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

Pharmacy Based

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

Version	**: 7th EDITION**
Document ID	**: PB_U. MANUAL_ADR_DAC**

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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 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, 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 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 details:

- 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 to Excel	Export Report From PDF file to Excel file	OK	OK Button
Yes	Yes Button	No	No Button
	Radio Button		Checkbox
SPUB56565698	System Automatic Generate Record No.	HPSF00088304	Automatically Display/Retrieve Box
	Reset Login Screen		Cancel
Home	Display Home Tab		Search Icon
	Show Help		Edit Record
Search	Search Record	Cancel	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

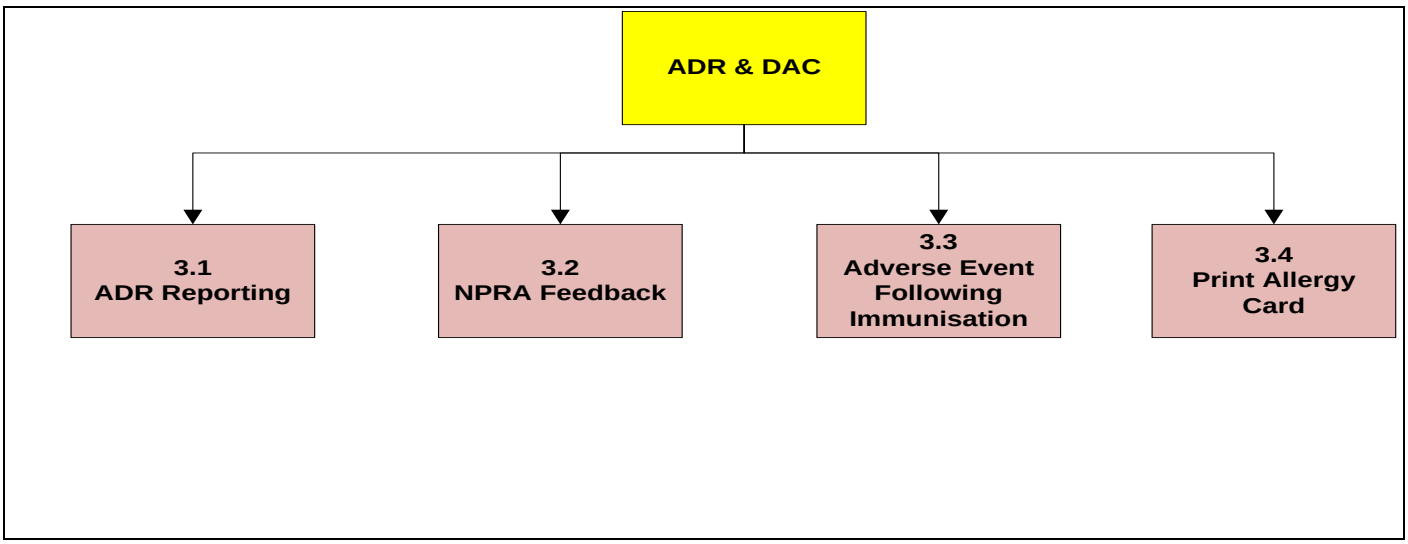


Figure 3.0

Functional Description

ADR & DAC comprises of four (4) 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).

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

- **Adverse Event Following Immunisation**
  This process used by prescriber and pharmacist to record any adverse reaction after immunisation.

- **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.

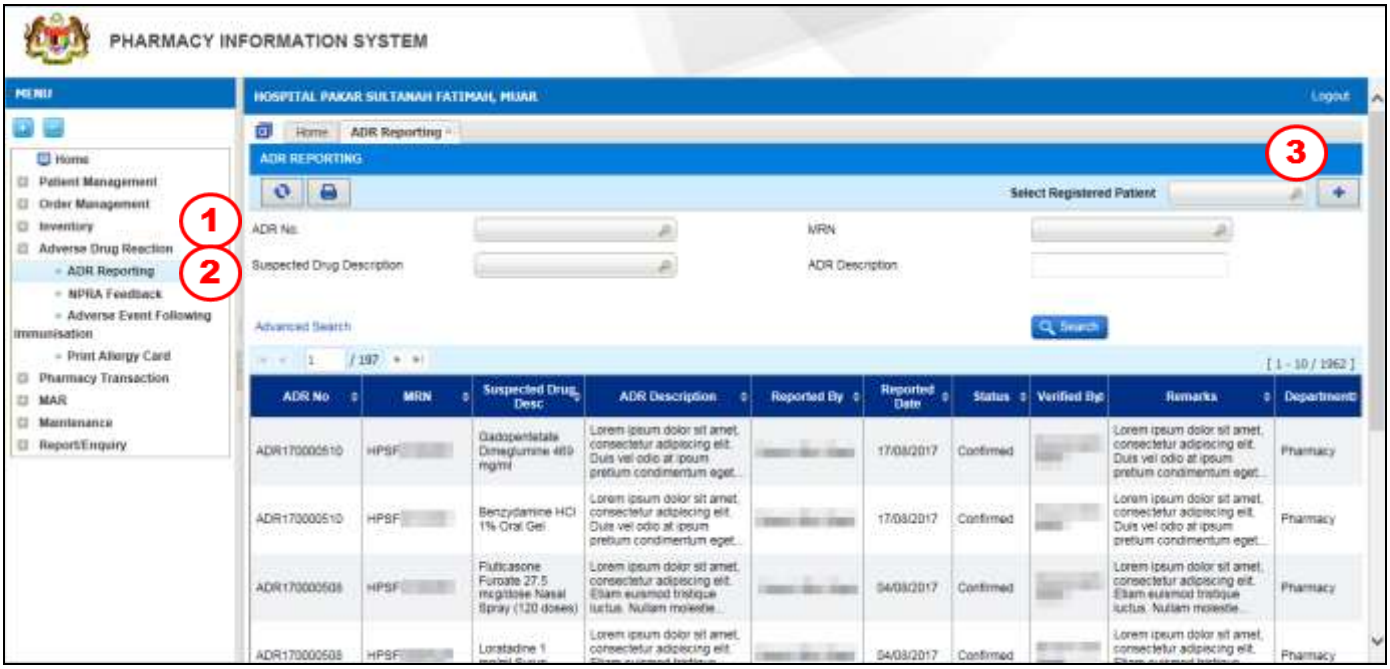


Figure 3.1-1 ADR Reporting Listing Page

Note

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

STEP 1
Click on 'Adverse Drug Reaction' menu

STEP 2
Click on 'ADR 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
Advance Search			
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	– All – Confirmed – Verify – Recorded	– All - Allow to search for records by status Confirmed, Verify and Recorded – Confirmed - Allow to search for records that have been confirmed – Verify - 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
l	Department	–	Allow to search by full or partial department name in facility

Table 3.1

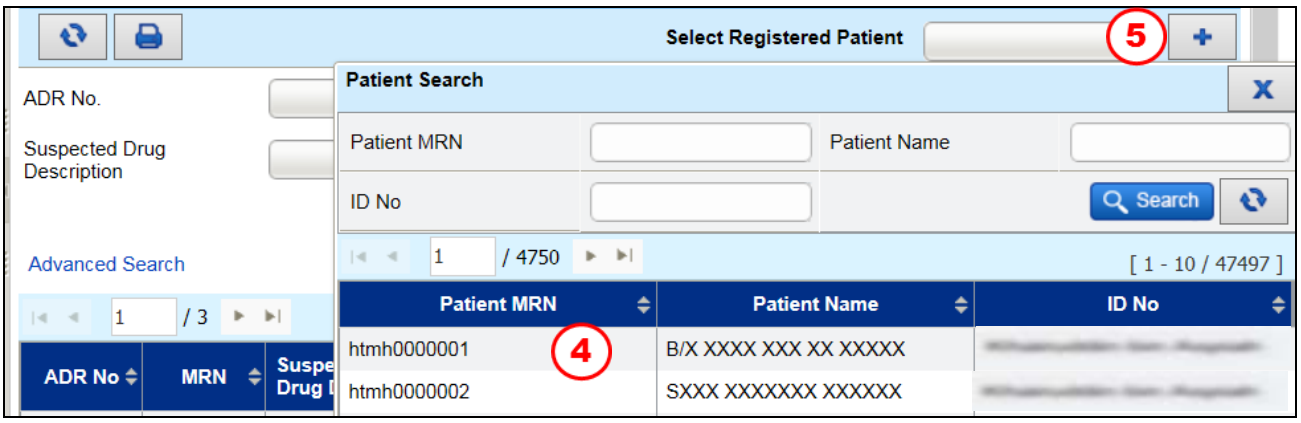


Figure 3.1-2 Enter/Select search MRN

STEP 4
Double-click on selected patient record

STEP 5
Click on the button and system will generate '***ADR Reporting'*** screen

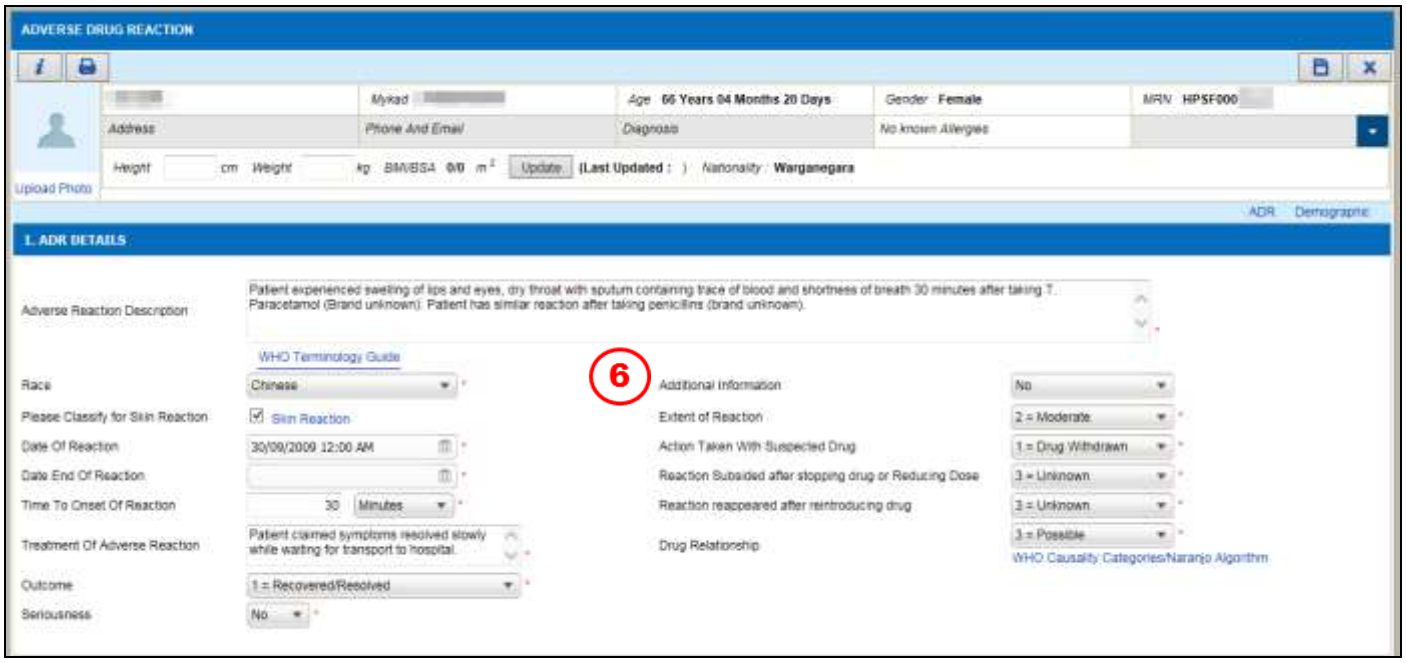


Figure 3.1-3 ADR Details Information

STEP 6

Enter the information in the mandatory field in ***ADR Details*** section:

a) ***Adverse Reaction Description***.
b) ***Date Of Reaction***
c) ***Date End Of Reaction***
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 stopping drug or Reducing Dose***
k) ***Reaction reappeared after reintroducing drug***
l) ***Drug Relationship***

Note

- **Non mandatory fields below can be entered if applicable**
  a) ***Please Classify for Skin Reaction***
  b) ***Additional Information***

- *User can refer the guideline from the link* WHO Terminology Guide *to enter the information in the field '**Adverse Reaction Description**'*

- *If "Yes" is selected for '**Additional Information'*** from *drop down box, another drop down box will appear with the following:*

  - *Brand Switching*
  - *Drug Interaction*
  - *Medication Error*
  - *Medication Ineffective*
  - *Others*

- ***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*

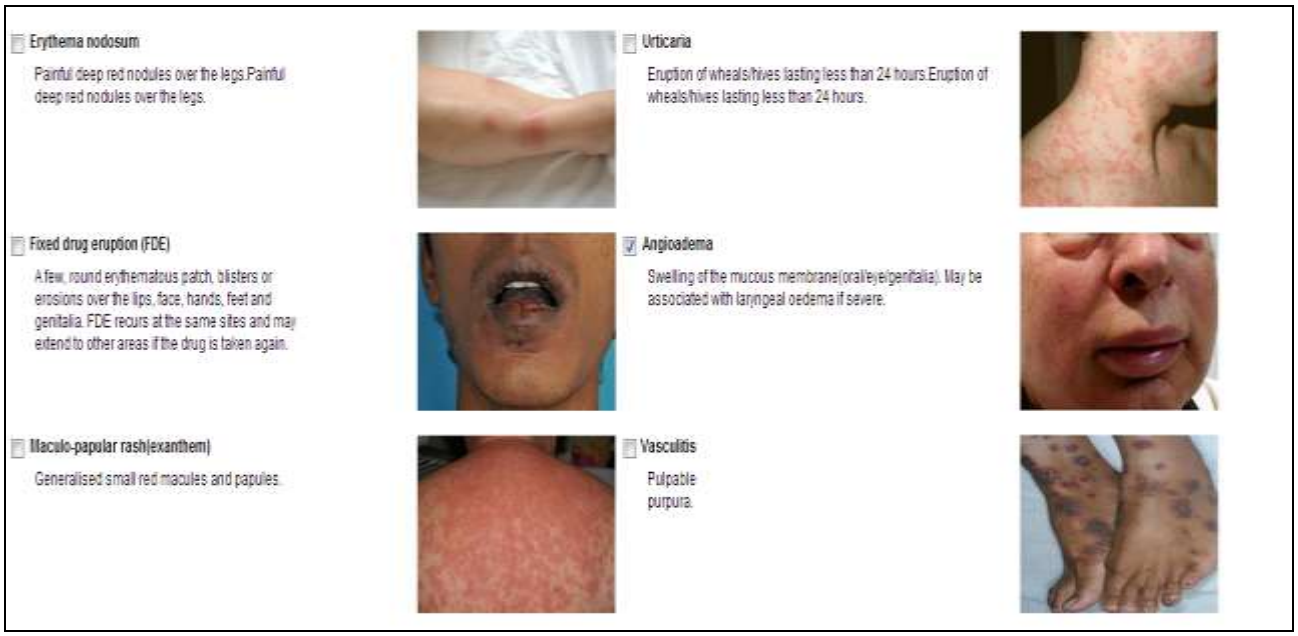


Figure 3.1-4 Skin Reaction Screen

Note

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

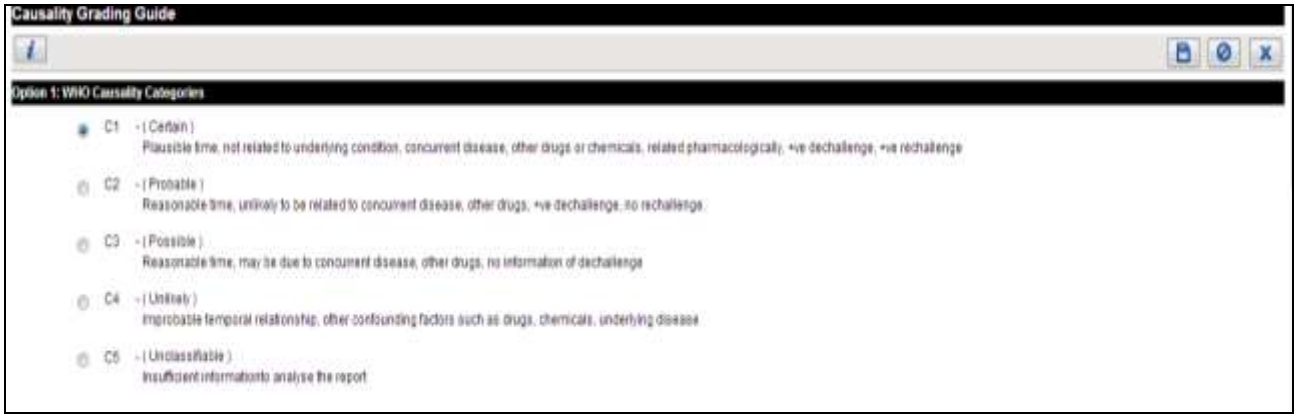


Figure 3.1-5 WHO Causality Grading

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.*

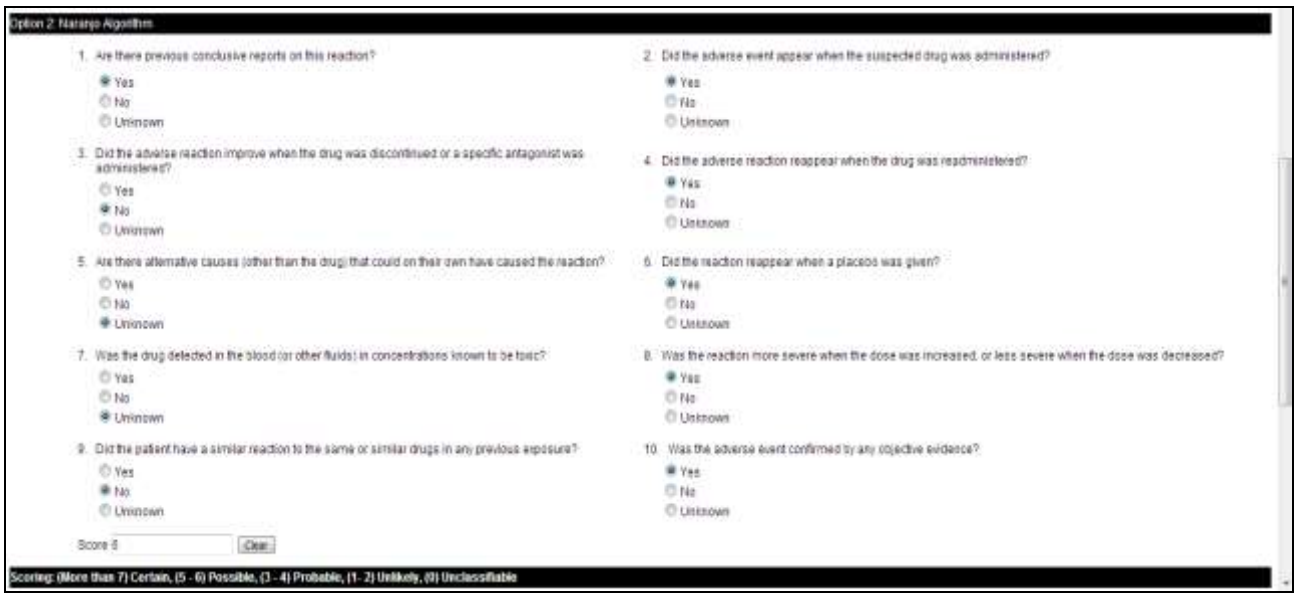


Figure 3.1-6 Naranjo Algorithm

- *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*

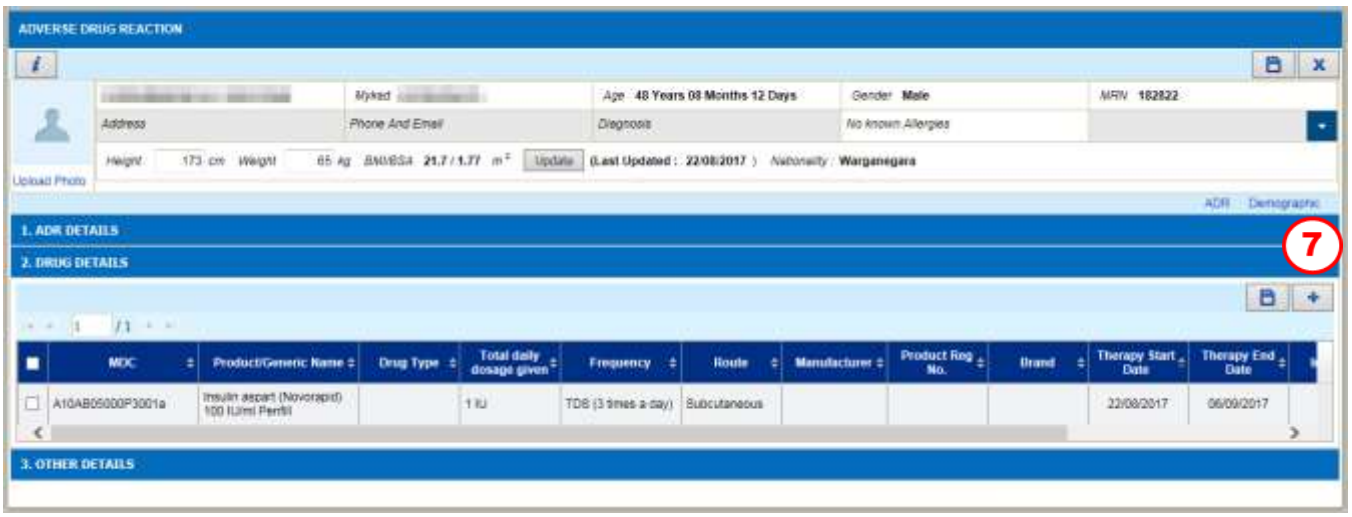


Figure 3.1-7 Drug Details

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

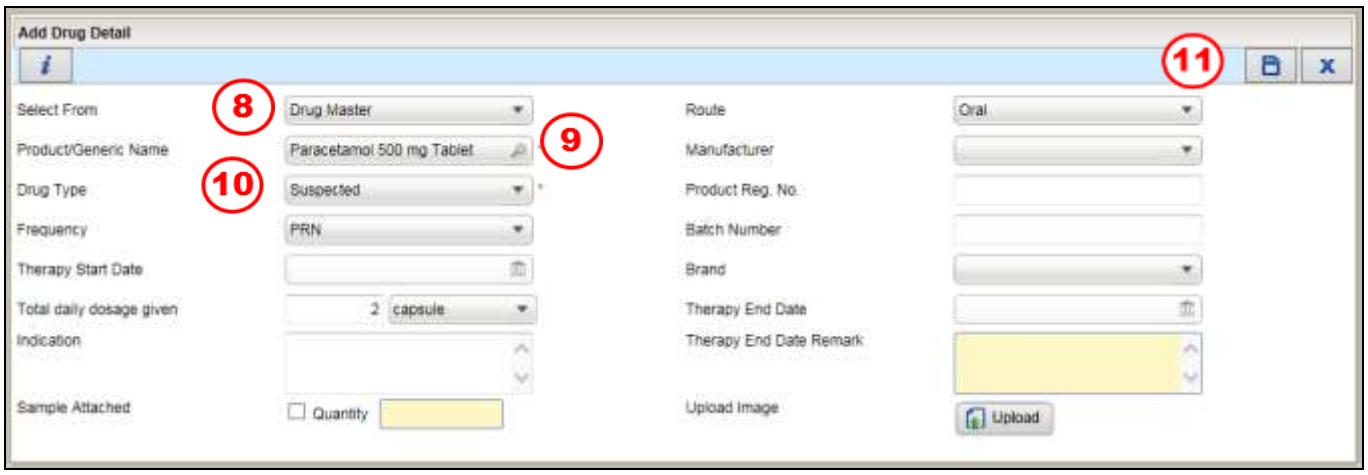


Figure 3.1-8 Add Drug Details

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

Note

- *Enter the other optional field if applicable*
  - ***a) Frequency***
  - ***b) Therapy Start Date***
  - ***c) Indication***
  - ***d) Total daily dosage given***
  - ***e) Route***
  - ***f) Manufacturer***
  - ***g) Product Reg No***
  - ***h) Batch No***
  - ***i) Brand***
  - ***j) Therapy End Date***
  - ***k) Therapy End Date Remarks***
  - ***l) Sample Attached***
  - **m) *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 11

Click on the button to save the record

Note

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

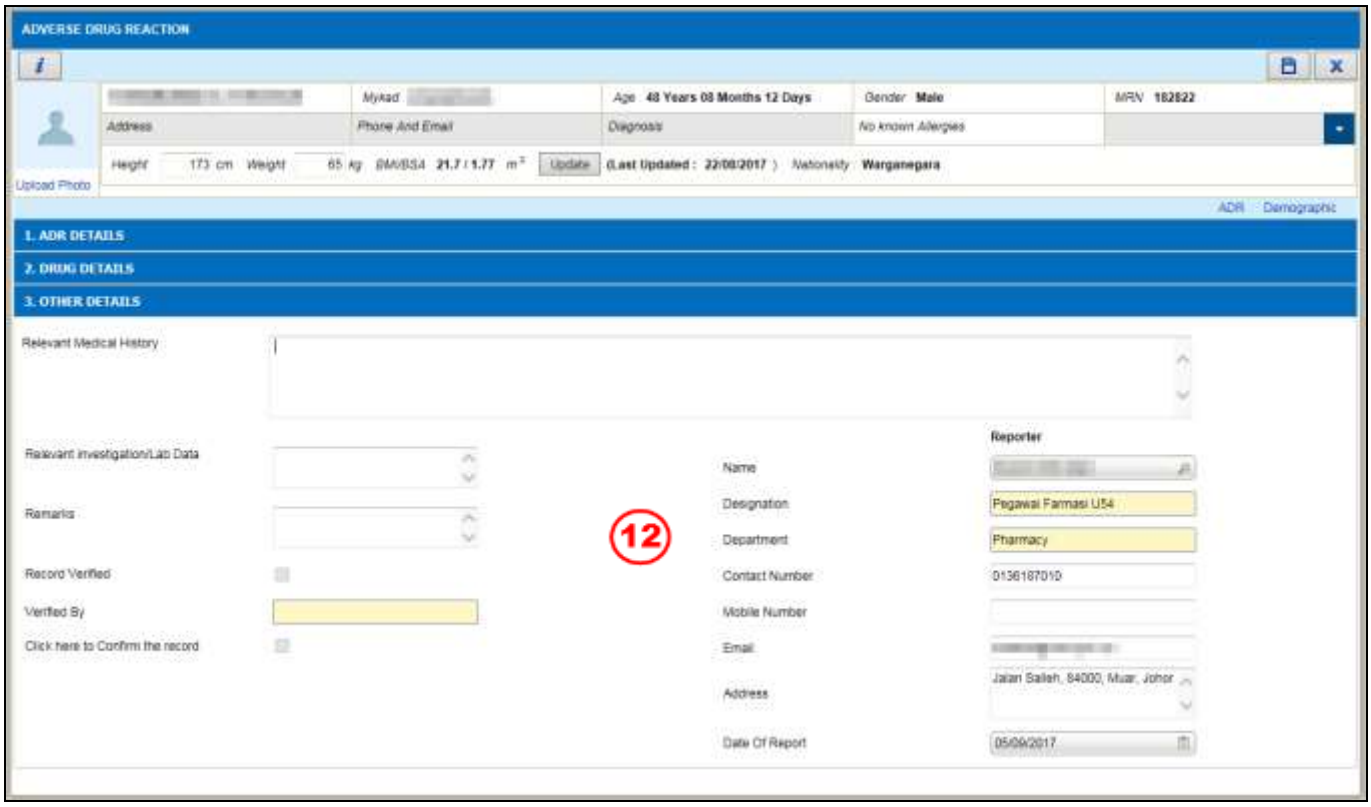


Figure 3.1-9 Other Details

STEP 12

Enter the information for below if applicable:

a) Relevant investigation Lab Data
b) Relevant Medical History
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

Figure 3.1-10 Record Verified

STEP 13
Select the ***Record Verified*** checkbox to verify the record. Once the checkbox is selected, adding and editing of data are not allowed

STEP 14
Click on the **Click here to Confirm the record** checkbox then print the form to send the form to NPCB

Figure 3.1-11 Save Record

STEP 15
Click on the button to save the record

Note

- *Click on the button to print the ADR Report as Figure 3.1-12*
- *Click on the button to close the transaction*

REPORT ON SUSPECTED ADVERSE DRUG REACTION

NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING

www.bpfk.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

R/N or Initials	Age	Sex	Wt	Ethnic Group	Institution
HPSF00071539	35 Years 04 Months 22 Days	Female		Malay	Hospital Pakar Sultanah Fatimah, Muar

ADVERSE REACTION DESCRIPTION

Patient came to KLWP department on 15/9/17 with the complian of normal rashes. At KLWP, Dr gave Cloxacillin Capsule 1000mg QID, Tablet Diclofenac Sodium 50 mg TDS for the pain and Tablet paracetamol 1000mg QID.Few mins after taking, patient appeared to have rashes around the neck, body, armpits and at the upper limbs. A day later, blisters appeared around the neck & body. Patient was then treated with IV Hydrocortisone 200 mg STAT on 22/9. Patient rashes and blister resolving soon.

Additional Information :

Skin Reaction :

Please specify Part of Body Affected :

Time to onset of reaction : 5 Minutes Date of reaction 15/09/2017 Date end of reaction : 25/10/2017

Reaction subsided after stopping drug/reducing dose : Yes ☐ No ☐ Unknown ☑

Reaction reappeared after reintroducing drug : Yes ☐ No ☐ Not applicable ☑

Extent of reaction : Mild ☐ Moderate ☑ Severe ☐

Treatment of adverse: 1)Hydrocortisone Sodium Succinate Injection 200mg STAT
2)Chlorpheniramine 10mg/ml Injection 10mg STAT

Outcome : Recovered ☐ Recovering ☑ Recovered With Sequelae ☐ Not Recovered ☐ Unknown ☐

Seriousness: Life Threatening ☐ Hospitalization / Prolong Hospitalization ☑ Disability / Incapacity ☐ Birth Defect ☐ Results In Death ☐ - Date of death:

Drug Reaction Relationship: Certain ☐ Probable ☐ Possible ☑ Unlikely ☐ Unclassifiable ☐

Suspected Drug :

Products/Generic Name	Dosage Given	Route	Frequency	Manufacturer	Product Reg. No.	Batch No.	Therapy Dates		Indication
							Start	End	
Paracetamol 500 mg Tablet	2 tablet	Oral	TDS (3 times a day)	CCM Pharmaceuticals Sdn. Bhd.		bm v	22/09/2017	29/09/2017	

Concomitant Drug :

Products/Generic Name	Dosage Given	Route	Frequency	Manufacturer	Product Reg. No.	Batch No.	Therapy Dates		Indication
							Start	End	
Cloxacillin 500mg Capsule	4000 mg	Oral	QID (4 times a day)	Dynapharm (M) Sdn Bhd	17c0751		15/09/201	22/09/201	
Calamine Lotion	1 app	LA	PRN				22/09/201	29/09/201	
Hydrocortisone Sodium Succinate 100mg Injection	100 mg	Intravenous	QID (4 times a day)				22/09/201	29/09/201	
Diclofenac Sodium 50 mg Tablet	150 mg	Oral	TDS (3 times a day)				15/09/201	20/09/201	For pain relief

Interaction Drug :

** Please attach further papers if necessary

Relevant Investigations/Laboratory Data	Relevant Medical History
	NKMI

Reporter

Name: Ko Wei Cheng Address :Jalan Salleh, ,

Designation : Pegawai Farmasi U41 Tel No :638

Email Address : weichengko@hotmail.com Date of Report :25/09/2017 Signature :

Figure 3.1-12 ADR Report

3.2 NPRA Feedback

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

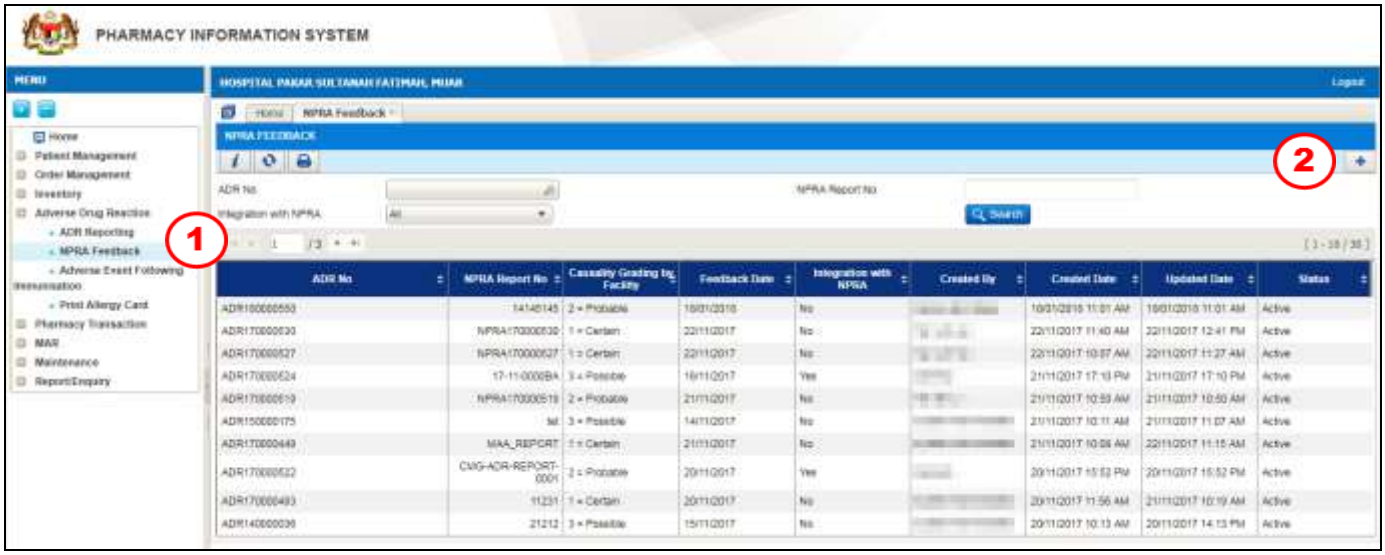


Figure 3.2-1 NPRA Feedback

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 'Adverse Drug Reaction' 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

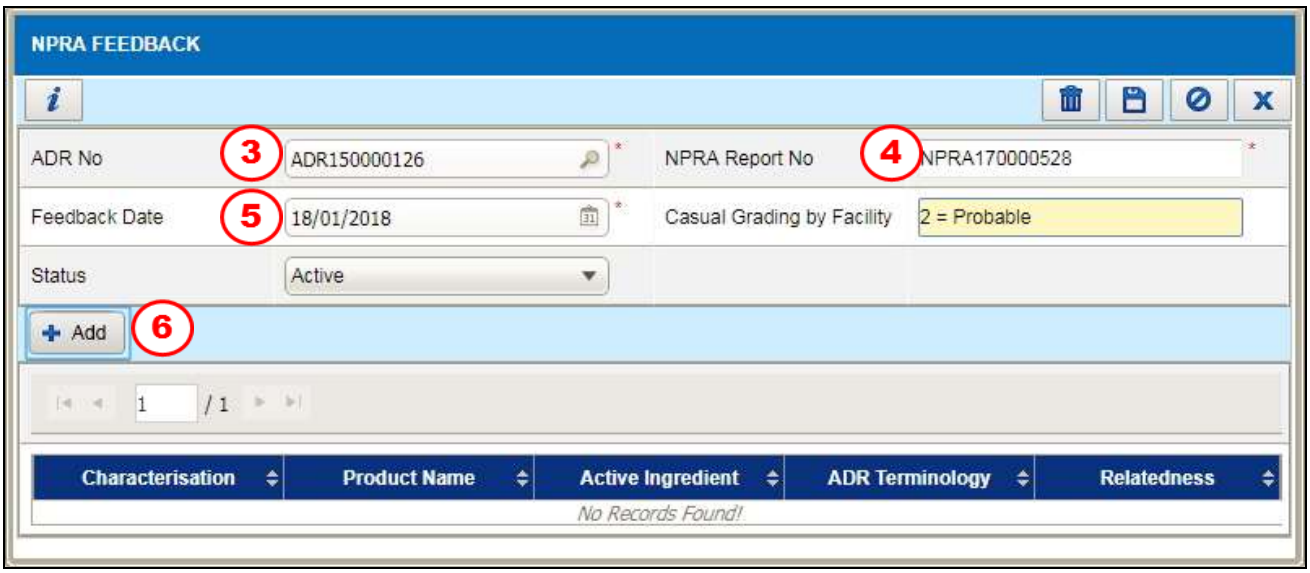


Figure 3.2-2 NPRA Feedback

STEP 3

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

Note
Casual Grading by Facility *will auto 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

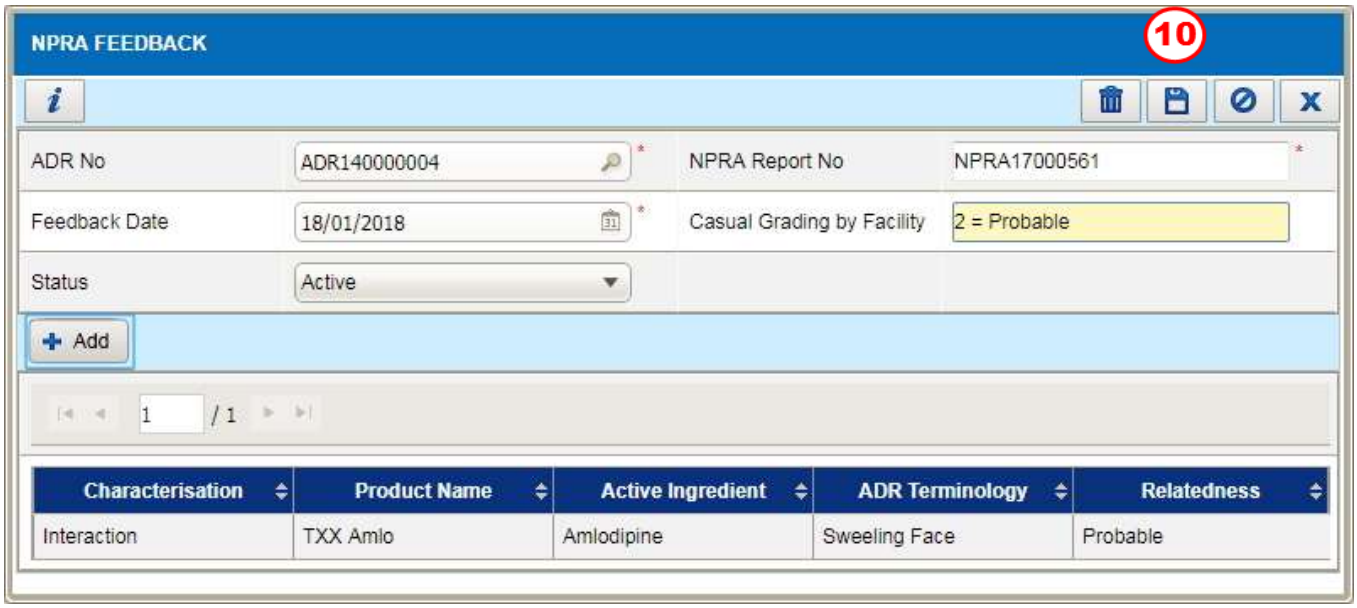


Figure 3.2-4 NPRA Feedback

STEP 10

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

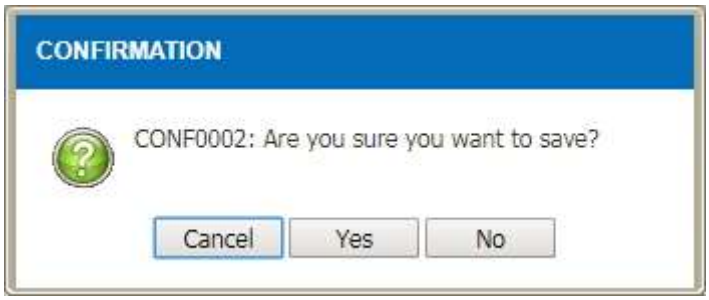


Figure 3.2-5 Confirmation Message

Note
Click on the Yes *button so save the record*

3.3 Adverse Event Following Immunization

The function of this menu is to record any vaccine reaction of the patient

Figure 3.3-1 Adverse Event Following Immunisation Listing Page

Note

Search for AEFI record by below criteria:-

No	Field	Description	Remark
a	AEFI No	–	Allow to search record by full or partial AEFI No
b	MRN	Patient MRN	Allow to search patient by full or partial MRN No
c	Vaccine Type	– All – Diphtheria/Tetanus/ Pertussis – Diphtheria/Tetanus/ Pertussis/Poliomyelitis – Hepatitis B – Human Papillomavirus (HPV) – Lain-lain – MMR	– All – Allow to search from criteria Diphtheria/Tetanus/Pertussis until MMR – Diphtheria/Tetanus/Pertussis – Allow to search Diphtheria/Tetanus/Pertussis vaccine type – Diphtheria/Tetanus/Pertussis/Poliomyelitis-Allow to search Diphtheria/Tetanus/ Pertussis/ Poliomyelitis vaccine type – Hepatitis B – Allow to search Hepatitis B vaccine type – Human Papillomavirus (HPV) - Allow to search Human Papillomavirus (HPV) vaccine type – Lain-lain – Allow to search vaccine which not classified – MMR – Allow to search MMR vaccine type
d	Reported Date From	–	Allow to search date before current date
e	Reported Date To	–	Allow to search date later than date on Reported Date From field
f	Reported By	User Login Name	Allow to search by full or partial User Login Name
g	Status	– All – Recorded – Submitted	– All - Allow to search record by status Recorded and Submitted – Recorded - Allow to search for records that are saved but not yet confirmed – Submitted - Allow to search for records that are saved and confirmed

Table 3.3

STEP 1

Select 'Adverse Drug Reaction' menu follow by' Adverse Event Following Immunisation' sub menu

STEP 2

Click on the button to create new patient record

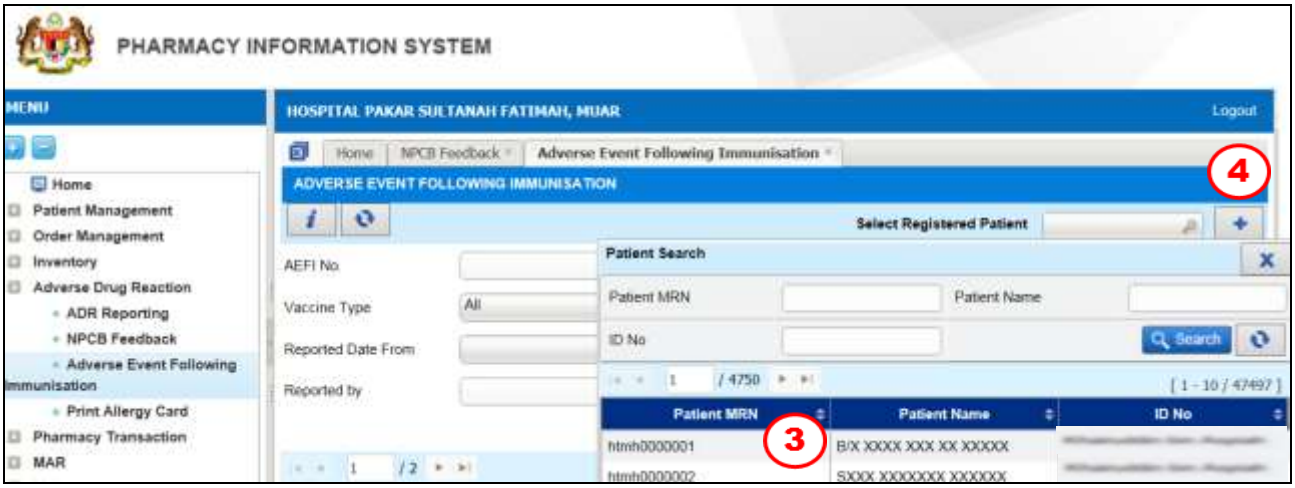


Figure 3.3-2 Select Registered Patient

STEP 3

Select patient record

STEP 4

Click on the button to begin recording Adverse Event Following Immunisation for the selected MRN

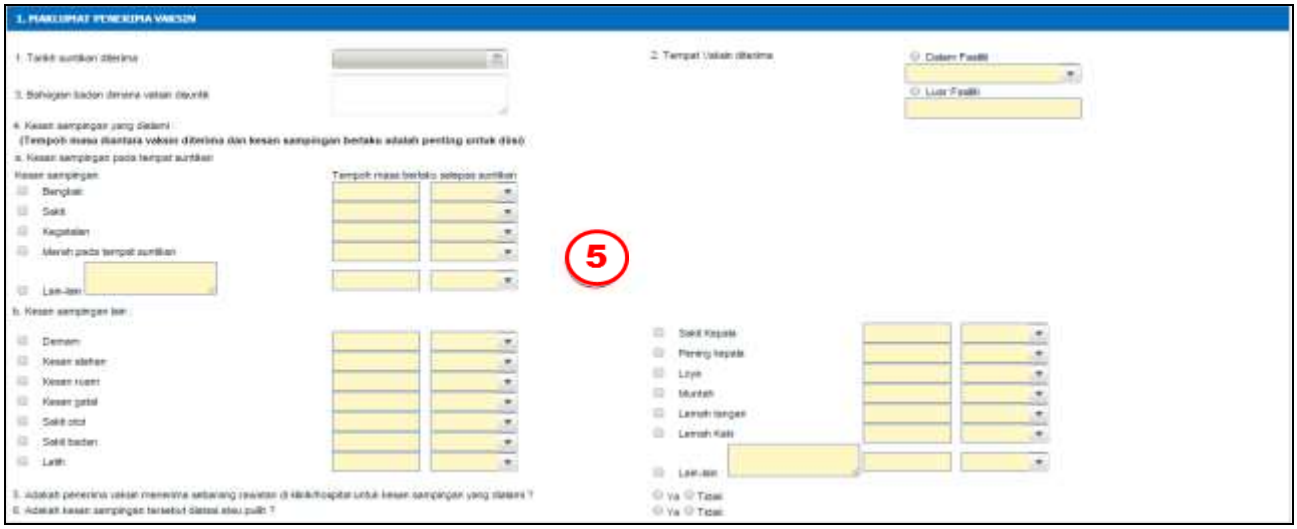


Figure 3.3-3 Maklumat Penerima Vaksin

STEP 5

Enter the information in Maklumat Penerima Vaksin section based on 6 main question if applicable:

1. Tarikh suntikan diterima
2. Tempat Vaksin diterima
3. Bahagian badan dimana vaksin disuntik
4. Kesan sampingan yang dialami
5. Adakah penerima vaksin menerima sebarang rawatan di klinik/hospital untuk kesan sampingan yang dialami

6. Adakah kesan sampingan tersebut diatasi atau pulih

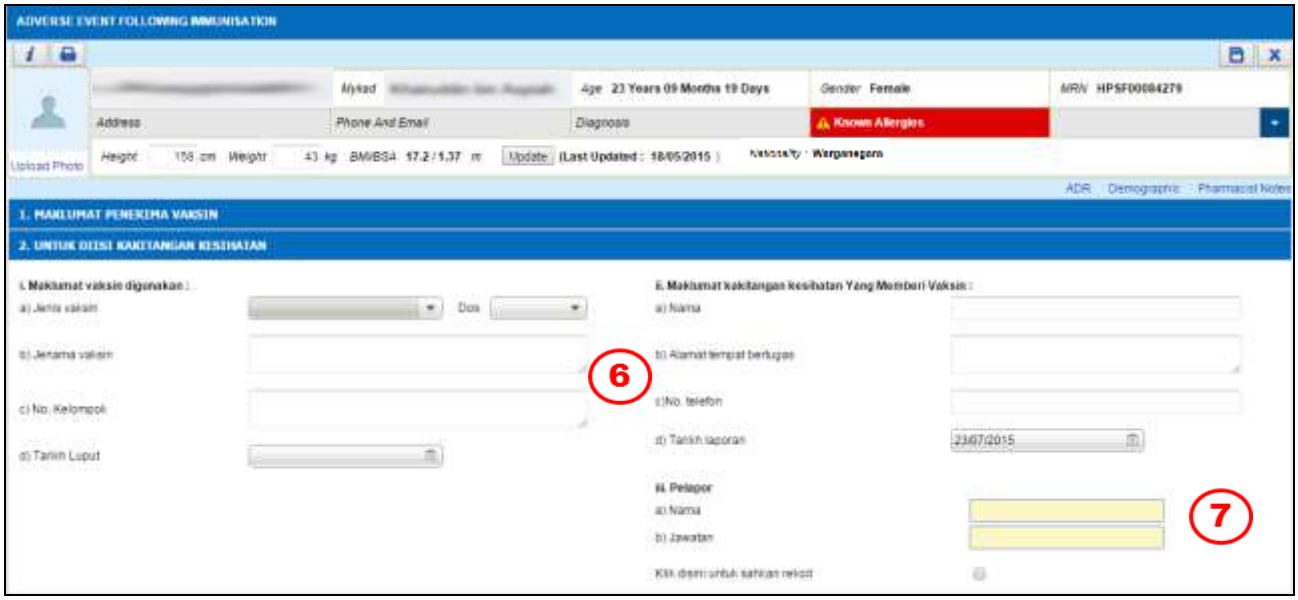


Figure 3.3-4 Untuk Diisi Kakitangan Kesihatan

STEP 6
Enter the information in Diisi Kakitangan Kesihatan section based on 2 sub sections below:

i. Maklumat vaksin digunakan
   a) Jenis vaksin
   b) Jenama vaksin
   c) No Kelompok
   d) Tarikh Luput
ii. Maklumat kakitangan kesihatan Yang Memberi Vaksin
   a) Nama
   b) Alamat tempat bertugas
   c) No telefon
   d) Tarikh Laporan

STEP 7
Click on the checkbox 'Click here to confirm the record' to complete the report

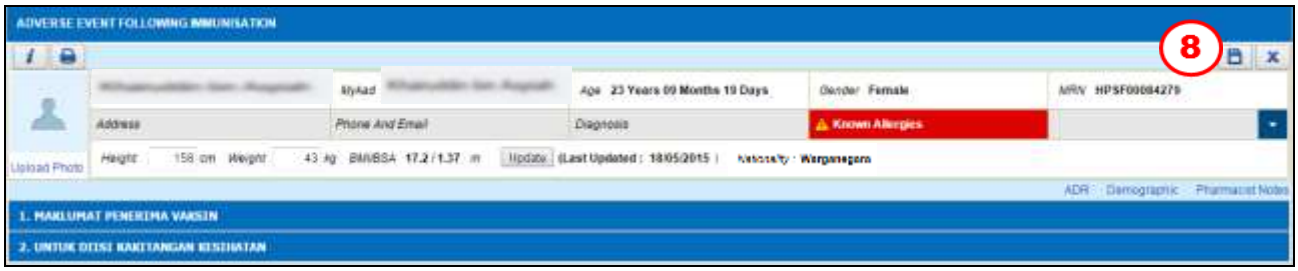


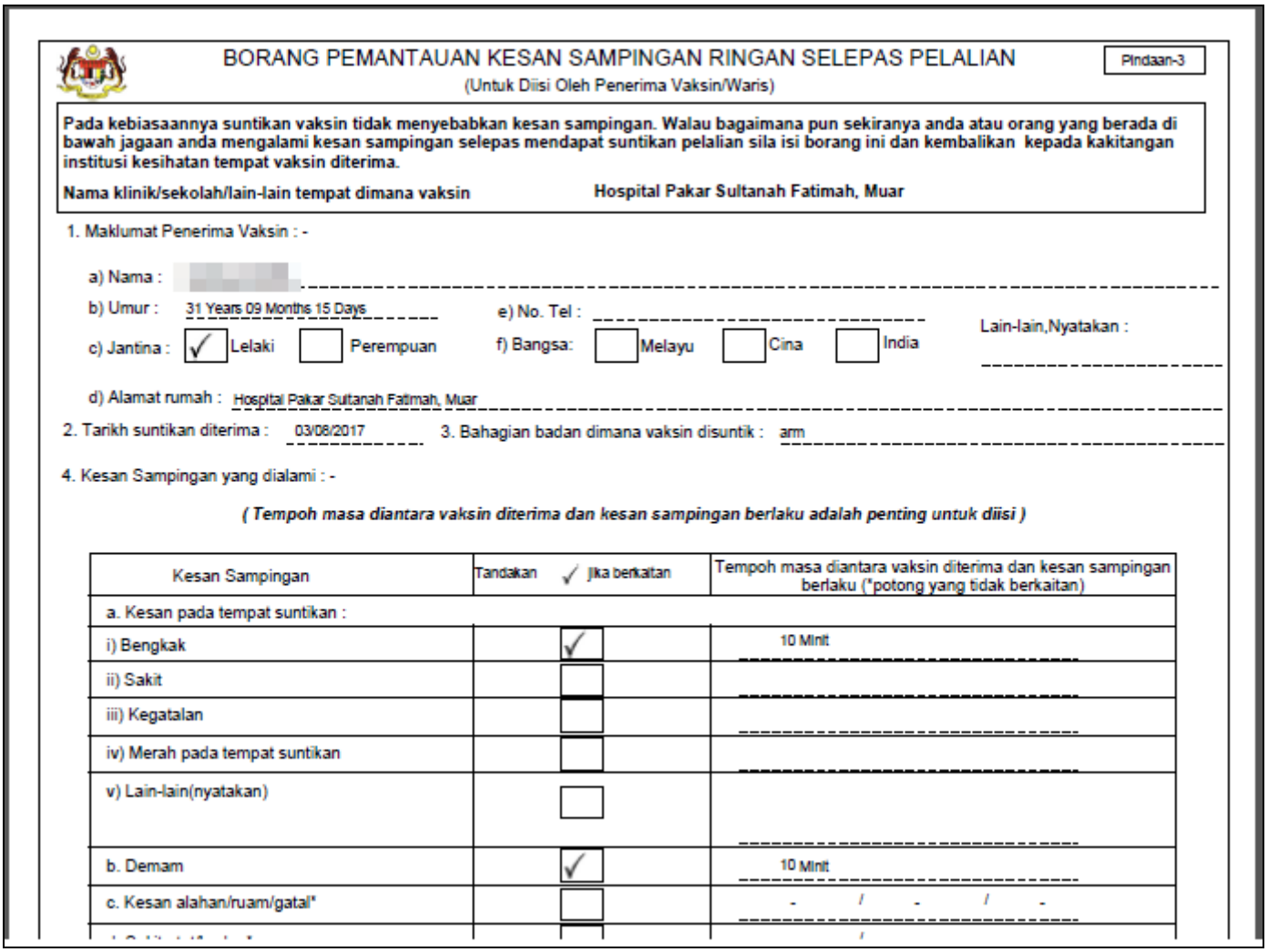
Figure 3.3-5 Save Record

STEP 8

Click on the button to save all the information

Note

- *Click on the button to print the Report as Figure 3.3-6*
- *Click on the button to close the transaction*



BORANG PEMANTAUAN KESAN SAMPINGAN RINGAN SELEPAS PELALIAN

Pindaan-3

(Untuk Diisi Oleh Penerima Vaksin/Waris)

Pada kebiasaannya suntikan vaksin tidak menyebabkan kesan sampingan. Walau bagaimana pun sekiranya anda atau orang yang berada di bawah jagaan anda mengalami kesan sampingan selepas mendapat suntikan pelalian sila isi borang ini dan kembalikan kepada kakitangan institusi kesihatan tempat vaksin diterima.

Nama klinik/sekolah/lain-lain tempat dimana vaksin **Hospital Pakar Sultanah Fatimah, Muar**

1. Maklumat Penerima Vaksin : -

a) Nama :

b) Umur : 31 Years 09 Months 15 Days

e) No. Tel :

c) Jantina : ✓ Lelaki ☐ Perempuan

f) Bangsa: ☐ Melayu ☐ Cina ☐ India

Lain-lain,Nyatakan :

d) Alamat rumah : Hospital Pakar Sultanah Fatimah, Muar

2. Tarikh suntikan diterima : 03/08/2017

3. Bahagian badan dimana vaksin disuntik : arm

4. Kesan Sampingan yang dialami : -

(Tempoh masa diantara vaksin diterima dan kesan sampingan berlaku adalah penting untuk diisi)

Kesan Sampingan	Tandakan ✓ jika berkaitan	Tempoh masa diantara vaksin diterima dan kesan sampingan berlaku (*potong yang tidak berkaitan)
a. Kesan pada tempat suntikan :		
i) Bengkak	✓	10 Minit
ii) Sakit	☐	
iii) Kegatalan	☐	
iv) Merah pada tempat suntikan	☐	
v) Lain-lain(nyatakan)	☐	
b. Demam	✓	10 Minit
c. Kesan alahan/ruam/gatal*	☐	- / - / -

Figure 3.3-6 Report

3.4 Print Allergy Card

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

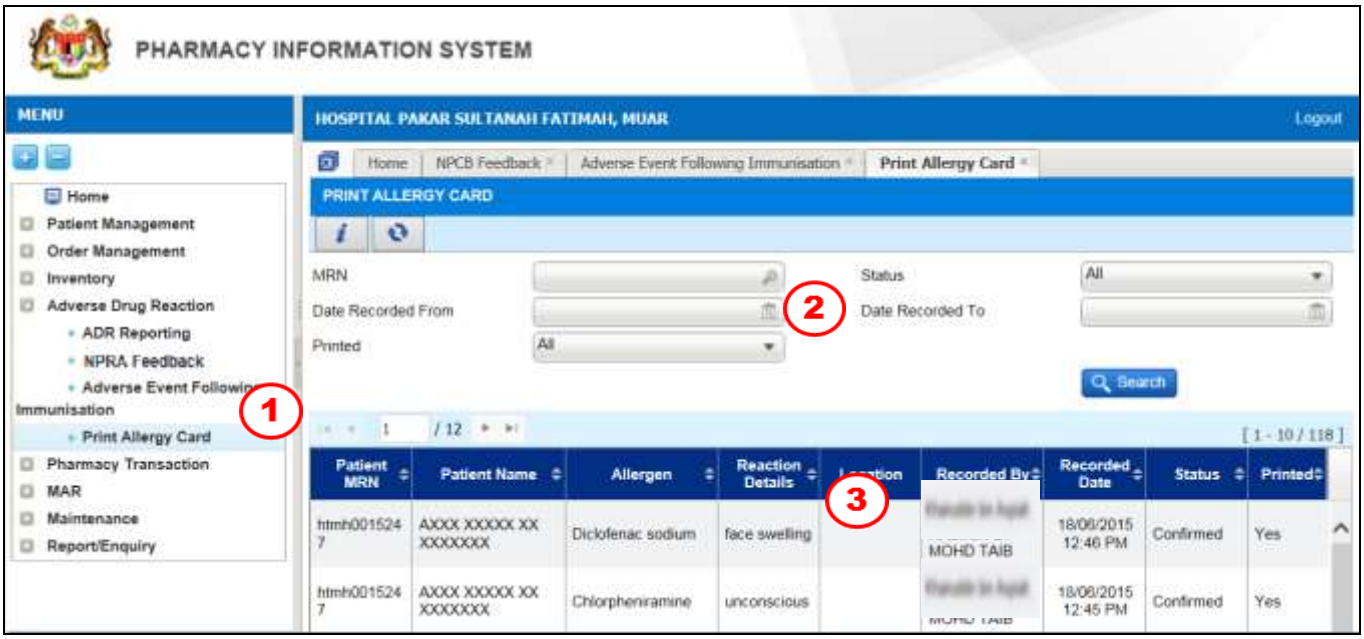


Figure 3.4-1 Print Allergy Card Listing Page

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 Occurance From	–	Allow to search date before current date
d	Date Occurance To	–	Allow to search date later than date on Date Occurance From field

Table 3.4-1

Click on the

button and the system will display all related records

STEP 3
Double-click on record then select the checkbox as shown in Figure 3.4-1

Figure 3.4-2 Selected Patient

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

Print In Malay | Print In English

System will display as shown in Figure 3.4-3.

Note

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

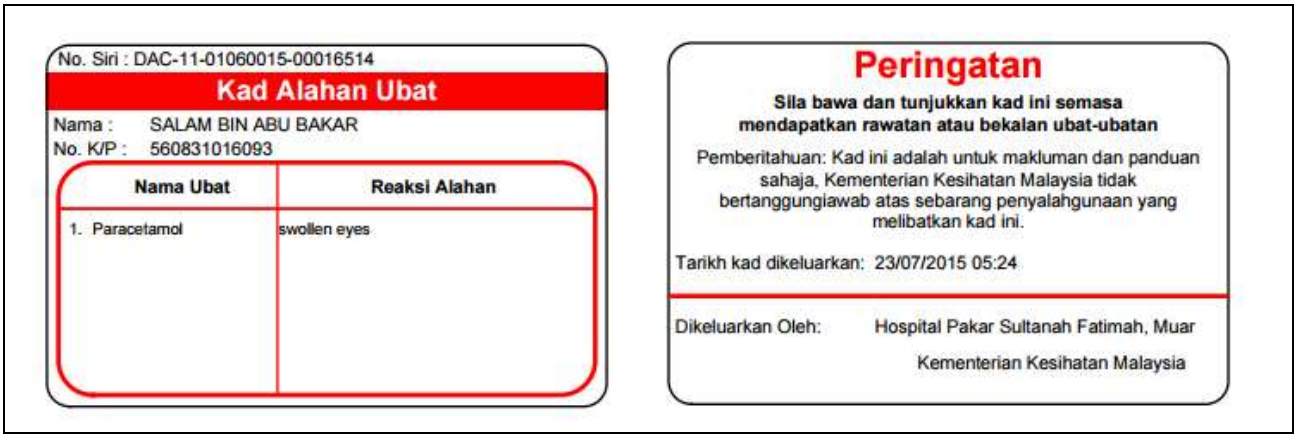


Figure 3.4-3 Allergy Card Sample

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*		