



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

---

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

<b>Version</b>	<b>: 13<sup>th</sup> Edition</b>
<b>Document ID</b>	<b>: PB_U. MANUAL_ADR_DAC</b>



**CONFIDENTIAL COPYRIGHTED MATERIAL** – *The information includes all concepts, comments, recommendations, and material, contained herein shall remain the property of Pharmacy Information System (PhIS & CPS) Project. No portion of this document shall be disclosed, duplicated or used in whole or in part of any purpose other than the purpose of the Pharmacy Information System (PhIS & CPS) Project execution only*

*Reference ID : PB\_U. MANUAL\_ADR & DAC-13<sup>th</sup> E*

*Application reference: PhIS & CPS v2.6.1*



## Table of Contents

1.0	Introduction .....	1
1.1	Overview of PhIS .....	1
1.2	Purpose and Objectives .....	1
1.3	Organised Sections .....	1
2.0	Application Standard Features .....	2
2.1	PhIS Legend .....	2
3.0	Adverse Drug Reaction & Drug Allergy Card .....	4
	Overview .....	4
	User Group .....	4
	Functional Diagram .....	4
	Functional Description .....	4
3.1	ADR Reporting .....	5
3.2	NPRA Feedback .....	18
3.3	Print Allergy Card .....	21
4.0	Acronyms .....	23
5.0	Links to Clinical Modules .....	23

## 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 detail:

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

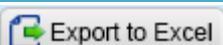
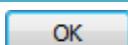
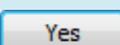
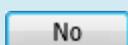
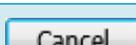
### 1.3 Organised Sections

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 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		Cancel
	Display Home Tab		Search Icon
	Show Help		Edit Record
	Search Record		Cancel Button
	Dropdown Box	<input type="text"/>	Empty Text Box
*	Mandatory Field		



ADR & DAC Module Legend			
<a href="#">Print In Malay</a>	Print DAC card in Malay	<a href="#">Causality Grading</a>	Causality Grading Guide
<a href="#">Print In English</a>	Print DAC card in English	<a href="#">WHO Terminology Guide</a>	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

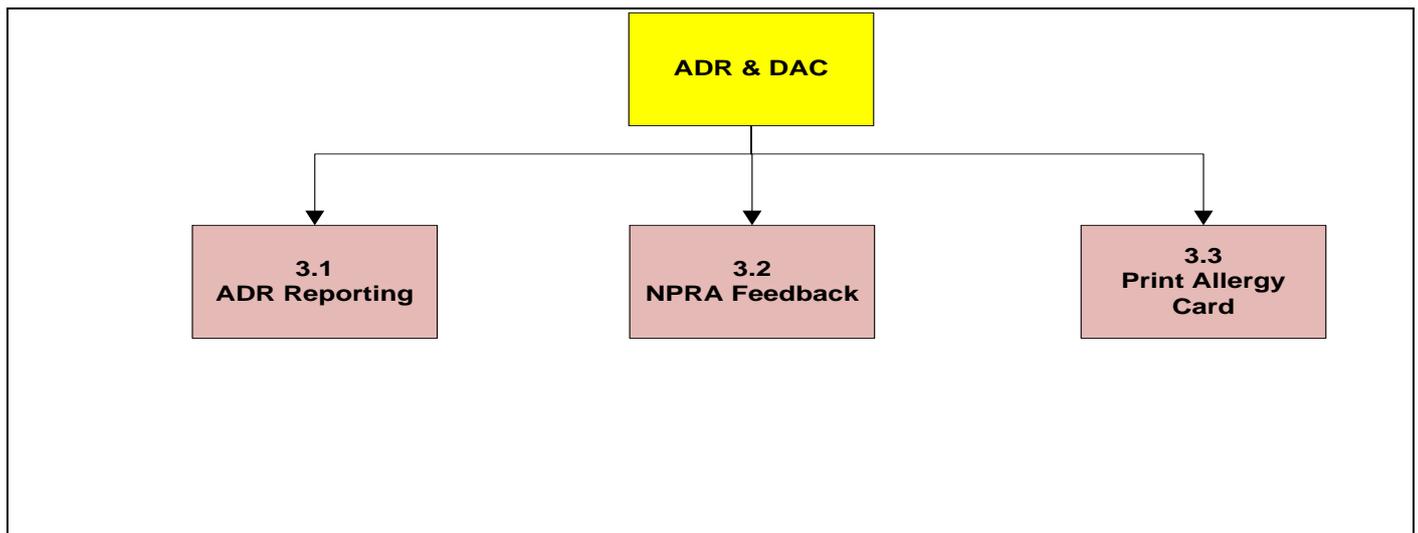


Figure 3.0

### 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.

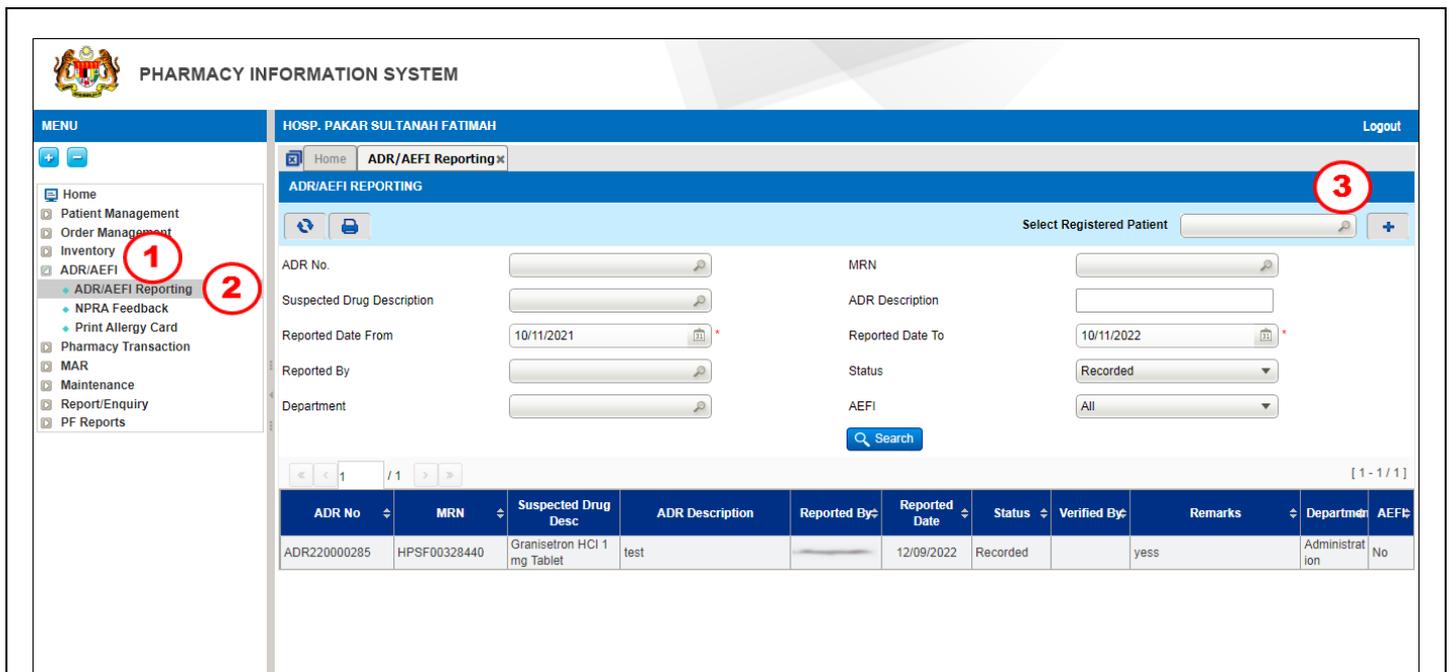


Figure 3.1-1 ADR Reporting Listing Page

**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	<ul style="list-style-type: none"> <li>- Confirmed</li> <li>- Verified</li> <li>- Recorded</li> <li>- Cancelled</li> <li>- NPRA Received</li> <li>- Feedback Received</li> </ul>	<ul style="list-style-type: none"> <li>- Confirmed <ul style="list-style-type: none"> <li>• Allow to search for records that have been confirmed</li> </ul> </li> <li>- Verified <ul style="list-style-type: none"> <li>• Allow to search for records that are verified but not yet confirmed</li> </ul> </li> <li>- Recorded <ul style="list-style-type: none"> <li>• Allow to search for records that are not yet verified and confirmed</li> </ul> </li> <li>- Cancelled <ul style="list-style-type: none"> <li>• Allow to search for records that are cancelled</li> </ul> </li> <li>- NPRA Received <ul style="list-style-type: none"> <li>• Allow to search for records that are NPRA receive but not get feedback yet</li> </ul> </li> <li>- Feedback Receive <ul style="list-style-type: none"> <li>• Allow to search for records that are receive feedback</li> </ul> </li> </ul>
l	Department	-	Allow to search by full or partial department name in facility
m	AEFI	<ul style="list-style-type: none"> <li>- All</li> <li>- Yes</li> <li>- No</li> </ul>	Allow to search and filter record for AEFI only, ADR only or both

Table 3.1

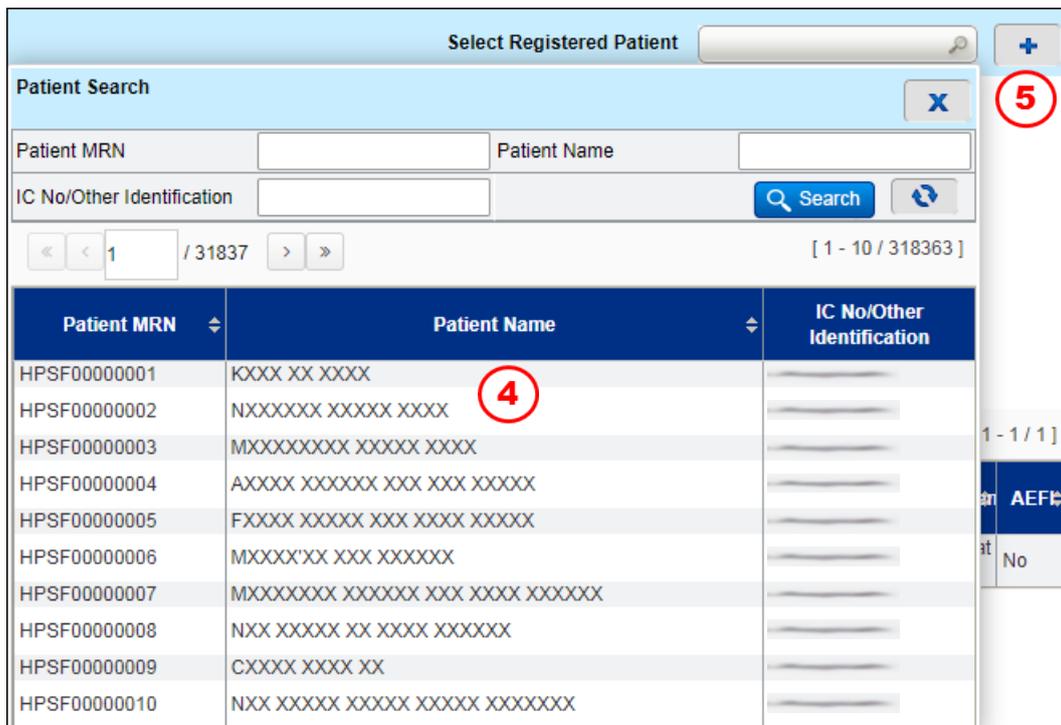


Figure 3.1-2 Enter/Select search MRN

**STEP 4**

Double-click on selected patient record

**STEP 5**

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

ADRAEFI REPORTING

	Mykad <input type="text"/>	Age 43 Years 09 Months 30 Days	Gender Male	MRN HPSF00328439
Address <input type="text"/>	Phone And Email <input type="text"/>	Diagnosis <input type="text"/>	Allergy: Need To Be Assessed	Vital Sign <input type="text"/>

Height  cm Weight  kg BMI/BSA 0/0 m<sup>2</sup>  (Last Updated : ) Nationality : Warganegara

1. ADR/AEFI DETAILS

AEFI

Adverse reaction description

[User Guide for ADR/AEFI Reporting via PhIS](#)      [Mild AEFI Terminology Guide](#)

Race

Please classify for skin reaction  Skin Reaction

Reaction start date

Reaction end date

Time-to-onset of reaction

Treatment of adverse reaction

Outcome

Seriousness

Extent of reaction

Action taken with suspected drug

Reaction subsided after action taken with suspected drug

Reaction reappeared after reintroducing suspected drug

Relatedness of suspected drug to reaction(s)

WHO Causality Categories/Naranjo Algorithm

2. DRUG DETAILS

3. OTHER DETAILS

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.

**WHO CAUSALITY CATEGORIES/NARANJO ALGORITHM GUIDE**

Option 1: WHO Causality Categories

- 1 = ( Certain )  
Plausible time, not related to underlying condition, concurrent disease, other drugs or chemicals, related pharmacologically, +ve dechallenge, +ve rechallenge
- 2 = ( Probable )  
Reasonable time, unlikely to be related to concurrent disease, other drugs, +ve dechallenge, no rechallenge.
- 3 = ( Possible )  
Reasonable time, may be due to concurrent disease, other drugs, no information of dechallenge
- 4 = ( Unlikely )  
Improbable temporal relationship, other confounding factors such as drugs, chemicals, underlying disease
- 5 = ( Unclassifiable )  
Insufficient information to analyse the report

**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.

Option 2: Naranjo Algorithm

1. Are there previous conclusive reports on this reaction? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	2. Did the adverse event appear when the suspected drug was administered? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown	4. Did the adverse reaction reappear when the drug was readministered? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	6. Did the reaction reappear when a placebo was given? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown	10. Was the adverse event confirmed by any objective evidence? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown

Score

Scoring: (More than 7) Certain, (5 - 6) Probable, (3 - 4) Possible, (1- 2) Unlikely, (0) Unclassifiable

**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

**ADR/AEFI REPORTING**

Mykad: [Redacted] Age: 43 Years 09 Months 30 Days Gender: Male MRN: HPSF00328439

Address: [Redacted] Phone And Email: [Redacted] Diagnosis: [Redacted] Allergy: Need To Be Assessed Vital Sign: [Redacted]

Height: [Redacted] cm Weight: [Redacted] kg BMI/BSA: 0/0 m<sup>2</sup> Update (Last Updated: ) Nationality: Warganegara

Medication Profile | ADR/AEFI | Demographic

**1. ADR/AEFI DETAILS**

**2. DRUG DETAILS**

MDC	Product/Generic Name	Drug Type	Dose	Frequency	Route	Manufacturer	Product Reg No.	Brand	Therapy Start Date	Therapy End Date	Therapy End Date Remark
<input type="checkbox"/> D06AX07183G1001XX	Gentamicin 0.1% Cream		1 app	BD (twice daily)	LA				03/11/2022	10/11/2022	
<input type="checkbox"/> N02BE01000T1001XX	Paracetamol 500 mg Tablet		2 tablet	PRN	Oral				03/11/2022	10/11/2022	
<input type="checkbox"/> P03AX01000L2002XX	Benzyl Benzoate 25 % Emulsion (Adult)		1 app	ON (every night)	LA				03/11/2022	10/11/2022	
<input type="checkbox"/> G04CA03110T1002XX	Terazosin HCl 2 mg Tablet		2 mg	OD (once daily)	Oral				03/11/2022	10/11/2022	

**3. OTHER DETAILS**

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

**Add Drug Detail**

Select From: (8)

Product/Generic Name: (9)

Drug Type: (10)

Frequency:

Therapy Start Date:

Dose:

Indication: (11)

Sample Attached:  Quantity:

Route: (12)

Manufacturer:

Product Reg. No.:

Batch Number:

Brand:

Therapy End Date:

Therapy End Date Remark:

Upload Image:

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

14
ADR/AEFI REPORTING

	Mykad	Age 43 Years 09 Months 30 Days	Gender Male	MRN HPSF00328439
Address	Phone And Email	Diagnosis	Allergy: Need To Be Assessed	Vital Sign

Upload Photo
Height  cm Weight  kg BMI/BSA 0/0 m<sup>2</sup>  (Last Updated : ) Nationality : Warganegara

[Medication Profile](#) | [ADR/AEFI](#) | [Demographic](#)

13

1. ADR/AEFI DETAILS

2. DRUG DETAILS

3. OTHER DETAILS

Relevant Medical History 13

Relevant investigation/Lab Data

Remarks

Reporter

Name

Designation

Department

Contact Number

Mobile Number

Email

Address

Date Of Report

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**

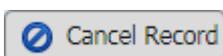
Fields of Reporter section that will be extracted automatically from the user account are:

- 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

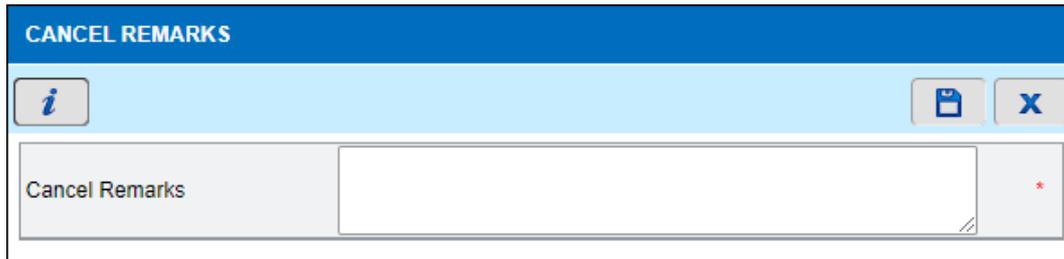


Figure 3.1-10 Cancel Remarks

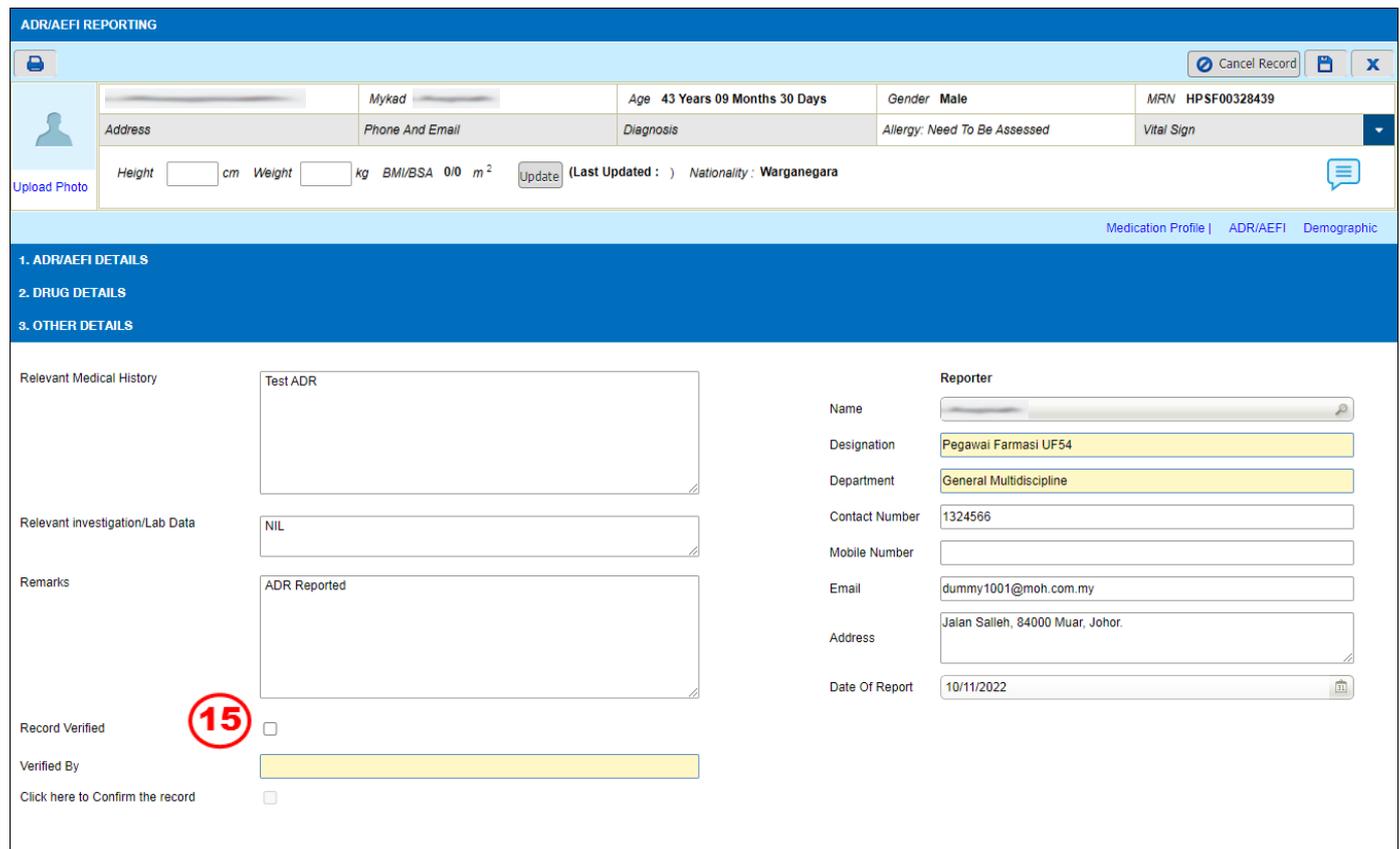


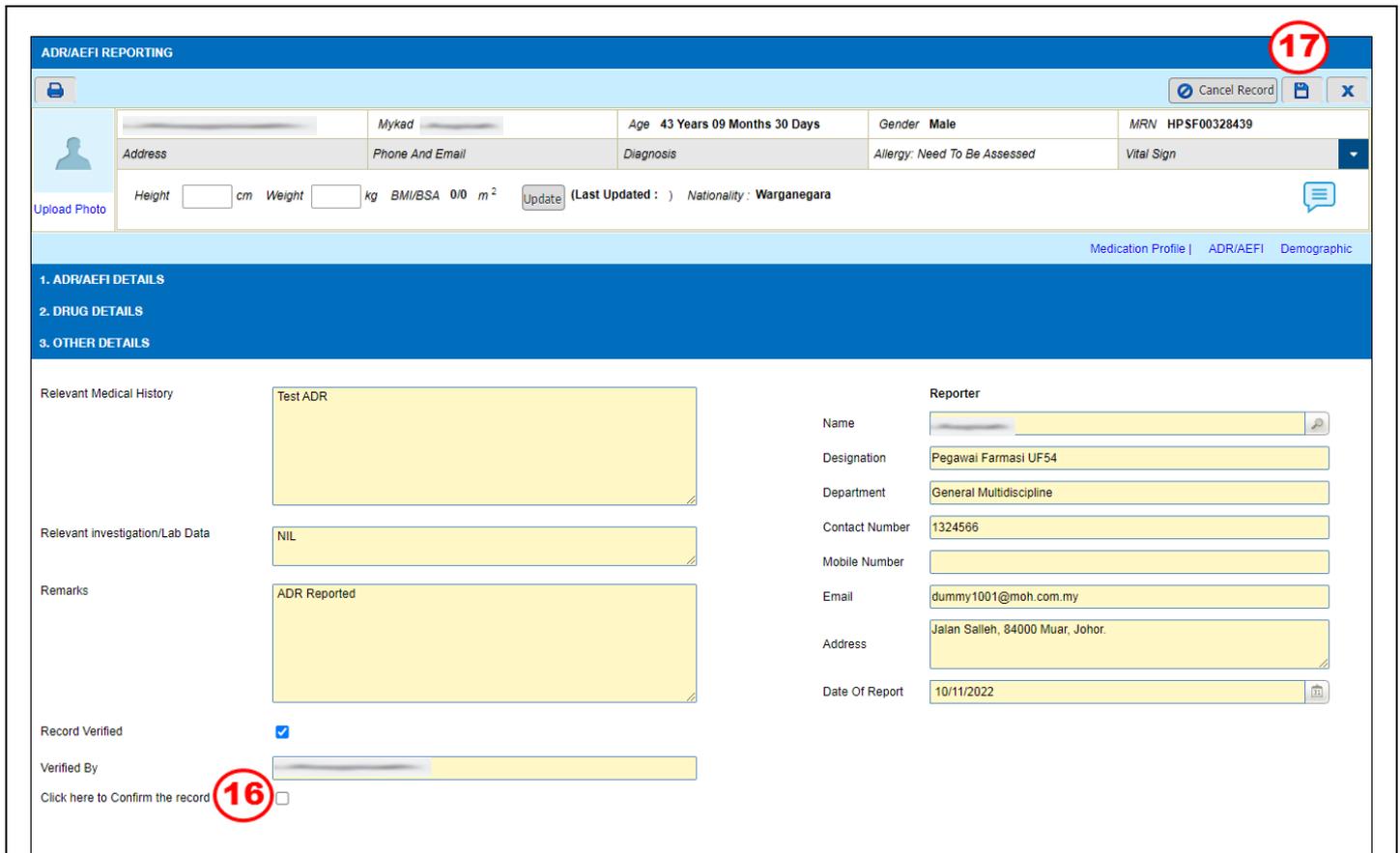
Figure 3.1-11 ADR Reporting

**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



**ADR/AEFI REPORTING** 17

Cancel Record [Save] [X]

Mykad: [Redacted] Age: 43 Years 09 Months 30 Days Gender: Male MRN: HPSF00328439

Address: [Redacted] Phone And Email: [Redacted] Diagnosis: [Redacted] Allergy: Need To Be Assessed Vital Sign: [Redacted]

Height: [ ] cm Weight: [ ] kg BMI/BSA: 0/0 m<sup>2</sup> [Update] (Last Updated: ) Nationality: Warganegara

Upload Photo [Message Icon]

Medication Profile | ADR/AEFI | Demographic

**1. ADR/AEFI DETAILS**  
**2. DRUG DETAILS**  
**3. OTHER DETAILS**

Relevant Medical History: Test ADR

Relevant investigation/Lab Data: NIL

Remarks: ADR Reported

Record Verified:

Verified By: [Redacted]

Click here to Confirm the record **16**

**Reporter**

Name: [Redacted]

Designation: Pegawai Farmasi UF54

Department: General Multidiscipline

Contact Number: 1324566

Mobile Number: [Redacted]

Email: dummy1001@moh.com.my

Address: Jalan Salleh, 84000 Muar, Johor.

Date Of Report: 10/11/2022

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

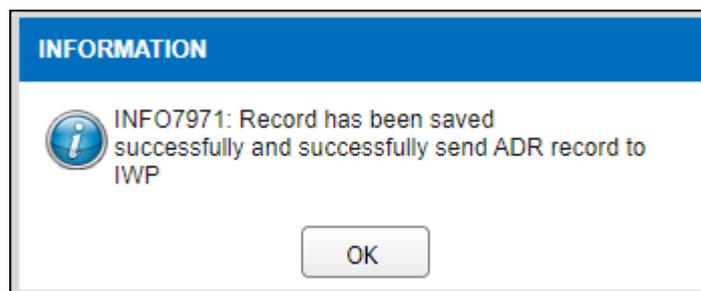


Figure 3.1-13 Information Message

- 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

**ADR REPORTING**

Select Registered Patient

ADR No.  MRN

Suspected Drug Description  ADR Description

Reported Date From  Reported Date To

Reported By  Status

Department

Basic Search

<< 1 / 5 >> [ 1 - 10 / 49 ]

ADR No	MRN	Suspected Drug Desc	ADR Description	Reported By	Reported Date	Status	Verified By	Remarks	Department
ADR180000858		Hepatitis B 10mcg HbsAg Vaccine (Pediatric)	Patient received hepatitis B vaccine at KK Sagil, Tangkak on 12/12/2018 around 1pm. He developed fever at... <small>Patient received hepatitis B vaccine</small>		16/12/2018	NPRA Received			Pharmacy

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

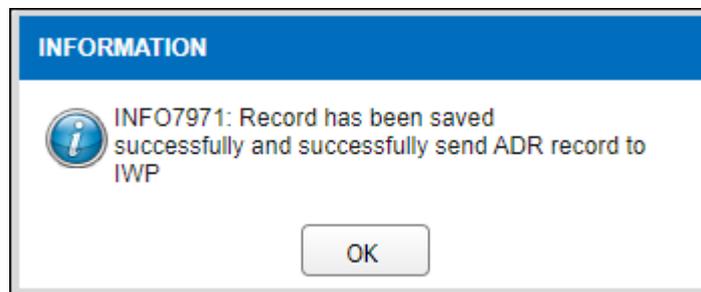


Figure 3.1-15 Information Message

- 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

**ADVERSE DRUG REACTION**

CXXX XXXX XXX Mykad  Age 34 Years 01 Months 02 Days Gender Male MRN

Address  Phone And Email  Diagnosis

Height  cm Weight  kg BMI/BSA 0/0 m<sup>2</sup> (Last Updated : ) Nationality : Warganegara

Upload Photo

ADR Demographic

1. ADR DETAILS

2. DRUG DETAILS

3. OTHER DETAILS

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

**ADR REPORTING**

Select Registered Patient

ADR No.  MRN

Suspected Drug Description  ADR Description

Reported Date From  Reported Date To

Reported By  Status

Department

Basic Search

< < 1 / 5 > >

ADR No	MRN	Suspected Drug Desc	ADR Description	Reported By	Reported Date	Status	Verified By	Remarks	Department
ADR180000858	HPSF00252137	Hepatitis B 10mcg HbsAg Vaccine (Pediatric)	Patient received hepatitis B vaccine at KK Sagil, Tangkak on 12/12/2018 around 1pm. He developed fever at... <small>Patient received hepatitis B vaccine</small>		16/12/2018	Feedback Received	J		Pharmacy

[ 1 - 10 / 49 ]

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

**NPRA FEEDBACK**

ADR No  \* NPRA Report No  \*

Feedback Date  \* Casual Grading by Facility

Status

< < 1 / 1 > >

[ 1 - 2 / 2 ]

Characterisation	Product Name	Active Ingredient	ADR Terminology	Relatedness
Suspected	EUVAX-B INJECTION 20MCG/1.0ML	HEPATITIS B VIRUS	Pyrexia	Probable
Suspected	EUVAX-B INJECTION 20MCG/1.0ML	HEPATITIS B VIRUS	Loose stools	Probable

Figure 3.1-18 NPRA Feedback

**18**

CXXX XXXX XXX Mykad  Age 34 Years 01 Months 02 Days Gender Male MRN

Address  Phone And Email  Diagnosis

Height  cm Weight  kg BMI/BSA 0/0 m<sup>2</sup> (Last Updated : ) Nationality : Warganegara

Upload Photo

ADR Demographic

1. ADR DETAILS  
2. DRUG DETAILS  
3. OTHER DETAILS

Figure 3.1-19 Print ADR Report

**STEP 18**

Click on the button to print the ADR Report



<b>REPORT ON SUSPECTED ADVERSE DRUG REACTION/AEFI</b>									
<b>NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING</b>									
<b>ADR NO : ADR210000283</b>				<a href="http://www.npra.gov.my">www.npra.gov.my</a>					
(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 <b>Confidential</b> .)									
REPORT No ..... (for office use only)									
<b>PATIENT INFORMATION</b>									
Patient NRIC	Age	Sex	Wt (kg)	Ethnic Group	Institution				
900821101010	31 Years 03 Months 17 Days	Female		Bintulu	Hosp. Pakar Sultanah Fatimah				
<b>ADVERSE REACTION DESCRIPTION</b>									
test									
<b>Skin Reaction</b> :									
<b>Please specify Part of Body Affected :</b>									
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 <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	N/A (drug continued) <input checked="" type="checkbox"/>					
Reaction reappeared after reintroducing suspected drug	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	N/A (not reintroduced) <input checked="" type="checkbox"/>					
Extent of reaction :	Mild <input checked="" type="checkbox"/>	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>	Unknown <input type="checkbox"/>					
Treatment of adverse reaction & action taken	iv hydrocortisone 100mg stat , bd 3/7								
Outcome :	Recovered <input checked="" type="checkbox"/>	Recovering <input type="checkbox"/>	Recovered With Sequelae <input type="checkbox"/>	Not Recovered <input type="checkbox"/>	Unknown <input type="checkbox"/>				
Seriousness:	Life Threatening <input type="checkbox"/>	Hospitalization/Prolonged Hospitalization <input type="checkbox"/>	Disability / <input type="checkbox"/>	Birth Defect <input type="checkbox"/>					
<b>Suspected Drug :</b>									
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-Cesophagea I Reflux Disease (Gord)
<b>Concomitant Drug :</b>									
<b>Interaction Drug :</b>									
** Please attach further papers if necessary									
<b>Relevant Investigations/Laboratory Data</b>				<b>Relevant Medical History</b>					
test				test					
<b>Reporter</b>									
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

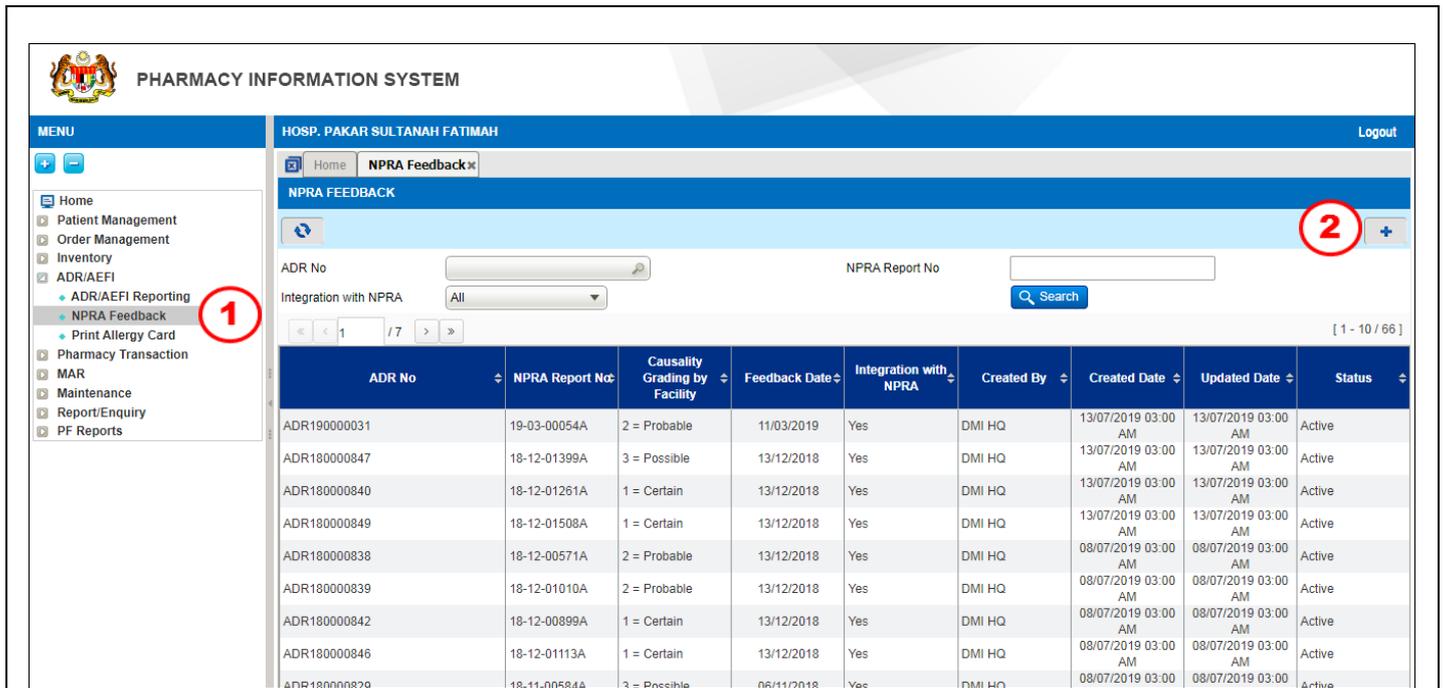


Figure 3.2-1 NPRA Feedback

**Note**

Search for NPRA Feedback record by below criteria: -

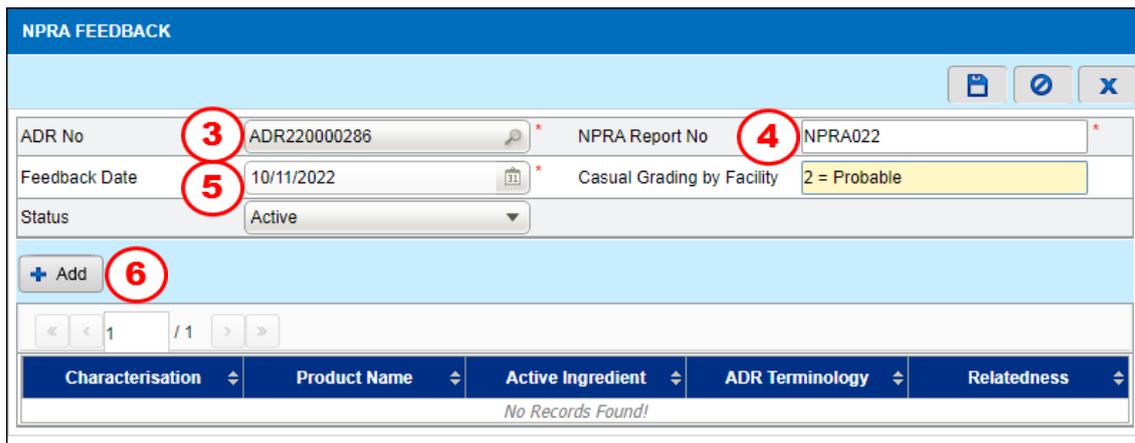
No	Field	Description	Remark
a	ADR No	Search by selecting a number from ADR No	Allow user to search existing transaction based on ADR No
b	NPRA Report No	Search by entering NPRA Report No	Allow user to search existing transaction based on NPRA Report No
c	Integration with NPRA	Select from drop down menu: - 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



ADR No	ADR220000286	NPRA Report No	NPRA022
Feedback Date	10/11/2022	Casual Grading by Facility	2 = Probable
Status	Active		

Characterisation	Product Name	Active Ingredient	ADR Terminology	Relatedness
No Records Found!				

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**

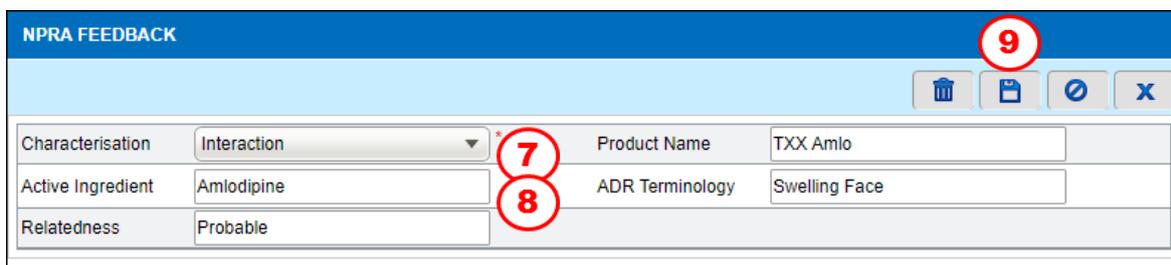
Enter **NPRA Report No**

**STEP 5**

Select **Feedback Date**

**STEP 6**

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



Characterisation	Interaction	Product Name	TXX Amlol
Active Ingredient	Amlodipine	ADR Terminology	Swelling Face
Relatedness	Probable		

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):

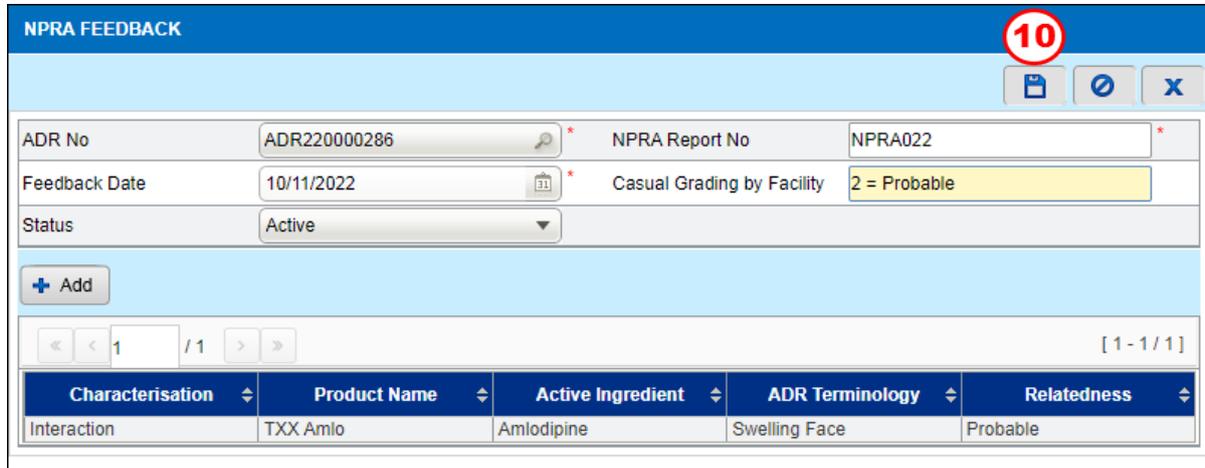
- **Active Ingredient**
- **Product Name**
- **ADR Terminology**
- **Relatedness**

**STEP 9**

Click on the  button to save the record

**Note**

Record will be updated as shown in Figure 3.2-4

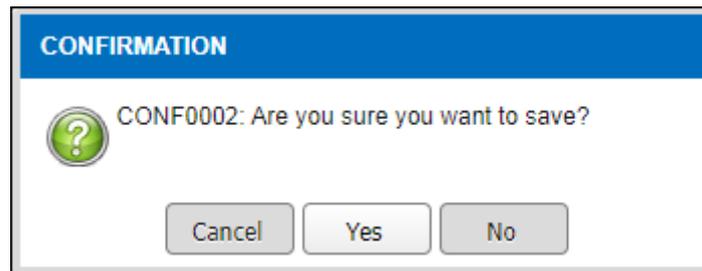


Characterisation	Product Name	Active Ingredient	ADR Terminology	Relatedness
Interaction	TXX Amllo	Amlodipine	Swelling Face	Probable

**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



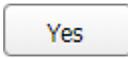
CONFIRMATION

CONF0002: Are you sure you want to save?

Cancel Yes No

**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

**PHARMACY INFORMATION SYSTEM**

HOSP. PAKAR SULTANAH FATIMAH Logout

Home | **Print Allergy Card**

**PRINT ALLERGY CARD**

MRN:  Status: All

Date Recorded From:  Date Recorded To:

Printed: All Search

Patient MRN	Patient Name	Allergen	Reaction Details	Location	Recorded By	Recorded Date	Status	Printed
HPSF00017312	XXXXXXXXXX XXXX XXX XXXXXX	NA	rash itchiness			27/05/2014 01:32 AM	Confirmed	No
HPSF00027296	TXX XXX XXX	metronidazole	rashes			03/07/2014 10:31 AM	To be confirmed	No
HPSF00026168	TXX XXX XXXX	Acetazolamide 250 mg Tablet	rash			03/07/2014 11:27 AM	To be confirmed	No
HPSF00026168	TXX XXX XXXX	Potassium Chloride 600 mg SR Tablet	rash			03/07/2014 11:28 AM	To be confirmed	No
HPSF00026168	TXX XXX XXXX	Tramadol HCl 50 mg Capsule/Tablet	rash			03/07/2014 11:29 AM	To be confirmed	No
HPSF00025632	SXXXXXX XXXXX XXXXXX	seafood	facial rash, swelling			03/07/2014 11:46 AM	To be confirmed	No
HPSF00020513	NXXX XXXXXXXX XXXXX XXXX XXXXXX	SEAFOOD	RASH			03/07/2014 11:47 AM	Confirmed	No
HPSF00017251	RXXXXX XXX XXXXXX		urticaria			26/05/2014 08:36 PM	Confirmed	No

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	<ul style="list-style-type: none"> <li>- All</li> <li>- Confirmed</li> <li>- Pending for Confirmation</li> <li>- To Print</li> </ul>	<ul style="list-style-type: none"> <li>- All - Allow to search records by status Confirmed, Pending for Confirmation and To Print</li> <li>- Confirmed - Allow to search records of patients with confirmed drug allergy</li> <li>- Pending For Confirmation - Allow to search records of patient with drug allergy that is pending confirmation</li> <li>- To Print - Allow to search records of patient with confirmed drug allergy where allergy cars is not printed yet</li> </ul>
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 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

**ALLERGY CARD PRINTING**

Print In Malay Print In English X



MXXXXX XXXXXX X XXXXXX	Mykad	Age 72 Years 04 Months 08 Days	Gender Female
Address	Phone And Email	Diagnosis	Known Allergies[ 1 ]
Height 160 cm Weight 63 kg BMI/BSA 24.6 / 1.67 m <sup>2</sup> <span>Update</span> (Last Updated : 07/03/2020 )		Nationality : Warganegara	

Type	Allergen	Reaction Details	Severity	Date/Time Occurrence	Recorded By	Date/Time Recorded	Status	Printed	Date/Time Printed	Printed By
Drug	Diclofenac Sodium 50 mg Tablet	rashes	Mild	28/05/2014 10:26 AM		28/05/2014 10:26 AM	Suspected	Yes	16/07/2020 09:30 AM	

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:

Print In Malay

Print In English

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

No. Siri : DAC-11-01060015-00016341

**Kad Alahan Ubat**

Nama : MXXXXX XXXXXX X XXXXXX

No. K/P :

Nama Ubat	Reaksi Alahan
1. Diclofenac (NO BRAND)	rashes

Peringatan

Sila bawa dan tunjukkan kad ini semasa mendapatkan rawatan atau bekalan ubat-ubatan

Pemberitahuan: Kad ini adalah untuk maklumat dan panduan sahaja, Kementerian Kesihatan Malaysia tidak bertanggungjawab atas sebarang penyalahgunaan yang melibatkan kad ini.

---

Tarikh kad dikeluarkan: 10/11/2022 11:39 AM

---

Dikeluarkan Oleh: Hosp. Pakar Sultanah Fatimah  
Kementerian Kesihatan Malaysia

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	<i>Inpatient</i>	<a href="#">Click Here</a>	12	<i>CDR Dispensing</i>	<a href="#">Click Here</a>
2	<i>CDR Order</i>	<a href="#">Click Here</a>	13	<i>Methadone Dispensing</i>	<a href="#">Click Here</a>
3	<i>TDM Order</i>	<a href="#">Click Here</a>	14	<i>PN Dispensing</i>	<a href="#">Click Here</a>
4	<i>PN Order</i>	<a href="#">Click Here</a>	15	<i>Order Management</i>	<a href="#">Click Here</a>
5	<i>IV Order</i>	<a href="#">Click Here</a>	16	<i>Patient Management</i>	<a href="#">Click Here</a>
6	<i>Prepacking</i>	<a href="#">Click Here</a>	17	<i>Radiopharmaceuticals</i>	<a href="#">Click Here</a>
7	<i>Galenical</i>	<a href="#">Click Here</a>	18	<i>Outpatient</i>	<a href="#">Click Here</a>
8	<i>MTAC</i>	<a href="#">Click Here</a>	19	<i>Special Drug Request</i>	<a href="#">Click Here</a>
9	<i>ADR &amp; DAC</i>	<a href="#">Click Here</a>	20	<i>MAR</i>	<a href="#">Click Here</a>
10	<i>Medication Counselling</i>	<a href="#">Click Here</a>	21	<i>DICE</i>	<a href="#">Click Here</a>
11	<i>Ward Pharmacy</i>	<a href="#">Click Here</a>	22		