Pharmacy Information System (PhIS) & Clinical Pharmacy System (CPS)

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

© 2011-2016 Pharmacy Information System (PhIS) Project

Reference ID : U.MANUAL_ ADR & DAC-4th E

Application reference: PhIS & CPS v1.4.1

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, 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
- NPCB Feedback
- Adverse Event Following Immunisation
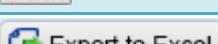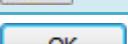- Print Allergy Card

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

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
X	Close Window	31	Calendar Icon
	Save Transaction		Delete Record
Export to Excel	Export Report From PDF file to Excel file	OK	OK Button
Yes	Yes Button	No	No Button
◯	Radio Button	☐	Checkbox
	System Automatic Generate Record No.		Automatically Display/Retrieve Box
C	Reset Login Screen	⊘	Cancel
Home	Display Home Tab		Search Icon
i	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)
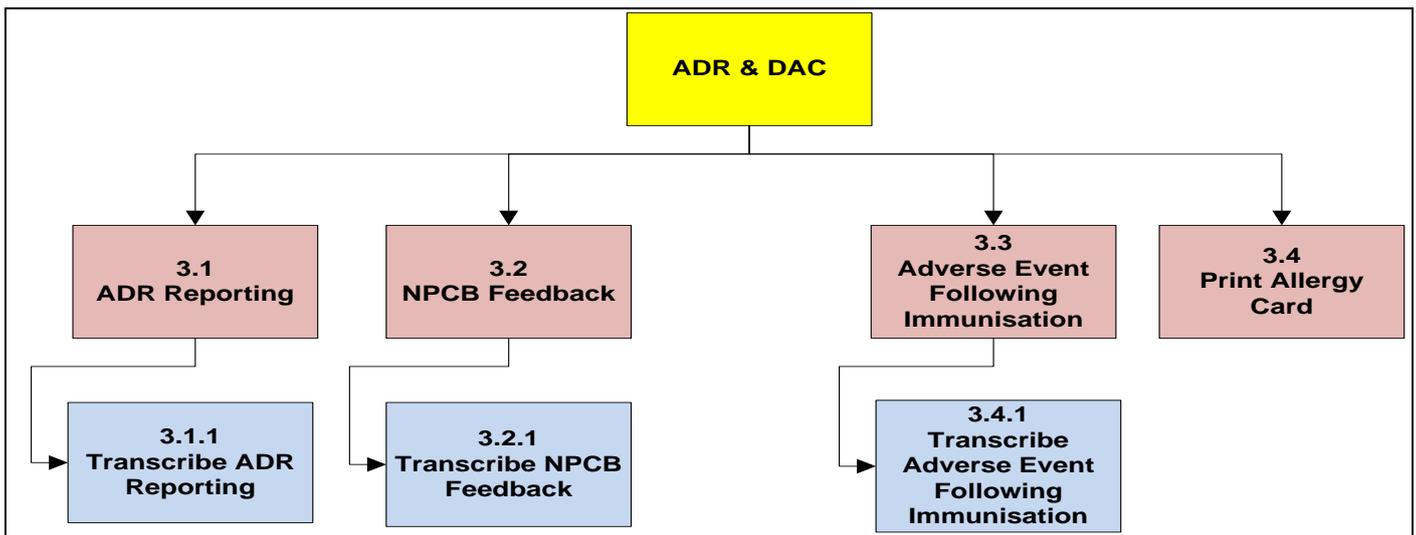
Functional Diagram

Figure 3.1

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

3.1.1 Transcribe ADR Reporting

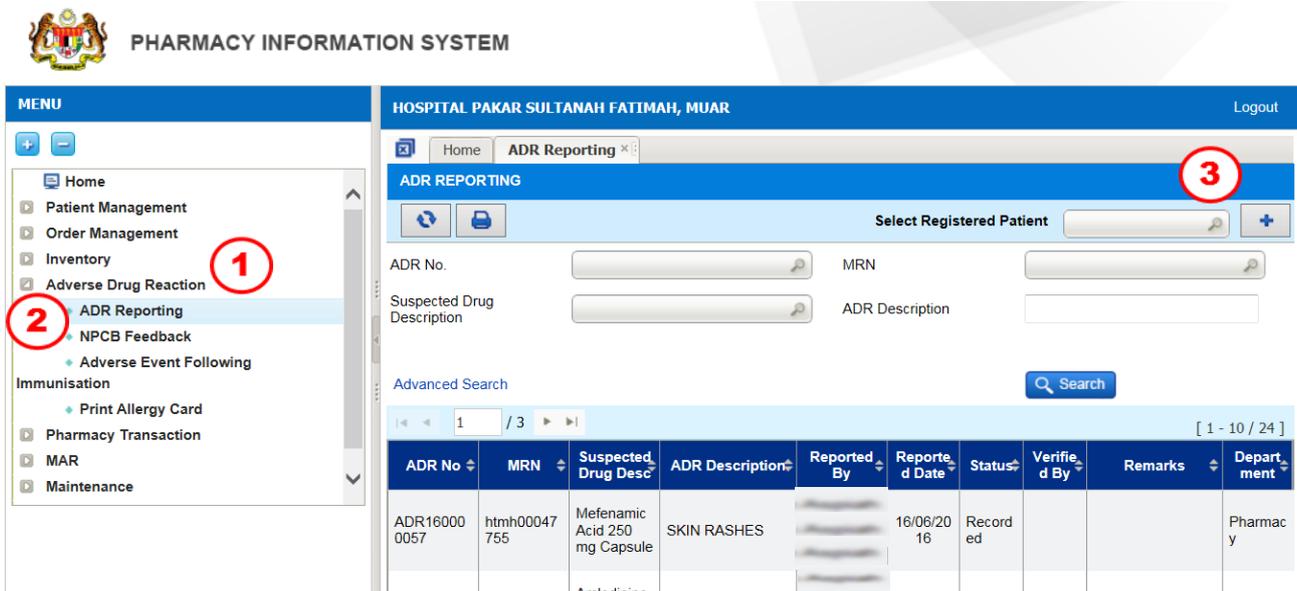This function is used to record any drug reaction of the patient before sending to NPCB.

Figure 3.1.1-1 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

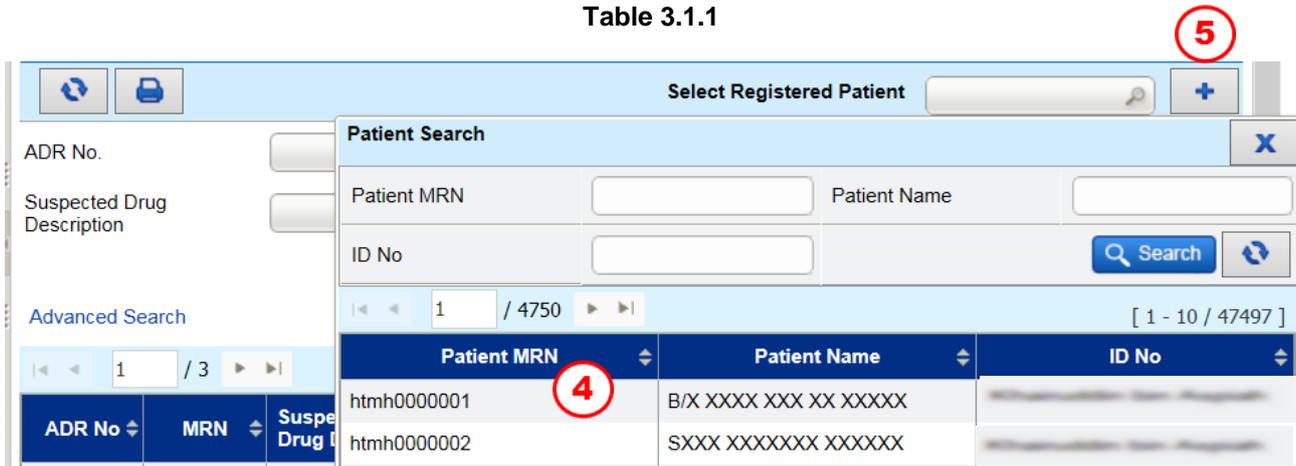**STEP 3**
Click on the [🔍] button to search for patient record

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 3.1.1

Figure 3.1.1-2 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

Note

Below options are provided for user to view the additional patient information. Click on the hyperlink as below:

   a) ***ADR***
      - *ADR reporting history details.*
   b) ***Demographic***
      - *Patient's demographic details.*

Figure 3.1.1-3 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) *Time To Onset of Reaction*
   d) *Treatment of Adverse Reaction*
   e) *Outcome*
   f) *Drug Relationship*
   g) *Extent of Reaction*
   h) *Reaction Subsided after stopping drug or Reducing Dose*
   i) *Reaction reappeared after reintroducing drug*

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:*
   - *Drug Interaction*
   - *Medication Error*
   - *Medication Ineffective*
   - *Others*

- *Race* field is retrieved from patient registration.

- Select *'Outcome'* from drop down box:
   - *Fatal*
   - *Not Yet Recovered*
   - *Recovered*
   - *Unknown*
- If 'Fatal' selected for outcome, enter the '*Date of Death'.*
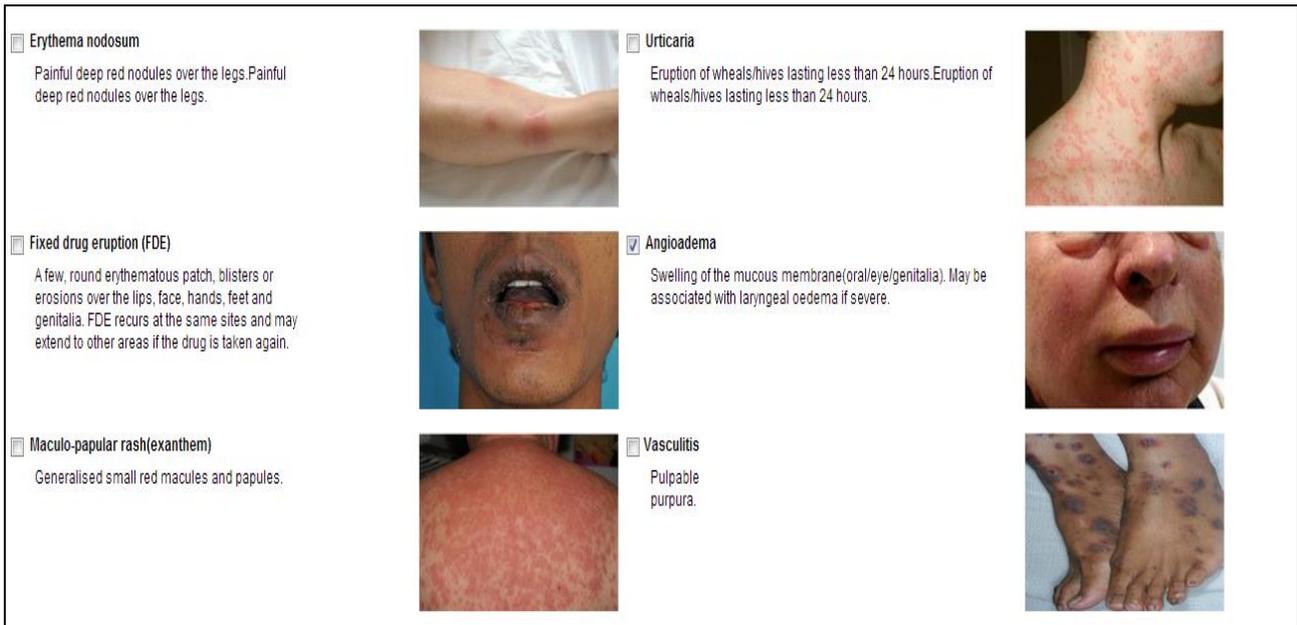
Figure 3.1.1-4 Skin Reaction Screen

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 3.1.1-4. Select the checkbox and click on the* [💾] *button to save the record.*
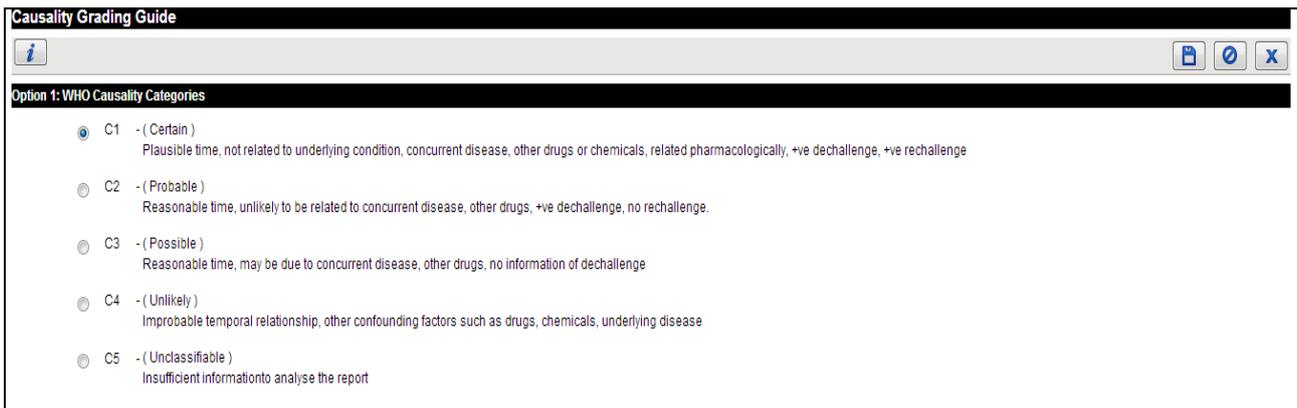

Figure 3.1.1-5 WHO Causality Grading

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 3.1.1-5 and Figure 3.1.1-6.*

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

Figure 3.1.1-6 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 3.1.1-7 Drug Details

STEP 7

Click on the ➕ button as shown in Figure 3.1.1-7 and '**Add Drug Detail'** screen will be displayed as shown in Figure 3.1.1-8
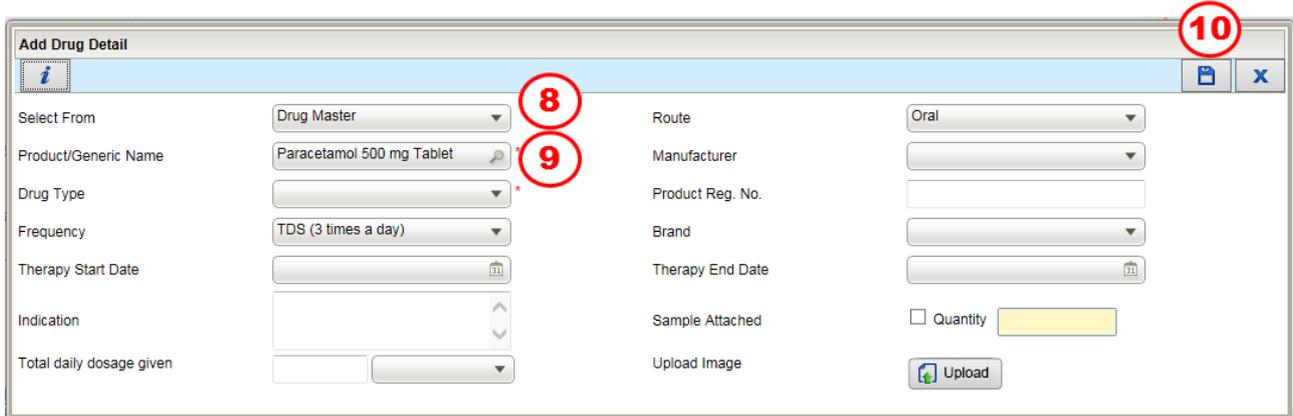
Figure 3.1.1-8 Add Drug Details

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

Note

- *Enter the other optional field if applicable*
    - ***a) Drug Type***
    - ***b) Frequency***
    - ***c) Therapy Start Date***
    - ***d) Indication***
    - ***e) Total daily dosage given***
    - ***f) Route***
    - ***g) Manufacturer***
    - ***h) Product Reg No***
    - ***i) Brand***
    - ***j) Sample Attached***
    - ***k) 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 10

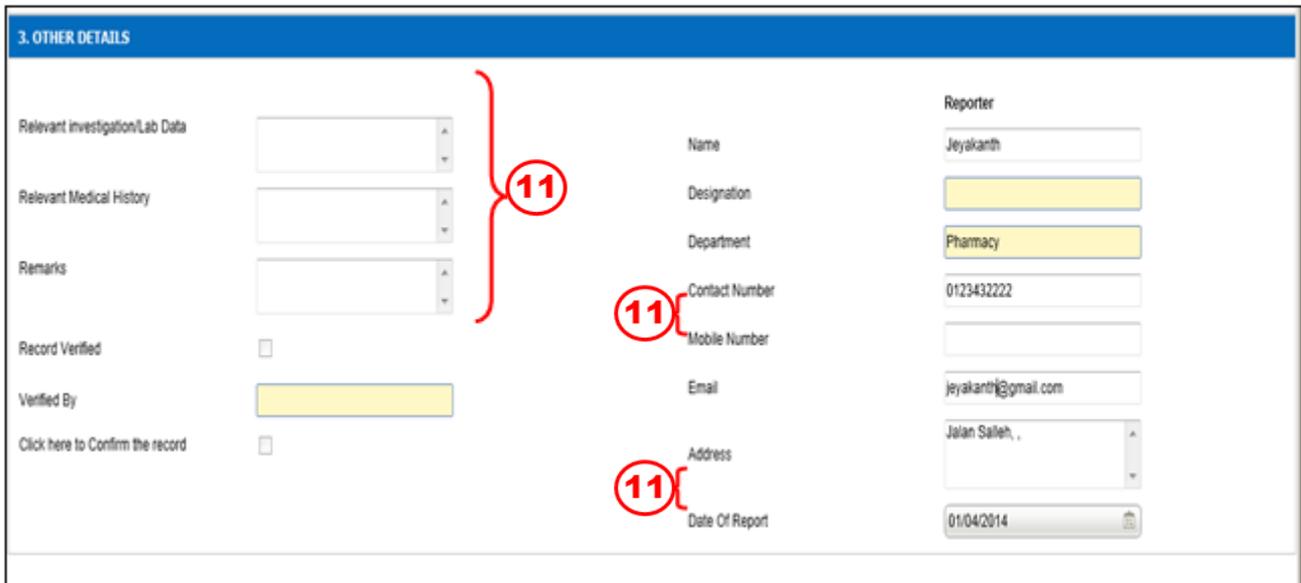Click on the [save icon] button to save the record

Figure 3.1.1-9 Other Details

STEP 11
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*
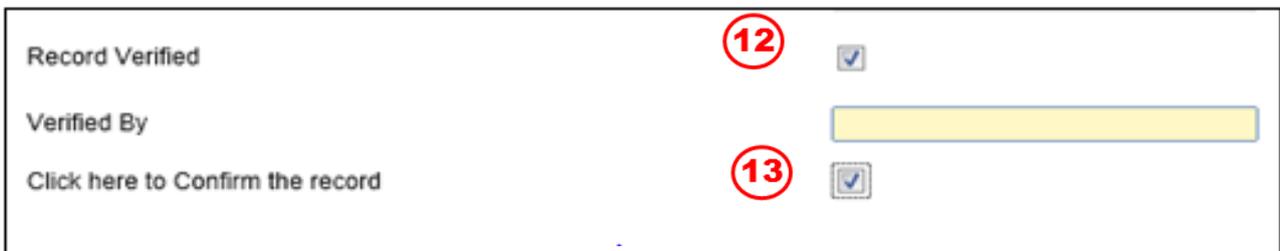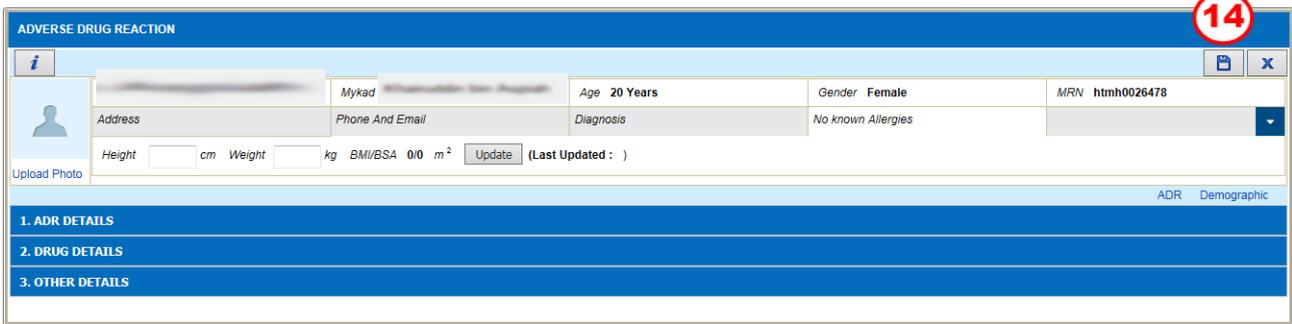   d) *Contact Number*
   e) *Email*
   f) *Address*

Figure 3.1.1-10 Record Verified

STEP 12
Select the *Record Verified* checkbox to verify the record. Once the checkbox is selected, adding and editing of data are not allowed

STEP 13
Click on the **Click here to Confirm the record** checkbox then print the form to send the form to NPCB

Figure 3.1.1-11 Save Record

STEP 14

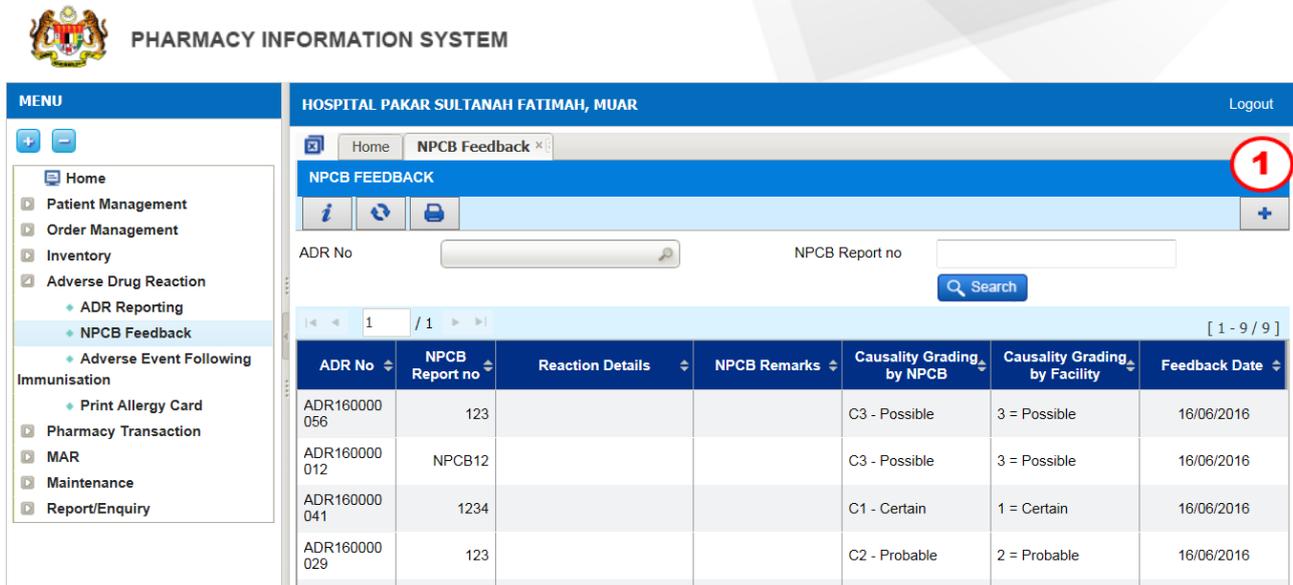Click on the [save] button to save the record then click [X] to close the window

3.2 NPCB Feedback

3.2.1 Transcribe NPCB Feedback

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

Figure 3.2.1-1 NPCB Feedback Listing Page

Note

Search for NPCB Feedback record by below criteria:

No	Field	Description	Remark
a	ADR No	–	Allow to search record by full or partial ADR No
b	NPCB Report No	–	Allow to search record by full or partial NPCB Report No

Table 3.2.1

STEP 1

Click at the [➕] button to create new '**NPCB Feedback'** report
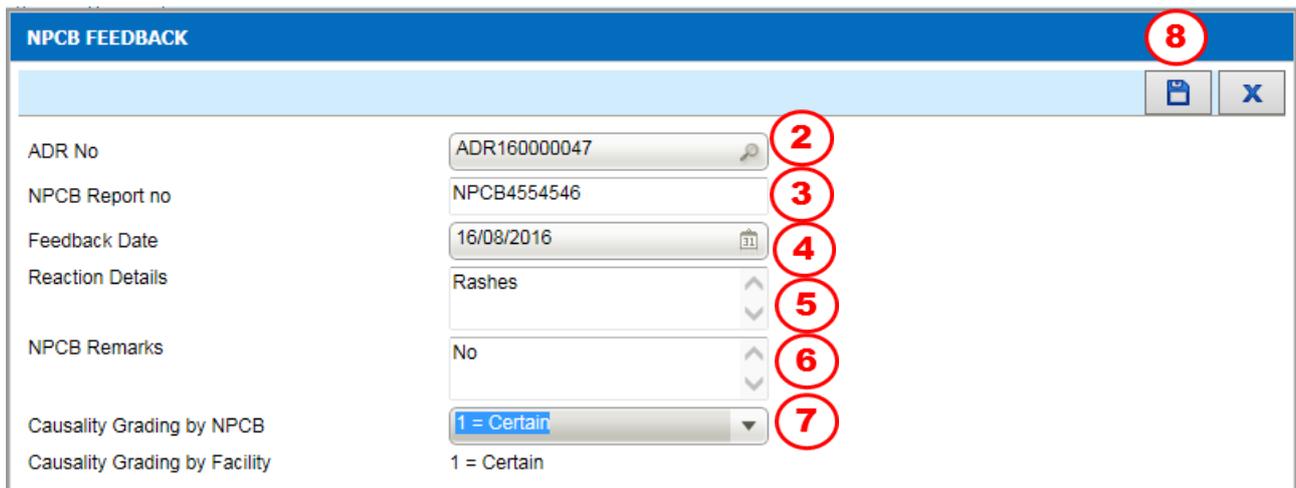
NPCB FEEDBACK ⑧

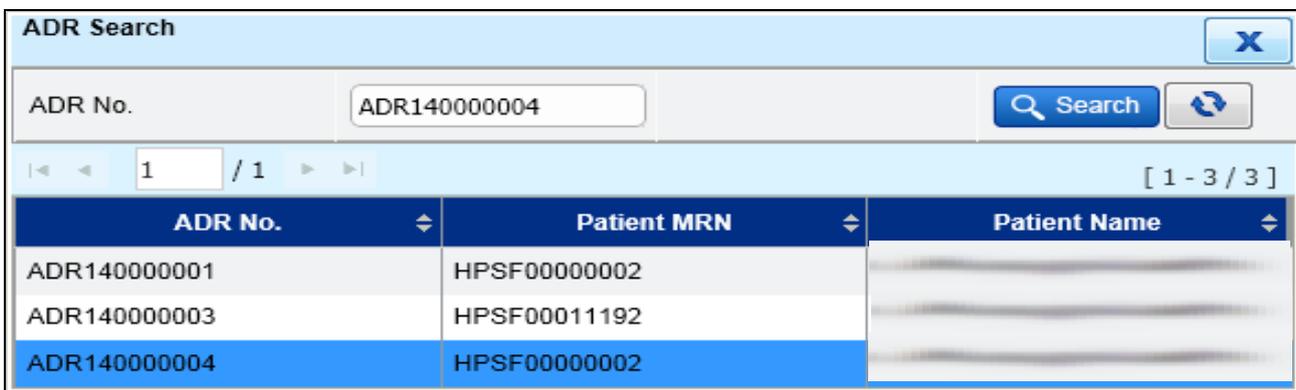|	
ADR No	ADR160000047 🔍 ②
NPCB Report no	NPCB4554546 ③
Feedback Date	16/08/2016 📅 ④
Reaction Details	Rashes ⑤
NPCB Remarks	No ⑥
Causality Grading by NPCB	1 = Certain ▼ ⑦
Causality Grading by Facility	1 = Certain

Figure 3.2.1-2 NPCB Feedback

ADR Search ✕

ADR No.	ADR140000004	🔍 Search ↻

◄◄ ◄ 1 / 1 ► ►| [1 - 3 / 3]

ADR No. ⬍	Patient MRN ⬍	Patient Name ⬍
ADR140000001	HPSF00000002	
ADR140000003	HPSF00011192	
ADR140000004	HPSF00000002	

Figure 3.2.1-3 ADR Search

STEP 2
Search ADR no from the list by clicking the icon 🔍 and system will display as shown in Figure 3.2.1-2 and generate the data for *'Causality Grading by Facility' field*

STEP 3
Enter **NPCB Report no**

STEP 4
Enter **Feedback Date** by choose from calendar

STEP 5
Enter **Reaction Details**

STEP 6
Enter **Pharmacist remarks**

STEP 7
Enter **Causality Grading** information

STEP 8
Click 💾 to save the record then click ✕ to close the window

3.3 Adverse Event Following Immunization

3.3.1 Transcribe Adverse Event Following Immunisation

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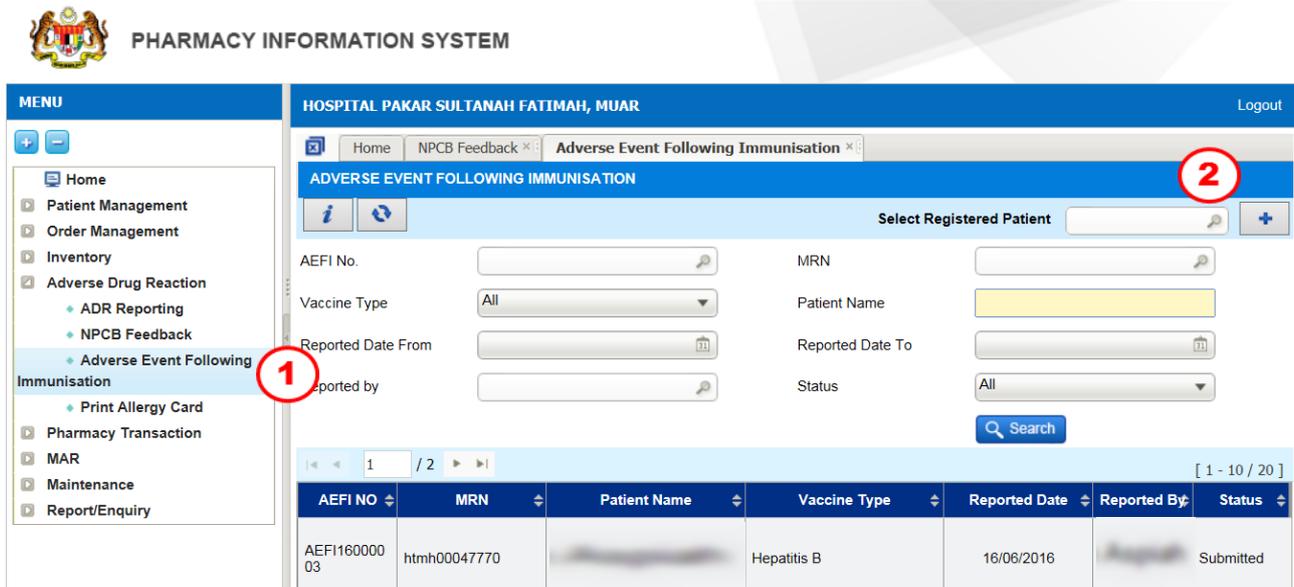

Figure 3.3.1-1 Adverse Event Following Immunisation Listing Page

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 3.3.1

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 3.3.1-2 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 3.3.1-3 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
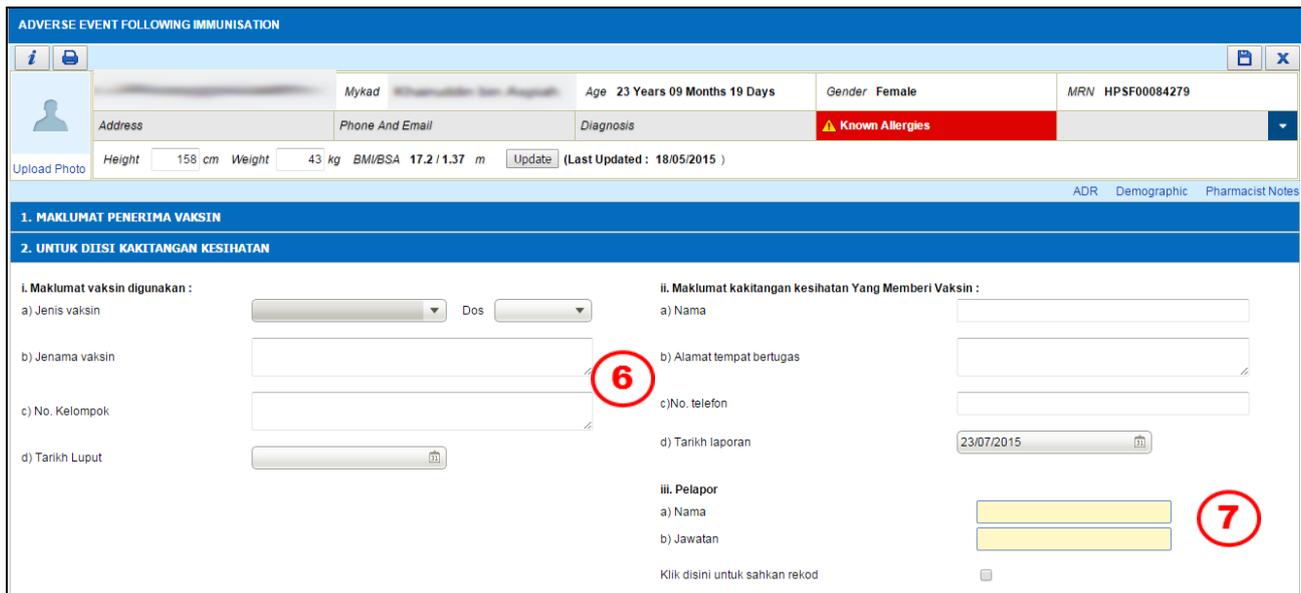
**Figure 3.3.1-4 Untuk Diisi Kakitangan Kesihatan**

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
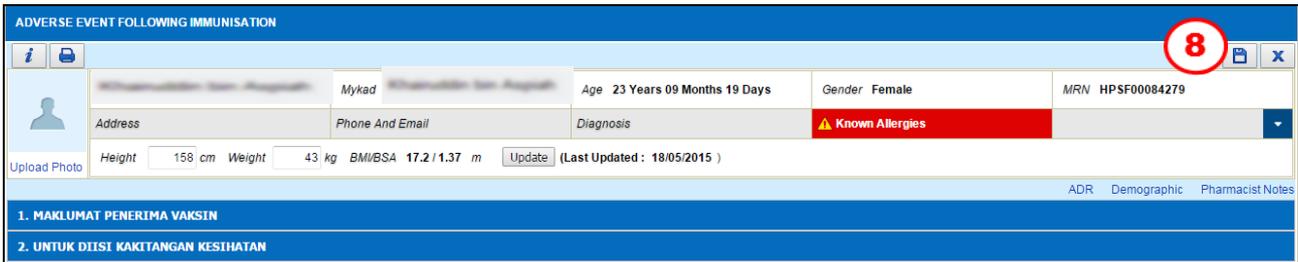
Figure 3.3.1-5 Save Record
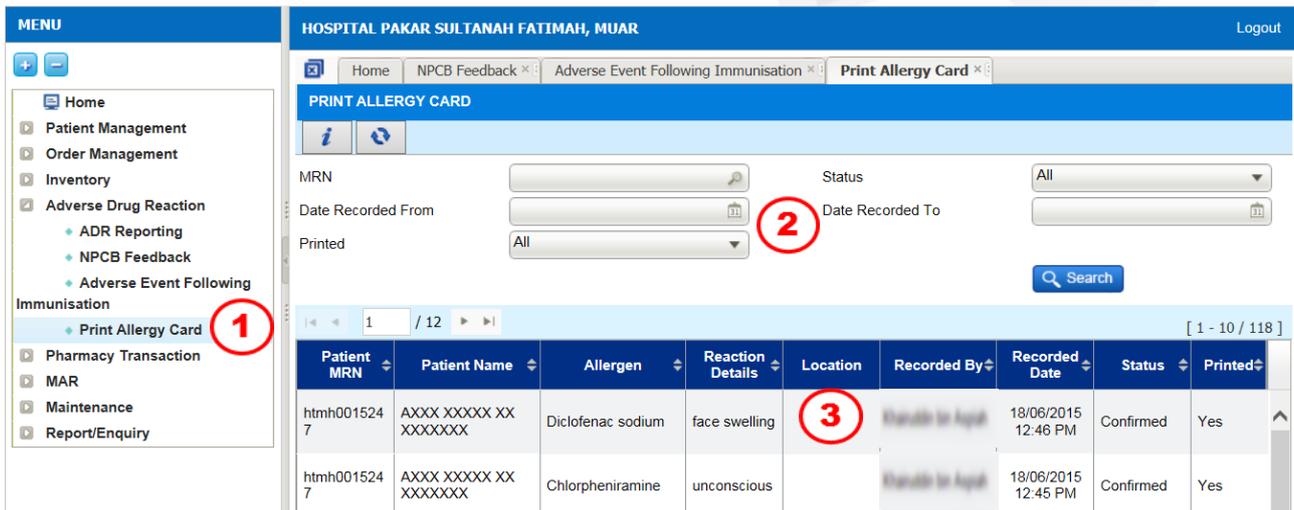
STEP 8

Click on the [save] button to save all the information

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

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

STEP 3

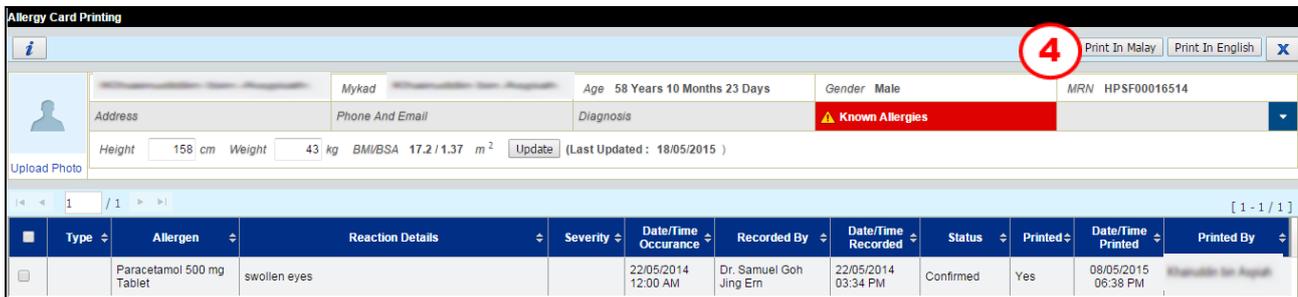Double-click on record then select the checkbox as shown in Figure 3.4-1

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:
- *Only confirmed and suspected allergen will be displayed on the card.*
- *User may need to use yellow paper to print the Drug Allergy Card.*

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	Radiopharma	*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		