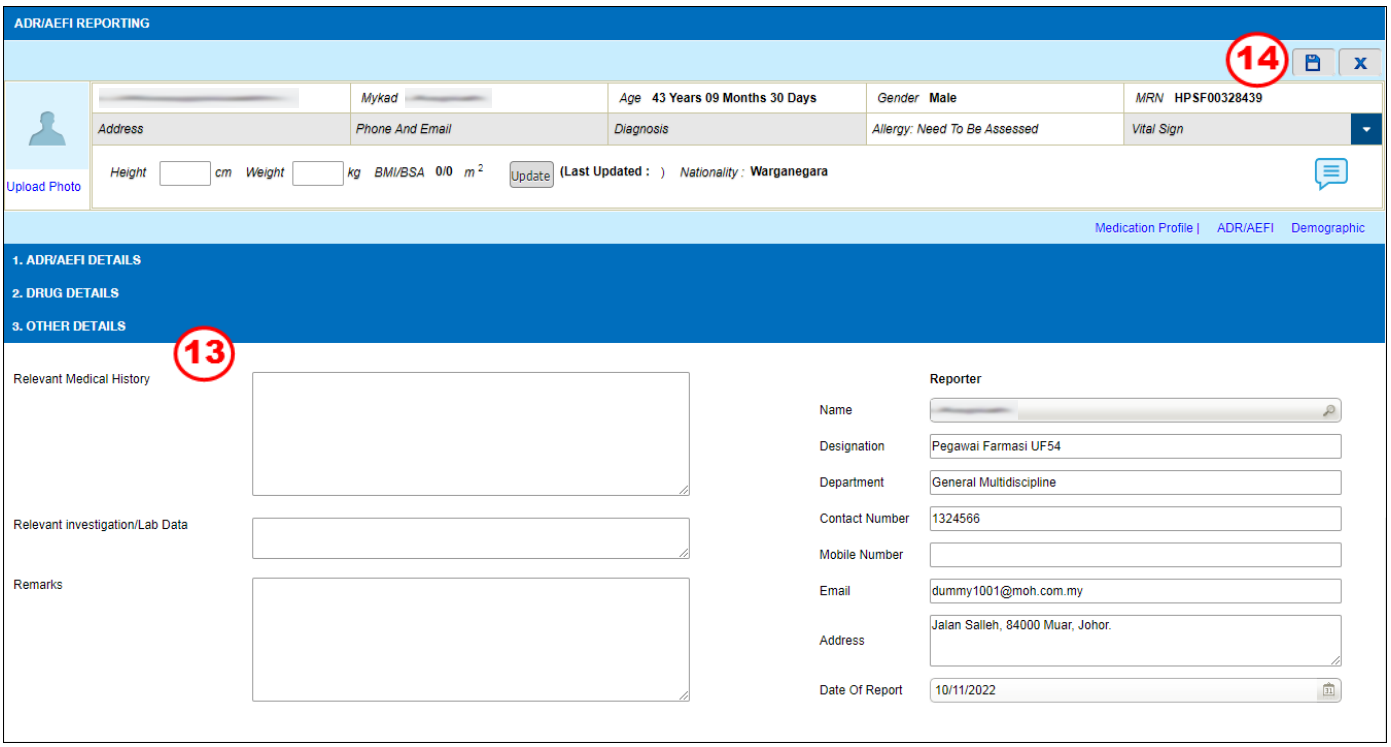


Figure 3.1-9 Other Details

STEP 13
Enter the information for below if applicable:

a) ***Relevant Medical History***
b) ***Relevant investigation Lab Data***
c) ***Remarks***
d) ***Mobile Number***
e) ***Date Of Report***

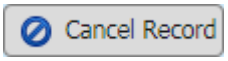
Note
Fields of Reporter section that will be extracted automatically from the user account are:

a) ***Name***
b) ***Designation***
c) ***Department***
d) ***Contact Number***
e) ***Email***
f) ***Address***

STEP 14

Click on the  button to save the record

Note

- *After save the record, Record Verified checkbox button will enable to verification process as shown in Figure 3.1-10*
- *User is allowed to cancel the record by click on the* 

button and fill in cancel remarks as per Figure 3.1-10

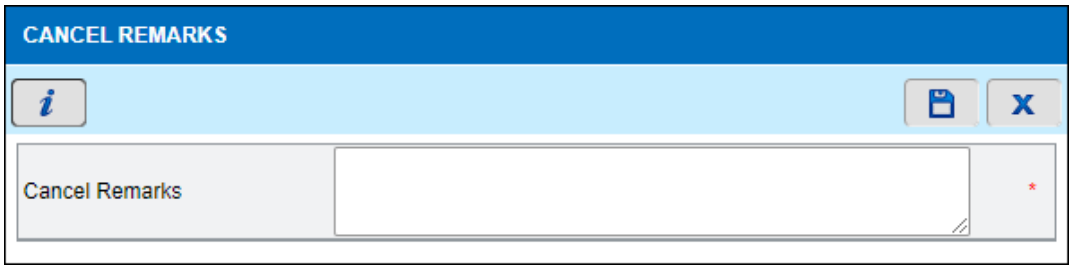


Figure 3.1-10 Cancel Remarks

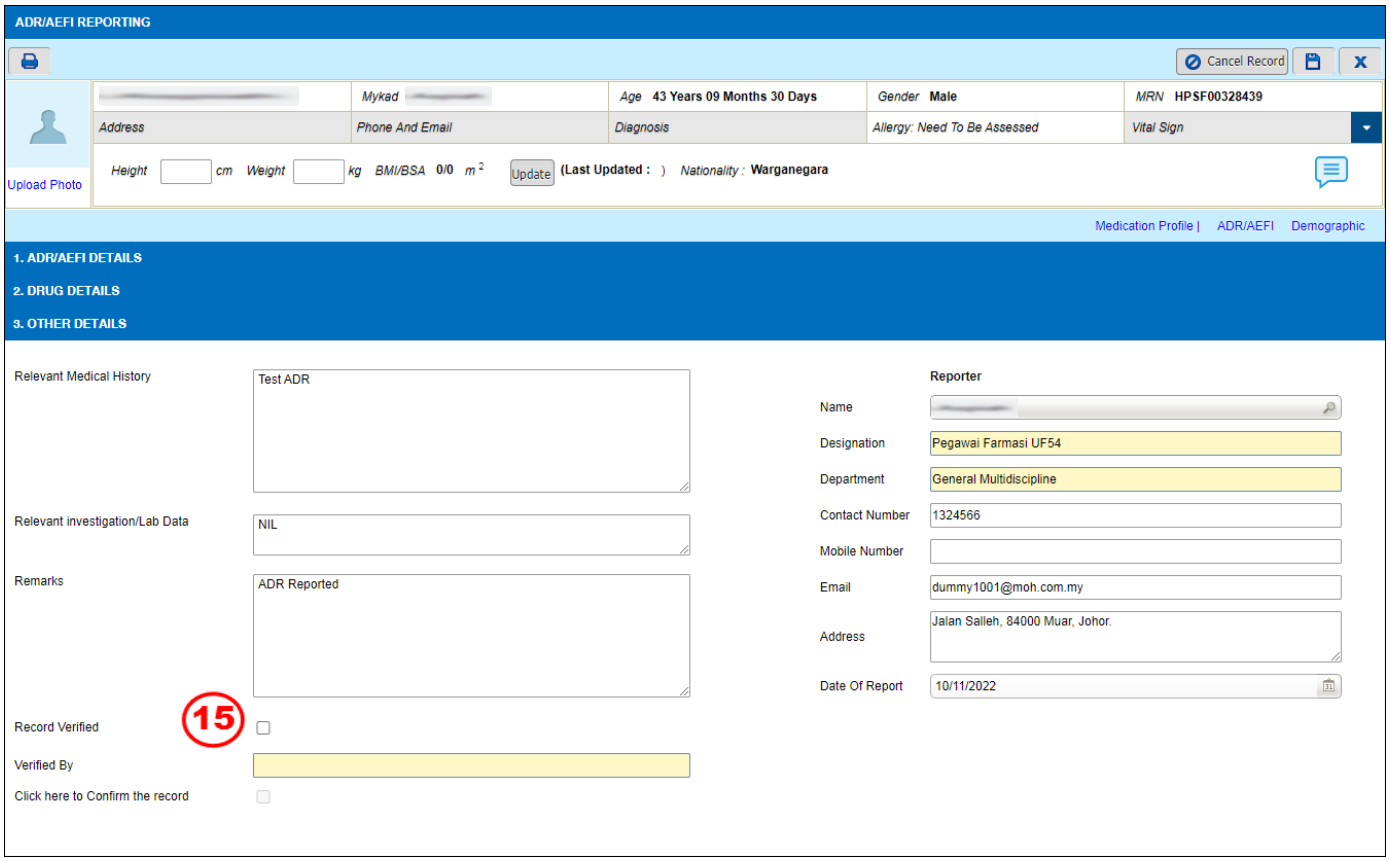


Figure 3.1-11 ADR Reporting

STEP 15
Click on the ***Record Verified*** ☐ checkbox

Note
Verified By *field will be auto display verification person name as shown in Figure 3.1-12*

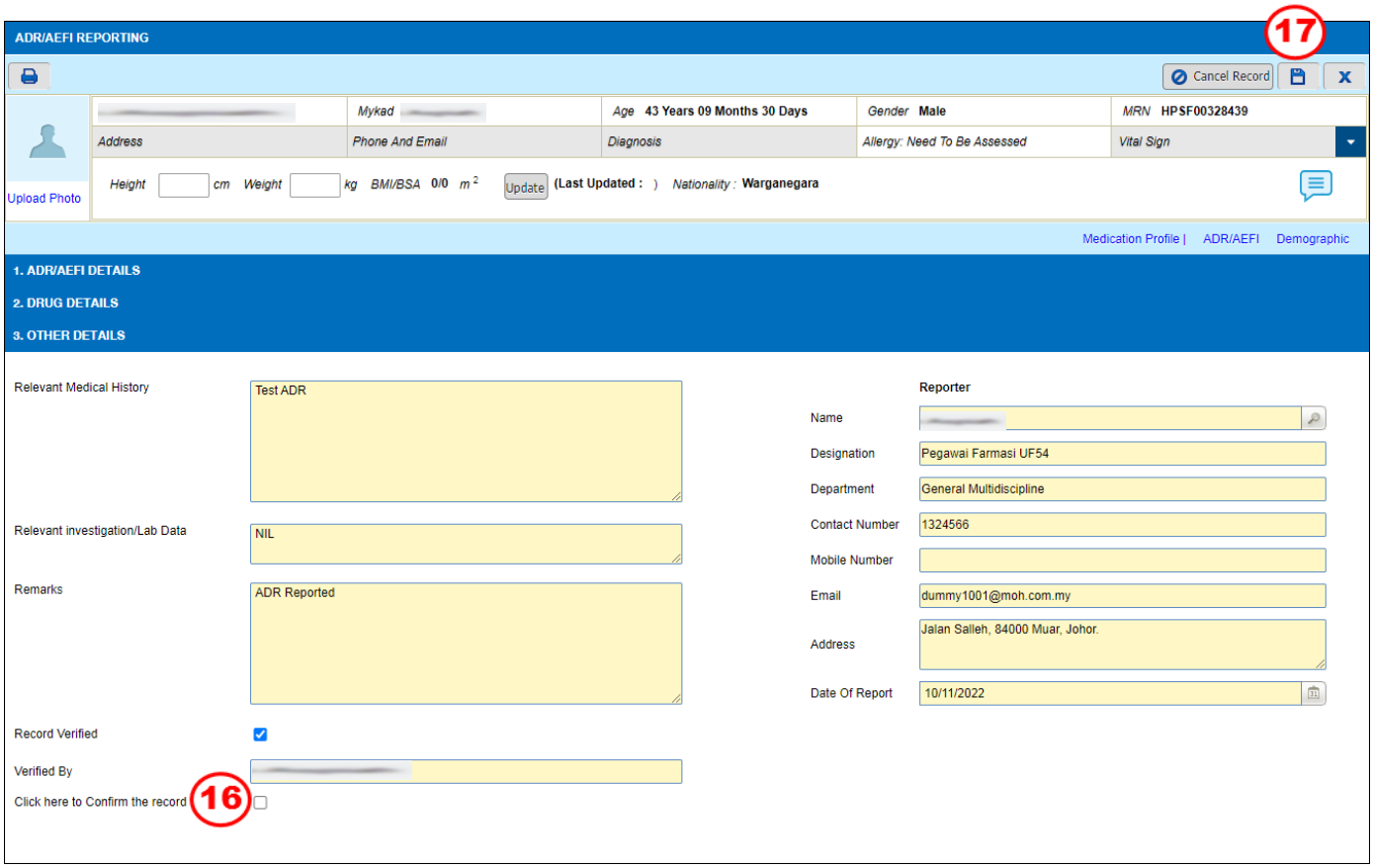


Figure 3.1-12 ADR Reporting

STEP 16
Click on the ***Click here to Confirm the record*** ☐ checkbox to confirm the ADR Reporting record

STEP 17

Click on the  button to save and the record will be sent automatically to NPRA

Note

- *If record successfully send to IWP, alert message will be display as shown in Figure 3.1-13*

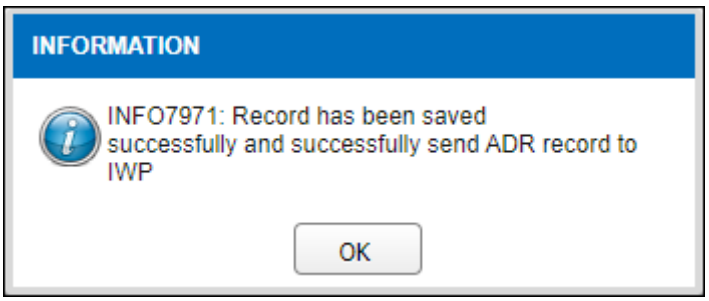


Figure 3.1-13 Information Message

- *Status for ADR Reporting will be change to **NPRA Received** for record that successfully send to NPRA and user can view the status at the ADR Reporting Listing Page as shown in Figure 3.1-14*

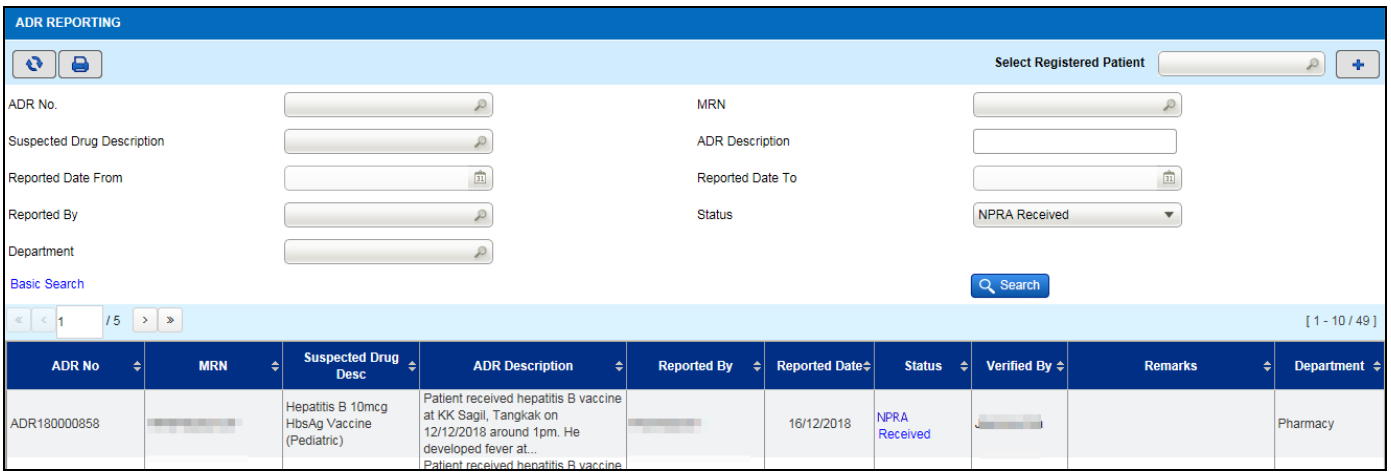


Figure 3.1-14 NPRA Received

- *if the record fail to send ADR record, Information Message will be displayed as shown in Figure 3.1-14*

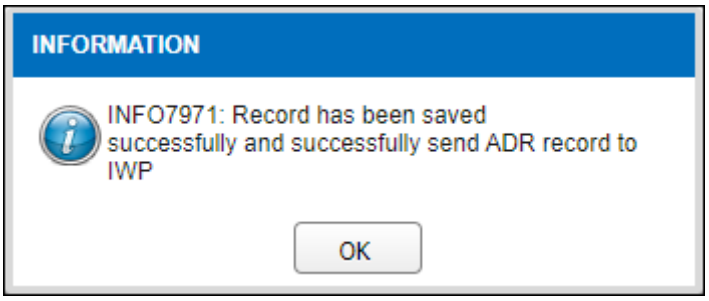


Figure 3.1-15 Information Message

- *Button Send to Integration*  *will be enable at ADR Reporting screen for user to click and resend the record to NPRA as shown in Figure 3.1-16*

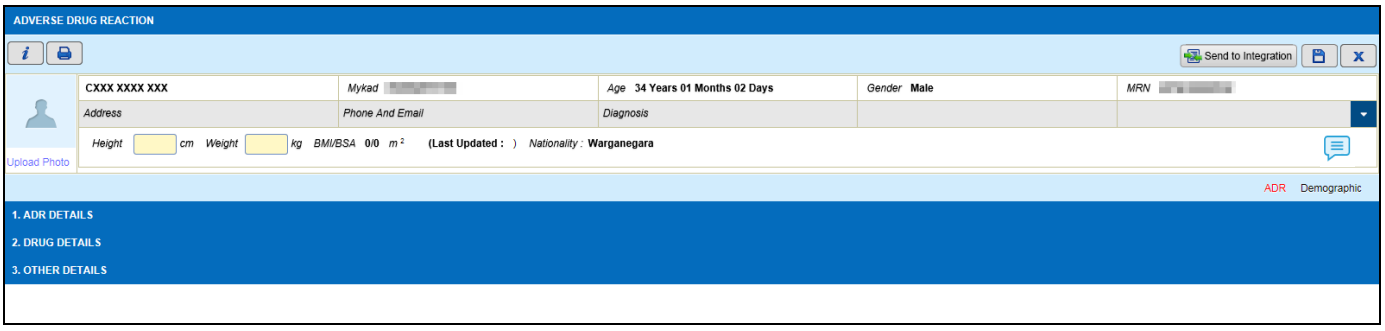


Figure 3.1-16 ADR Reporting - Send to Integration

- *ADR Record that already got a feedback from NPRA, user can view the information in the ADR Listing Page where the status is* ***Feedback Received*** *as shown in Figure 3.1-17*

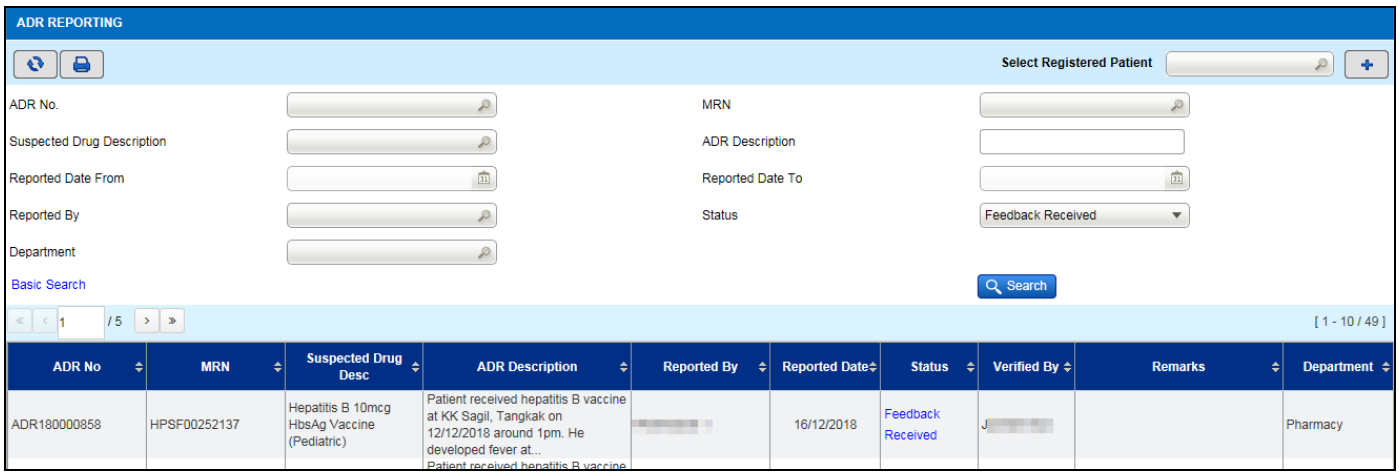


Figure 3.1-17 NPRA Feedback

- *Click on the status Feedback Received hyperlink and NPRA Feedback screen will be shown in Figure 3.1-18*

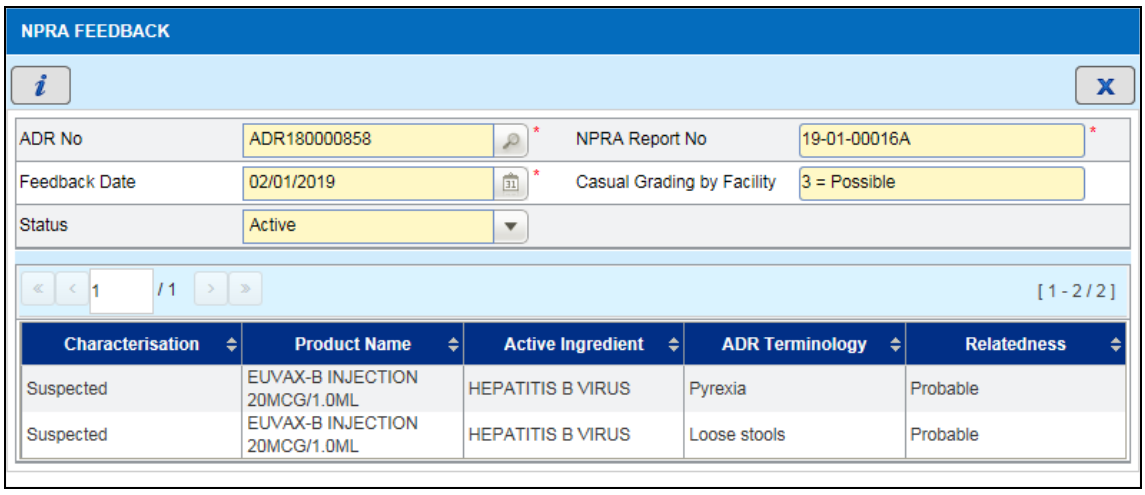


Figure 3.1-18 NPRA Feedback

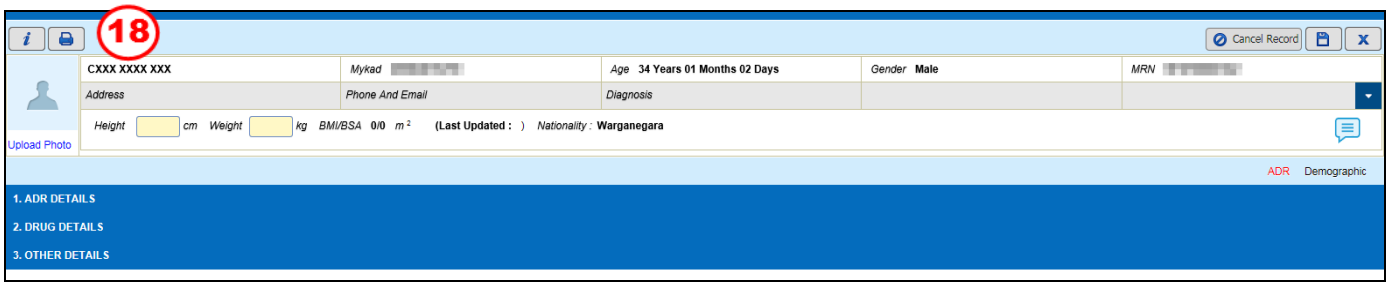


Figure 3.1-19 Print ADR Report

STEP 18

Click on the  button to print the ADR Report

REPORT ON SUSPECTED ADVERSE DRUG REACTION/AEFI

NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING

ADR NO : ADR210000283 *www.npra.gov.my*

(Please report **all** suspected drug reaction including those for vaccines and traditional medicines. Do not hesitate to report if some details are not known. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No ..... (for office use only)

PATIENT INFORMATION

Patient NRIC	Age	Sex	Wt (kg)	Ethnic Group	Institution
900821101010	31 Years 03 Months 17 Days	Female		Bintulu	Hosp. Pakar Sultanah Fatimah

ADVERSE REACTION DESCRIPTION

test

Skin Reaction :

Please specify Part of Body Affected :

Time-to-onset of reaction	1 Hours	Reaction start date :	01/12/2021	Reaction end date :	05/12/2021

Action taken with suspected drug : 1 = Drug Withdrawn

Reaction subsided after action taken with suspected drug	Yes		No		Unknown		N/A (drug continued) ✓
Reaction reappeared after reintroducing suspected drug	Yes		No		Unknown		N/A (not reintroduced) ✓
Extent of reaction :	Mild	✓	Moderate		Severe		Unknown
Treatment of adverse reaction & action taken	iv hydrocortisone 100mg stat , bd 3/7						
Outcome :	Recovered	✓	Recovering		Recovered With Sequelae		Not Recovered / Unknown
Seriousness:	Life Threatening		Hospitalization/Prolonged Hospitalization		Disability /		Birth Defect

Suspected Drug :

Products/Generic Name	Dose	Route	Frequency	Manufacturer	Product Reg. No.	Batch No.	Therapy Dates		Indication
							Start	End	
Lansoprazole 30 mg Tablet	1 caplet	Oral	OD (once daily)				01/12/2021	03/12/2021	Peptic Ulcer and Gastro-Oesophageal Reflux Disease (Gord)

Concomitant Drug :

Interaction Drug :

** Please attach further papers if necessary

Relevant Investigations/Laboratory Data	Relevant Medical History
test	test

Reporter

Name: Stephanie Chow Siew Fern Address : Jalan Salleh, 84000 Muar, Johor.

Designation : Pegawai Farmasi UF48 (PFK) Tel No : 593

Email Address : dummy@moh Date of Report : 07/12/2021 Signature :

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the reaction.Thank you

Figure 3.1-20 ADR Report

3.2 NPRA Feedback

The function of this menu is to record any feedback from NPRA into the system

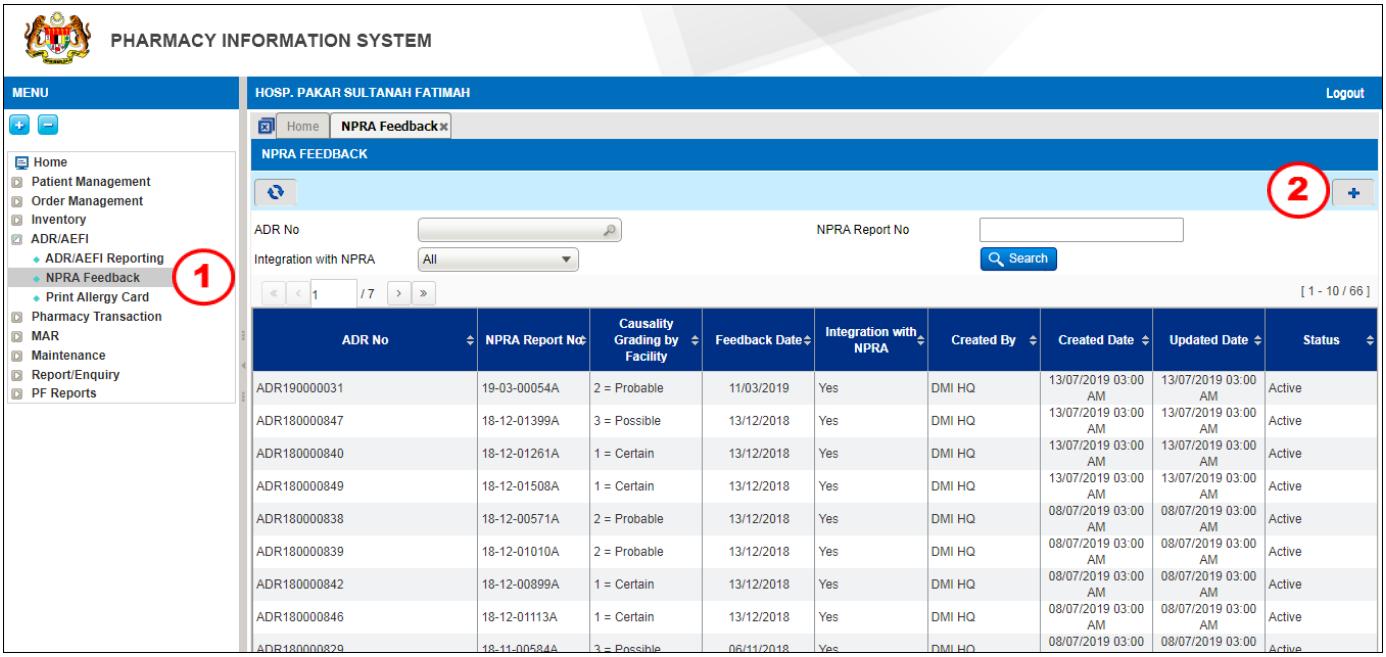


Figure 3.2-1 NPRA Feedback

Note

Search for NPRA Feedback record by below criteria: -

No	Field	Description	Remark
a	ADR No	Search by selecting a number from ADR No	Allow user to search existing transaction based on ADR No
b	NPRA Report No	Search by entering NPRA Report No	Allow user to search existing transaction based on NPRA Report No
c	Integration with NPRA	Select from drop down menu: - All - Yes - No	All – allow to search all transaction Yes – allow to search data that synchronized from NPRA No – allow to search data recording by user

STEP 1

Click on the 'ADR/AEFI' menu follow by 'NPRA Feedback' sub menu

STEP 2

Click on the  button and NPRA Feedback screen will be displayed as Figure 3.2-2

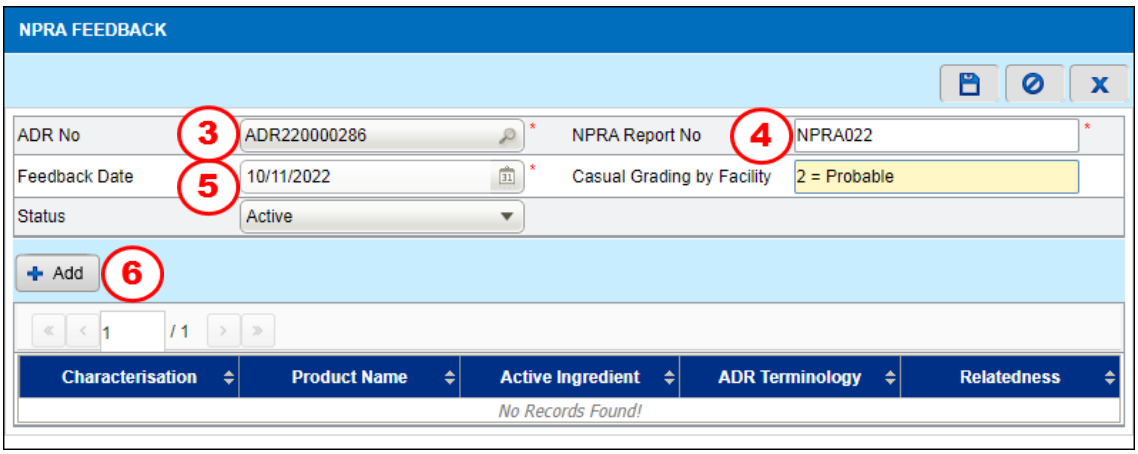


Figure 3.2-2 NPRA Feedback

STEP 3

Select ***ADR No*** from the search button

Note
Casual Grading by Facility *will auto be displayed based on the value recorded in ADR Reporting*

STEP 4
Enter ***NPRA Report No***

STEP 5
Select ***Feedback Date***

STEP 6

Click on the Add button and NPRA Feedback screen will be displayed as Figure 3.2-3

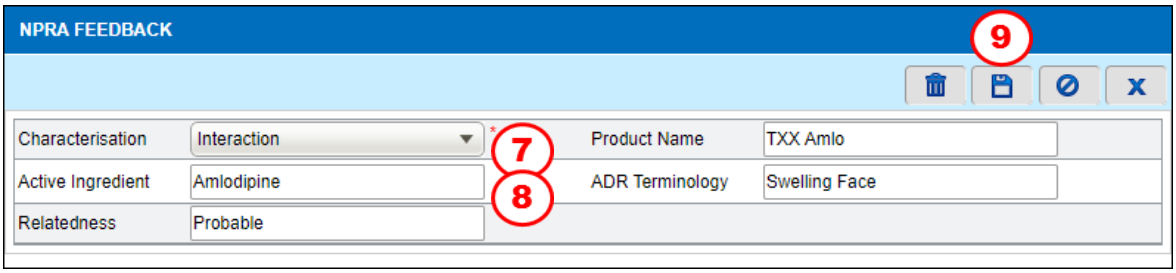


Figure 3.2-3 NPRA Feedback

STEP 7
Select ***Characterisation*** from drop down menu:

- Concomitant
- Interaction
- Suspected

STEP 8
Enter value in below field (if applicable):

- ***Active Ingredient***
- ***Product Name***
- ***ADR Terminology***
- ***Relatedness***

STEP 9

Click on the  button to save the record

Note

Record will be updated as shown in Figure 3.2-4

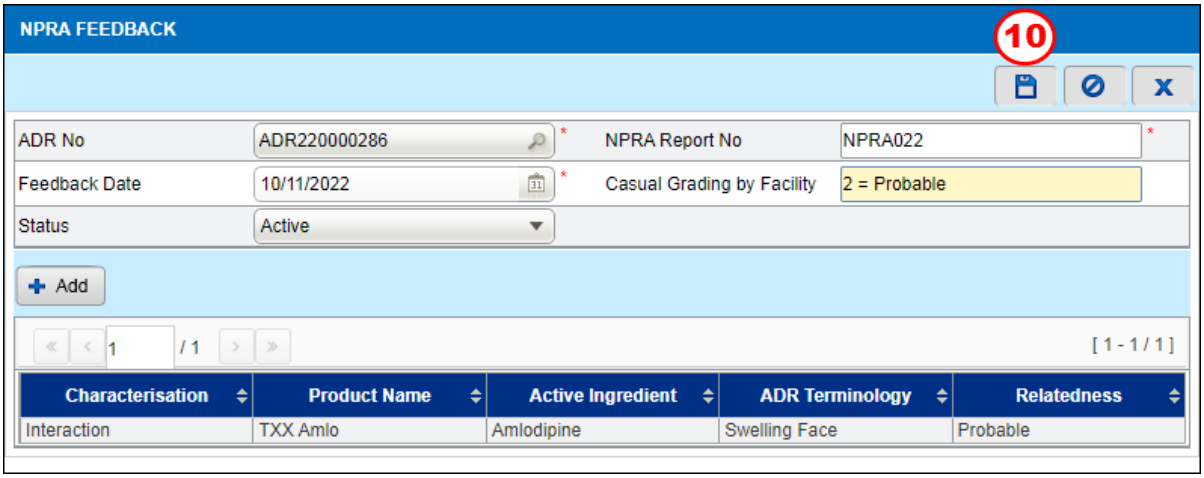


Figure 3.2-4 NPRA Feedback

STEP 10

Click on the  button to save the NPRA Feedback and confirmation message will be displayed as Figure 3.2-5

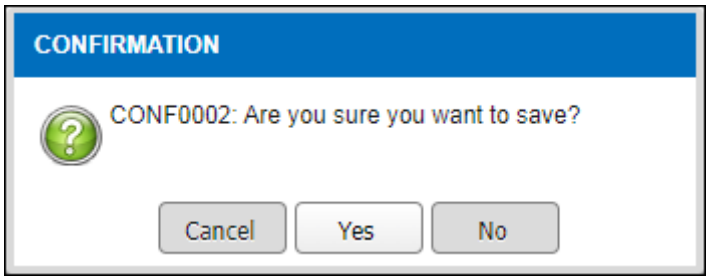
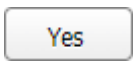


Figure 3.2-5 Confirmation Message

Note

Click on the  *button so save the record*

3.3 Print Allergy Card

The function of this menu is to print an allergy card for the patient

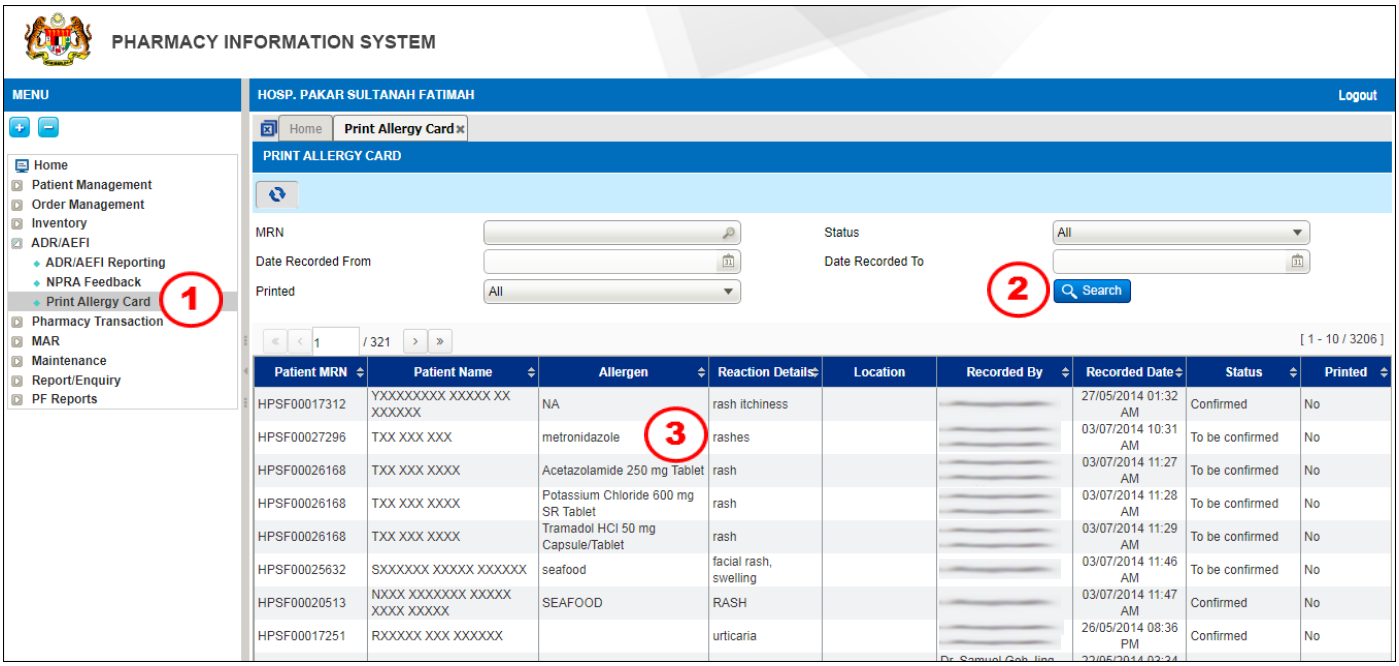


Figure 3.3-1 Print Allergy Card Listing Page

STEP 1
Select on 'Adverse Drug Reaction' menu followed by 'Print Allergy Card' sub menu

STEP 2
Search for the patient by below criteria:

No	Field	Description	Remark
a	MRN	Patient MRN	Allow to search patient by full or partial MRN No
b	Status	– All – Confirmed – Pending for Confirmation – To Print	– All - Allow to search records by status Confirmed, Pending for Confirmation and To Print – Confirmed - Allow to search records of patients with confirmed drug allergy – Pending For Confirmation - Allow to search records of patient with drug allergy that is pending confirmation – To Print - Allow to search records of patient with confirmed drug allergy where allergy cars is not printed yet
c	Date Recorded From	–	Allow to search date before current date
d	Date Recorded To	–	Allow to search date later than date on Date Recorded To field

Table 3.3-1

Click on the Search button and the system will display all related records

STEP 3
Double-click on record then select the checkbox as shown in Figure 3.3-1

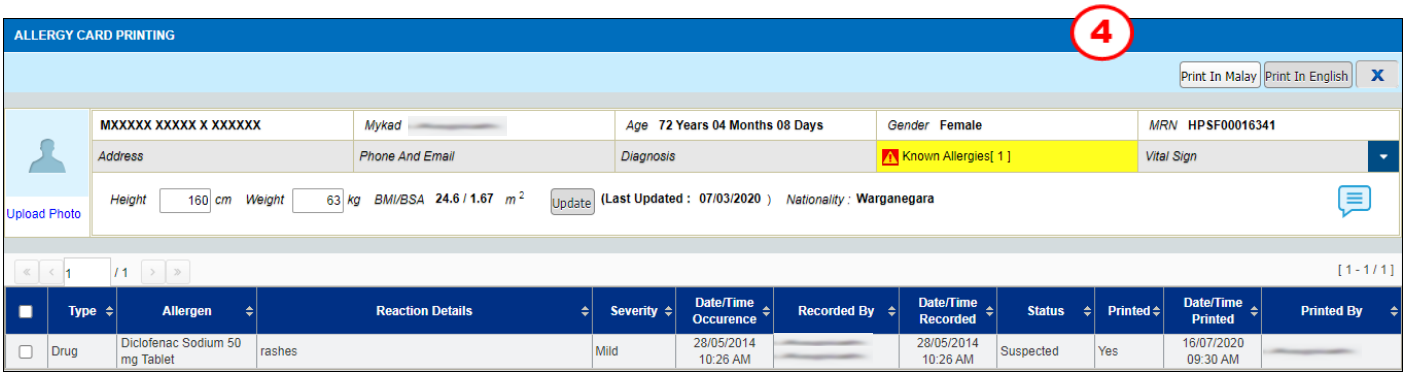


Figure 3.3-2 Selected Patient

STEP 4
Select to print the card in Malay or English by clicking on one of the below buttons:

System will display as shown in Figure 3.3-3.

Note

- *Condition to print Allergy Card is:*
  - *a) Allergy record with status Confirmed and Suspected*
  - *b) Allergen Type = Drug*

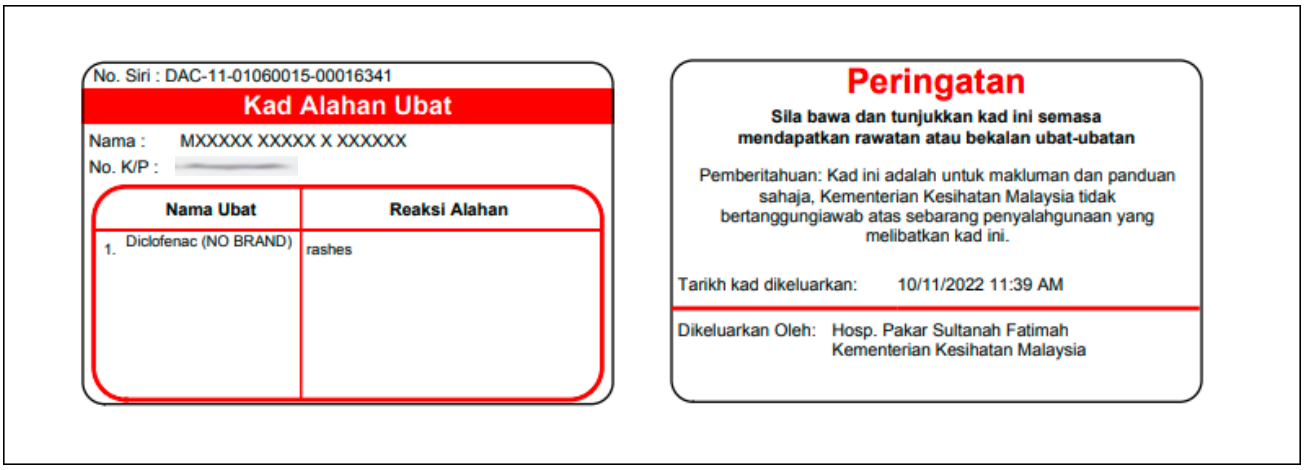


Figure 3.3-3 Allergy Card Sample

4.0 Acronyms

Abbreviation	Definition
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
MOH	Ministry Of Health
MRN	Medical Record Number
ADR & DAC	Adverse Drug Reaction and Drug Allergic Card

5.0 Links to Clinical Modules

No	*Module*	*PDF Links*	*No*	*Module*	*PDF Links*
1	*Inpatient*	*Click Here*	*12*	*CDR Dispensing*	*Click Here*
2	*CDR Order*	*Click Here*	*13*	*Methadone Dispensing*	*Click Here*
3	*TDM Order*	*Click Here*	*14*	*PN Dispensing*	*Click Here*
4	*PN Order*	*Click Here*	*15*	*Order Management*	*Click Here*
5	*IV Order*	*Click Here*	*16*	*Patient Management*	*Click Here*
6	*Prepacking*	*Click Here*	*17*	*Radiopharmaceuticals*	*Click Here*
7	*Galenical*	*Click Here*	*18*	*Outpatient*	*Click Here*
8	*MTAC*	*Click Here*	*19*	*Special Drug Request*	*Click Here*
9	*ADR & DAC*	*Click Here*	*20*	*MAR*	*Click Here*
10	*Medication Counselling*	*Click Here*	*21*	*DICE*	*Click Here*
11	*Ward Pharmacy*	*Click Here*	*22*		