



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

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

Version	: 13th Edition
Document ID	: U. MANUAL_ADR_DAC



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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

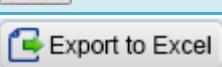
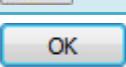
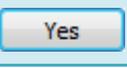
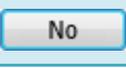
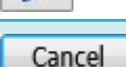
1.3 Organised Sections

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			
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

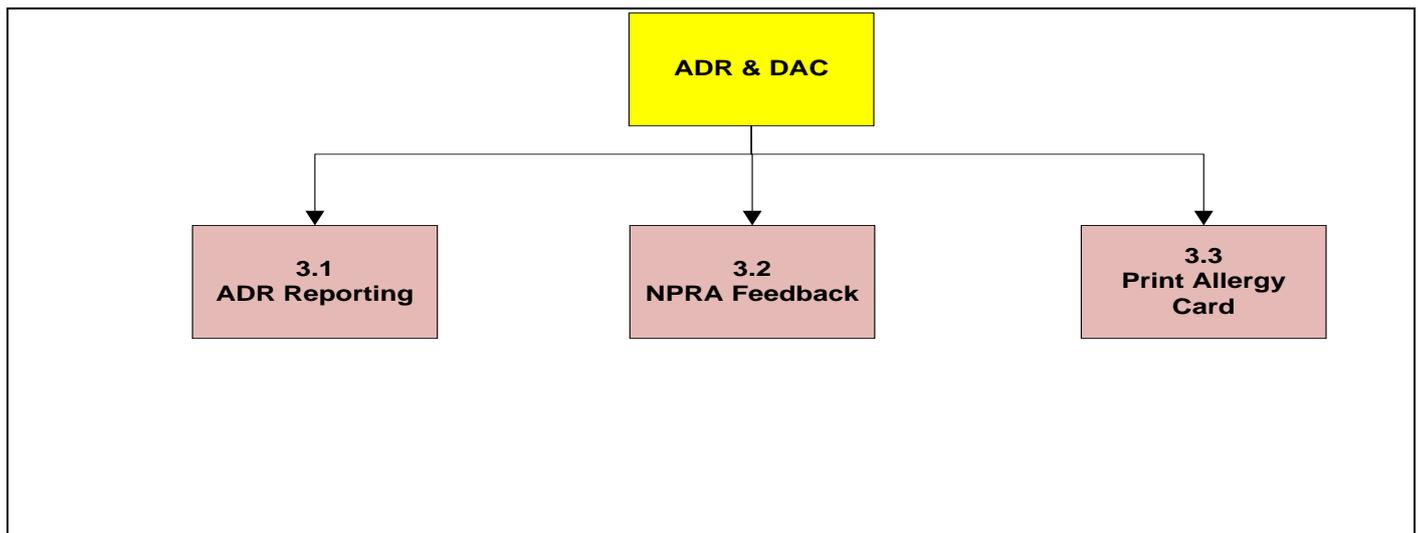


Figure 3.0

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.

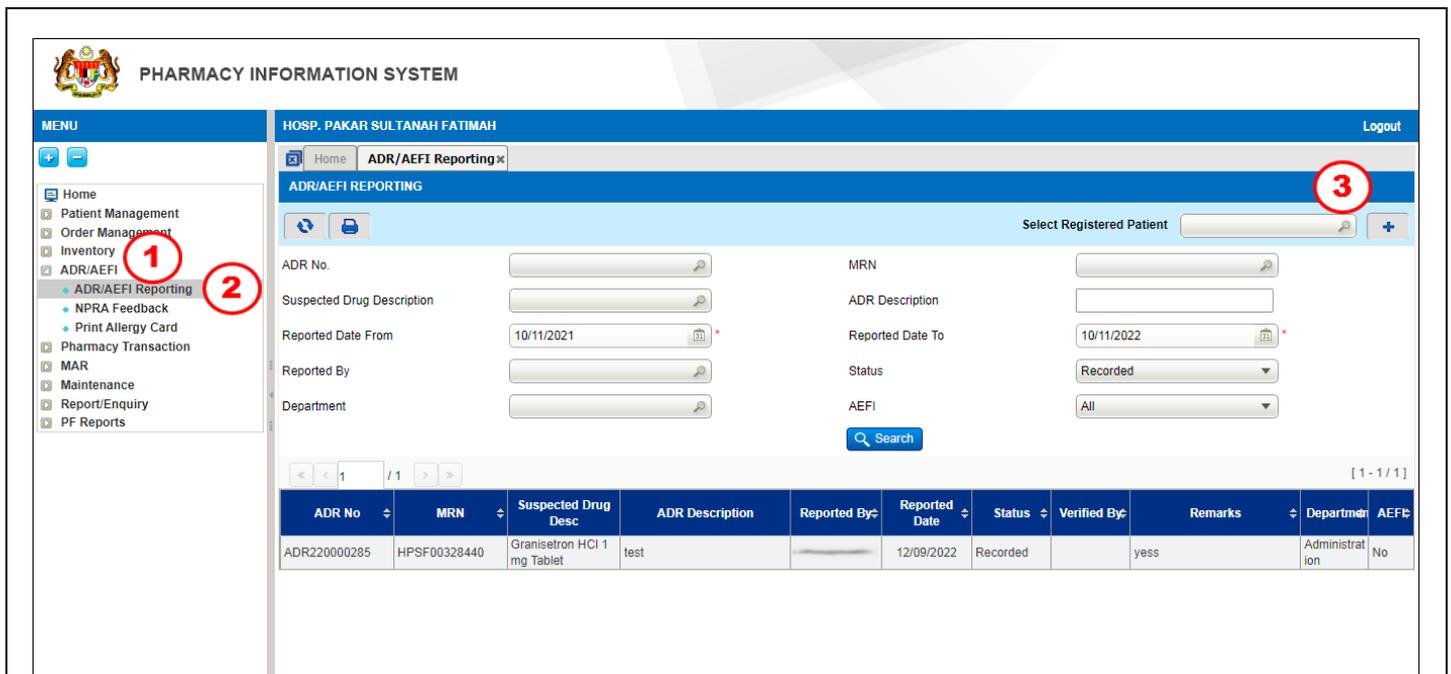


Figure 3.1-1 ADR Reporting Listing Page

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

Table 3.1

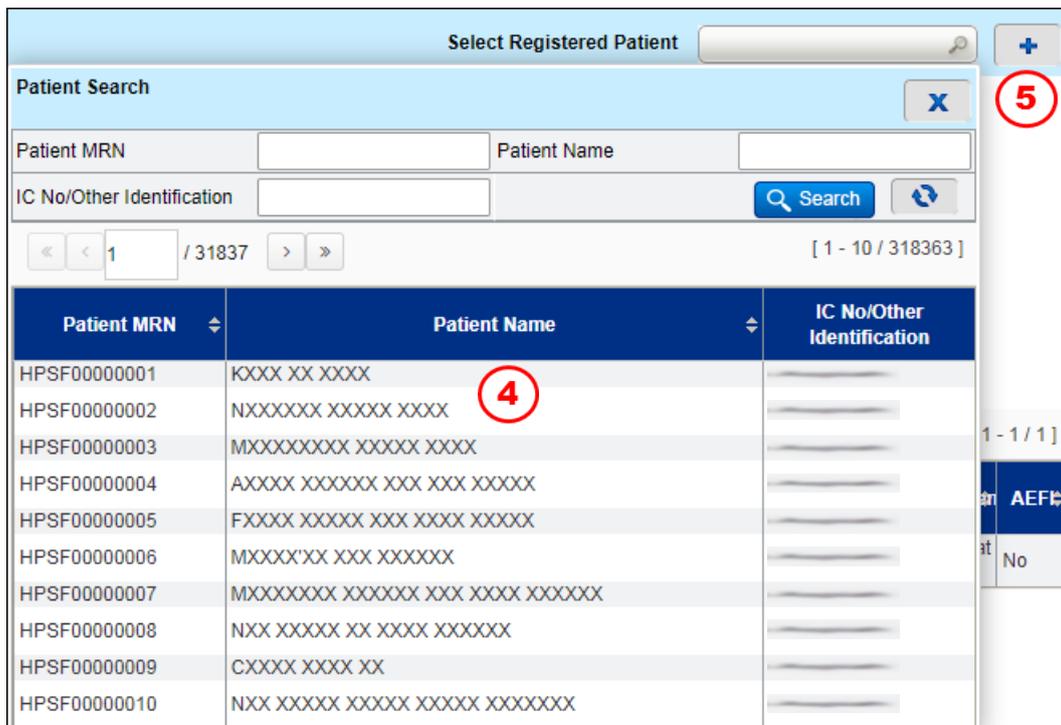


Figure 3.1-2 Enter/Select search MRN

STEP 4

Double-click on selected patient record

STEP 5

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

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 m² (Last Updated :) Nationality : Warganegara

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

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,  [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.

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 m² 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: [Redacted] (8)

Product/Generic Name: [Redacted] (9)

Drug Type: [Redacted] (10)

Frequency: [Redacted]

Therapy Start Date: [Redacted]

Dose: [Redacted]

Indication: [Redacted] (11)

Sample Attached: Quantity: [Redacted]

Route: [Redacted] (12)

Manufacturer: [Redacted]

Product Reg. No.: [Redacted]

Batch Number: [Redacted]

Brand: [Redacted]

Therapy End Date: [Redacted]

Therapy End Date Remark: [Redacted]

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 m² (Last Updated :) Nationality : Warganegara

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

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

13 Relevant Medical History

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

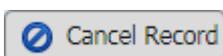
Fields of Reporter section that will be extracted automatically from the user account are:

- 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

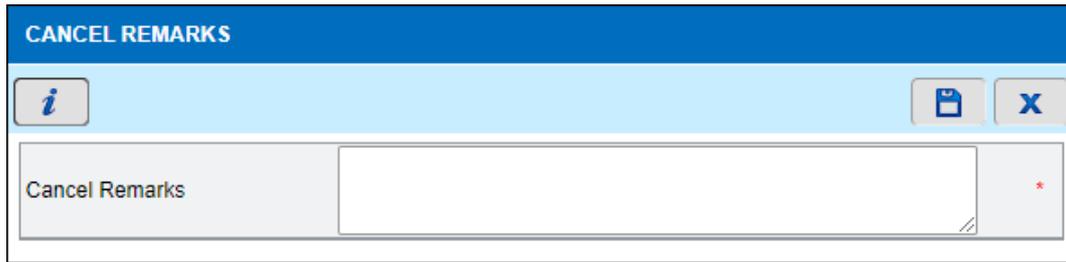


Figure 3.1-10 Cancel Remarks

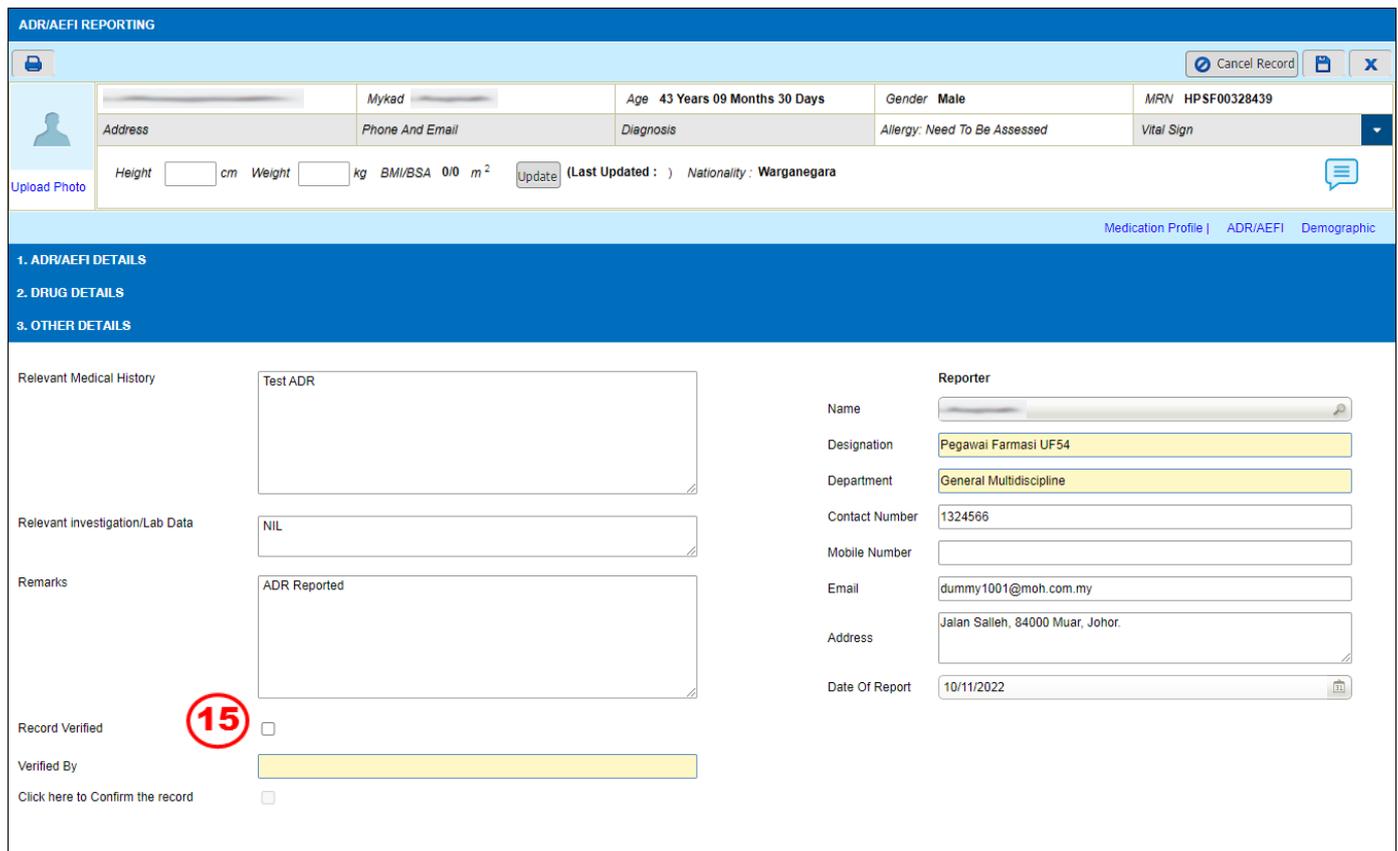


Figure 3.1-11 ADR Reporting

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

17
ADR/AEFI REPORTING

Cancel Record
[Save]
[X]

	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 m² Update (Last Updated :) Nationality : Warganegara

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

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

<p>Relevant Medical History</p> <div style="border: 1px solid #ccc; background-color: #fff9c4; padding: 5px; min-height: 40px;">Test ADR</div> <p>Relevant investigation/Lab Data</p> <div style="border: 1px solid #ccc; background-color: #fff9c4; padding: 5px; min-height: 20px;">NIL</div> <p>Remarks</p> <div style="border: 1px solid #ccc; background-color: #fff9c4; padding: 5px; min-height: 40px;">ADR Reported</div> <p>Record Verified <input checked="" type="checkbox"/></p> <p>Verified By <input style="width: 150px;" type="text"/></p> <p>Click here to Confirm the record 16 <input type="checkbox"/></p>	<p>Reporter</p> <p>Name <input style="width: 150px;" type="text"/></p> <p>Designation <input style="width: 150px;" type="text" value="Pegawai Farmasi UF54"/></p> <p>Department <input style="width: 150px;" type="text" value="General Multidiscipline"/></p> <p>Contact Number <input style="width: 150px;" type="text" value="1324566"/></p> <p>Mobile Number <input style="width: 150px;" type="text"/></p> <p>Email <input style="width: 150px;" type="text" value="dummy1001@moh.com.my"/></p> <p>Address <input style="width: 150px;" type="text" value="Jalan Salleh, 84000 Muar, Johor."/></p> <p>Date Of Report <input style="width: 150px;" type="text" value="10/11/2022"/></p>
--	---

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

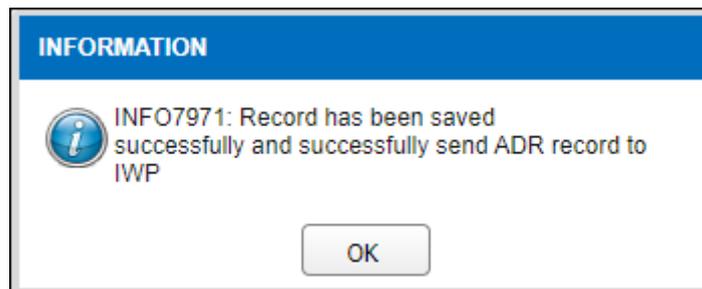


Figure 3.1-13 Information Message

- 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 Sagli, Tangkak on 12/12/2018 around 1pm. He developed fever at... Patient received hepatitis B vaccine		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

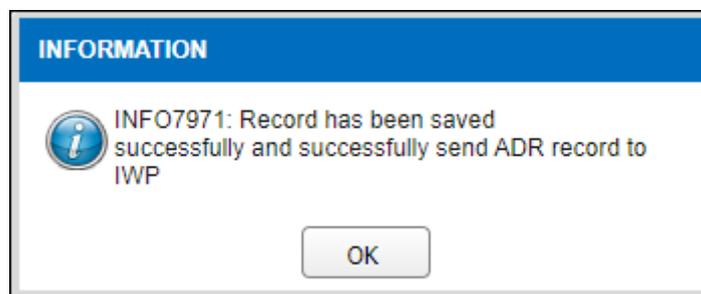


Figure 3.1-15 Information Message

- 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 m² (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 m² (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

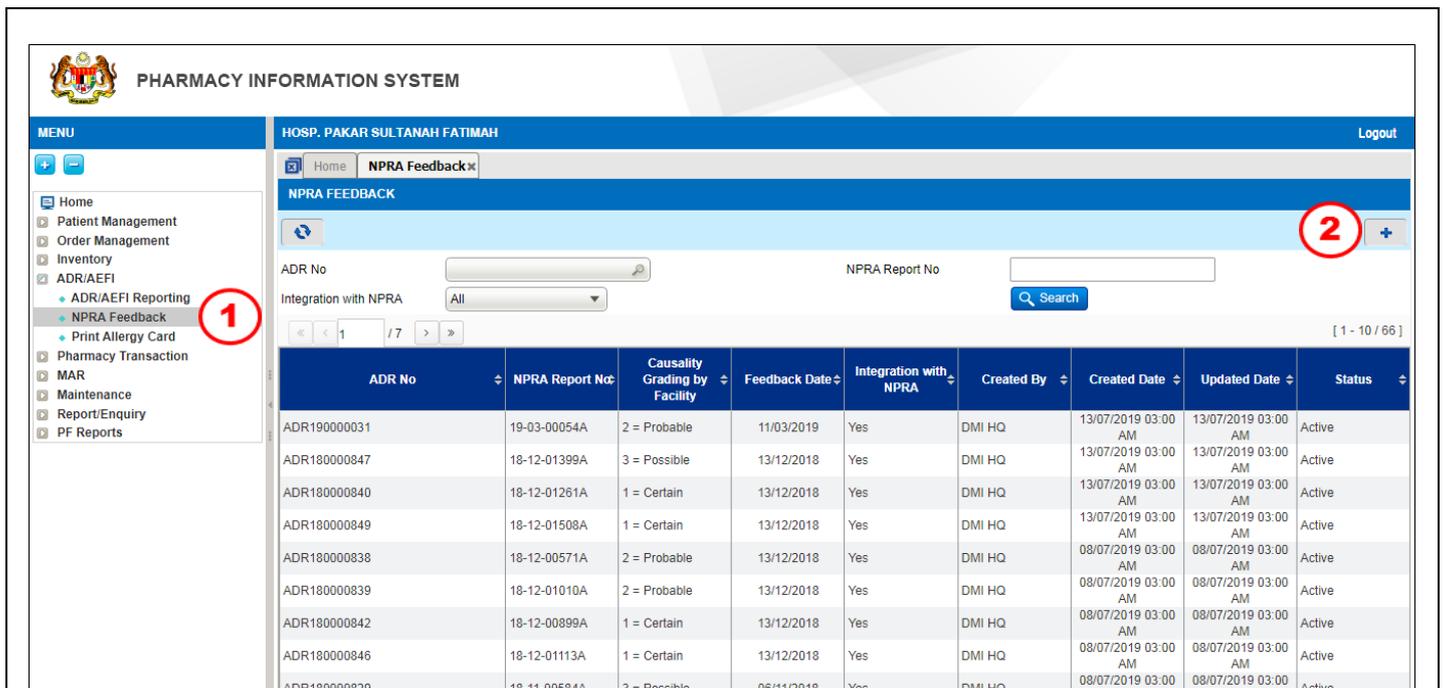


REPORT ON SUSPECTED ADVERSE DRUG REACTION/AEFI									
NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING									
ADR NO : ADR210000283				www.npra.gov.my					
(Please report all suspected drug reaction including those for vaccines and traditional medicines. Do not hesitate to report if some details 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 <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"/>					
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-Cesophagea I 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



ADR No	NPRA Report No	Causality Grading by Facility	Feedback Date	Integration with NPRA	Created By	Created Date	Updated Date	Status
ADR190000031	19-03-00054A	2 = Probable	11/03/2019	Yes	DMI HQ	13/07/2019 03:00 AM	13/07/2019 03:00 AM	Active
ADR180000847	18-12-01399A	3 = Possible	13/12/2018	Yes	DMI HQ	13/07/2019 03:00 AM	13/07/2019 03:00 AM	Active
ADR180000840	18-12-01261A	1 = Certain	13/12/2018	Yes	DMI HQ	13/07/2019 03:00 AM	13/07/2019 03:00 AM	Active
ADR180000849	18-12-01508A	1 = Certain	13/12/2018	Yes	DMI HQ	13/07/2019 03:00 AM	13/07/2019 03:00 AM	Active
ADR180000838	18-12-00571A	2 = Probable	13/12/2018	Yes	DMI HQ	08/07/2019 03:00 AM	08/07/2019 03:00 AM	Active
ADR180000839	18-12-01010A	2 = Probable	13/12/2018	Yes	DMI HQ	08/07/2019 03:00 AM	08/07/2019 03:00 AM	Active
ADR180000842	18-12-00899A	1 = Certain	13/12/2018	Yes	DMI HQ	08/07/2019 03:00 AM	08/07/2019 03:00 AM	Active
ADR180000846	18-12-01113A	1 = Certain	13/12/2018	Yes	DMI HQ	08/07/2019 03:00 AM	08/07/2019 03:00 AM	Active
ADR180000829	18-11-00584A	3 = Possible	06/11/2018	Yes	DMI HQ	08/07/2019 03:00 AM	08/07/2019 03:00 AM	Active

Figure 3.2-1 NPRA Feedback

Note

Search for NPRA Feedback record by below criteria: -

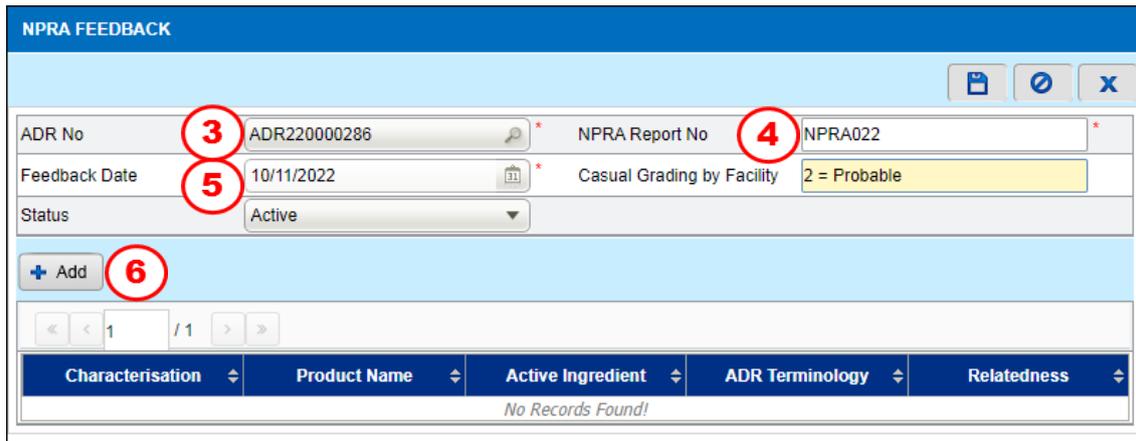
No	Field	Description	Remark
a	ADR No	Search by selecting a number from ADR No	Allow user to search existing transaction based on ADR No
b	NPRA Report No	Search by entering NPRA Report No	Allow user to search existing transaction based on NPRA Report No
c	Integration with NPRA	Select from drop down menu: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

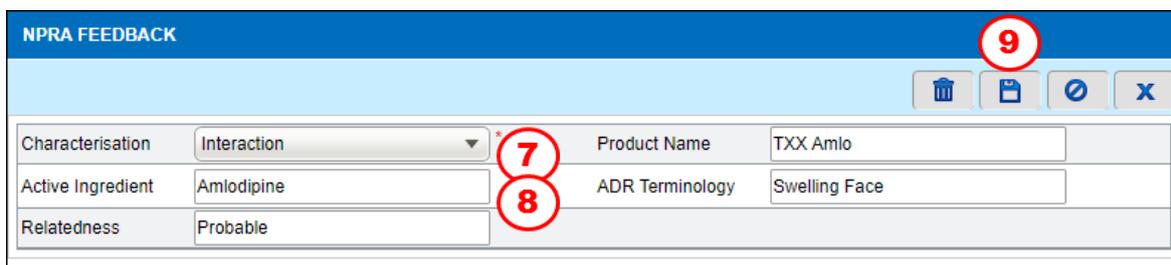
Enter **NPRA Report No**

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 Amla
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):

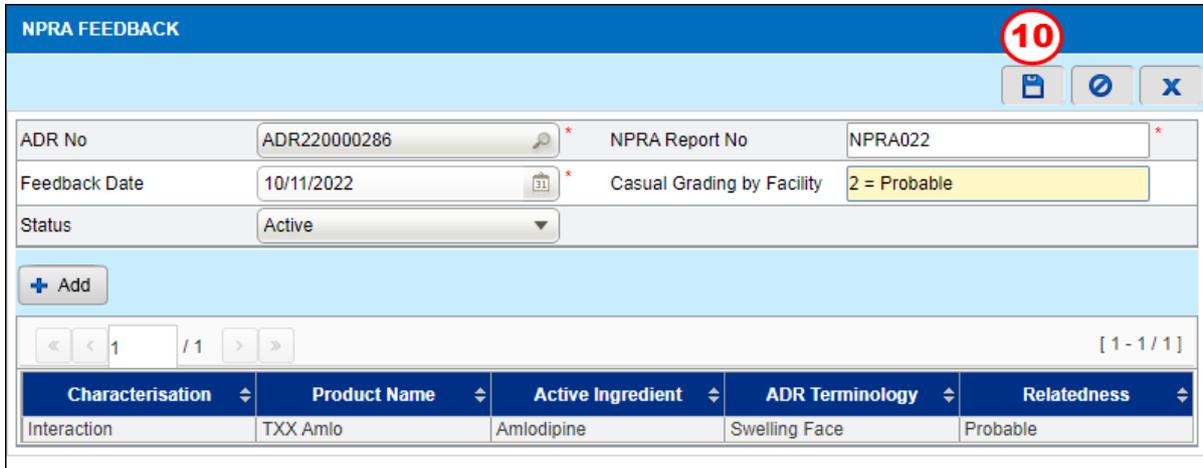
- **Active Ingredient**
- **Product Name**
- **ADR Terminology**
- **Relatedness**

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

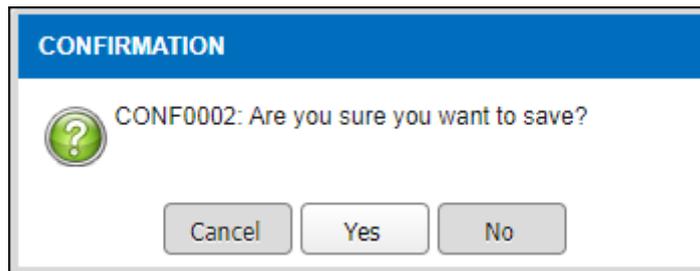
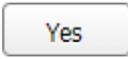


Figure 3.2-5 Confirmation Message

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	<ul style="list-style-type: none"> - All - Confirmed - Pending for Confirmation - To Print 	<ul style="list-style-type: none"> - 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 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 4

	MXXXXX XXXXXX X XXXXXX	Mykad [REDACTED]	Age 72 Years 04 Months 08 Days	Gender Female	MRN HPSF00016341
	Address	Phone And Email	Diagnosis	Known Allergies[1]	Vital Sign

Height cm Weight kg BMI/BSA 24.6 / 1.67 m² (Last Updated : 07/03/2020) Nationality : Warganegara

[1 - 1 / 1]

☐	Type	Allergen	Reaction Details	Severity	Date/Time Occurrence	Recorded By	Date/Time Recorded	Status	Printed	Date/Time Printed	Printed By
<input type="checkbox"/>	Drug	Diclofenac Sodium 50 mg Tablet	rashes	Mild	28/05/2014 10:26 AM	[REDACTED]	28/05/2014 10:26 AM	Suspected	Yes	16/07/2020 09:30 AM	[REDACTED]

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

No. Siri : DAC-11-01060015-00016341
Kad Alahan Ubat

Nama : MXXXXX XXXXXX X XXXXXX
No. K/P : [REDACTED]

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