



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

---

## **User Manual Integrated Web Portal (IWP)**

### **Special Approval Medicine (Approval)**

<b>Version</b>	<b>: 12<sup>th</sup> Edition</b>
<b>Document ID</b>	<b>: HQ_U.MANUAL_IWP_SPECIAL APPROVAL MEDICINE (APPROVAL)</b>



PhIS & CPS Project  
User Manual – Special Approval Medicine (Approval)



© 2011-2021 *Pharmacy Information System & Clinic Pharmacy System (PhIS& CPS) Project*

*CONFIDENTIALCOPYRIGHTEDMATERIAL–The information includes all concepts, comments, recommendations, and material, contained herein shall remain the property of Pharmacy Information System & Clinic Pharmacy 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 & Clinic Pharmacy System (PhIS& CPS) Project execution only*

*Reference ID : HQ\_U.MANUAL\_IWP\_SPECIAL APPROVAL MEDICINE (APPROVAL)-12<sup>th</sup> E*

*Application reference: PhIS& CPS v2.5.1*



## Table of Contents

1.0	Introduction .....	1
1.1	Overview of PhIS .....	1
1.2	Purpose and Objectives .....	1
1.3	Organized Sections .....	1
2.0	Application Standard Features .....	2
2.1	PhIS Legend .....	2
3.0	Special Approval Medicine (Approval) .....	3
	Overview .....	3
	User Group .....	3
	Functional Diagram .....	3
	Functional Description .....	3
3.1	Special Approval Medicine .....	4
3.1.1	Special Approval Medicine Approval .....	4
3.1.2	Special Approval Medicine Assignment .....	41
4.0	Acronyms .....	44
5.0	Links to IWP Modules .....	44

## 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 that geared toward pharmacy excellent care. This implementation would transform most of the current manual process to electronic system would benefit facility end user in the health care sector.

There are 12 modules to assist service 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 Card(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 IWP Special Approval Medicine (Approval) sub-module and its key features and functionalities. The primary objective is to help guide users through the process of completing PhIS application process.

User will understand the following activities in detail:

- KPK Drug Approval
- KPK Item Assign

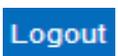
### 1.3 Organized Sections

These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Maintenance (General)
- Section 4 : Acronyms
- Section 5 : Link to IWP Modules

## 2.0 Application Standard Features

### 2.1 PhIS Legend

Standard Legend			
	Login		Reset Login screen
	Logout		Show Help
	Expand Menu		Add/Create New Record
	Collapse Menu		Calendar Icon
	Refresh Screen		Cancel Data Entry
	Search Icon		Mandatory Field
	Search Record		Edit Record
	Close Window		Save Record
	Close All Open Tabs		Delete Record
	Close Screen		Print Document
	Radio Button		Context Menu
	Checkbox		

**Note**

- To learn more about Login Information, kindly click [Login Information](#) Modules for descriptive STEP.

## 3.0 Special Approval Medicine (Approval)

### Overview

The module will provide a portal for configuration guide for the user which describe the basic and advance featured available on the system for KPK. This featured allow user to view, key in the relevant data and approve or reject the transaction.

### User Group

This module is intended for BPF users (subject to user assigned by the BPF)

### Functional Diagram

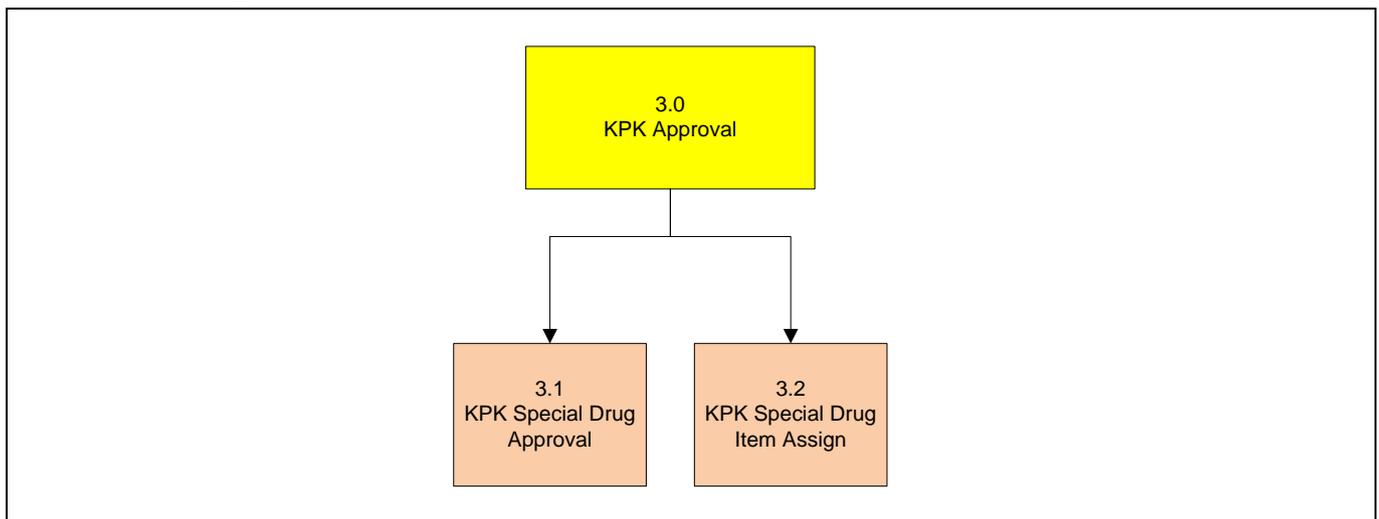


Figure 3.0-1

### Functional Description

KPK Approval module comprises of two (2) main sub modules:

- **KPK Special Drug Approval**

KPK Special Drug Approval screen allows user to approve and fill the approved quantity for KPK Drug Approval.

- **KPK Special Drug Item Assign**

KPK Special Drug Item Assign screen allow user to choose the Item Code for KPK Drug that has been approved at KPK Special Drug Approval screen.

### 3.1 Special Approval Medicine

This function is used to approve special medicine request from the facility and recommend item code for the approved drug.

#### 3.1.1 Special Approval Medicine Approval

This function is used to approve special medicine request from the facility

#### Approval Process – Secretariat

TASK LIST						
<input type="text" value="Facility Name"/>						
<span>&lt; 1 / 2 &gt;</span> <span style="float: right;">[ 1 - 10 / 19 ]</span>						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	C1254/2021	01/07/2021 11:03 AM	New Request	Hospital Pakar Sultanah Fatimah, Muar	

Figure 3.1.1-1 Task List

#### Note

User have option to Click on the Transaction No hyperlink and the Special Approval Medicine screen will be displayed as shown in the Figure 3.1.1-3 to proceed Secretariat task.

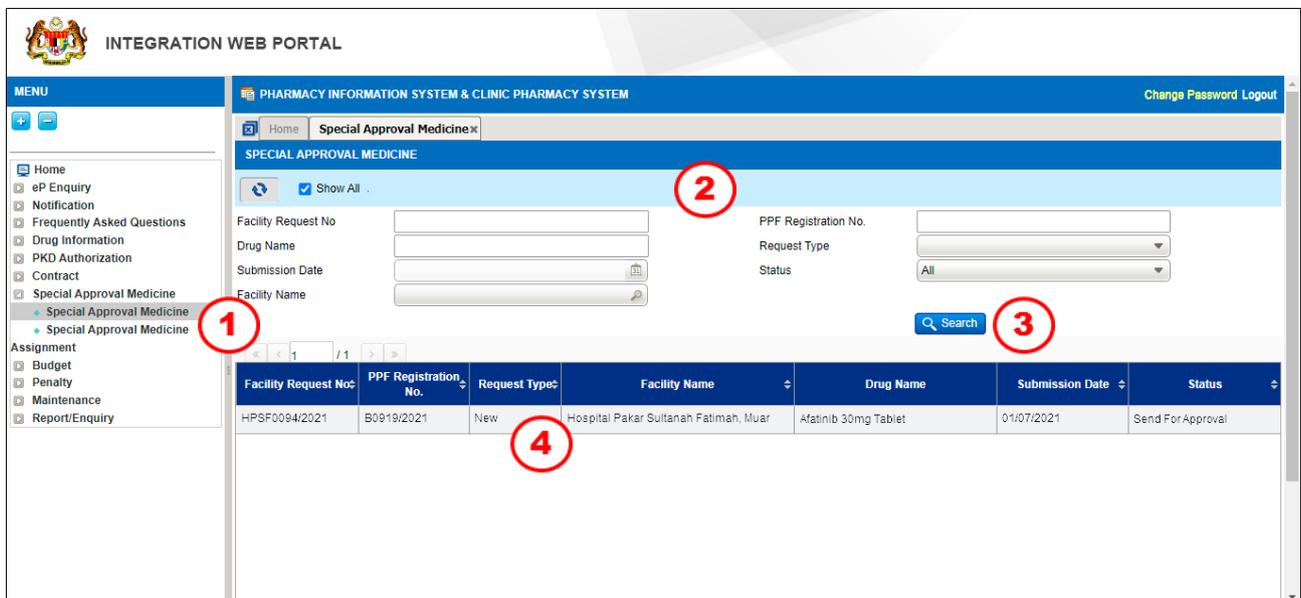


Figure 3.1.1-2 Special Approval Medicine List Page

#### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine'.

#### STEP 2

These search criteria can be used to search for existing Special Approval Medicine records:

- a) Facility Request No
- b) PPF Register No
- c) Drug Name
- d) Request Type
- e) Submission Date
- f) Status
- g) Facility Name

**Note**

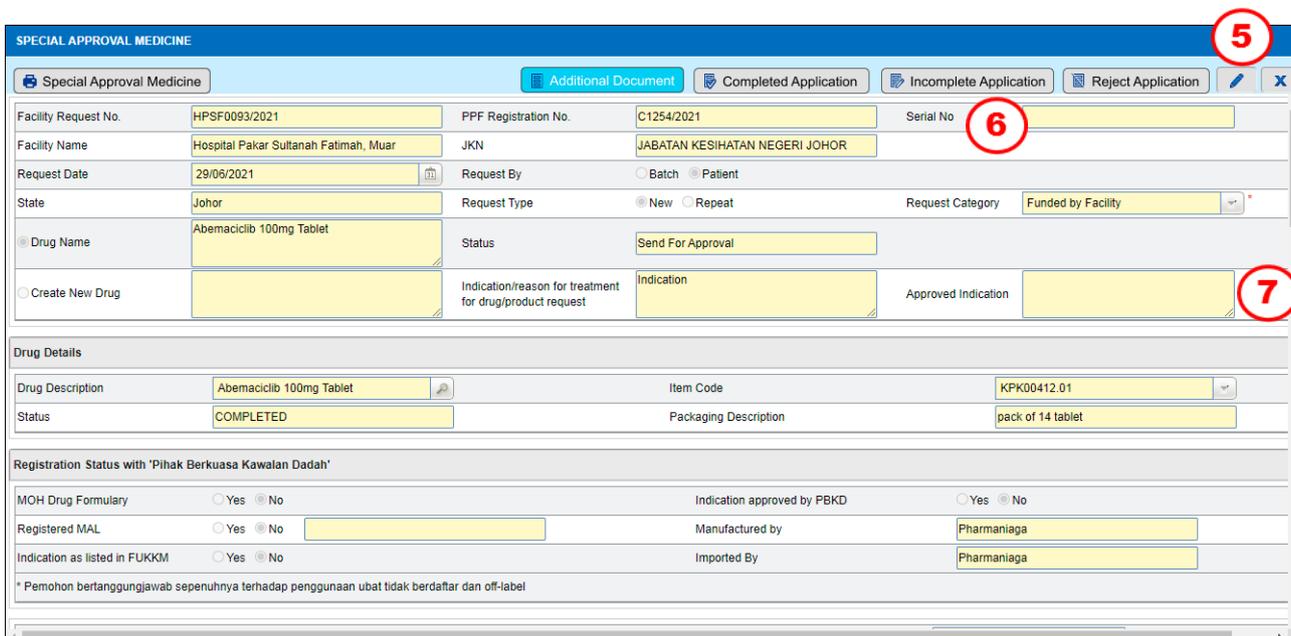
It is recommended to set search 'Status' to 'Send for Approval' if there are too many search results

**STEP 3**

Click on the  button. The result(s) display will be based on the entered criteria.

**STEP 4**

Double click on the selected record and the details of the Special Approval Medicine will be displayed as Figure 3.1.1-2



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine | Additional Document | Completed Application | Incomplete Application | Reject Application

Facility Request No. HPSF0093/2021 | PPF Registration No. C1254/2021 | Serial No. **6**

Facility Name Hospital Pakar Sultanah Fatimah, Muar | JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 | Request By Batch Patient | Request Type New Repeat | Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet | Status Send For Approval

Create New Drug | Indication/reason for treatment for drug/product request Indication Approved Indication **7**

**Drug Details**

Drug Description Abemaciclib 100mg Tablet | Item Code KPK00412.01

Status COMPLETED | Packaging Description pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary Yes No | Indication approved by PBKD Yes No

Registered MAL Yes No | Manufactured by Pharmaniaga

Indication as listed in FUKKM Yes No | Imported By Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

**Figure 3.1.1-3 Special Approval Medicine Edit Page**

**STEP 5**

Click on the  button to edit the Special Approval Medicine screen and fill all the criteria with mandatory flag \*

**Note**

- User is allowed to enter the value of drug assignment even request status not yet 'Approved by KPK/PKPF'. By default, status of drug assign as pending.
- If request is by existing drug name, drug name will be displayed in drug description. User is not allowed to change this value.
- If request is by 'new drug', user has to assign new drug name. Once assign and click on save button for request status as "Approved by KPK/PKPF", status will change to 'Completed'. This status will reflect in 'KPK Special Drug Item Assign' screen.
- Once completed, user is not allowed to change the drug and item. No changes for existing function in 'KPK Special Drug Item Assign'.
- 'Prepacking item' will be exclude from item code assignment list. User should not assign prepacking item as KPK item
- User able to click on  button for incomplete application
- Click on  button to reject application

- Click on  button to view additional information added by facility for incomplete application. Button will be highlighted in blue  if any details added by user at facility

**STEP 6**

Enter the **Serial No** column

**Note**

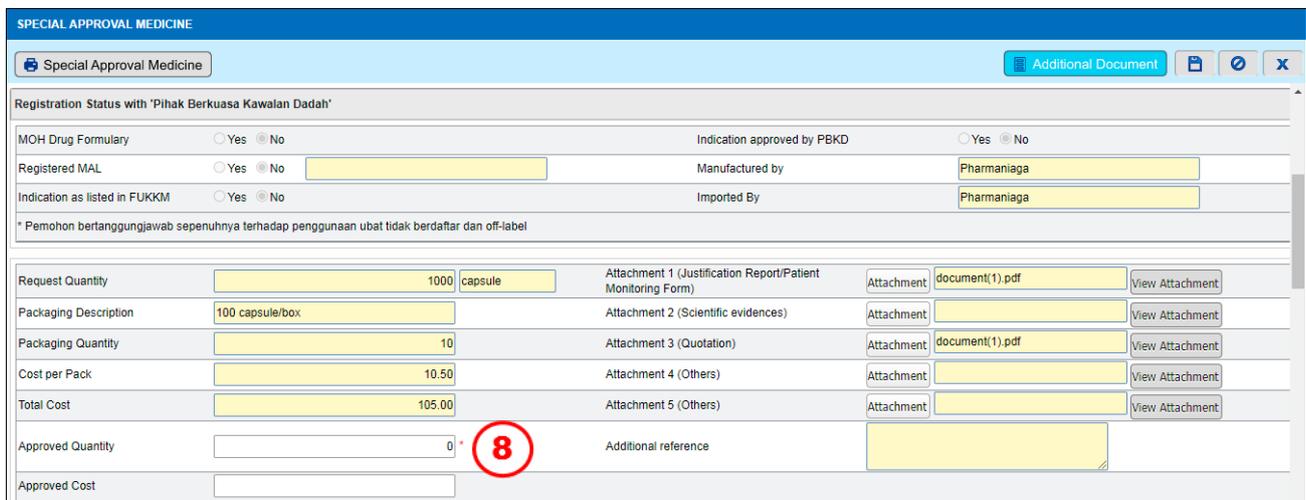
- User is allowed to enter the Serial No column, its free text with maximum 300 characters. This value will be maintained by HQ. Same fields will be displayed in Facility as read-only.

**STEP 7**

Enter the **Approved Indication** column

**Note**

User is allowed to enter the 'Approved Indication'. Free text with maximum 300 characters. This value will be maintained by HQ. Same fields will be displayed in Facility as read-only.



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine Additional Document

Registration Status with 'Pihak Berkuasa Kawalan Dadah'

MOH Drug Formulary  Yes  No Indication approved by PBKD  Yes  No

Registered MAL  Yes  No  Manufactured by

Indication as listed in FUKKM  Yes  No Imported By

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Request Quantity	<input type="text" value="1000"/> capsule	Attachment 1 (Justification Report/Patient Monitoring Form)	Attachment	<input type="text" value="document(1).pdf"/>	<input type="button" value="View Attachment"/>
Packaging Description	<input type="text" value="100 capsule/box"/>	Attachment 2 (Scientific evidences)	Attachment	<input type="text" value=""/>	<input type="button" value="View Attachment"/>
Packaging Quantity	<input type="text" value="10"/>	Attachment 3 (Quotation)	Attachment	<input type="text" value="document(1).pdf"/>	<input type="button" value="View Attachment"/>
Cost per Pack	<input type="text" value="10.50"/>	Attachment 4 (Others)	Attachment	<input type="text" value=""/>	<input type="button" value="View Attachment"/>
Total Cost	<input type="text" value="105.00"/>	Attachment 5 (Others)	Attachment	<input type="text" value=""/>	<input type="button" value="View Attachment"/>
Approved Quantity	<input type="text" value="0"/> <b>8</b>	Additional reference	<input type="text" value=""/>		
Approved Cost	<input type="text" value=""/>				

**Figure 3.1.1-3 KPK Special Drug Approval**

**STEP 8**

Enter the **Approved Quantity** column



Secretariat

Remarks  **9**

Action By

JKKU Approval  Yes  No

Date

**Figure 3.1.1-4 Secretariat Review**

**STEP 9**

Enter **Remarks**, **JKKU Approval** and **Date** accordingly

SPECIAL APPROVAL MEDICINE
10

Special Approval Medicine
Additional Document
X

Facility Request No.	HPSF0093/2021	PPF Registration No.	C1254/2021	Serial No.	A86002900
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	29/06/2021	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat		Request Category
<input checked="" type="radio"/> Drug Name	Abemaciclib 100mg Tablet	Status	Send For Approval		
<input type="radio"/> Create New Drug		Indication/reason for treatment for drug/product request	Indication	Approved Indication	Complete

**Drug Details**

Drug Description	Abemaciclib 100mg Tablet	Item Code	KPK00412.01
Status	COMPLETED	Packaging Description	pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input type="radio"/> Yes <input checked="" type="radio"/> No
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	Pharmaniaga
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	Pharmaniaga

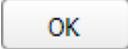
\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

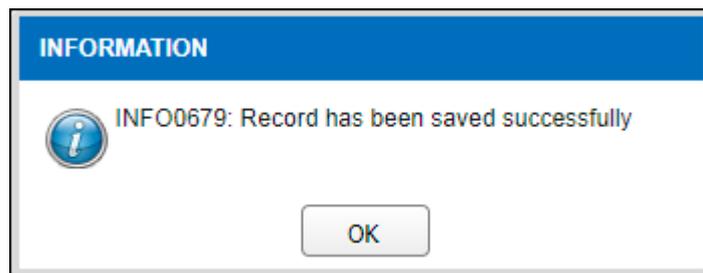
**Figure 3.1.1-5 Special Approval Medicine**

**STEP 10**

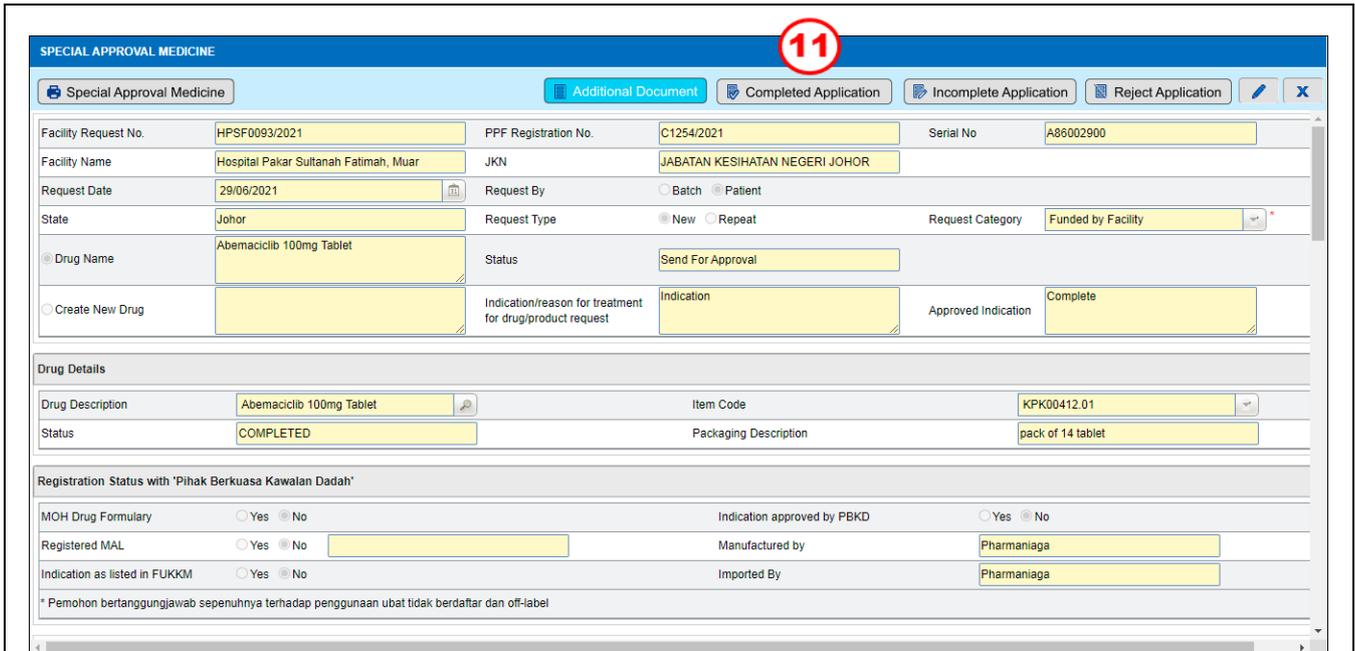
Click on the  button to save the record

**Note**

Record will save when user click on the  button as shown in Figure 3.1.1-6



**Figure 3.1.1-6 Information Message**



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine | Additional Document | Completed Application | Incomplete Application | Reject Application

Facility Request No. HPSF0093/2021 | PPF Registration No. C1254/2021 | Serial No. A86002900

Facility Name Hospital Pakar Sultanah Fatimah, Muar | JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 | Request By Batch Patient | Request Type New Repeat | Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet | Status Send For Approval

Indication/reason for treatment for drug/product request | Indication | Approved Indication Complete

**Drug Details**

Drug Description Abemaciclib 100mg Tablet | Item Code KPK00412.01

Status COMPLETED | Packaging Description pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary Yes No | Indication approved by PBKD Yes No

Registered MAL Yes No | Manufactured by Pharmaniaga

Indication as listed in FUKKM Yes No | Imported By Pharmaniaga

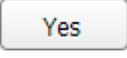
\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-7 Special Approval Medicine

**STEP 11**

Click on the  button to approve the record.

**Note**

- Confirmation message will be display as shown in Figure 3.1.1-8, click on  button

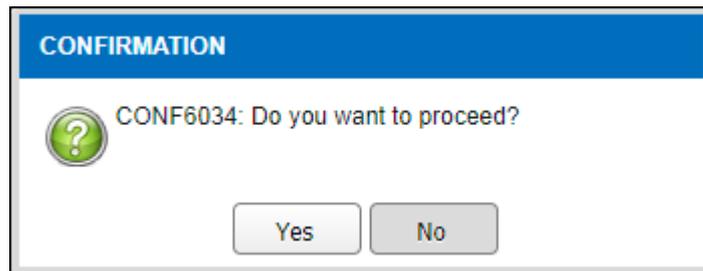


Figure 3.1.1-8 Confirmation Message

- Status will be updated to 'Pending Ketua Seksyen Recommendation' and status will be sync back to facility
- All field disabled for secretariat
- Request will flow to Ketua Seksyen for recommendation

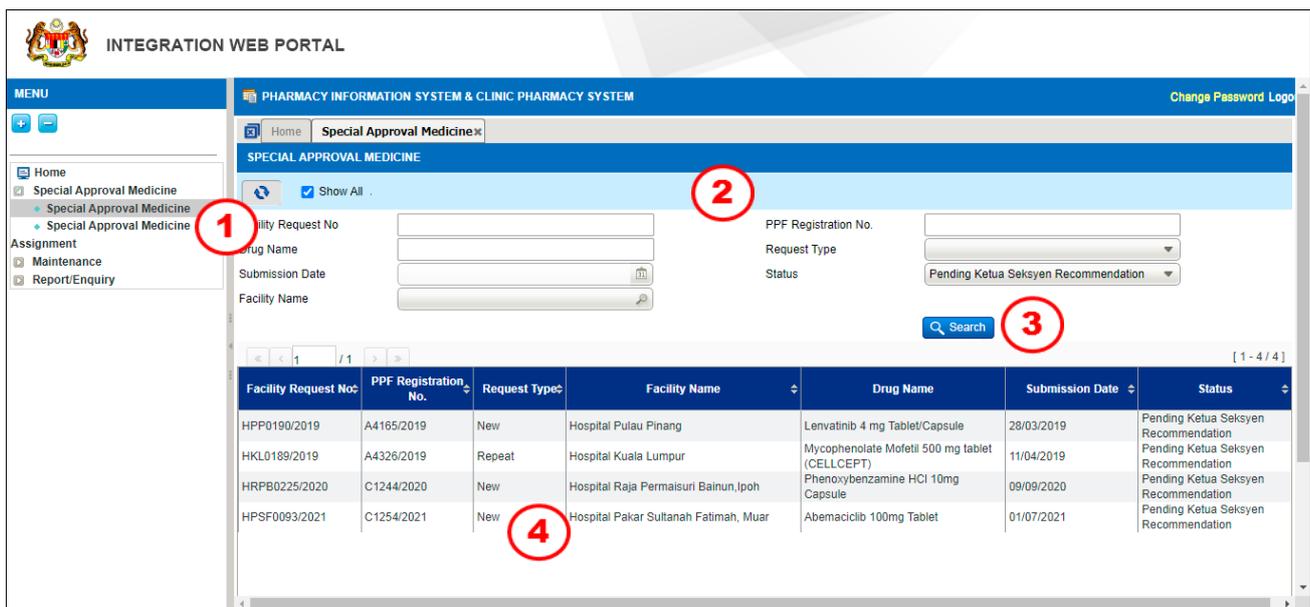
## Approval Process – Ketua Seksyen

TASK LIST						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	C1254/2021	06/07/2021 12:54 PM	Pending Ketua Seksyen Recommendation	Hospital Pakar Sultanah Fatimah, Muar	HQ KPK Secretariat

Figure 3.1.1-9 Task List

### Note

User have option to Click on the Transaction No hyperlink and the Special Approval Medicine screen will be displayed as shown in the Figure 3.1.1-11 to proceed Ketua Seksyen task.



INTEGRATION WEB PORTAL

MENU

- Home
- Special Approval Medicine
- Special Approval Medicine
- Special Approval Medicine
- Assignment
- Maintenance
- Report/Enquiry

PHARMACY INFORMATION SYSTEM & CLINIC PHARMACY SYSTEM

Home Special Approval Medicine

SPECIAL APPROVAL MEDICINE

Facility Request No:

Drug Name:

Submission Date:

Facility Name:

PPF Registration No.:

Request Type:

Status: Pending Ketua Seksyen Recommendation

Search

Facility Request No.	PPF Registration No.	Request Type	Facility Name	Drug Name	Submission Date	Status
HPP0190/2019	A4165/2019	New	Hospital Pulau Pinang	Lenvatinib 4 mg Tablet/Capsule	28/03/2019	Pending Ketua Seksyen Recommendation
HKL0189/2019	A4326/2019	Repeat	Hospital Kuala Lumpur	Mycophenolate Mofetil 500 mg tablet (CELLCEPT)	11/04/2019	Pending Ketua Seksyen Recommendation
HRPB0225/2020	C1244/2020	New	Hospital Raja Permaisuri Bainun, Ipoh	Phenoxybenzamine HCl 10mg Capsule	09/09/2020	Pending Ketua Seksyen Recommendation
HPSF0093/2021	C1254/2021	New	Hospital Pakar Sultanah Fatimah, Muar	Abemaciclib 100mg Tablet	01/07/2021	Pending Ketua Seksyen Recommendation

Figure 3.1.1-10 Special Approval Medicine

### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine'.

### STEP 2

These search criteria can be used to search for existing Special Approval Medicine records:

- Facility Request No
- PPF Register No
- Drug Name
- Request Type
- Submission Date
- Status
- Facility Name

### Note

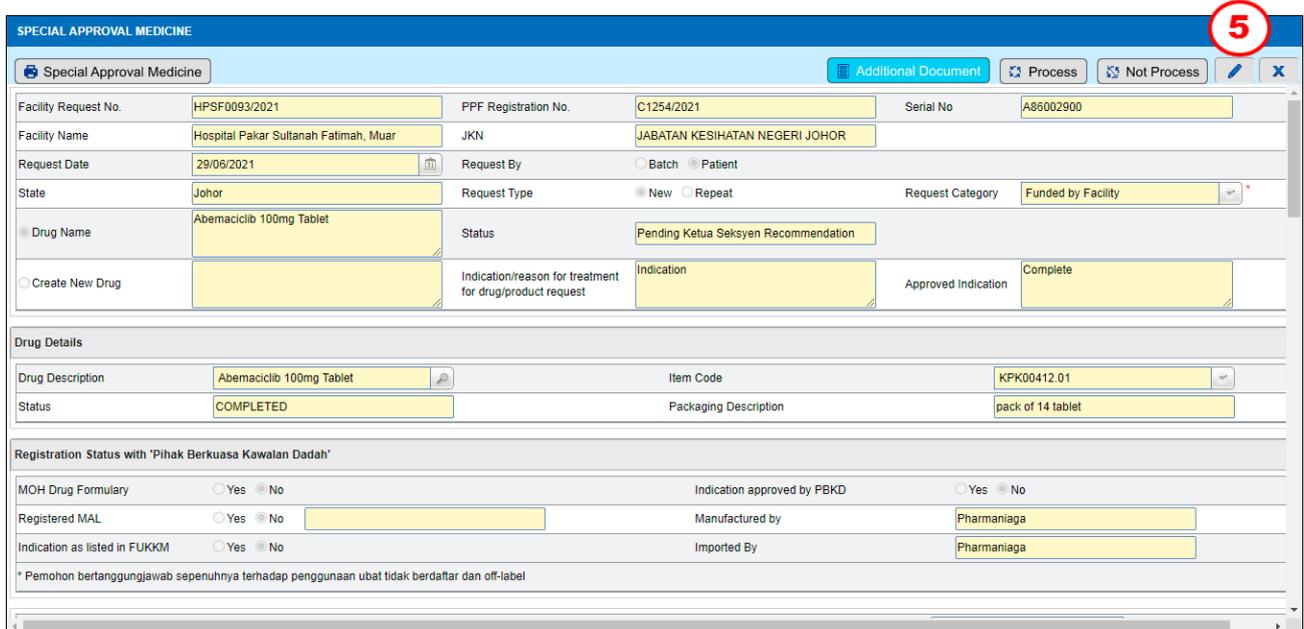
It is recommended to set search 'Status' to 'Pending Ketua Sekyen Recommendation' if there are too many search results

### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

**STEP 4**

Double click on the selected record and the details of the Special Approval Medicine will be displayed as Figure 3.1.1-11



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine | Additional Document | Process | Not Process

Facility Request No. HPSF0093/2021 | PPF Registration No. C1254/2021 | Serial No. A86002900

Facility Name Hospital Pakar Sultanah Fatimah, Muar | JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 | Request By  Batch  Patient

State Johor | Request Type  New  Repeat | Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet | Status Pending Ketua Seksyen Recommendation

Indication/reason for treatment for drug/product request | Indication | Approved Indication Complete

**Drug Details**

Drug Description Abemaciclib 100mg Tablet | Item Code KPK00412.01

Status COMPLETED | Packaging Description pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary  Yes  No | Indication approved by PBKD  Yes  No

Registered MAL  Yes  No | Manufactured by Pharniagi

Indication as listed in FUKKM  Yes  No | Imported By Pharniagi

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

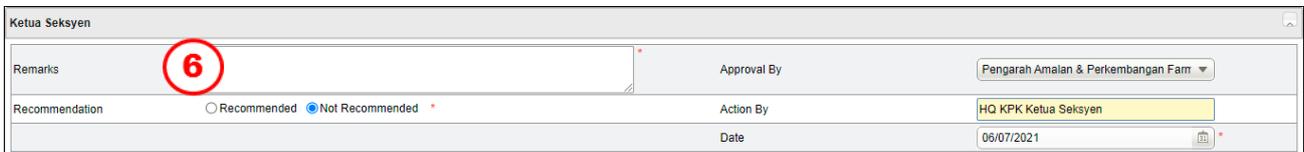
Figure 3.1.1-11 Special Approval Medicine

**STEP 5**

Click on  button to edit the record

**Note**

If user click on  button, status will be updated to 'Not Processed' and status will be sync back to facility



**Ketua Seksyen**

Remarks  | Approval By Pengarah Amalan & Perkembangan Farm

Recommendation  Recommended  Not Recommended | Action By HQ KPK Ketua Seksyen

Date 06/07/2021

Figure 3.1.1-12 Ketua Seksyen Review

**STEP 6**

Enter **Remarks**, **Recommendation** and **Date** accordingly

**Note**

'Approve By' value will be defaulted based on request criteria, however 'Ketua Seksyen' still able to change the value:

- Pengarah Amalan & Perkembangan Farmasi (Pegarah A&P)
- Pengarah Kanan Perkhidmatan Farmasi (PKPF)
- Ketua Pengarah Kesihatan (KPK)

SPECIAL APPROVAL MEDICINE
7

Special Approval Medicine
Additional Document
X

Facility Request No.	HPSF0093/2021	PPF Registration No.	C1254/2021	Serial No	A86002900
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	29/06/2021	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat		
Drug Name	Abemaciclib 100mg Tablet	Status	Pending Ketua Seksyen Recommendation		
Indication/reason for treatment for drug/product request		Indication		Approved Indication	Complete

**Drug Details**

Drug Description	Abemaciclib 100mg Tablet	Item Code	KPK00412.01
Status	COMPLETED	Packaging Description	pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PEKD	<input type="radio"/> Yes <input checked="" type="radio"/> No
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	Pharmaniaga
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-13 Special Approval Medicine

**STEP 7**

Click on  button to save the record

**Note**

Record will save when user click on the  button as shown in Figure 3.1.1-14

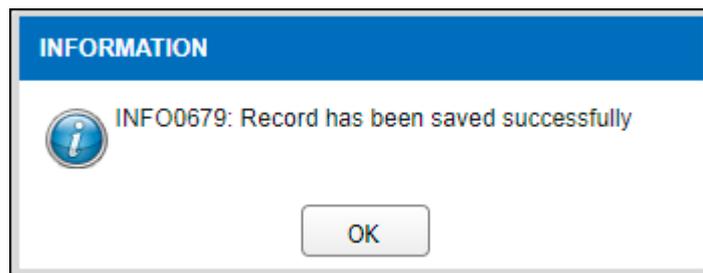
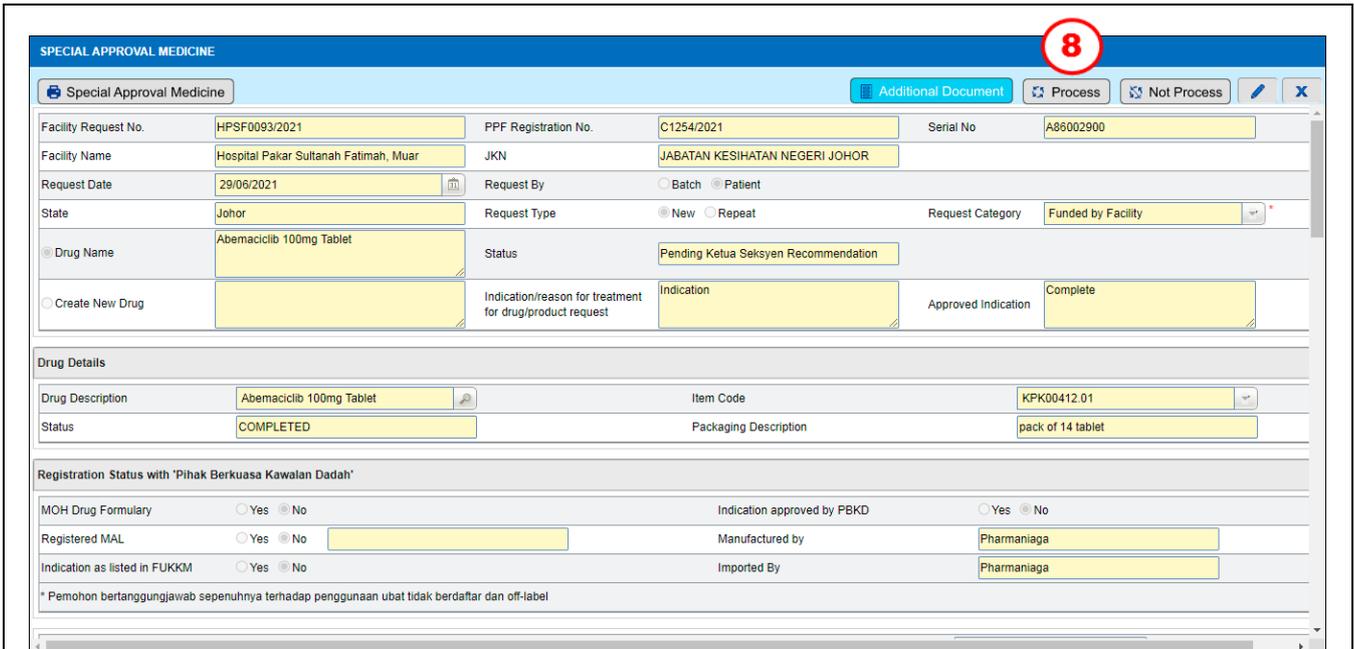


Figure 3.1.1-14 Information Message



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine | Additional Document | Process | Not Process

Facility Request No. HPSF0093/2021 | PPF Registration No. C1254/2021 | Serial No. A86002900

Facility Name Hospital Pakar Sultanah Fatimah, Muar | JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 | Request By Batch Patient

State Johor | Request Type New Repeat | Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet | Status Pending Ketua Seksyen Recommendation

Indication/reason for treatment for drug/product request | Indication | Approved Indication Complete

**Drug Details**

Drug Description Abemaciclib 100mg Tablet | Item Code KPK00412.01

Status COMPLETED | Packaging Description pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary Yes No | Indication approved by PBKD Yes No

Registered MAL Yes No | Manufactured by Pharmaniaga

Indication as listed in FUKKM Yes No | Imported By Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-15 Special Approval Medicine

**STEP 8**

Click on the  button to approve the record.

**Note**

- Confirmation message will be display as shown in Figure 3.1.1-16, click on  button

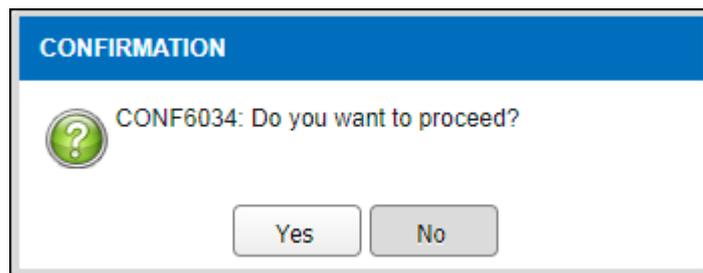


Figure 3.1.1-16 Confirmation Message

- Status will be updated to 'Pending Endorsement by TP' and status will be sync back to facility
- Ketua Seksyen still able to change 'Approval By' value to another user after assigned if the status still 'Pending Endorsement by TP'
- Request will flow to Timbalan Pengarah for endorsement

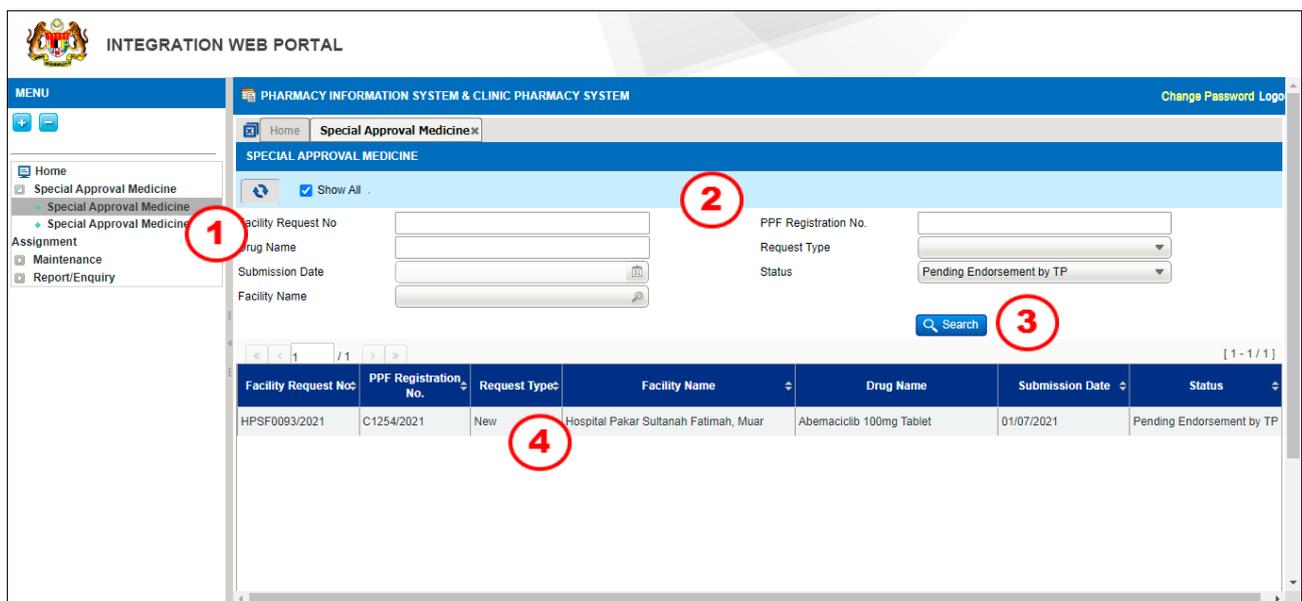
## Approval Process – Timbalan Pengarah

TASK LIST						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	C1254/2021	06/07/2021 01:58 PM	Pending Endorsement by TP	Hospital Pakar Sultanah Fatimah, Muar	HQ KPK Ketua Seksyen

Figure 3.1.1-17 Task List

### Note

User have option to Click on the Transaction No hyperlink and the Special Approval Medicine screen will be displayed as shown in the Figure 3.1.1-19 to proceed Timbalan Pengarah task.



INTEGRATION WEB PORTAL

MENU

- Home
- Special Approval Medicine
- Special Approval Medicine
- Special Approval Medicine
- Assignment
- Maintenance
- Report/Enquiry

PHARMACY INFORMATION SYSTEM & CLINIC PHARMACY SYSTEM

Home Special Approval Medicine

SPECIAL APPROVAL MEDICINE

Show All

Facility Request No.

Drug Name

Submission Date

Facility Name

PPF Registration No.

Request Type

Status

Search

Facility Request No.	PPF Registration No.	Request Type	Facility Name	Drug Name	Submission Date	Status
HPSF0093/2021	C1254/2021	New	Hospital Pakar Sultanah Fatimah, Muar	Abemaciclib 100mg Tablet	01/07/2021	Pending Endorsement by TP

Figure 3.1.1-18 Special Approval Medicine

### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine'.

### STEP 2

These search criteria can be used to search for existing Special Approval Medicine records:

- Facility Request No
- PPF Register No
- Drug Name
- Request Type
- Submission Date
- Status
- Facility Name

### Note

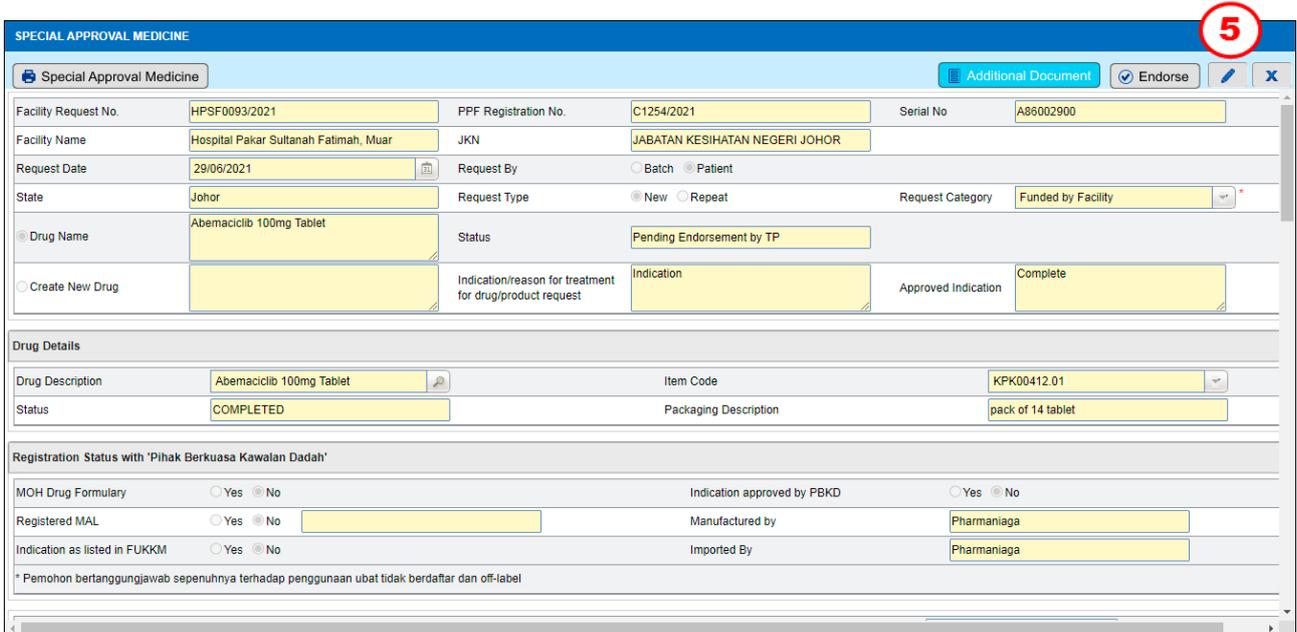
It is recommended to set search 'Status' to 'Pending Endorsement by TP' if there are too many search results

### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

**STEP 4**

Double click on the selected record and the details of the Special Approval Medicine will be displayed as Figure 3.1.1-19



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine Additional Document Endorse

Facility Request No. HPSF0093/2021 PPF Registration No. C1254/2021 Serial No. A86002900

Facility Name Hospital Pakar Sultanah Fatimah, Muar JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 Request By Batch Patient

State Johor Request Type New Repeat Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet Status Pending Endorsement by TP

Create New Drug Indication/reason for treatment for drug/product request Indication Approved Indication Complete

**Drug Details**

Drug Description Abemaciclib 100mg Tablet Item Code KPK00412.01

Status COMPLETED Packaging Description pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary Yes No Indication approved by PBKD Yes No

Registered MAL Yes No Manufactured by Pharmaniaga

Indication as listed in FUKKM Yes No Imported By Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

**Figure 3.1.1-19 Special Approval Medicine**

**STEP 5**

Click on  button to edit the record



**Timbalan Pengarah**

Remarks Action By HQ KPK Timbalan Pengarah

Date 06/07/2021

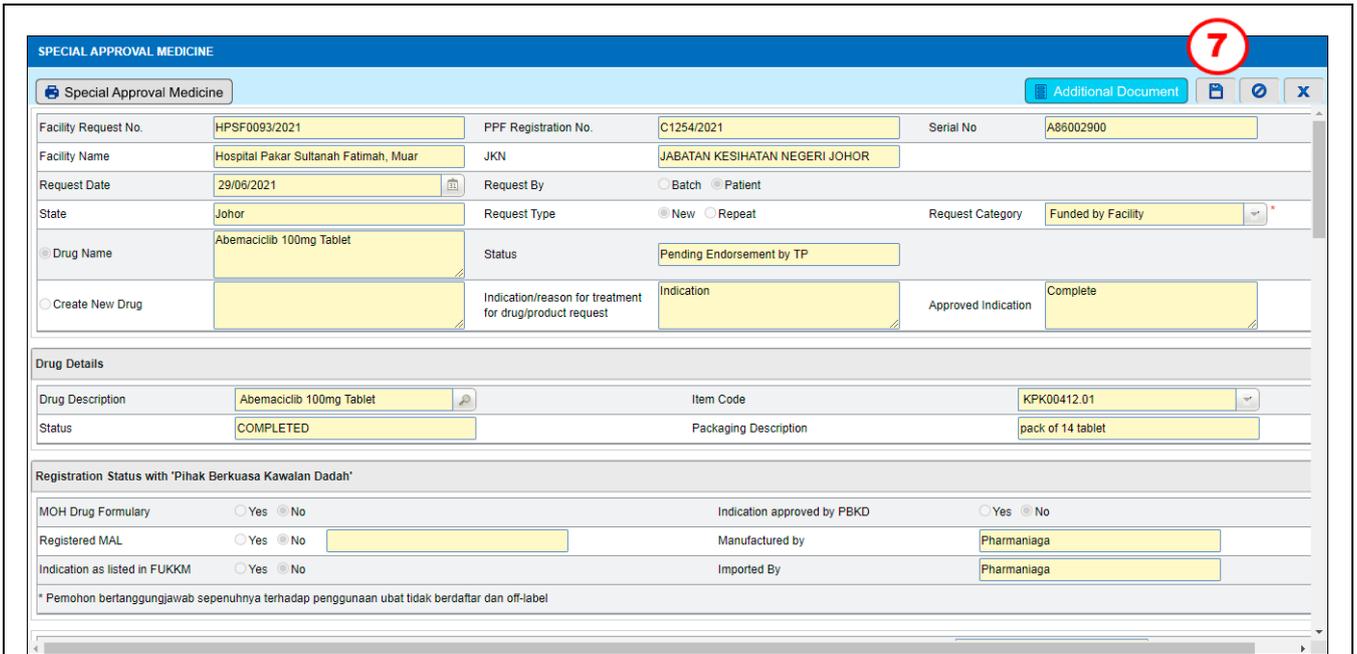
**Figure 3.1.1-20 Timbalan Pengarah Review**

**STEP 6**

Enter **Remarks** and **Date** accordingly

**Note**

- Action By value will be defaulted to Timbalan Pengarah name
- Date will be defaulted to current date during endorsement



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine Additional Document

Facility Request No. HPSF0093/2021 PPF Registration No. C1254/2021 Serial No. A86002900

Facility Name Hospital Pakar Sultanah Fatimah, Muar JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 Request By  Batch  Patient

State Johor Request Type  New  Repeat Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet Status Pending Endorsement by TP

Create New Drug Indication/reason for treatment for drug/product request Indication Approved Indication Complete

**Drug Details**

Drug Description Abemaciclib 100mg Tablet Item Code KPK00412.01

Status COMPLETED Packaging Description pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary  Yes  No Indication approved by PBKD  Yes  No

Registered MAL  Yes  No Manufactured by Pharmaniaga

Indication as listed in FUKKM  Yes  No Imported By Pharmaniaga

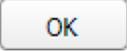
\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-21 Special Approval Medicine

**STEP 7**

Click on  button to save the record

**Note**

Record will save when user click on the  button as shown in Figure 3.1.1-22

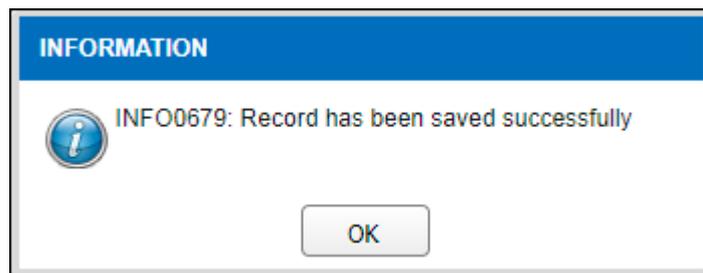
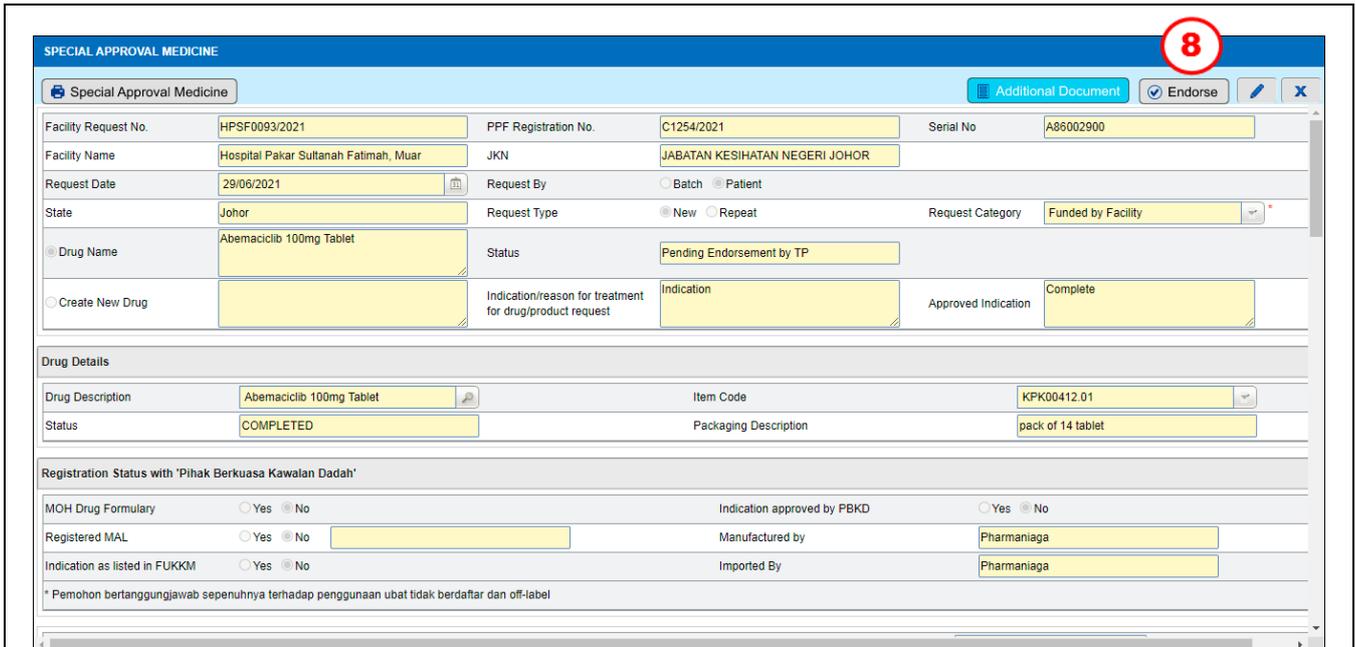


Figure 3.1.1-22 Information Message



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine Additional Document Endorse

Facility Request No.	HPSF0093/2021	PPF Registration No.	C1254/2021	Serial No	A86002900
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	29/06/2021	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Funded by Facility
Drug Name	Abemaciclib 100mg Tablet	Status	Pending Endorsement by TP		
Create New Drug		Indication/reason for treatment for drug/product request	Indication	Approved Indication	Complete

**Drug Details**

Drug Description	Abemaciclib 100mg Tablet	Item Code	KPK00412.01
Status	COMPLETED	Packaging Description	pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input type="radio"/> Yes <input checked="" type="radio"/> No
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	Pharmaniaga
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	Pharmaniaga

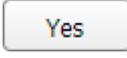
\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-23 Special Approval Medicine

**STEP 8**

Click on the  button to endorse the record.

**Note**

- Confirmation message will be display as shown in Figure 3.1.1-24, click on  button

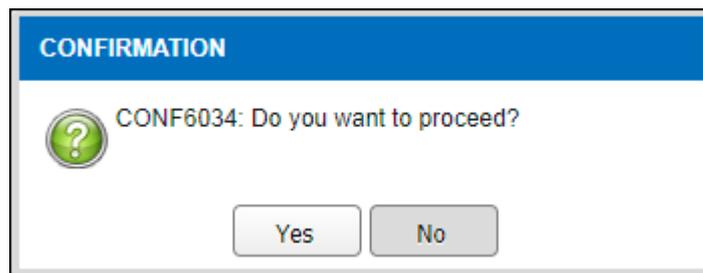


Figure 3.1.1-24 Confirmation Message

- Status will be updated base on Approval By value selected as below:
  - Pengarah Amalan & Perkembangan Farmasi (Pengarah A&P)
    - Status will be updated to 'Pending Pengarah A&P Approval'
    - Task list will be created for 'Pengarah A&P', Type = 'Special Drug Request Approval' with status 'Pending Pengarah A&P Approval'
  - Pengarah Kanan Perkhidmatan Farmasi (PKPF)
    - Status will be updated to 'Pending PKPF Approval'
    - Task list will be created for 'PKPF', Type = 'Special Drug Request Approval' with status 'Pending PKPF Approval'
  - Ketua Pengarah Kesihatan (KPK)
    - Status will be updated to 'Pending KPK Approval'
    - Task list will be created for 'KPK', Type = 'Special Drug Request Approval' with status 'Pending KPK Approval'

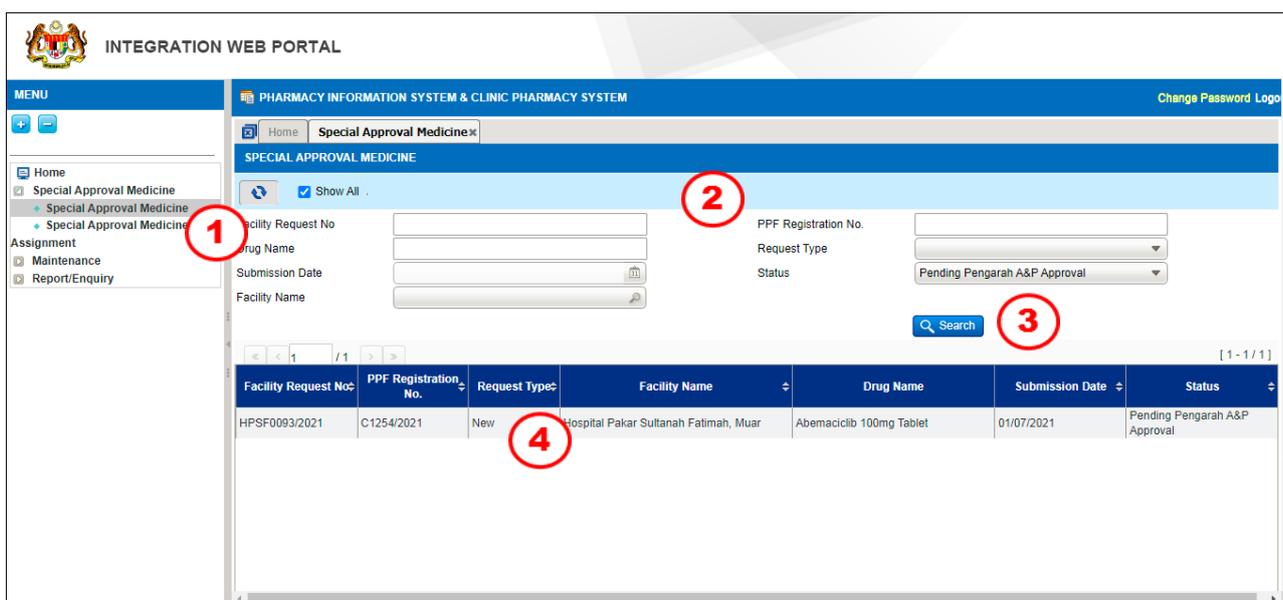
## Approval Process – Pengarah Amalan & Perkembangan Farmasi (Pegarah A&P)

TASK LIST						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	C1254/2021	06/07/2021 03:34 PM	Pending Pengarah A&P Approval	Hospital Pakar Sultanah Fatimah, Muar	HQ KPK Timbalan Pengarah

Figure 3.1.1-25 Task List

### Note

User have option to Click on the Transaction No hyperlink and the Special Approval Medicine screen will be displayed as shown in the Figure 3.1.1-27 to proceed Pengarah Amalan & Perkembangan Farmasi task.



INTEGRATION WEB PORTAL

PHARMACY INFORMATION SYSTEM & CLINIC PHARMACY SYSTEM

Special Approval Medicine

Special Approval Medicine

Special Approval Medicine

Assignment

Maintenance

Report/Enquiry

Facility Request No

Drug Name

Submission Date

Facility Name

PPF Registration No.

Request Type

Status

Pending Pengarah A&P Approval

Search

Facility Request No	PPF Registration No.	Request Type	Facility Name	Drug Name	Submission Date	Status
HPSF0093/2021	C1254/2021	New	Hospital Pakar Sultanah Fatimah, Muar	Abemaciclib 100mg Tablet	01/07/2021	Pending Pengarah A&P Approval

Figure 3.1.1-26 Special Approval Medicine

### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine'.

### STEP 2

These search criteria can be used to search for existing Special Approval Medicine records:

- Facility Request No
- PPF Register No
- Drug Name
- Request Type
- Submission Date
- Status
- Facility Name

### Note

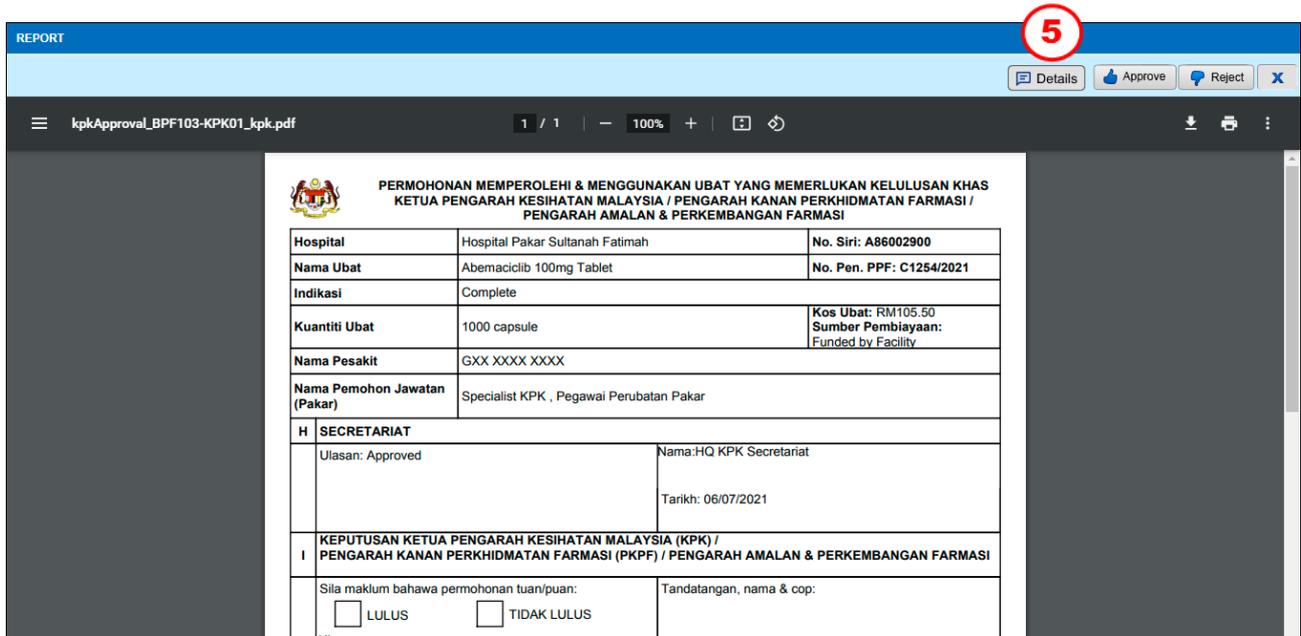
It is recommended to set search 'Status' to 'Pending Pengarah A&P Approval' if there are too many search results

### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

**STEP 4**

Double click on the selected record and the details of the Special Approval Medicine will be displayed as Figure 3.1.1-27



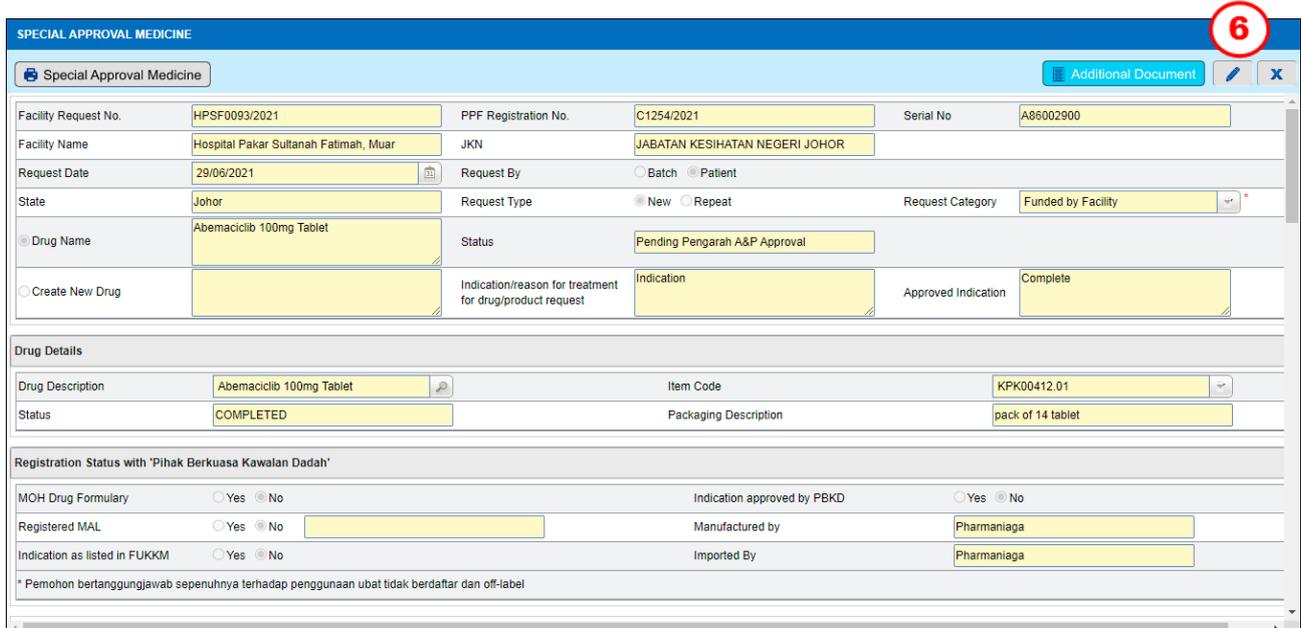
The screenshot shows a PDF report titled "PERMOHONAN MEMPEROLEHI & MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN & PERKEMBANGAN FARMASI". A red circle with the number 5 highlights the "Details" button in the top right corner of the report viewer.

Hospital	Hospital Pakar Sultanah Fatimah	No. Siri: A86002900
Nama Ubat	Abemaciclib 100mg Tablet	No. Pen. PPF: C1254/2021
Indikasi	Complete	
Kuantiti Ubat	1000 capsule	Kos Ubat: RM105.50 Sumber Pembiayaan: Funded by Facility
Nama Pesakit	GXX XXXX XXXX	
Nama Pemohon Jawatan (Pakar)	Specialist KPK, Pegawai Perubatan Pakar	
<b>H SECRETARIAT</b>		
Ulasan: Approved	Nama: HQ KPK Secretariat	
	Tarikh: 06/07/2021	
<b>I KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Sila maklum bahawa permohonan tuani/puan:		
<input type="checkbox"/> LULUS	<input type="checkbox"/> TIDAK LULUS	Tandatangan, nama & cop:

Figure 3.1.1-27 Special Approval Medicine Report

**STEP 5**

Click on  button to view details of request



The screenshot shows the "SPECIAL APPROVAL MEDICINE" details form. A red circle with the number 6 highlights the "Additional Document" button in the top right corner.

Facility Request No.	HPSF0093/2021	PPF Registration No.	C1254/2021	Serial No.	A86002900
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	29/06/2021	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Funded by Facility
Drug Name	Abemaciclib 100mg Tablet	Status	Pending Pengarah A&P Approval		
Create New Drug		Indication/reason for treatment for drug/product request	Indication	Approved Indication	Complete
<b>Drug Details</b>					
Drug Description	Abemaciclib 100mg Tablet	Item Code	KPK00412.01		
Status	COMPLETED	Packaging Description	pack of 14 tablet		
<b>Registration Status with 'Pihak Berkuasa Kawalan Dadah'</b>					
MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	Pharmaniaga		
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	Pharmaniaga		

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-28 Special Approval Medicine

**STEP 6**

Click on  button to edit the record



Ketua Pengarah Kesihatan Malaysia (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF) / Pengarah Amalan & Perkembangan Farmasi

Remarks: 7

Attachment: Attachment  View Attachment 

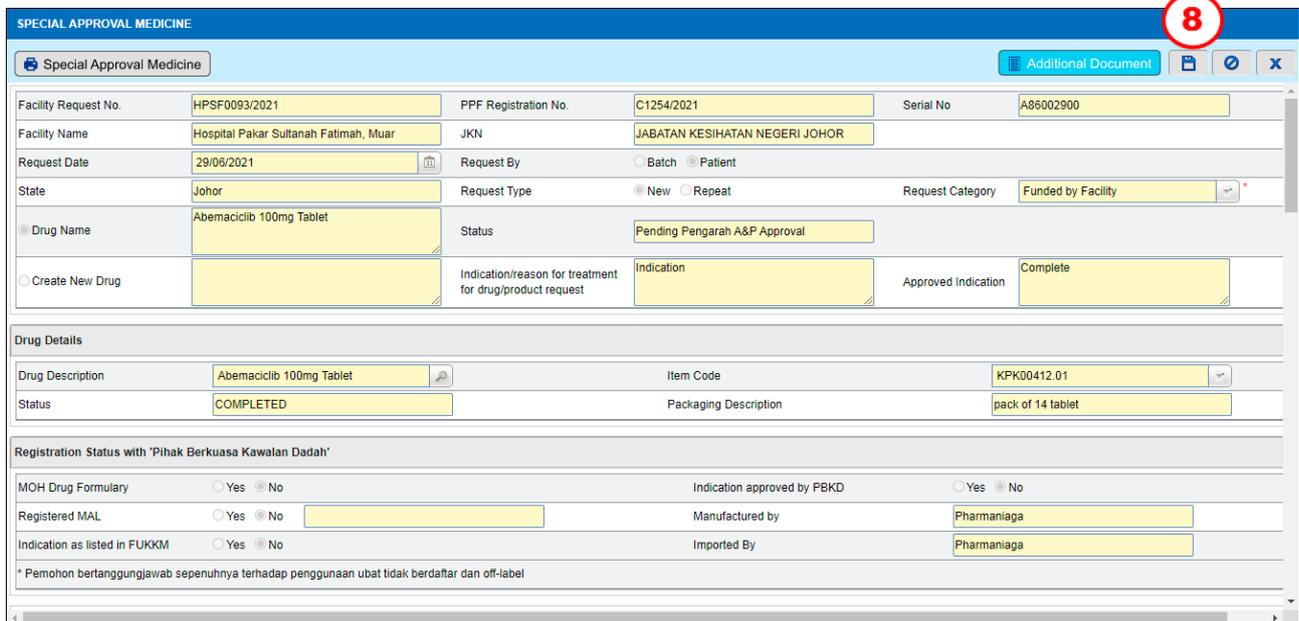
Recommendation By: HQ KPK Pengarah A&P

Date: 07/07/2021

Figure 3.1.1-29 Pengarah A&P Review

**STEP 7**

Enter **Remarks**, **Attachment** and **Date** accordingly



SPECIAL APPROVAL MEDICINE

Special Approval Medicine Additional Document 

Facility Request No. HPSF0093/2021 PPF Registration No. C1254/2021 Serial No. A86002900

Facility Name Hospital Pakar Sultanah Fatimah, Muar JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 29/06/2021 Request By  Batch  Patient

State Johor Request Type  New  Repeat Request Category Funded by Facility

Drug Name Abemaciclib 100mg Tablet Status Pending Pengarah A&P Approval

Create New Drug  Indication/reason for treatment for drug/product request Indication Approved Indication Complete

Drug Details

Drug Description Abemaciclib 100mg Tablet Item Code KPK00412.01

Status COMPLETED Packaging Description pack of 14 tablet

Registration Status with 'Pihak Berkuasa Kawalan Dadah'

MOH Drug Formulary  Yes  No Indication approved by PBKD  Yes  No

Registered MAL  Yes  No Manufactured by Pharmaniaga

Indication as listed in FUKKM  Yes  No Imported By Pharmaniaga

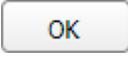
\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-30 Special Approval Medicine

**STEP 8**

Click on  button to save the record

**Note**

Record will save when user click on the  button as shown in Figure 3.1.1-31

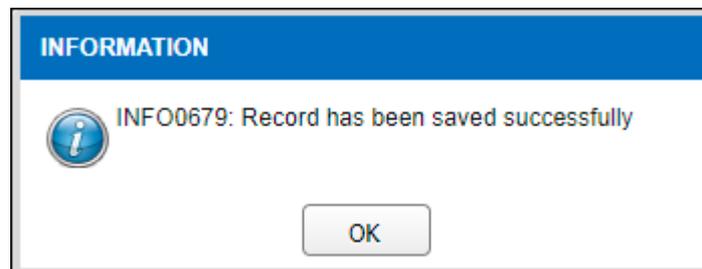


Figure 3.1.1-31 Information Message

SPECIAL APPROVAL MEDICINE
9

Special Approval Medicine
Additional Document
X

Facility Request No.	HPSF0093/2021	PPF Registration No.	C1254/2021	Serial No.	A86002900
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	29/06/2021	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Funded by Facility
<input checked="" type="radio"/> Drug Name	Abemaciclib 100mg Tablet	Status	Pending Pengarah A&P Approval		
<input type="radio"/> Create New Drug		Indication/reason for treatment for drug/product request	Indication	Approved Indication	Complete

**Drug Details**

Drug Description	Abemaciclib 100mg Tablet	Item Code	KPK00412.01
Status	COMPLETED	Packaging Description	pack of 14 tablet

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input type="radio"/> Yes <input checked="" type="radio"/> No
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	Pharmaniaga
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-32 Special Approval Medicine

**STEP 9**

Click on  button to close the detail

REPORT
10

kpkApproval\_BPF103-KPK01\_kpk.pdf
1 / 1 | 100%
X



**PERMOHONAN MEMPEROLEHI & MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS  
KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI /  
PENGARAH AMALAN & PERKEMBANGAN FARMASI**

Hospital	Hospital Pakar Sultanah Fatimah	No. Siri:	A86002900
Nama Ubat	Abemaciclib 100mg Tablet	No. Pen. PPF:	C1254/2021
Indikasi	Complete	Kos Ubat:	RM105.50
Kuantiti Ubat	1000 capsule	Sumber Pembiayaan:	Funded by Facility
Nama Pesakit	GXX XXXX XXXX		
Nama Pemohon Jawatan (Pakar)	Specialist KPK, Pegawai Perubatan Pakar		

**H SECRETARIAT**

Ulasan: Approved	Nama: HQ KPK Secretariat
Tarikh: 06/07/2021	

**I KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) /  
PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN & PERKEMBANGAN FARMASI**

Sila maklum bahawa permohonan tuan/puan:	Tandatangan, nama & cop:
<input type="checkbox"/> LULUS <input type="checkbox"/> TIDAK LULUS	

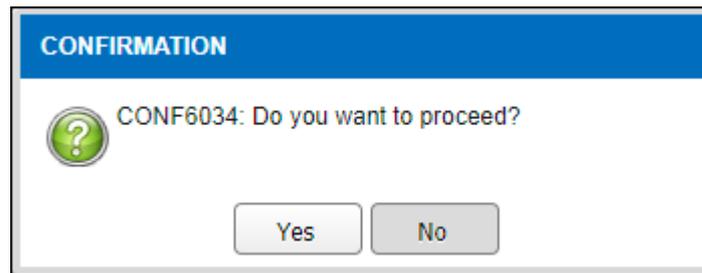
Figure 3.1.1-33 Special Approval Medicine Report

**STEP 10**

Click on  button to approve the record

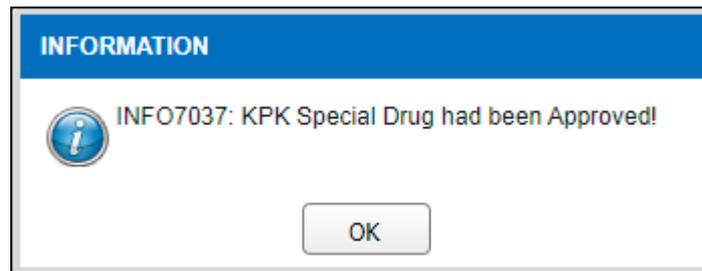
**Note**

- Confirmation message will be display as shown in Figure 3.1.1-34, click on  button



**Figure 3.1.1-34 Confirmation Message**

- Once click on yes button, information message will be shown in Figure 3.1.1-35



**Figure 3.1.1-35 Information Message**

- Status will be updated to 'Approved by KPK/PKPF/Pengarah A&P'
- If user click on  Reject button, status will be updated to 'Reject by KPK/PKPF/Pengarah A&P' and status will be sync back to facility
- All field will be disabled

## Approval Process – Pengarah Kanan Perkhidmatan Farmasi (PKPF)

TASK LIST						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	C1250/2020	12/03/2021 02:53 PM	Pending PKPF Approval	Hospital Pakar Sultanah Fatimah, Muar	HQ KPK Timbalan Pengarah

Figure 3.1.1-36 Task List

### Note

User have option to Click on the Transaction No hyperlink and the Special Approval Medicine screen will be displayed as shown in the Figure 3.1.1-38 to proceed Pengarah Kanan Perkhidmatan Farmasi task.

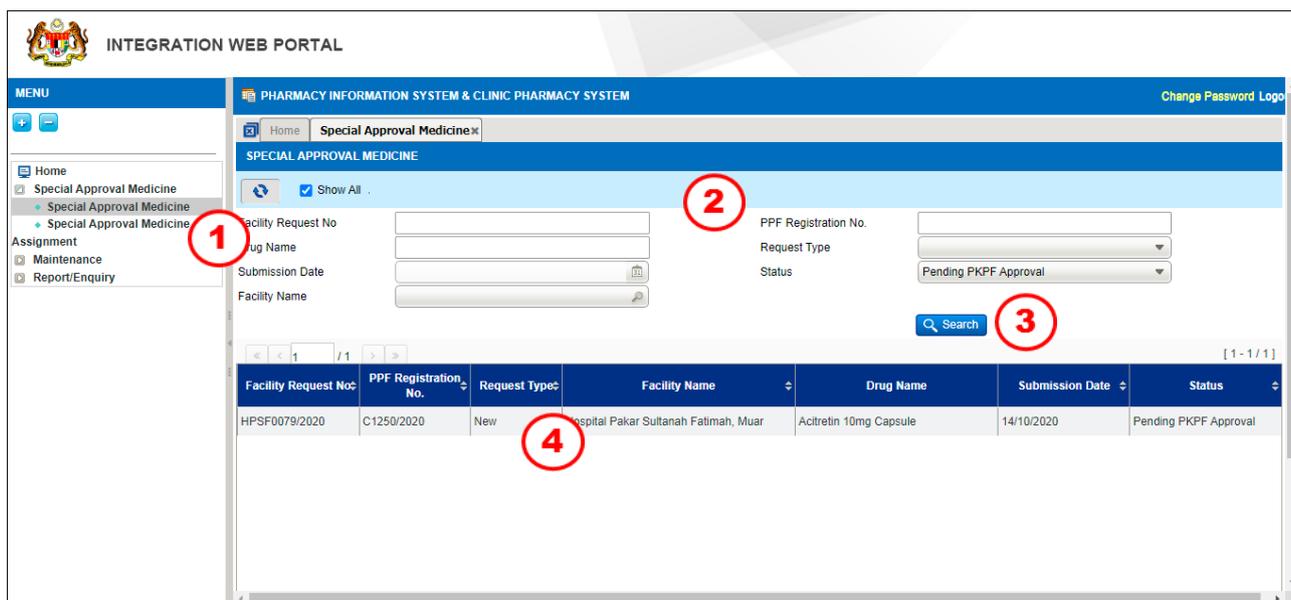


Figure 3.1.1-37 Special Approval Medicine

### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine'.

### STEP 2

These search criteria can be used to search for existing Special Approval Medicine records:

- a) Facility Request No
- b) PPF Register No
- c) Drug Name
- d) Request Type
- e) Submission Date
- f) Status
- g) Facility Name

### Note

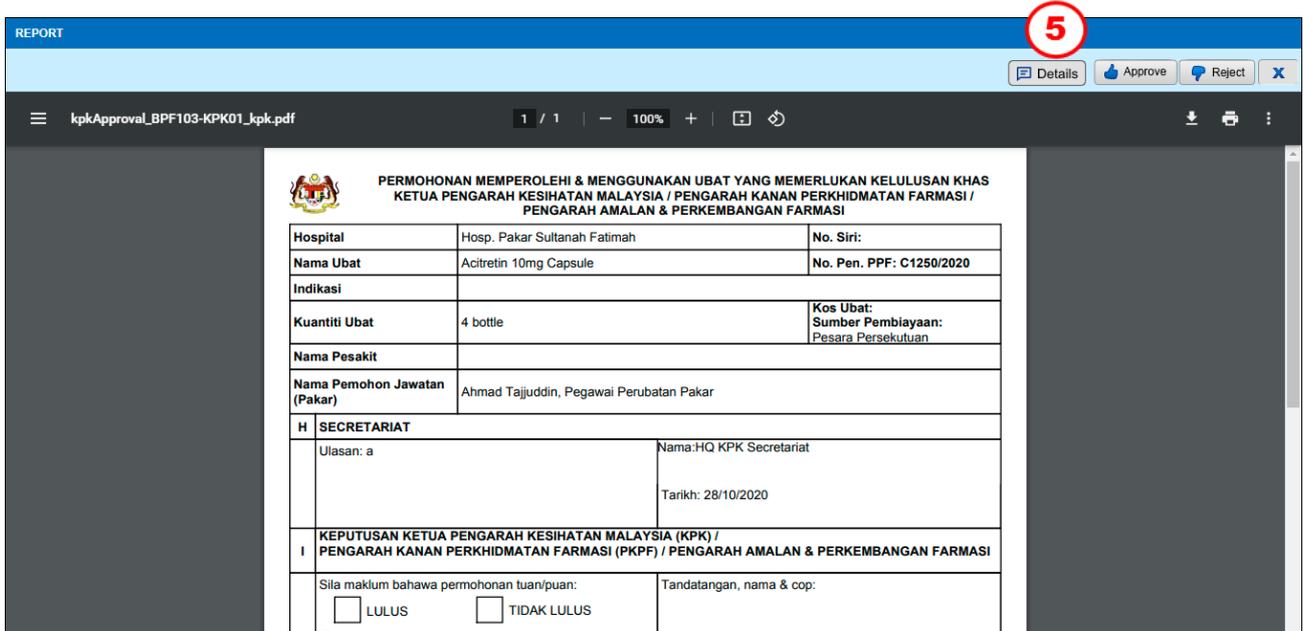
It is recommended to set search 'Status' to 'Pending PKPF Approval' if there are too many search results

### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

**STEP 4**

Double click on the selected record and the details of the Special Approval Medicine will be displayed as Figure 3.1.1-38



REPORT

Details Approve Reject X

kpkApproval\_BPF103-KPK01\_kpk.pdf 1 / 1 100%

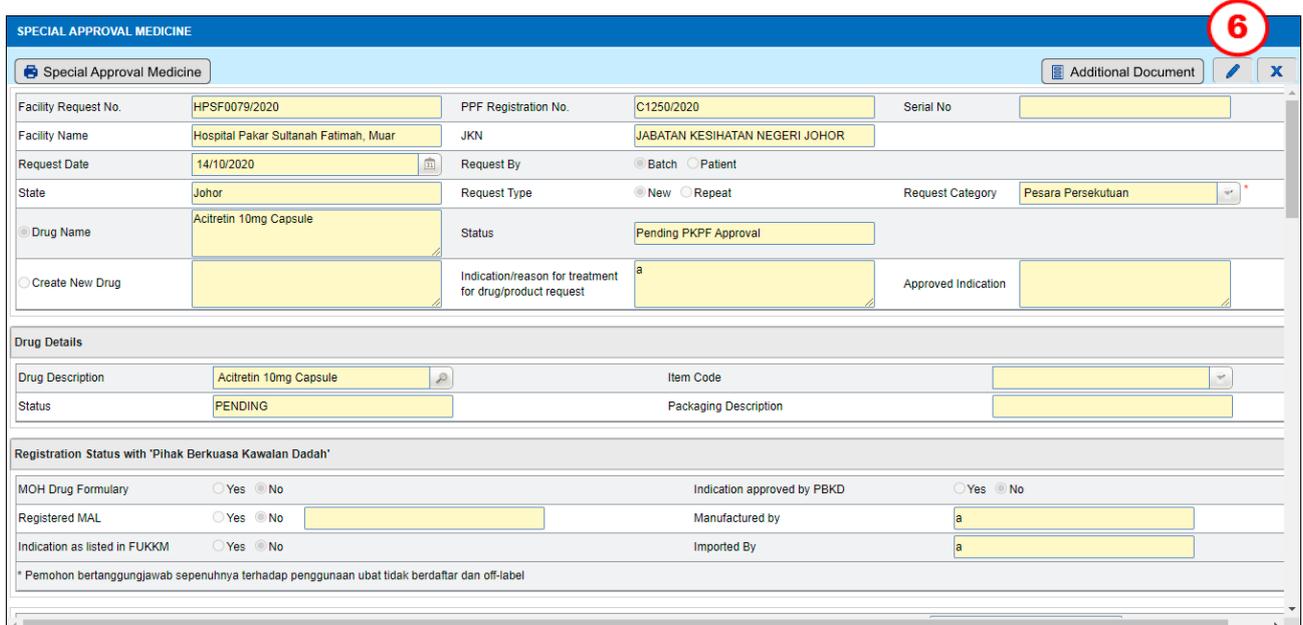
**PERMOHONAN MEMPEROLEHI & MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN & PERKEMBANGAN FARMASI**

Hospital	Hosp. Pakar Sultanah Fatimah	No. Siri:
Nama Ubat	Acitretin 10mg Capsule	No. Pen. PPF: C1250/2020
Indikasi		
Kuantiti Ubat	4 bottle	Kos Ubat: Sumber Pembiayaan: Pesara Persekutuan
Nama Pesakit		
Nama Pemohon Jawatan (Pakar)	Ahmad Tajuddin, Pegawai Perubatan Pakar	
<b>H SECRETARIAT</b>		
Ulasan: a	Nama: HQ KPK Secretariat	
	Tarikh: 28/10/2020	
<b>I KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Sila maklum bahawa permohonan tuan/puan: <input type="checkbox"/> LULUS <input type="checkbox"/> TIDAK LULUS		Tandatangan, nama & cop:

**Figure 3.1.1-38 Special Approval Medicine Report**

**STEP 5**

Click on  button to view details of request



SPECIAL APPROVAL MEDICINE

Special Approval Medicine Additional Document X

Facility Request No. HPSF0079/2020 PPF Registration No. C1250/2020 Serial No.

Facility Name Hospital Pakar Sultanah Fatimah, Muar JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 14/10/2020 Request By Batch Patient

State Johor Request Type New Repeat Request Category Pesara Persekutuan

Drug Name Acitretin 10mg Capsule Status Pending PKPF Approval

Create New Drug Indication/reason for treatment for drug/product request a Approved Indication

**Drug Details**

Drug Description Acitretin 10mg Capsule Item Code

Status PENDING Packaging Description

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary Yes No Indication approved by PBKD Yes No

Registered MAL Yes No Manufactured by a

Indication as listed in FUKKM Yes No Imported By a

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

**Figure 3.1.1-39 Special Approval Medicine**

**STEP 6**

Click on  button to edit the record



Figure 3.1.1-40 PKPF Review

**STEP 7**

Enter **Remarks**, **Attachment** and **Date** accordingly

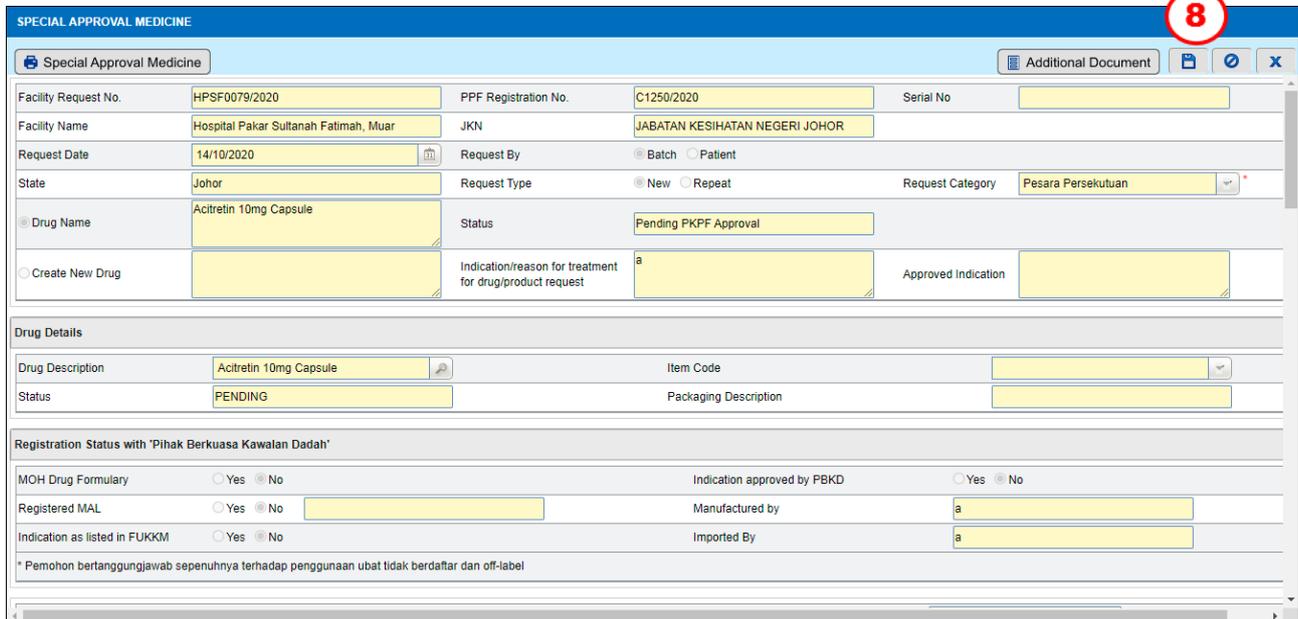


Figure 3.1.1-41 Special Approval Medicine

**STEP 8**

Click on  button to save the record

**Note**

Record will save when user click on the  button as shown in Figure 3.1.1-42

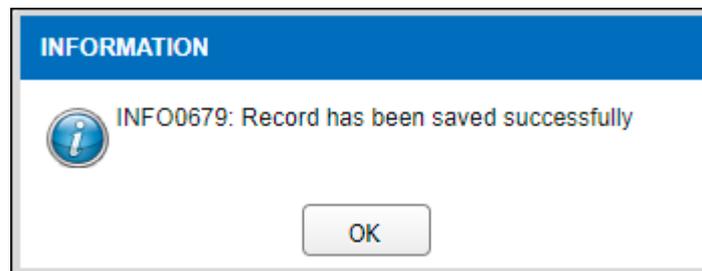


Figure 3.1.1-42 Information Message

9

**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine Additional Document X

Facility Request No.	HPSF0079/2020	PPF Registration No.	C1250/2020	Serial No.	
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	14/10/2020	Request By	<input checked="" type="radio"/> Batch <input type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Pesara Persekutuan
Drug Name	Acitretin 10mg Capsule	Status	Pending PKPF Approval		
Create New Drug		Indication/reason for treatment for drug/product request	a	Approved Indication	

**Drug Details**

Drug Description	Acitretin 10mg Capsule	Item Code	
Status	PENDING	Packaging Description	

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input type="radio"/> Yes <input checked="" type="radio"/> No
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	a
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	a

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-43 Special Approval Medicine

**STEP 9**

Click on button to close the detail

10

**REPORT**

Details Approve Reject X

kpkApproval\_BPF103-KPK01\_kpk.pdf 1 / 1 100%

<b>PERMOHONAN MEMPEROLEHI &amp; MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Hospital	Hosp. Pakar Sultanah Fatimah	No. Siri:
Nama Ubat	Acitretin 10mg Capsule	No. Pen. PPF: C1250/2020
Indikasi		Kos Ubat: Sumber Pembiayaan: Pesara Persekutuan
Kuantiti Ubat	4 bottle	
Nama Pesakit		
Nama Pemohon Jawatan (Pakar)	Ahmad Tajuddin, Pegawai Perubatan Pakar	
<b>H SECRETARIAT</b>		
Ulasan: a	Nama: HQ KPK Sekretariat	
	Tarikh: 28/10/2020	
<b>I KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Sila maklum bahawa permohonan tuan/puan:	Tandatangan, nama & cop:	
<input type="checkbox"/> LULUS <input type="checkbox"/> TIDAK LULUS		

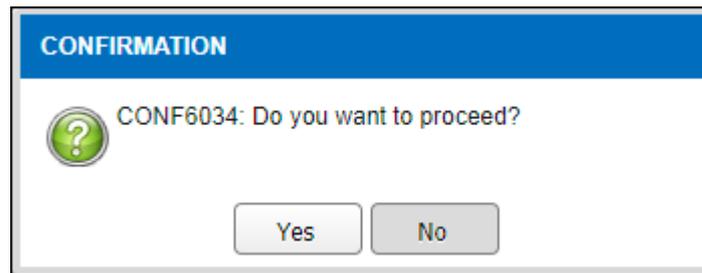
Figure 3.1.1-44 Special Approval Medicine Report

**STEP 10**

Click on button to approve the record

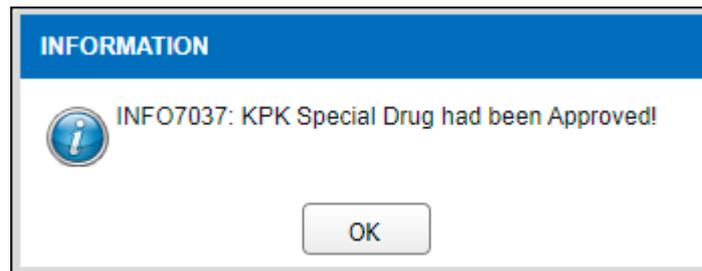
**Note**

- Confirmation message will be display as shown in Figure 3.1.1-45, click on button



**Figure 3.1.1-45 Confirmation Message**

- Once click on yes button, information message will be shown in Figure 3.1.1-46



**Figure 3.1.1-46 Information Message**

- Status will be updated to 'Approved by KPK/PKPF/Pengarah A&P'
- If user click on  Reject button, status will be updated to 'Reject by KPK/PKPF/Pengarah A&P' and status will be sync back to facility
- All field will be disabled

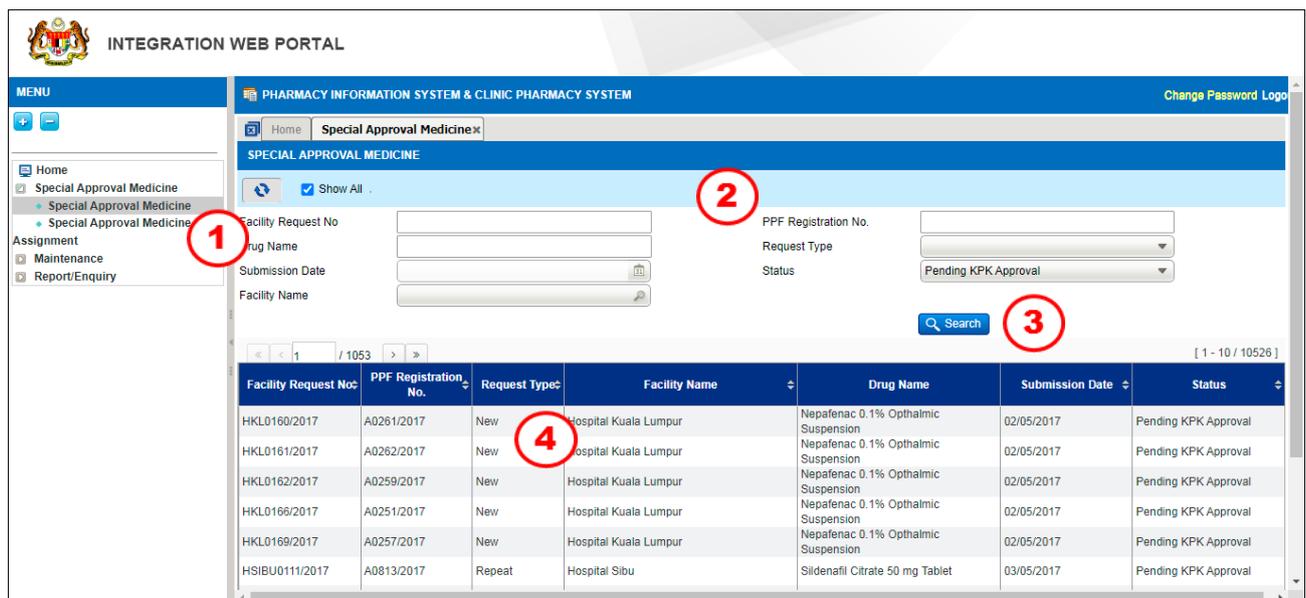
## Approval Process – Ketua Pengarah Kesihatan (KPK)

TASK LIST						
<input type="text" value="Facility Name"/>						
<input type="text" value="1"/> / <input type="text" value="1"/>						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	A2406/2020	03/08/2020	Pending KPK Approval	Hospital Pakar Sultanah Fatimah, Muar	HQ KPK Timbalan Pengarah

Figure 3.1.1-47 Task List

### Note

User have option to Click on the Transaction No hyperlink and the Special Approval Medicine screen will be displayed as shown in the Figure 3.1.1-49 to proceed Ketua Pengarah Kesihatan task.



Facility Request No	PPF Registration No.	Request Type	Facility Name	Drug Name	Submission Date	Status
HKL0160/2017	A0261/2017	New	Hospital Kuala Lumpur	Nepafenac 0.1% Ophthalmic Suspension	02/05/2017	Pending KPK Approval
HKL0161/2017	A0262/2017	New	Hospital Kuala Lumpur	Nepafenac 0.1% Ophthalmic Suspension	02/05/2017	Pending KPK Approval
HKL0162/2017	A0259/2017	New	Hospital Kuala Lumpur	Nepafenac 0.1% Ophthalmic Suspension	02/05/2017	Pending KPK Approval
HKL0166/2017	A0251/2017	New	Hospital Kuala Lumpur	Nepafenac 0.1% Ophthalmic Suspension	02/05/2017	Pending KPK Approval
HKL0169/2017	A0257/2017	New	Hospital Kuala Lumpur	Nepafenac 0.1% Ophthalmic Suspension	02/05/2017	Pending KPK Approval
HSIBU0111/2017	A0813/2017	Repeat	Hospital Sibul	Sildenafil Citrate 50 mg Tablet	03/05/2017	Pending KPK Approval

Figure 3.1.1-48 Special Approval Medicine

### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine'.

### STEP 2

These search criteria can be used to search for existing Special Approval Medicine records:

- a) Facility Request No
- b) PPF Register No
- c) Drug Name
- d) Request Type
- e) Submission Date
- f) Status
- g) Facility Name

### Note

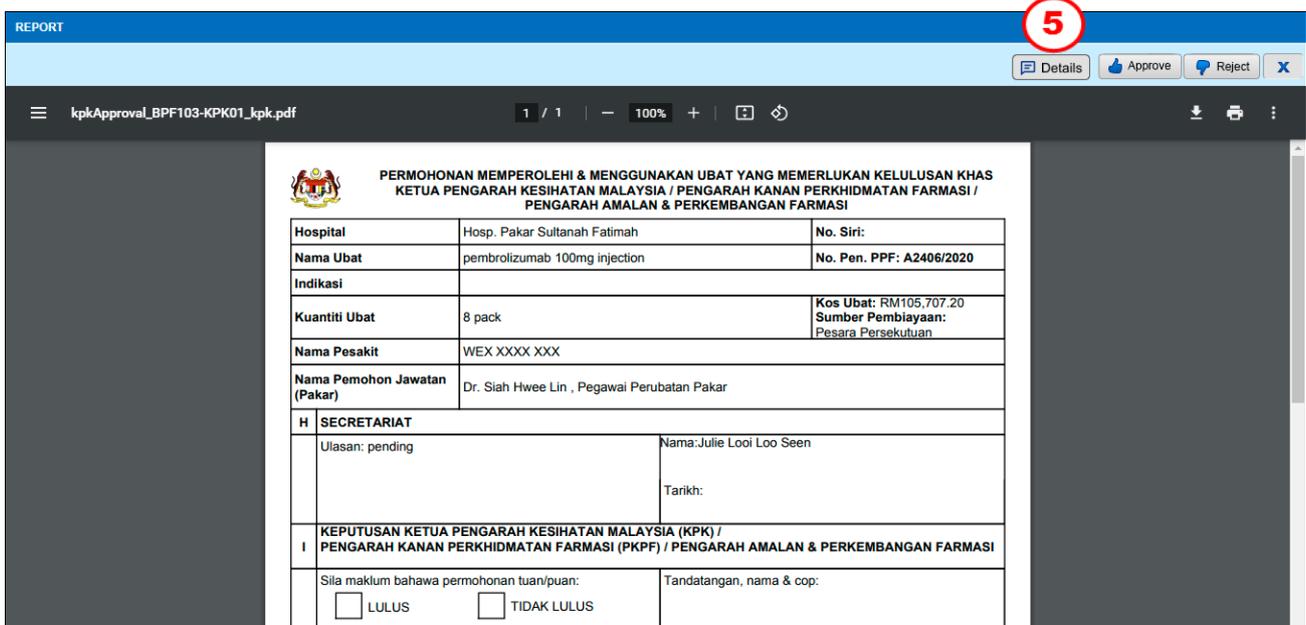
It is recommended to set search 'Status' to 'Pending KPK Approval' if there are too many search results

### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

**STEP 4**

Double click on the selected record and the details of the Special Approval Medicine will be displayed as Figure 3.1.1-49

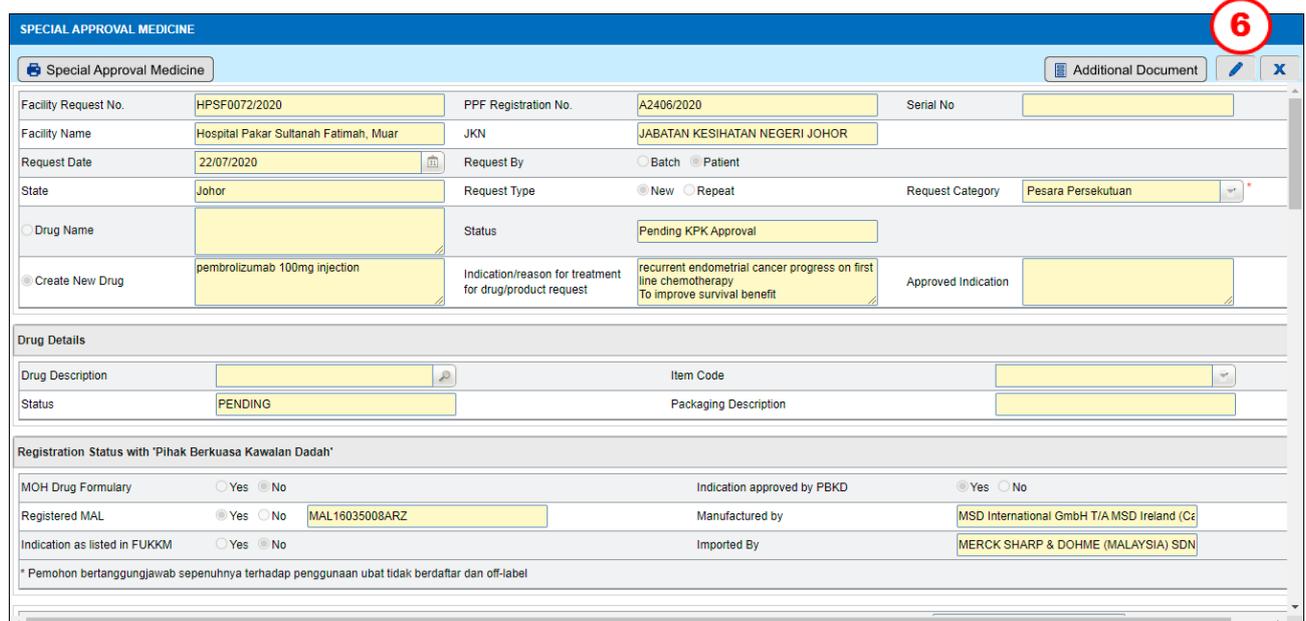


PERMOHONAN MEMPEROLEHI & MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN & PERKEMBANGAN FARMASI		
Hospital	Hosp. Pakar Sultanah Fatimah	No. Siri:
Nama Ubat	pembrolizumab 100mg injection	No. Pen. PPF: A2406/2020
Indikasi		
Kuantiti Ubat	8 pack	Kos Ubat: RM105,707.20 Sumber Pembiayaan: Pesara Persekutuan
Nama Pesakit	WEX XXXX XXX	
Nama Pemohon Jawatan (Pakar)	Dr. Siah Hwee Lin , Pegawai Perubatan Pakar	
<b>H SECRETARIAT</b>		
Ulasan: pending	Nama: Julie Looi Loo Seen	
	Tarikh:	
<b>I KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Sila maklum bahawa permohonan tuan/puan:		
<input type="checkbox"/> LULUS	<input type="checkbox"/> TIDAK LULUS	Tandatangan, nama & cop:

**Figure 3.1.1-49 Special Approval Medicine Report**

**STEP 5**

Click on  button to view details of request



**SPECIAL APPROVAL MEDICINE**

Special Approval Medicine Additional Document

Facility Request No. HPSF0072/2020 PPF Registration No. A2406/2020 Serial No. [ ]

Facility Name Hospital Pakar Sultanah Fatimah, Muar JKN JABATAN KESIHATAN NEGERI JOHOR

Request Date 22/07/2020 Request By Batch Patient

State Johor Request Type New Repeat Request Category Pesara Persekutuan

Drug Name [ ] Status Pending KPK Approval

Create New Drug pembrolizumab 100mg injection Indication/reason for treatment for drug/product request recurrent endometrial cancer progress on first line chemotherapy To improve survival benefit Approved Indication [ ]

**Drug Details**

Drug Description [ ] Item Code [ ]

Status PENDING Packaging Description [ ]

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary Yes No Indication approved by PBKD Yes No

Registered MAL Yes No MAL16035008ARZ Manufactured by MSD International GmbH T/A MSD Ireland (C)

Indication as listed in FUKKM Yes No Imported By MERCK SHARP & DOHME (MALAYSIA) SDN

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

**Figure 3.1.1-50 Special Approval Medicine**

**STEP 6**

Click on  button to edit the record

Ketua Pengarah Kesihatan Malaysia (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF) / Pengarah Amalan & Perkembangan Farmasi	
Remarks <b>7</b> Approved	Recommendation By HQ KPK
Attachment <input type="text"/> <input type="button" value="View Attachment"/>	Date 07/07/2021

Figure 3.1.1-51 KPK Review

**STEP 7**

Enter **Remarks**, **Attachment** and **Date** accordingly

SPECIAL APPROVAL MEDICINE <b>8</b>				
Special Approval Medicine		Additional Document		
Facility Request No.	HPSF0072/2020	PPF Registration No.	A2406/2020	Serial No.
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR	
Request Date	22/07/2020	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient	
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category
Drug Name		Status	Pending KPK Approval	
<input checked="" type="radio"/> Create New Drug	pembrolizumab 100mg injection	Indication/reason for treatment for drug/product request	recurrent endometrial cancer progress on first line chemotherapy To improve survival benefit	Approved Indication
Drug Details				
Drug Description		Item Code		
Status	PENDING	Packaging Description		
Registration Status with 'Pihak Berkuasa Kawalan Dadah'				
MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Registered MAL	<input checked="" type="radio"/> Yes <input type="radio"/> No MAL16035008ARZ	Manufactured by	MSD International GmbH T/A MSD Ireland (C)	
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	MERCK SHARP & DOHME (MALAYSIA) SDN	
* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label				

Figure 3.1.1-52 Special Approval Medicine

**STEP 8**

Click on  button to save the record

**Note**

Record will save when user click on the  button as shown in Figure 3.1.1-53

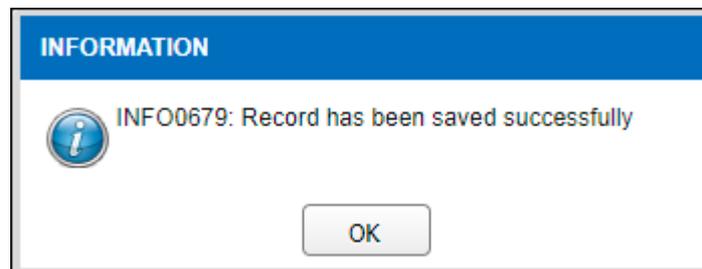


Figure 3.1.1-53 Information Message

SPECIAL APPROVAL MEDICINE
9

Special Approval Medicine
Additional Document ✕

Facility Request No.	HPSF0072/2020	PPF Registration No.	A2406/2020	Serial No.	
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	22/07/2020	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Pesara Persekutuan
Drug Name		Status	Pending KPK Approval		
<input checked="" type="radio"/> Create New Drug	pembrolizumab 100mg injection	Indication/reason for treatment for drug/product request	recurrent endometrial cancer progress on first line chemotherapy To improve survival benefit	Approved Indication	

**Drug Details**

Drug Description		Item Code	
Status	PENDING	Packaging Description	

**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input checked="" type="radio"/> Yes <input type="radio"/> No
Registered MAL	<input checked="" type="radio"/> Yes <input type="radio"/> No MAL16035008ARZ	Manufactured by	MSD International GmbH T/A MSD Ireland (C)
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	MERCK SHARP & DOHME (MALAYSIA) SDN

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-54 Special Approval Medicine

**STEP 9**

Click on button to close the detail

REPORT
10

kpkApproval\_BPF103-KPK01\_kpk.pdf
1 / 1 | 100% | + - 🖨 🔍

<b>PERMOHONAN MEMPEROLEHI &amp; MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Hospital	Hosp. Pakar Sultanah Fatimah	No. Siri:
Nama Ubat	pembrolizumab 100mg injection	No. Pen. PPF: A2406/2020
Indikasi		
Kuantiti Ubat	8 pack	Kos Ubat: RM105,707.20 Sumber Pembiayaan: Pesara Persekutuan
Nama Pesakit	WEX XXXX XXX	
Nama Pemohon Jawatan (Pakar)	Dr. Siah Hwee Lin , Pegawai Perubatan Pakar	
<b>H SECRETARIAT</b>		
Ulasan: pending	Nama: Julie Looi Loo Seen	
	Tarikh:	
<b>I KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
Sila maklum bahawa permohonan tuan/puan:		Tandatangan, nama & cop:
<input type="checkbox"/> LULUS <input type="checkbox"/> TIDAK LULUS		

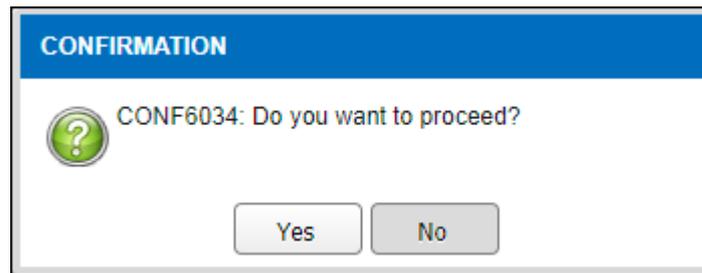
Figure 3.1.1-55 Special Approval Medicine Report

**STEP 10**

Click on button to approve the record

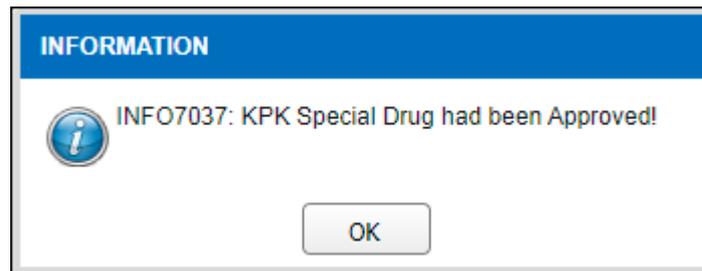
**Note**

- Confirmation message will be display as shown in Figure 3.1.1-56, click on button



**Figure 3.1.1-56 Confirmation Message**

- Once click on yes button, information message will be shown in Figure 3.1.1-57



**Figure 3.1.1-57 Information Message**

- Status will be updated to 'Approved by KPK/PKPF/Pengarah A&P'
- If user click on  Reject button, status will be updated to 'Reject by KPK/PKPF/Pengarah A&P' and status will be sync back to facility
- All field will be disabled

### Print Permit - Secretariat

TASK LIST						
No.	Transaction Type	Transaction No.	Date/Time	Task Status	From Facility	From User
1	Special Approval Medicine	C1254/2021	07/07/2021 12:27 PM	Pending to Print Permit	Hospital Pakar Sultanah Fatimah, Muar	HQ KPK Pengarah A&P

Figure 3.1.1-58 Task List

**Note**

Print permit task list will be displayed for request that has been approved by KPK/PKPF or Pengarah A&P

**STEP 1**

Click on transaction number to view record

SPECIAL APPROVAL MEDICINE

Special Approval Medicine
Print Permit
Additional Document

Facility Request No.	HPSF0093/2021	PPF Registration No.	C1254/2021	Serial No.	A86002900
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR		
Request Date	29/06/2021	Request By	<input type="radio"/> Batch <input checked="" type="radio"/> Patient		
State	Johor	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat	Request Category	Funded by Facility
Drug Name	Abemaciclib 100mg Tablet	Status	Approved by KPK/PKPF/Pengarah A&P		
Indication/reason for treatment for drug/product request		Indication		Approved Indication	Complete

**Drug Details**

Drug Description	Abemaciclib 100mg Tablet	Item Code	KPK00412.01
Status	COMPLETED	Packaging Description	pack of 14 tablet

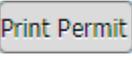
**Registration Status with 'Pihak Berkuasa Kawalan Dadah'**

MOH Drug Formulary	<input type="radio"/> Yes <input checked="" type="radio"/> No	Indication approved by PBKD	<input type="radio"/> Yes <input checked="" type="radio"/> No
Registered MAL	<input type="radio"/> Yes <input checked="" type="radio"/> No	Manufactured by	Pharmaniaga
Indication as listed in FUKKM	<input type="radio"/> Yes <input checked="" type="radio"/> No	Imported By	Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

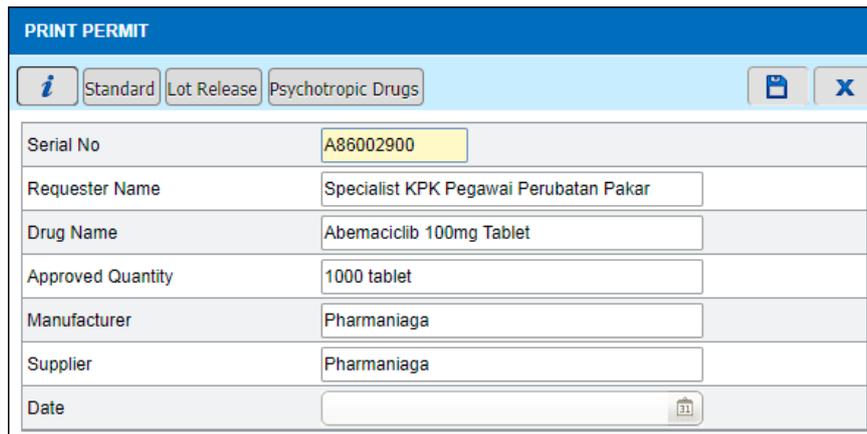
Figure 3.1.1-59 Special Approval Medicine

**STEP 2**

Click on  button to print out special approval medicine permit

**Note**

Task list will be removed once user click on  button



The screenshot shows a web application window titled "PRINT PERMIT". At the top, there are three buttons: "Standard", "Lot Release", and "Psychotropic Drugs". The "Standard" button is highlighted. Below the buttons is a table with the following fields:

Serial No	A86002900
Requester Name	Specialist KPK Pegawai Perubatan Pakar
Drug Name	Abemaciclib 100mg Tablet
Approved Quantity	1000 tablet
Manufacturer	Pharmaniaga
Supplier	Pharmaniaga
Date	

**Figure 3.1.1-60 Print Permit**

**Note**

- To print permit user able to choose three type of permit as shown in Figure 3.1.1-60
- User able edit or change Requester Name, Drug Name, Approved Quantity, Manufacturer, Supplier and Date. All the details will appear in the permit after saving the record
- Click on the **Standard** button to print standard permit as shown in Figure 3.1.1-61 below.



AKTA JUALAN DADAH 1952  
PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984  
(Peraturan 15(6))

**PENGECCUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN  
PENYAKIT YANG MENGANCAM NYAWA (No.Siri :A86002900)**

KKM-600-34/4/

Pengecualian ini diberikan kepada:

Nama Pemohon : **Specialist KPK Pegawai Perubatan Pakar,**  
Hospital/Institusi : **Hospital Pakar Sultanah Fatimah, Muar**  
Nama Produk : **Abemaciclib 100mg Tablet**  
Kuantiti : **1000 tablet**

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

- (1) Pengimportan ini dikehendaki bagi kegunaan pemohon ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
- (2) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk tersebut tidak melanggar mana-mana hak milik paten atau/dan data exclusivity.
- (3) Tatacara yang berkaitan dengan pengimportan, penyimpanan serta pembekalan hendaklah dipatuhi. Segala rekod dan dokumen hendaklah disimpan bagi tujuan audit.
- (4) Aduan produk dan kesan advers akibat dari penggunaan produk tidak berdaftar tersebut adalah dibawah tanggungjawab pemohon sepenuhnya. Laporan aduan produk dan kesan advers hendaklah dikemukakan kepada Bahagian Amalan dan Perkembangan Farmasi.
- (5) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah;
  - a) memulangkan semula permit import ini; dan
  - b) menghantar sesalinan borang import Kastam.  
kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- (6) Pengecualian ini sah untuk pengimportan dalam **tempoh satu (1) tahun** dari tarikh ia dikeluarkan. Walaubagaimanapun, permit import ini terbatal apabila produk yang berdaftar telah berada di pasaran.
- (7) **Dokumen ini merupakan hak kerajaan Malaysia. Kehilangan dokumen ini perlu dilaporkan kepada pihak polis.**

Tarikh:

Pengarah Kanan Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia.

**Figure 3.1.1-61 KPK Permit – Standard**

- Click on the **Lot Release** button to print lot release permit as shown in Figure 3.1.1-62 below.

  
**AKTA JUALAN DADAH 1952**  
**PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984**  
(Peraturan 15(6))

**PENGECCUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN**  
**PENYAKIT YANG MENGANCAM NYAWA (No.Siri :A86002900)**

KKM-600-34/4/  
Pengecualian ini diberikan kepada:

Nama Pemohon : **Specialist KPK Pegawai Perubatan Pakar,**  
Hospital/Institusi : **Hospital Pakar Sultanah Fatimah, Muar**  
Nama Produk : **Abemaciclib 100mg Tablet**  
Kuantiti : **1000 tablet**  
Nama Pembekal : **Pharmaniaga**  
Nama Pengilang : **Pharmaniaga**

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

- (1) Syarat-syarat khusus untuk produk **vaksin dan plasma:**
  - a. Keluaran-keluaran tersebut hanya dibenarkan untuk diimport melalui Lapangan Terbang Antarabangsa Kuala Lumpur (KLIA), Sepang, Selangor dan Lapangan Terbang Antarabangsa Pulau Pinang, Pulau Pinang sahaja.
  - b. Pengimportan keluaran-keluaran tersebut hendaklah dilakukan oleh pengimport yang mempunyai Lesen Racun Jenis A yang sah di bawah Akta Racun 1952 (Akta 366) iaitu ..... (perlu tambah).
  - c. Pengimportan keluaran-keluaran tersebut adalah tertakluk kepada **penilaian dokumentasi** dan **pemeriksaan rangkaian sejuk** oleh pihak Bahagian Regulatori Farmasi Negara.
- (2) Pengimportan ini dihaskan bagi kegunaan pemohon ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
- (3) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk tersebut tidak melanggar mana-mana hak milik paten atau/dan *data exclusivity*.
- (4) Tatacara yang berkaitan dengan pengimportan, penyimpanan serta pembekalan hendaklah dipatuhi. Segala rekod dan dokumen hendaklah disimpan bagi tujuan audit.
- (5) Aduan produk dan kesan advers akibat dari penggunaan produk tidak berdaftar tersebut adalah dibawah tanggungjawab pemohon sepenuhnya. Laporan aduan produk dan kesan advers hendaklah dikemukakan kepada Bahagian Amalan dan Perkembangan Farmasi.
- (6) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah;
  - a) memulangkan semula permit import ini; dan
  - b) menghantar sesalanan borang import Kastam.kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- (7) Pengecualian ini sah untuk pengimportan dalam **tempoh satu (1) tahun** dari tarikh ia dikeluarkan. Walaubagaimanapun, permit import ini terbatal apabila produk yang berdaftar telah berada di pasaran.
- (8) **Dokumen ini merupakan hak kerajaan Malaysia. Kehilangan dokumen ini perlu dilaporkan kepada pihak polis.**

Tarikh: \_\_\_\_\_

Pengarah Kanan Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia.

Figure 3.1.1-62 KPK Permit – Lot Release

- Click on the **Psychotropic Drugs** button to print psychotropic drugs as shown in Figure 3.1.1-63 below.



**AKTA JUALAN DADAH 1952**  
**PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984**  
(Peraturan 15(6))

**PENGECEUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN**  
**PENYAKIT YANG MENGANCAM NYAWA (No.Siri :A86002900)**

KKM-600-34/4/  
Pengecualian ini diberikan kepada:

Nama Pemohon : **Specialist KPK Pegawai Perubatan Pakar,**  
Hospital/Institusi : **Hospital Pakar Sultanah Fatimah, Muar**  
Nama Produk : **Abemaciclib 100mg Tablet**  
Kuantiti : **1000 tablet**

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

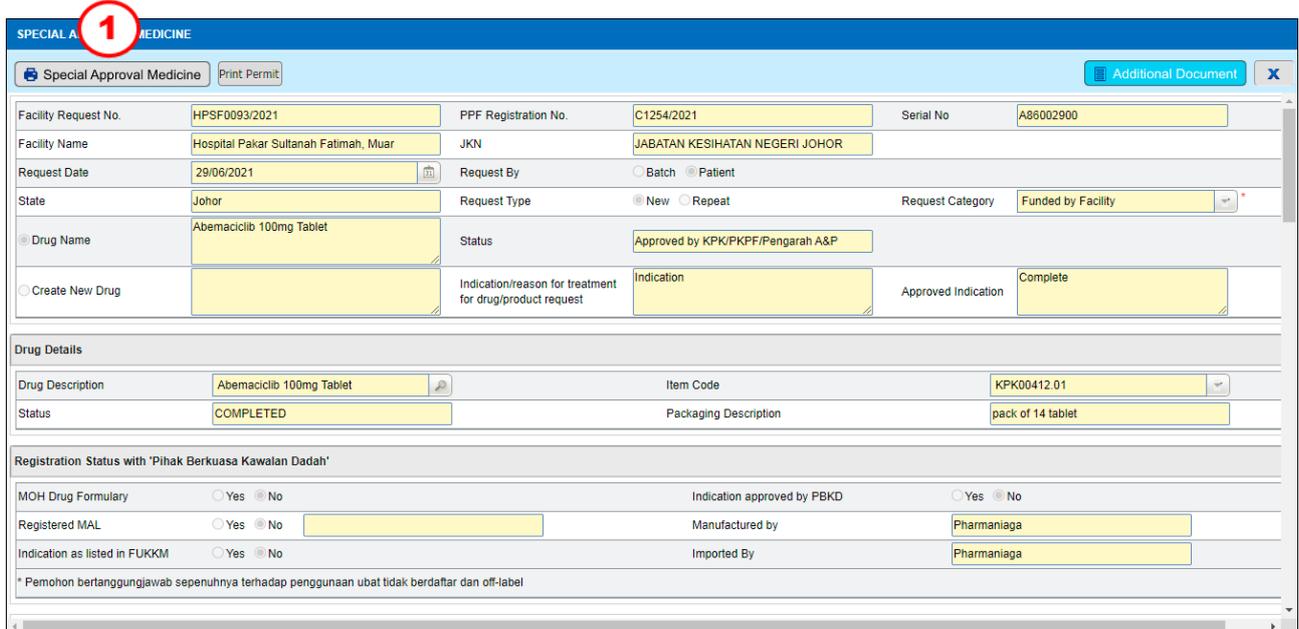
- (1) Pengimportan ini dikhaskan bagi kegunaan pemohon ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
- (2) **Pengimport perlu memohon kebenaran import DADAH BERBAHAYA kerana bahan ini dikawal di bawah Akta Dadah Berbahaya 1952**
- (3) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk tersebut tidak melanggar mana-mana hak milik paten atau/dan data exclusivity.
- (4) Tatacara yang berkaitan dengan pengimportan, penyimpanan serta pembekalan hendaklah dipatuhi. Segala rekod dan dokumen hendaklah disimpan bagi tujuan audit.
- (5) Aduan produk dan kesan advers akibat dari penggunaan produk tidak berdaftar tersebut adalah dibawah tanggungjawab pemohon sepenuhnya. Laporan aduan produk dan kesan advers hendaklah dikemukakan kepada Bahagian Amalan dan Perkembangan Farmasi.
- (6) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah;
  - a) memulangkan semula permit import ini; dan
  - b) menghantar sesalanan borang import Kastam.  
kepada Pengarah Kanan Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- (7) Pengecualian ini sah untuk pengimportan dalam **tempoh satu (1) tahun** dari tarikh ia dikeluarkan. Walaubagaimanapun, permit import ini terbatal apabila produk yang berdaftar telah berada di pasaran.
- (8) **Dokumen ini merupakan hak kerajaan Malaysia. Kehilangan dokumen ini perlu dilaporkan kepada pihak polis.**

Tarikh:

Pengarah Kanan Perkhidmatan Farmasi  
Kementerian Kesihatan Malaysia.

**Figure 3.1.1-63 KPK Permit – Psychotropic Drugs**

## Print Request Form



The screenshot shows a web-based form titled "SPECIAL APPROVAL MEDICINE". A red circle with the number "1" highlights a printer icon in the top left corner. The form contains the following fields and sections:

- Facility Request No.:** HPSF0093/2021
- PPF Registration No.:** C1254/2021
- Serial No.:** A86002900
- Facility Name:** Hospital Pakar Sultanah Fatimah, Muar
- JKN:** JABATAN KESIHATAN NEGERI JOHOR
- Request Date:** 29/06/2021
- Request By:**  Batch  Patient
- State:** Johor
- Request Type:**  New  Repeat
- Request Category:** Funded by Facility
- Drug Name:** Abemaciclib 100mg Tablet
- Status:** Approved by KPK/PKPF/Pengarah A&P
- Indication/reason for treatment for drug/product request:** Indication: Complete
- Approved Indication:** Complete
- Drug Details:**
  - Drug Description:** Abemaciclib 100mg Tablet
  - Item Code:** KFK00412.01
  - Status:** COMPLETED
  - Packaging Description:** pack of 14 tablet
- Registration Status with 'Pihak Berkuasa Kawalan Dadah':**
  - MOH Drug Formulary:**  Yes  No
  - Indication approved by PBKD:**  Yes  No
  - Registered MAL:**  Yes  No
  - Manufactured by:** Pharmaniaga
  - Indication as listed in FUKKM:**  Yes  No
  - Imported By:** Pharmaniaga

\* Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label

Figure 3.1.1-64 Special Approval Medicine

### STEP 1

Click on  button to print special approval medicine form

### Note

Once click on special approval medicine record will be display as shown in Figure 3.1.1-65, Figure 3.1.1-66 and Figure 3.1.1-67 as below



**PERMOHONAN MEMPEROLEHI & MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN & PERKEMBANGAN FARMASI**

**No. Siri**

**Fasiliti:** HPSF0093/2021

**Prog. Perkhidmatan Farmasi:** C1254/2021

**PERHATIAN:** Permohonan yang tidak lengkap **TIDAK** akan diproses.

<b>1</b>	Hospital yang memohon: Hospital Pakar Sultanah Fatimah	<b>5</b>	Nama ubat / keluaran dimohon (nama generik): Abemaciclib 100mg Tablet
<b>2</b>	Negeri: Johor	<b>6</b>	Status pendaftaran Pihak Berkuasa Kawalan Dadah (PBKD): <a href="http://npra.gov.my/index.php/en/consumers/information/products-search.html">http://npra.gov.my/index.php/en/consumers/information/products-search.html</a>  Tidak berdaftar dan tiada dalam FUKKM* <i>Indikasi seperti diluluskan oleh PBKD - Tidak Indikasi seperti terdapat dalam FUKKM - Tidak</i> Nama Pengilang: Pharmaniaga Nama Pengimport: Pharmaniaga * <i>Pemohon bertanggungjawab sepenuhnya terhadap penggunaan ubat tidak berdaftar dan off-label</i>
<b>3</b>	Jenis permohonan: Baru	<b>7</b>	Kuantiti dimohon (maksimum 12 bulan): 1000 capsule Saiz Bungkus: 100 capsule/box Kos/Pek: 10.50 Kos Sebenarnya: RM105.50 Sumber Pembiayaan: Funded by Facility
<b>4</b>	Nama Pesakit: 1 Nama: GXX XXXX XXXX No KP: 130614011405 No Pendaftaran: HPSF00000014 Diagnosis: Cancer Dosis: 200mg BID Jangkamasa Rawatan: 12 Month Ringkasan sejarah rawatan pesakit: Terdapat peningkatan yang tidak perlu		

<b>A</b>	<b>INDIKASI/TUJUAN RAWATAN BAGI UBAT/KELUARAN YANG DIMOHON</b>		
	Indication		
<b>B</b>	<b>UBAT/KELUARAN ALTERNATIF SEDIA ADA DALAM FUKKM BAGI INDIKASI DIMOHON</b>		
	<b>UBAT/KELUARAN</b>	<b>TEMPOH PENGGUNAAN</b>	<b>SEBAB-SEBAB TIDAK DAPAT DIGUNAKAN</b>
1	Octreotide	Long Term	Affect Tsh
<b>C</b>	<b>MAKLUMAT PAKAR YANG MEMOHON</b>		
	Ulasan: Urgent	Nama: Specialist KPK Jawatan: Pegawai Perubatan Pakar Disiplin: General Medicine Tarikh: 29/06/2021	
<b>D</b>	<b>KETUA JABATAN</b>		
	Ulasan: Recommended	Nama: Head of Department KPK Tarikh: 30/06/2021	
<b>E</b>	<b>KETUA PEGAWAI FARMASI</b>		
	Ulasan: Recommended	Peruntukan yang diperlukan: RM105.00 Peruntukan sedia ada: RM1,000.00  Nama: Chief Pharmacist KPK Tarikh: 30/06/2021	
<b>F</b>	<b>PENGESAHAN PENGARAH HOSPITAL</b>		

BPF/103-KPK01 (Pindaan 4)

m/s 1

Figure 3.1.1-65 Special Approval Medicine Form Page 1



 <b>PERMOHONAN MEMPEROLEHI &amp; MENGGUNAKAN UBAT YANG MEMERLUKAN KELULUSAN KHAS KETUA PENGARAH KESIHATAN MALAYSIA / PENGARAH KANAN PERKHIDMATAN FARMASI / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>		
<b>Hospital</b>	Hospital Pakar Sultanah Fatimah	<b>No. Siri: A86002900</b>
<b>Nama Ubat</b>	Abemaciclib 100mg Tablet	<b>No. Pen. PPF: C1254/2021</b>
<b>Indikasi</b>	Complete	
<b>Kuantiti Ubat</b>	1000 capsule	<b>Kos Ubat: RM105.50</b> <b>Sumber Pembiayaan: Funded by Facility</b>
<b>Nama Pesakit</b>	GXX XXXX XXXX	
<b>Nama Pemohon Jawatan (Pakar)</b>	Specialist KPK , Pegawai Perubatan Pakar	
<b>H</b>	<b>SECRETARIAT</b>	
	Ulasan: Approved	Nama:HQ KPK Secretariat Tarikh: 06/07/2021
<b>I</b>	<b>KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) / PENGARAH AMALAN &amp; PERKEMBANGAN FARMASI</b>	
	Sila maklum bahawa permohonan tuan/puan: <input checked="" type="checkbox"/> LULUS <input type="checkbox"/> TIDAK LULUS Ulasan: Approved	Tandatangan, nama & cop: HQ KPK Pengarah A&P Tarikh: 07/07/2021

**Peringatan :**

1. Urusan perolehan bagi setiap permohonan yang telah diluluskan hendaklah mengikut tatacara perolehan tertakluk kepada Arahan Perbendaharaan yang telah ditetapkan.
2. Peruntukan bagi proses perolehan hendaklah menggunakan peruntukan semasa yang telah diberikan dan bukan sebagai alasan untuk memohon peruntukan tambahan.

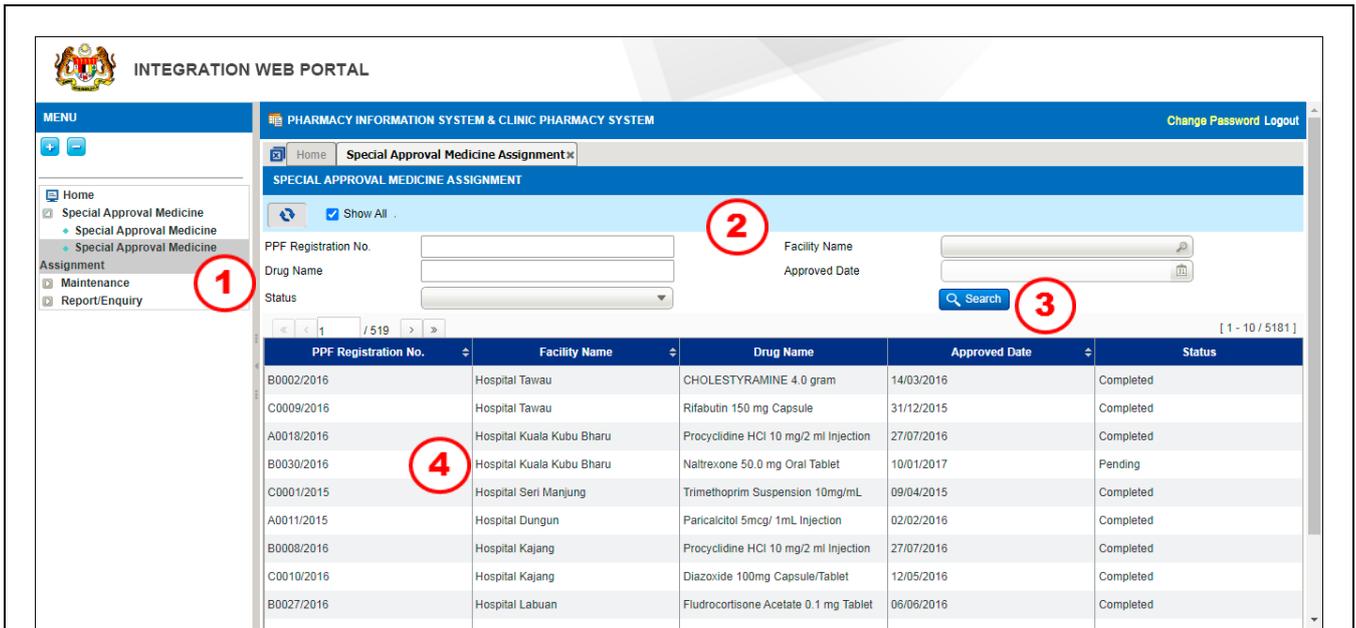
---

BPF/103-KPK01 (Pindaan 4) m/s 3

Figure 3.1.1-67 Special Approval Medicine Form Page 3

### 3.1.2 Special Approval Medicine Assignment

This function is used to assign KPK Drug Item



INTEGRATION WEB PORTAL

PHARMACY INFORMATION SYSTEM & CLINIC PHARMACY SYSTEM

Special Approval Medicine Assignment

PPF Registration No.  Facility Name

Drug Name  Approved Date

Status

[ 1 - 10 / 5181 ]

PPF Registration No.	Facility Name	Drug Name	Approved Date	Status
B0002/2016	Hospital Tawau	CHOLESTYRAMINE 4.0 gram	14/03/2016	Completed
C0009/2016	Hospital Tawau	Rifabutin 150 mg Capsule	31/12/2015	Completed
A0018/2016	Hospital Kuala Kubu Bharu	Procyclidine HCl 10 mg/2 ml Injection	27/07/2016	Completed
B0030/2016	Hospital Kuala Kubu Bharu	Naltrexone 50.0 mg Oral Tablet	10/01/2017	Pending
C0001/2015	Hospital Seri Manjung	Trimethoprim Suspension 10mg/mL	09/04/2015	Completed
A0011/2015	Hospital Dungun	Paricalcitol 5mcg/ 1mL Injection	02/02/2016	Completed
B0008/2016	Hospital Kajang	Procyclidine HCl 10 mg/2 ml Injection	27/07/2016	Completed
C0010/2016	Hospital Kajang	Diazoxide 100mg Capsule/Tablet	12/05/2016	Completed
B0027/2016	Hospital Labuan	Fludrocortisone Acetate 0.1 mg Tablet	06/06/2016	Completed

Figure 3.1.2-1 Special Approval Medicine Assignment List Page

#### STEP 1

Click on 'Special Approval Medicine' followed by 'Special Approval Medicine Assignment'.

#### STEP 2

These search criteria can be used to search for existing Special Approval Medicine Assignment:

- PPF Register No
- Facility Name
- Drug Name
- Approve Date
- Status

#### Note

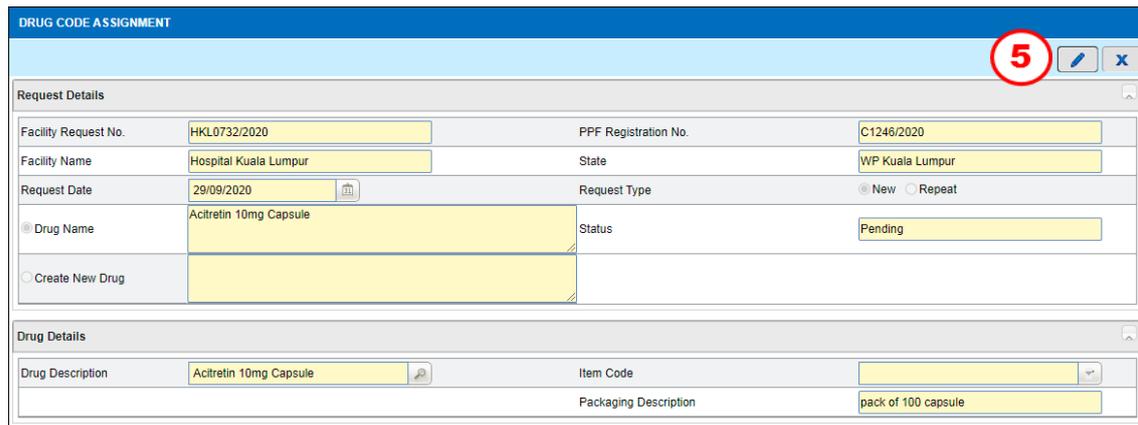
It is recommended to set 'Status' to 'Pending' if there are too many search results

#### STEP 3

Click on the  button. The result(s) display will be based on the entered criteria.

#### STEP 4

Double click on the selected record and the details of the Special Approval Medicine Assignment will be displayed as Figure 3.1.2-2.



**DRUG CODE ASSIGNMENT**

Request Details

Facility Request No.	HKL0732/2020	PPF Registration No.	C1246/2020
Facility Name	Hospital Kuala Lumpur	State	WP Kuala Lumpur
Request Date	29/09/2020	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat
<input checked="" type="radio"/> Drug Name	Acitretin 10mg Capsule	Status	Pending
<input type="radio"/> Create New Drug			

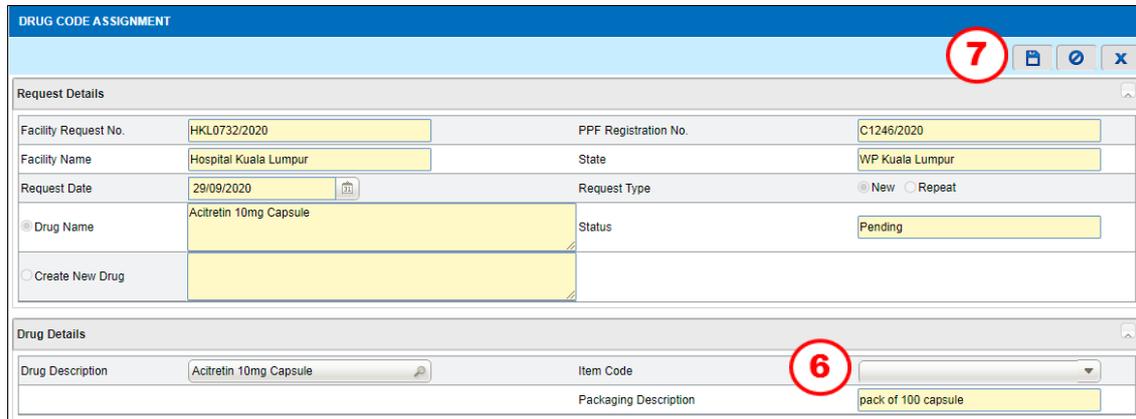
Drug Details

Drug Description	Acitretin 10mg Capsule	Item Code	
		Packaging Description	pack of 100 capsule

Figure 3.1.2-2 Drug Code Assignment

**STEP 5**

Click on the  button to edit the Special Approval Medicine Assignment screen and fill the compulsory



**DRUG CODE ASSIGNMENT**

Request Details

Facility Request No.	HKL0732/2020	PPF Registration No.	C1246/2020
Facility Name	Hospital Kuala Lumpur	State	WP Kuala Lumpur
Request Date	29/09/2020	Request Type	<input checked="" type="radio"/> New <input type="radio"/> Repeat
<input checked="" type="radio"/> Drug Name	Acitretin 10mg Capsule	Status	Pending
<input type="radio"/> Create New Drug			

Drug Details

Drug Description	Acitretin 10mg Capsule	Item Code	
		Packaging Description	pack of 100 capsule

Figure 3.1.2-3 Drug Code Assignment

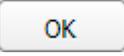
**STEP 6**

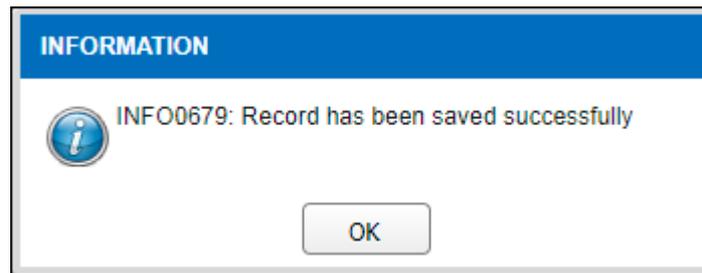
Click on the dropdown box to choose **Item Code**

**STEP 7**

Click on the  button to save the record for the Special Approval Medicine Assignment

**Note**

- After saved, the status will be updated to Completed. Once completed, status will be sent to facility with updated drug information.
- Record will save when user click on the  button as shown in Figure 3.1.2-4



**Figure 3.1.2-4 Information Message**

- Click on the  button to close the Special Approval Medicine Assignment screen.



## 4.0 Acronyms

Abbreviation	Definition
MOH	Ministry of Health
KKM	Kementerian Kesihatan Malaysia
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
PKU	Packaging Keeping Unit
SKU	Store Keeping Unit
BPF	Bahagian Perkhidmatan Farmasi
NPRA	National Pharmaceutical Regulatory Agency

## 5.0 Links to IWP Modules

No	Module	PDF Links
1	<i>Notification</i>	<a href="#">Click Here</a>
2	<i>Frequency Asked Question</i>	<a href="#">Click Here</a>
3	<i>Drug Information</i>	<a href="#">Click Here</a>
4	<i>Contract</i>	<a href="#">Click Here</a>
5	<i>KPK Approval</i>	<a href="#">Click Here</a>
6	<i>Maintenance – Pharmacy</i>	<a href="#">Click Here</a>
7	<i>Maintenance – Inventory</i>	<a href="#">Click Here</a>
8	<i>Maintenance – General</i>	<a href="#">Click Here</a>
9	<i>Maintenance – HQ Security</i>	<a href="#">Click Here</a>