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

System Design Document
(SDD)

Special Drug Request

Version	**: 1.0**
Document ID	**: PhIS_CPS/SDD/SDR**

REVISION HISTORY

Version No	Date of Release	Prepared by	Reviewed by	List of changes from Previous Version
1.0	13/06/2018	Zainura Said	Chew Ming Ping	Document baselined

Table of Content

1.   Introduction

Pharmaniaga Logistics Sdn. Bhd. executes software development, enhancement and maintenance projects for its clients. The term "project" is used to describe the full set of activities from the time the proposal is accepted and project initiation note or contract is signed to the time all the software and services are delivered according to the acceptance of the proposal/contract.

This process is to ensure both user requirements and software requirements of the projects developments are gathered appropriately from stakeholders and are documented in User Requirements Specification (URS) and System Design Documentation (SDD) specifically.

2.   Purpose

The purpose of the document is to describe the purpose and functionality of the software product requested by client. This document outlines the project's details, requirements, interface, design issues, and components to ensure that each requirement has been met.

3. Detailed System Design

3.1 Special Drug Request

```
                    ┌─────────────────┐
                    │  Special Drug   │
                    │    Request      │
                    └─────────────────┘
              ┌────────────┼────────────┐
              ▼            ▼            ▼
      ┌───────────┐ ┌───────────┐ ┌───────────┐
      │Special Drug│ │Special Drug│ │   Drug    │
      │  Request  │ │ Approval  │ │Assignment │
      └───────────┘ └───────────┘ └───────────┘
```

3.2 Block Diagram

```
┌──────────────┐    ┌──────────────┐    ┌──────────────┐    ┌──────────────┐
│ Requested for│    │Recommendation│    │ Reviewed by  │    │Recommendation│
│ Special Drug │───▶│   by HOD     │───▶│  Pharmacist  │───▶│  by Chief    │
│ by Specialist│    │              │    │              │    │ Pharmacist   │
│              │    │              │    │              │    │   Officer    │
└──────────────┘    └──────────────┘    └──────────────┘    └──────────────┘
                                                                    │
                                                                    ▼
    ┌──────────┐    ┌──────────────┐    ┌──────────────┐
    │ Inventory:│    │   Approval   │    │Recommendation│
    │ Approved  │◀───│  Process in  │◀───│ by Hospital  │
    │  Special  │    │  HQ (IWP)    │    │   Director   │
    │   Drug    │    │              │    │              │
    └──────────┘    └──────────────┘    └──────────────┘
```
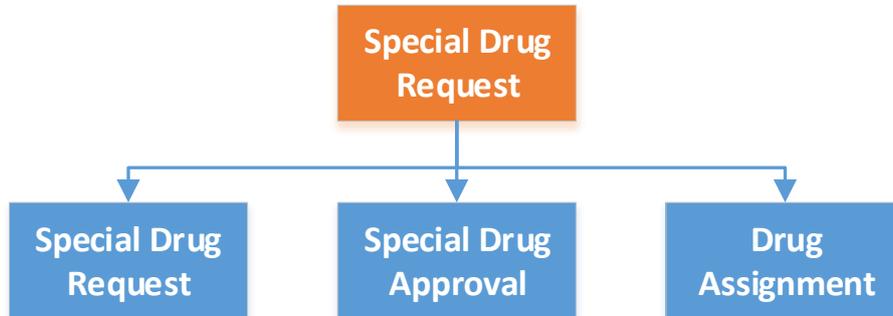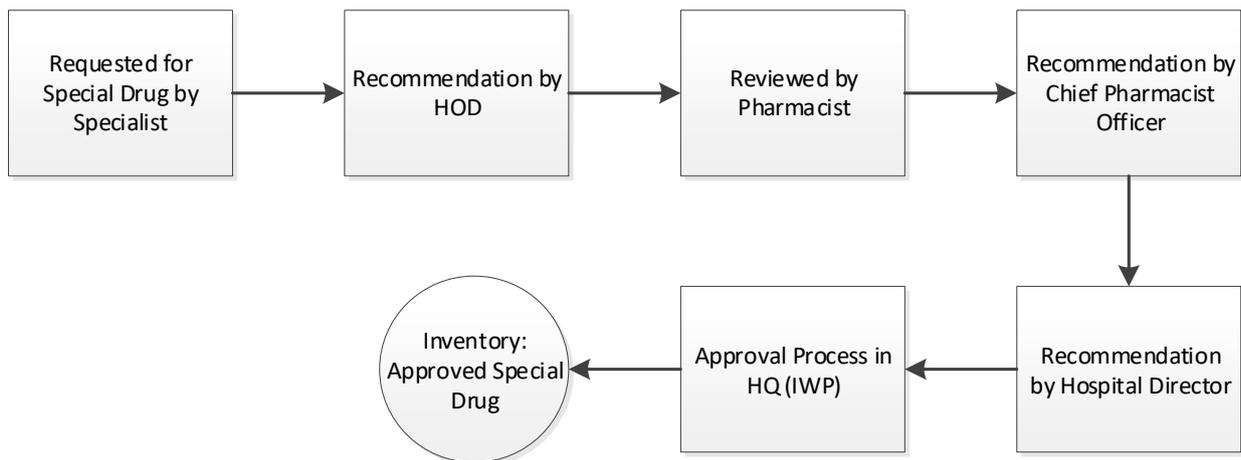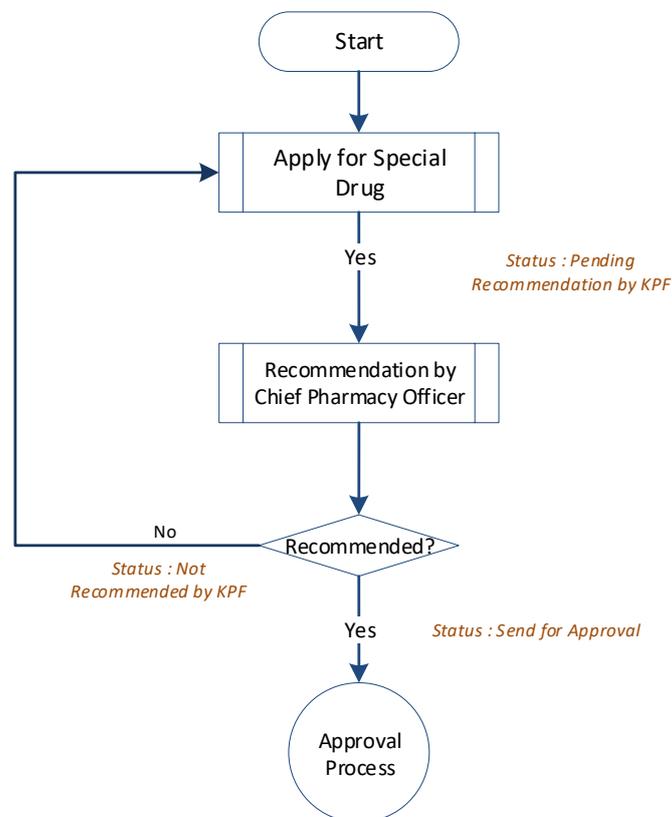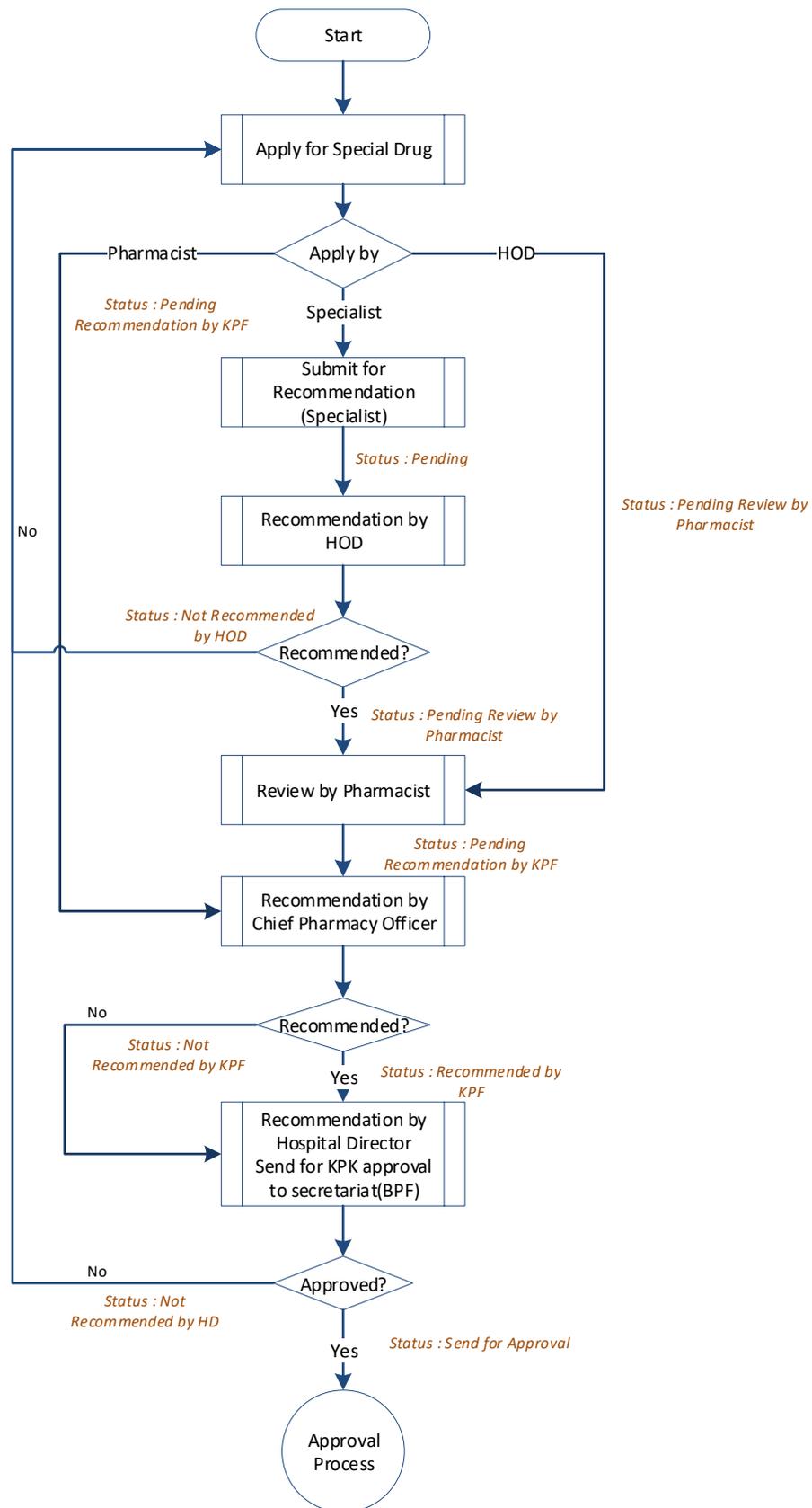
3.3 Special Drug Request

3.3.1 Purpose

To allow patients to get treatment with unlisted medicines in FUKKM or unregistered in Malaysia as a last resort after using medicines listed in FUKKM for such indications / illnesses.

Approval from the Director General of Health (KPK) / Senior Director of Pharmaceutical Services (PKPF) is required to obtain and use those medicines.

3.3.2 Screen Navigation Diagram

Screen Navigation: Special Drug Request (Pharmacy based flow)

```
                          ┌─────────────┐
                          │    Start     │
                          └──────┬──────┘
                                 │
                          ┌──────▼───────┐
        ┌─────────────────┤ Apply for Special Drug │
        │                 └──────┬───────┘
        │                        │
Pharmacist          ┌────────────▼────────────┐          HOD
        ◄───────────┤      Apply by            ├────────────┐
        │           └────────────┬────────────┘            │
Status : Pending              Specialist                    │
Recommendation by KPF             │                         │
        │           ┌─────────────▼─────────────┐           │
        │           │  Submit for                │           │
        │           │  Recommendation            │           │
        │           │  (Specialist)              │           │
        │           └─────────────┬─────────────┘           │
        │                  Status : Pending                  │
        │           ┌─────────────▼─────────────┐           │
  No    │           │  Recommendation by         │    Status : Pending Review by
        │           │  HOD                       │         Pharmacist
        │           └─────────────┬─────────────┘           │
        │  Status : Not Recommended              │           │
        │        by HOD           │                         │
        │           ◄─────────────┤  Recommended?  ├─        │
        │           └─────────────┬─────────────┘           │
        │                        Yes   Status : Pending Review by
        │                         │           Pharmacist     │
        │           ┌─────────────▼─────────────┐           │
        │           │  Review by Pharmacist      ◄───────────┘
        │           └─────────────┬─────────────┘
        │                 Status : Pending
        │                 Recommendation by KPF
        │           ┌─────────────▼─────────────┐
        └──────────►│  Recommendation by         │
                    │  Chief Pharmacy Officer    │
                    └─────────────┬─────────────┘
              No    ┌─────────────▼─────────────┐
        ◄───────────┤      Recommended?          │
        │           └─────────────┬─────────────┘
Status : Not              Yes         Status : Recommended by
Recommended by KPF         │                   KPF
        │           ┌─────────────▼─────────────┐
        │           │  Recommendation by         │
        └──────────►│  Hospital Director         │
                    │  Send for KPK approval     │
                    │  to secretariat(BPF)       │
                    └─────────────┬─────────────┘
              No    ┌─────────────▼─────────────┐
        ◄───────────┤      Approved?             │
        │           └─────────────┬─────────────┘
Status : Not              Yes
Recommended by HD          │   Status : Send for Approval
                    ┌──────▼──────┐
                    │   Approval   │
                    │   Process    │
                    └─────────────┘
```

Screen Navigation: Special Drug Request (Full based flow)

3.3.3   **Detail Functionality and Screen**

3.3.3.1   **Special Drug Request Listing**

3.2.3.1.1   Screen Design

ID	SDR.SD1
Description	Special Drug Request listing
Diagram	

Notes	o Click on Add button to create new indent o Click on search button to search for the transaction o Double click on transaction record to view the transaction
Cross References	

3.2.3.1.2   Application Business Rules

No.	Name	Description
1.	Request List	➢ Full based User able to view to list based on their role. i. User = Specialist This list will show all request requested by specific specialist only. It will not show another request by other requester. ii. User = Head of Department (HOD) This list will contain all request where • Status = Pending and above. • Requester (specialist)'s department same with the HOD's department iii. User = Pharmacist • This list will contain all request where status = 'Pending review by Pharmacist' and above. • Pharmacist also can create a new request. Pharmacist also can see list of requests by him/herself. iv. User = Chief Pharmacist • This list will contain all request where status = 'Pending recommendation by KPF' and above. v. User = Hospital Director • This list will contain all request where status = 'Not Recommended by KPF', 'Recommended by KPF' and above. For record with status 'Not

No.	Name	Description
		Recommended by KPF', it will be highlighted with different colour. ➢ Pharmacy based i. User = Pharmacist • This list will contain ii. User = Chief Pharmacist • This list will contain all request where status = 'Pending recommendation by KPF' and above.
2.	Search Transaction	Click on the 'Search' button to search the existing record: i. If user enters multiple search criteria, system will display the search results based on the specified criteria ii. If no criteria entered, system will display all transactions iii. System will display the records that match any keyword entered regardless of the letter type (uppercase or lowercase).
3.	Request list	Double click on any record to view the record details. List will display the following information: i. Active Ingredient a. If user request by drug name, it will show the drug name. b. If user request for new drug, it will show the new drug name entered ii. Request Date - Display request date iii. Facility Request No - Display Facility Request No iv. BPF Register No – Display BPF Register No v. Request Type – Display request type vi. Status – Display status
4.	Create New Transaction	Click on the 'Create New Record (+)' button to create new transaction record.
5.	Refresh Listing	Click on the 'Refresh' button to reset all search criteria: i. Facility Request No. – Display as empty field ii. Active Ingredient – Display as empty field iii. Status – All iv. BPF Register No – Display as empty field v. Request Type – All vi. Request Date – Display as empty field Search results will display all records based on above reset search criteria.

3.2.3.1.3   Input Validation Rules

No.	Name	Description	Manda tory	Format
1.	Facility Request No	User to enter free text value to search for facility request no.	No	Text field
2.	BPF Register No	User to enter free text value to search for BPF request no.	No	Text field
3.	Active Ingredient	User to enter free text value to search for active ingredient	No	Text field

No.	Name	Description	Manda tory	Format
4.	Request Type	Default to 'All' however user can select specific value: • New • Repeat	No	Drop down list
5.	Status	Value refer to reference code, domain = 'KPK_STATUS' Default to 'All' however user can select specific value.	No	Drop down list
6.	Request Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	No	Calendar

3.3.3.2   Special Drug Request

3.2.3.2.1   Screen Design

ID	SDR.SD2
Description	Special Drug Request screen

Diagram

➢ ***Full based***

    i.   New Request (Full based) – By Specialist

ii. Add patient details

PATIENT DETAILS

MRN	
Patient Name	
ID No	
Diagnosis	
Drug Name	Abacavir 300mg Tab
Dosage	
Frequency	
Duration	
Summary of patient indication history	
Remarks (Please specify detail dosage/regime if applicable)	

+ Alternative Treatment

1 / 1		
Item	**Duration**	**Reason/Comment**
No record is found		

iii. Add alternative treatment

ALTERNATIVE TREATMENT

Alternative Treatment	
Duration	
Reason	

iv.   New Request (Full based) – By Pharmacist

SPECIAL DRUG REQUEST

Facility Request No.		BPF Register No.	
Facility Name	Hospital Pakar Sultanah Fatimah, Muar	JKN	JABATAN KESIHATAN NEGERI JOHOR
Request Date	07/06/2018	Request By	◉ Batch ○ Patient
State	Johor	Request Type	○ New ○ Repeat*
◉ Drug Name		Status	New Request
○ Create New Drug (Enter Active Ingredient, Strenght and Dosage Form)		Indication/reason for treatment for drug/product request	

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		Attachment 1 (Justification report)	Attachment / View Attachment 🗑
Packaging Description		Attachment 2 (Scientific evidences)	Attachment / View Attachment 🗑
Packaging Quantity		Attachment 3 (Quotation)	Attachment / View Attachment 🗑
Cost per Pack		Attachment 4 (Others)	Attachment / View Attachment 🗑
Total Cost		Attachment 5 (Others)	Attachment / View Attachment 🗑
Additional reference		**Maximum size allowed = 2MB per attachment	

Pharmacist

Remarks		Reviewed By	Pharmacist OP Outpatient
		Designation	Pegawai Farmasi UF41
		Reviewed Date	

v.   Recommendation by HOD

SPECIAL DRUG REQUEST

Recommend   Not Recommend   X

Facility Request No.	HTMH0031/2018	BPF Register No.	
Facility Name	Hospital Tanah Merah	JKN	JABATAN KESIHATAN NEGERI KELANTAN
Request Date	08/06/2018	Request By	○ Batch ◉ Patient
State	Kelantan	Request Type	◉ New ○ Repeat*
◉ Drug Name	Abacavir 300mg Tab	Status	Pending
○ Create New Drug (Enter Active Ingredient, Strenght and Dosage Form)		Indication/reason for treatment for drug/product request	test

vi. Review by Pharmacist

SPECIAL DRUG REQUEST

Send To KPF

Facility Request No.	HTMH0033/2018	BPF Register No.	
Facility Name	Hospital Tanah Merah	JKN	JABATAN KESIHATAN NEGERI KELANTAN
Request Date	08/06/2018	Request By	○ Batch ● Patient
State	Kelantan	Request Type	● New ○ Repeat*
● Drug Name	Acyclovir 400 mg Tablet	Status	Pending Review by Pharmacist
○ Create New Drug (Enter Active Ingredient, Strenght and Dosage Form)		Indication/reason for treatment for drug/product request	test

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			Attachment 1 (Justification report)	Attachment		View Attachment
Packaging Description			Attachment 2 (Scientific evidences)	Attachment		View Attachment
Packaging Quantity			Attachment 3 (Quotation)	Attachment		View Attachment
Cost per Pack			Attachment 4 (Others)	Attachment		View Attachment
Total Cost			Attachment 5 (Others)	Attachment		View Attachment
Additional reference			**Maximum size allowed = 2MB per attachment			

vii. Recommendation by Chief Pharmacist

SPECIAL DRUG REQUEST

Recommend   Not Recommend   X

Facility Request No.	HTMH0033/2018	BPF Register No.	
Facility Name	Hospital Tanah Merah	JKN	JABATAN KESIHATAN NEGERI KELANTAN
Request Date	08/06/2018	Request By	○ Batch ● Patient
State	Kelantan	Request Type	● New ○ Repeat*
● Drug Name	Acyclovir 400 mg Tablet	Status	Recommended by KPF
○ Create New Drug (Enter Active Ingredient, Strenght and Dosage Form)		Indication/reason for treatment for drug/product request	test

Registration Status with 'Pihak Berkuasa Kawalan Dadah'

MOH Drug Formulary	● Yes ○ No	Indication approved by PBKD	○ Yes ● No
Registered MAL	○ Yes ● No	Manufactured by	test

viii. Recommendation by Hospital Director

SPECIAL DRUG REQUEST

Recommend   Not Recommend   X

Facility Request No.	HTMH0036/2018	BPF Register No.	
Facility Name	Hospital Tanah Merah	JKN	JABATAN KESIHATAN NEGERI KELANTAN
Request Date	08/06/2018	Request By	● Batch ○ Patient
State	Kelantan	Request Type	● New ○ Repeat*
● Drug Name	Abiraterone 250mg Tablet	Status	Pending Recommendation by KPF
○ Create New Drug (Enter Active Ingredient, Strenght and Dosage Form)		Indication/reason for treatment for drug/product request	test

Registration Status with 'Pihak Berkuasa Kawalan Dadah'

➢ **Pharmacy based**

    i.   New Request (Pharmacy based)

SPECIAL DRUG REQUEST

Facility Request No.		BPF Register No.	
Facility Name	Hospital Kulim	JKN	JABATAN KESIHATAN NEGERI KEDAH
Request Date	07/06/2018	Request By	○ Batch ◉ Patient
State	Kedah	Request Type	○ New ○ Repeat*
◉ Drug Name		Status	New Request
○ Create New Drug (Enter Active Ingredient, Strenght and Dosage Form)		Indication/reason for treatment for drug/product request	

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		▼	Attachment 1 (Justification report)	Attachment		View Attachment
Packaging Description			Attachment 2 (Scientific evidences)	Attachment		View Attachment
Packaging Quantity			Attachment 3 (Quotation)	Attachment		View Attachment
Cost per Pack			Attachment 4 (Others)	Attachment		View Attachment
Total Cost			Attachment 5 (Others)	Attachment		View Attachment
Additional reference			**Maximum size allowed = 2MB per attachment			

Patient

➕

|◄ ◄ | 1 | /1 | ► ►|

MRN	Patient Name	Diagnosis	Dosage	Frequency	Duration	Alternative Treatment
			No Records Found!			

Specialist

Remarks		Requested By	
Attachment	Attachment	View Attachment	Designation	
Request Date		Discipline	

Recommendation by Head of Department

Remarks		Recommendation By	
		Designation	
		Date	

Pharmacist

Remarks		Reviewed By	Pharmacist KPK
		Designation	
		Reviewed Date	

Recommendation By Head of Pharmacy Department

Remarks		Recommendation By	
Allocation Required		Date	
Existing Allocation			

Recommendation By Hospital Director

Remarks		Recommendation By	
		Date	

Notes	Save and Confirm the request
Cross References	

3.2.3.2.2 Application Business Rules

No.	Name	Description

1.	Create New Transaction	➤ Full based
		Request can be done by Specialist/HOD or by Pharmacist
		  ○ Requester = Specialist/HOD
		    Request By = Patient, patient information is required.
		  ○ Requester = by Pharmacist
		    Request By = Batch, patient information is not required.
		➤ Pharmacy based
		All information will be displayed for pharmacist to fill in.

2.	Request By	Radio button to flag Request by Batch or Patient • Batch - Disable the patient information part. This information is not required • Patient - Enable Patient information part. This information need to be fill in. user can enter more than 1 patient record.

3.	Request Type	• Radio button to flag if the request is New or Repeat request. If type = Repeat, allow user to enter and search for previous request. User able to search by no BPF Register No, Drug Name, Patient Name and ID Number.
		• When user choose the number, system will retrieve previous request information and display the value for below fields:
		  ○ Indication/reason for treatment for drug/product request
		  ○ Drug name - If previously request by active ingredient, display 'Drug Name' in new request. (For new request and required drug is not listed, user can request by active ingredient. Once request approved at HQ level, 'Drug name' will be assigned for that active ingredient. For subsequent request, user has to use drug name instead of active ingredient name.)
		  ○ MOH Drug Formulary
		  ○ Registered MAL
		  ○ Indication approved by PBKD

No.	Name	Description
		o Manufactured by o Imported by
4.	Create New Drug	If drug required is not exist, user can request for new drug. On click of this option, entry field will be enabled for user to enter drug details with Active Ingredient, strength and dosage form information.
5.	Attachment	For each request, user must attach together the following document • Attachment 1 (Justification report) • Attachment 2 (Scientific evidences) • Attachment 3 (Quotation) • Attachment 4 (Others) • Attachment 5 (Others) Each attachment is limit to 2 MB. Attachment 1 and 3 are mandatory.

6.	Registration Status	In Drug master, each KPK drug can be defined with below category:
		
		• Registered but not available in FUKKM
		• Not Registered but available in FUKKM
		• Not Registered and not available in FUKKM
		
		Based on above value, display default value for registration status.
		
		• 'Registered but not available in FUKKM'
		   o Default 'Registered MAL' = Yes
		• 'Not Registered but available in FUKKM'
		   o Default 'MOH Drug Formulary' = Yes and
		   o Default 'Registered MAL' = No
		   o Default 'Indication Approved by PBKD'= No
		• 'Not Registered and not available in FUKKM'
		   o Default 'MOH Drug Formulary' = No
		   o Default 'Registered MAL' = No
		   o Default 'Indication Approved by PBKD'= No
		
		When user choose 'Registered MAL' = No, default the value for 'Indication Approved by PBKD' as No. User still can change this value.

7.	Request validation	Validation on request selection. If user choose on 'Not Valid' combination, alert message will be displayed. Refer to Request validation.
8.	Alternative treatment	List the medicines in the FUKKM that have been used by the patient, the duration of use and the reasons the drug is no longer available / alternative medicines are needed. Each patient can have multiple information.
9.	Save record	Click on save button to save the request • Request status remain as 'New Request' • Confirm button will be displayed.
10.	Specialist information	➢ Full based If request by specialist, specialist information will be auto populated. o Requested by

No.	Name	Description
		o Designation o Discipline ➢ Pharmacy based User to select specialist name from registered user list. Designation and discipline will be auto populated for the selected user.
11.	Head of Department information	➢ Full based If request by HOD, HOD information will be auto populated. o Recommendation by o Designation ➢ Pharmacy based User to select HOD name from registered user list. Designation will be auto populated for the selected user.
12.	Pharmacist Information	Pharmacist name will be auto populated based on login user, o Reviewed by o Designation
13.	Chief Pharmacist Information	Chief Pharmacist name will be auto populated based on login user, o Recommendation by
14.	Hospital Director Information	➢ Full based Hospital director name will be auto populated based on login user, o Recommendation by ➢ Pharmacy based User to select HD name from registered user list.

15.	Confirm record	➢ Full based
		On click of confirm button, status of request will be changed as below:
		o User role = Specialist,
		     o Status will be changed to 'Pending'.
		     o Request will flow to 'Recommendation by HOD' process.
		o User role = HOD,
		     o Status will be change to 'Pending Review by Pharmacist'.
		     o Skip the 'Recommendation by HOD' process. Request will flow to 'Review by Pharmacist' process.
		o User role = Pharmacist,
		     o Status will be change to 'Pending Recommendation by KPF'.
		     o Skip the 'Recommendation by HOD' and 'Review by Pharmacist' processes. Request will flow to 'Recommendation by KPF process.
		➢ Pharmacy based
		     o Status will be change to 'Pending Recommendation by KPF'.
		     o Request will flow to 'Recommendation by KPF process.

16.	Facility Request No.	Request number will be auto generated when the user clicks on 'Save' button. The running number is by facility. a. Format: '*4 digits running no (0001)*' / '*Year (YYYY)*'. E.g.: 0001/2012 b. Number will be increased by 1 for every new request. E.g.: 0001/2012,

No.	Name	Description
		0002/2012… 9999/2012.
		c. Number will be reset to 0001 every year
		E.g.: 2012 → 0001/2012, 0002/2012
		2013→ 0001/2013, 0002/2013
17.	BPF Register No	Register number will be blank. This number will be auto generated only when secretariat receive the request (Status = Send for approval). The running number is by type of request.
		a. Format – '*Request type*' '*4 digits running no (0001)*' / '*Year (YYYY)*'. Request type:
		• A - 'Registered MAL' = Yes
		• B - 'KKM Drug List' = Yes and 'Registered MAL' = No
		• C - 'KKM Drug List' = No and 'Registered MAL' = No
		E.g.: A0001/2012,B0001/2012, C0001/2012
		b. Number will be increased by 1 for every new request by type. E.g.: A0001/2012, A0002/2012, B0001/2012, B0002/2012.
		c. Number will be reset to 0001 every year
		E.g.: 2012 → A0001/2012, A0002/2012
		2013→ A0001/2013, A0002/2013
18.	Recommendation by Head of Department. *Apply to full based only.	HOD has provision to recommend or not the request by click on 'Recommend' or 'Not Recommend' button.
		Status of request will be changed as below:
		a. Click on 'Not Recommend' button,
		o Status will be change to 'Not Recommended by HOD'.
		o Request will not flow to 'Review by Pharmacist' process.
		b. Click on 'Recommend' button,
		o Status will be change to 'Pending Review by Pharmacist'.
		o Request will flow to 'Review by Pharmacist' process.
19.	Review by Pharmacist	Pharmacist has to fill in request details section. Other section is read only.
		On click of 'Send to KPF' button:
		o Status of request will be changed to 'Pending Recommendation by KPF'.
		o Request will flow to 'Recommendation by KPF' process.
20.	Recommendation by Head of Pharmacy	Chief Pharmacist has provision to recommend or not the request by click on 'Recommend' or 'Not Recommend' button.
		➢ Full based
		Status of request will be changed as below:
		a. Click on 'Not Recommend' button,
		o Status will be change to 'Not Recommended by KPF'
		o Request will flow to 'Approval by HD' process.
		b. Click on 'Recommend' button
		o Status will be change to 'Recommended by KPF'.
		o Request will flow to 'Approval by HD' process.
		➢ Pharmacy based

No.	Name	Description

		a. Click on 'Not Recommend' button,
		    o Status will be change to 'Not Recommended by KPF'
		    o Request will not flow to secretariat for KPK approval.
		 b. Click on 'Recommend' button
		    o Status will be change to 'Send for Approval'.
		    o Request will be sent to HQ and flow to 'Approval by KPK' process. BPF Register No will be generated.
		    o User is allowed to print this request after has been recommended by KPF.

21.	Recommendation by Hospital Director
	
	 *Apply to full based only.
		Hospital Director has provision to recommend or not the request by click on 'Recommend' or 'Not Recommend' button.
		 a. Click on 'Not Recommend' button,
		    o Status will be change to 'Not Recommended by HD'.
		    o Request will not flow to secretariat for KPK approval.
		 b. Click on 'Recommend' button,
		    o Status will be change to 'Send for Approval'.
		    o Request will be sent to HQ and flow to 'Approval by KPK' process. BPF Register No will be generated.
		    o User is allowed to print this request after has been recommended by HD

22.	Print KPK form	Refer to KPK Form

3.2.3.2.3 Input Validation Rules

No.	Name	Description	Mandatory	Format
Request header				
1.	Facility Request No	This field will automatically be assigned with a system generated allocation no when user saves the transaction	Yes	Read-only
2.	Facility Name	Default to facility name	Yes	Read-only
3.	Request Date	Default to current date. However, user is allowed to change the date.	Yes	Calendar
4.	State	Default to facility's state	Yes	Read-only
5.	Drug Name	List of drugs from drug master where 'Special Approved Drug' flag is true. Mandatory if user request by drug.	Yes	Searching field
6.	Create New Drug	User to enter drug details with Active Ingredient, strength and dosage form information. Maximum 100 character is allowed. Mandatory if user request by new drug.	Yes	Text field
7.	BPF Register No	This number will be auto generated only when secretariat receive the request (Status = Send for approval).	No	Read-only
8.	JKN	Default to facility's JKN define in external facilities master	Yes	Read-only
9.	Request By	Radio button to flag Request by Batch or Patient	Yes	Radio

No.	Name	Description	Mandatory	Format
		• Batch - Disable the patient information part. This information is not required • Patient - Enable Patient information part. This information need to be fill in. Patient must be registered before can be selected. User can enter more than 1 patient record.		button
10.	Request Type	Radio button to flag if the request is New or Repeat request. If type = Repeat, allow user to enter and search for previous request. User able to search by no BPF Register No, Drug Name, Patient Name and ID Number.	Yes	Radio button
11.	Status	It will show status of current request. By default, for new request the status will be 'New Request'.	Yes	Read-only
12.	Indication/ reason for treatment for drug/product request	The indication of the drug requested or the purpose of this drug is required by the patient User to enter free text value with maximum 300 characters.	Yes	Text field
Registration Status with 'Pihak Berkuasa Kawalan Dadah'				
13.	MOH Drug Formulary	Radio button with Yes/No option	Yes	Radio button
14.	Registered MAL	Radio button with Yes/No option. If Yes, text field will be enabled for user to enter registration information. User to enter free text value with maximum 50 characters.	Yes	Radio button
15.	Indication as listed in FUKKM	Radio button with Yes/No option	Yes	Radio button
16.	Indication approved by PBKD	Radio button with Yes/No option	Yes	Radio button
17.	Manufactured by	User to enter free text value with maximum 50 characters.	No	Text field
18.	Imported by	User to enter free text value with maximum 50 characters.	No	Text field
Request Details				
19.	Request Quantity	Numeric value with maximum 10 digits	Yes	Text field
20.	Request Quantity UOM	Field will display all UOM from UOM master.	Yes	Drop down list
21.	Packaging Description	This field is free text with a capacity of 100 characters.	Yes	Text field
22.	Packaging Quantity	Numeric value with maximum 10 digits	Yes	Text field
23.	Cost per Pack	Numeric field with 2 decimal point (10,2).	Yes	Text field

No.	Name	Description	Mand atory	Format
24.	Total Cost	Total cost will be auto calculated Total Cost = *Packaging Quantity x Total Cost per Pack* Numeric field with 2 decimal point (10,2)	Yes	Text field
25.	Additional reference	User to enter free text value with maximum 500 characters.	No	Text field
Patient Details				
26.	Patient Information	To display patient information from patient registration list.	Yes	Searching field
27.	Diagnosis	This field is free text with a capacity of 100 characters.	No	Text field
28.	Dosage	Numeric value with maximum 10 digits	No	Text field
29.	Frequency	Do display list of frequency from frequency master list	No	Searching field
30.	Duration	Numeric value with maximum 3 digits. Duration value will be display in combo box with selection of Days, Weeks of Months	No	Text field
31.	Summary of patient indication history	History of patient care and justification of application detailed. This field is free text with a capacity of 2000 characters.	No	Text field
32.	Remarks (Please specify detail dosage/regim e if applicable)	This field is free text with a capacity of 500 characters.	No	Text field
Patient – Alternative/Treatment				
33.	Item	This field is free text with a capacity of 50 characters.	Yes	Text field
34.	Duration	This field is free text with a capacity of 50 characters.	Yes	Text field
35.	Reason/Com ment	This field is free text with a capacity of 100 characters.	Yes	Text field
Specialist				
36.	Remarks	This field is free text with a capacity of 300 characters.	Yes	Text field
37.	Request Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar
38.	Attachment	To insert attachment.	No	Others
39.	Requested By	For full based, default to user login. For pharmacy based, user to select specialist name from registered user list.	Yes	Searching field
40.	Designation	Will be displayed based on selected user name	No	Read-Only
41.	Discipline	Will be displayed based on selected user name	No	Read-Only
Recommendation by Head of Department				

No.	Name	Description	Mand atory	Format
42.	Remarks	This field is free text with a capacity of 300 characters.	Yes	Text field
43.	Recommendat ion By	For full based, default to user login. For pharmacy based, user to select HOD name from registered user list.	Yes	Searching field
44.	Designation	Will be displayed based on selected user name		
45.	Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar
Pharmacist				
46.	Remarks	This field is free text with a capacity of 300 characters.	Yes	Text field
47.	Reviewed By	Default to user login.	Yes	Searching field
48.	Designation	Will be displayed based on selected user name		
49.	Reviewed Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar
Recommendation by Head of Pharmacy				
50.	Remarks	This field is free text with a capacity of 300 characters.	Yes	Text field
51.	Allocation Required	Allocation Required will be displayed from 'Total Cost' in request details section.	Yes	Text field
52.	Existing Allocation	Existing Allocation to be entered by KPF. Numeric field with 2 decimal point (10,2). This field is mandatory.	Yes	Text field
53.	Recommendat ion By	Default to user login.	Yes	Searching field
54.	Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar
Recommendation by Hospital Director				
55.	Remarks	This field is free text with a capacity of 300 characters.	Yes	Text field
56.	Recommendat ion By	For full based, default to user login. For pharmacy based, user to select HDD name from registered user list.	Yes	Searching field
57.	Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar

3.3.4 Integration

None

3.4 Special Drug Approval

3.4.1 Purpose

Approval from the Director General of Health (KPK) / Senior Director of Pharmaceutical Services (PKPF) is required to obtain and use those medicines.

3.4.2 Screen Navigation Diagram
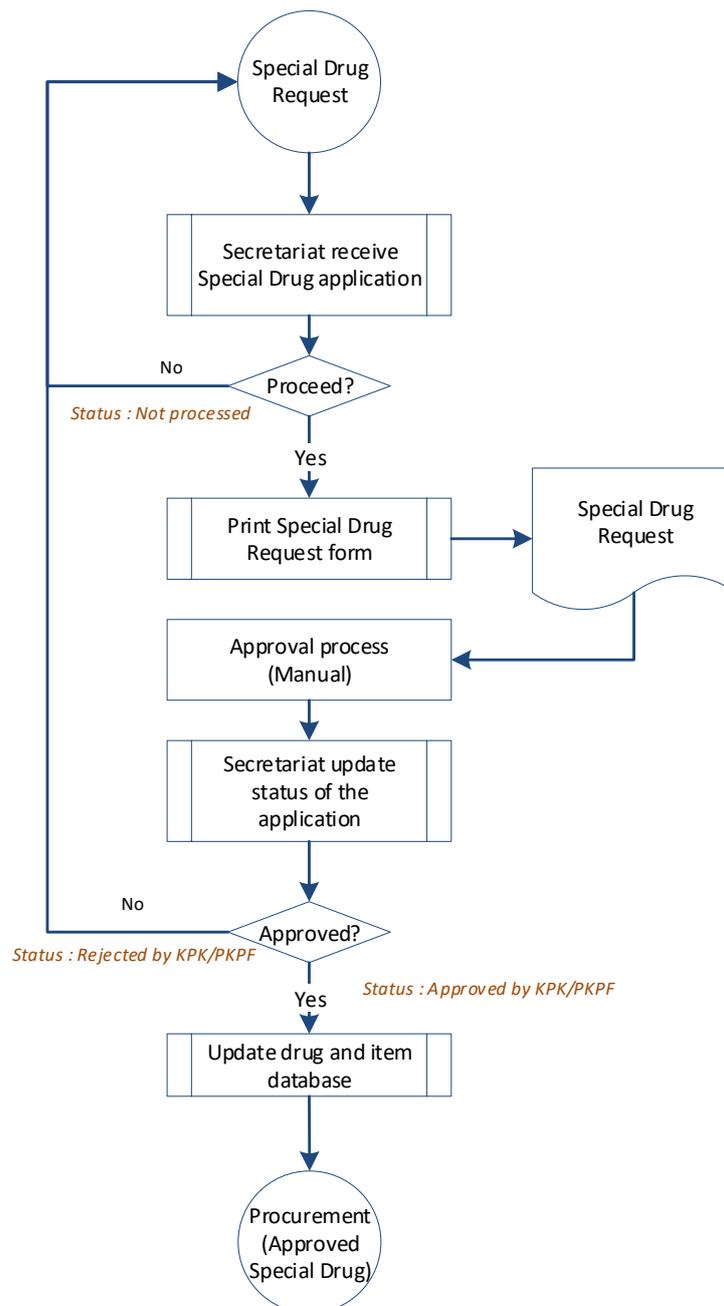
Screen Navigation: Special Drug Approval

3.4.3 Detail Functionality and Screen

3.4.3.1 Special Drug Approval Listing

3.2.3.1.1 Screen Design

ID	SDR.SD3
Description	Special Drug Approval listing
Diagram	

Notes	o Click on search button to search for the transaction o Double click on transaction record to view the transaction
Cross References	

3.2.3.1.2 Application Business Rules

No.	Name	Description
1.	Search Transaction	Click on the 'Search' button to search the existing record: i. If user enters multiple search criteria, system will display the search results based on the specified criteria ii. If no criteria entered, system will display all transactions iii. System will display the records that match any keyword entered regardless of the letter type (uppercase or lowercase).

2.	Request list	List will display all request submitted by all facilities.
		Double click on any record to view the record details.
		List will display the following information:
		i. Facility Request No
		ii. BPF Register No
		iii. Request Type
		iv. Facility Name
		v. Drug Name
		    o If user request by drug name, it will show the drug name.
		    o If user request for new drug, it will show the new drug name entered
		vi. Submission Date
		vii. Status

No.	Name	Description
3.	Refresh Listing	Click on the 'Refresh' button to reset all search criteria: i. Facility Request No. – Display as empty field ii. Drug Name – Display as empty field iii. Submission Date – Display as empty field iv. Facility name – Display as empty field v. BPF Register No – Display as empty field vi. Request Type – Display as empty field vii. Status – All Search results will display all records based on above reset search criteria.

3.2.3.1.3   Input Validation Rules

No.	Name	Description	Mandatory	Format
1.	Facility Request No	User to enter free text value to search for facility request no.	No	Text field
2.	Drug name	User to enter free text value to search for drug name	No	Text field
3.	Submission Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	No	Calendar
4.	Facility Name	List of facility from external facility master.	No	Searching field
5.	BPF Register No	User to enter free text value to search for BPF request no.	No	Text field
6.	Request Type	Default to 'All' however user can select specific value: • New • Repeat	No	Drop down list
7.	Status	Value refer to reference code, domain = 'KPK_STATUS' Default to 'All' however user can select specific value.	No	Drop down list

3.4.3.2 **Special Drug Approval**

3.2.3.2.1 Screen Design

ID	SDR.SD4
Description	Special Drug Approval screen

Diagram

  i.   Approval screen

  ii.   Secretariat section

Notes	• Click on 'Not process' button to return the form • Click on 'Approve' button to approve the request • Click on 'Reject' button to reject the request
Cross References	PhIS_CPS_SDD_Inventory_Procurement_v1.0 - 3.2.8 Approve Special Drug

3.2.3.2.2   Application Business Rules

No.	Name	Description
1.	Completed Form	• Allow secretariat to update on 'Completed Form' flag and date. Date will be defaulted to system date when user check on checkbox. User is allowed to change this date. • User will update this flag if request is completed and no more pending information from requester. This information will be used when system want to calculate for consumer charter (Archive target). • Status will become "Pending for KPK Approval" if 'Completed Form' is checked.
2.	Approval Status	• Click on 'Not Process button, 　o Status will be change to 'Not Processed'. 　o Status will be send back to requester. • Click on 'Approve' button, 　o Status will be change to 'Approved by KPK/PKPF'. 　o Administrator need to define drug code or create a new drug if drug requested not exist in drug master database. 　o Display drug details section for drug assignment • Click on 'Reject' button, 　o Status will be change to 'Rejected by KPK/PKPF'. 　o Status will be send back to requester.
3.	Drug Details	• This section only available after user approved the request, where Request status = 'Approved by KPK/PKPF'. By default, status of drug assign = 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, status will change to 'Completed'. This status will reflect in 'Drug Assignment' screen too. • Once completed, user is not allowed to change the drug and item. • Updated details will be send back to requester.
4.	Print permit	• Once approval done, request status will be sent back to facility. If status = 'Approved by KPK/PKPF' user in facility can print the permit and proceed with procurement process. • Refer to Print Permit

3.2.3.2.3   Input Validation Rules

No.	Name	Description	Mand atory	Format
Request Details				
1.	Approved Quantity	Numeric value with maximum 10 digits	Yes	Text field
2.	Approved Cost	Numeric field with 2 decimal point (10,2).	Yes	Text field
Secretariat				
3.	Remarks	This field is free text with a capacity of 3000 characters.	Yes	Text field
4.	Completed form	Checkbox to update on 'Completed Form' flag. Calendar will be disable and cleared if checkbox is unchecked. Date will be defaulted to system date when user check on checkbox.	No	Checkbox with calendar
5.	Recommendat ion By	Value refer to reference code, domain =' Secretariat'.	Yes	Drop down list
6.	Action by	Default to user login's name.	Yes	Read-only
7.	Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar
Pengarah Amalan & Perkembangan Farmasi				
8.	Remarks	This field is free text with a capacity of 300 characters.	No	Text field
9.	Recommendat ion	Radio button with selection of 'Recommended' and 'Not Recommended'	Yes	Radio button
10.	Recommendat ion By	Value refer to reference code, domain = 'Pengarah Amalan dan Perkembangan Farmasi'.	Yes	Drop down list
11.	Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar
Ketua Pengarah Kesihatan Malaysia (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF)				
12.	Remarks	This field is free text with a capacity of 300 characters.	No	Remarks
13.	Recommendat ion By	Value refer to reference code, domain = 'Ketua Pengarah Kesihatan'.	Yes	Drop down list
14.	Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	Yes	Calendar

3.4.4   Integration

None

3.5   Drug Assignment

3.5.1   Purpose

To assign approved drug for request in order for user to proceed with procurement function. If requested drug is new and not exist in system, administrator need to created new drug before assignment can be done.

3.5.2   Screen Navigation Diagram
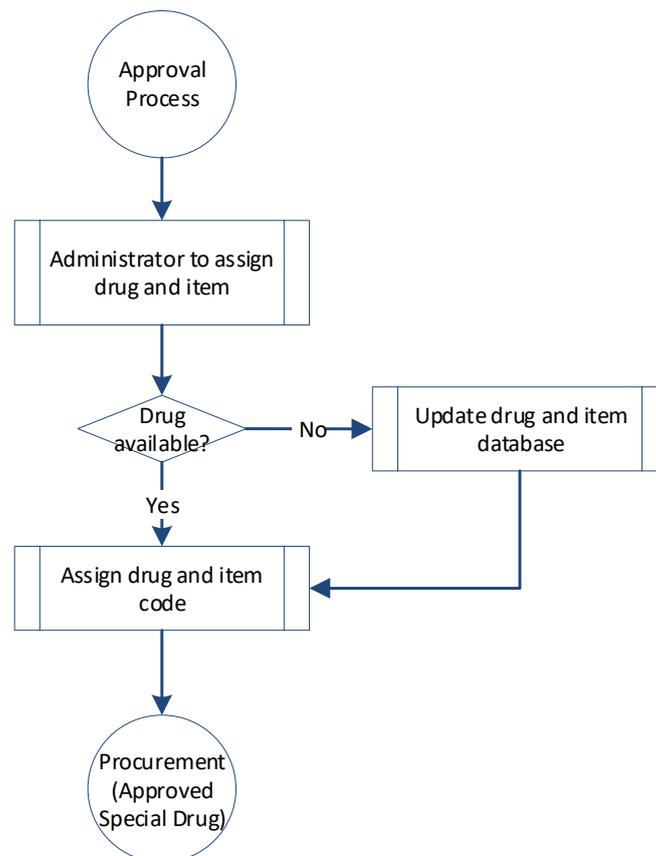
Screen Navigation: Drug code assignment

3.5.3 Detail Functionality and Screen

3.5.3.1 Drug Assignment Listing

3.2.3.1.1 Screen Design

ID	SDR.SD5
Description	Drug Assignment listing
Diagram	

Notes	o Click on search button to search for the transaction o Double click on transaction record to view the transaction
Cross References	

3.2.3.1.2 Application Business Rules

No.	Name	Description
1.	Search Transaction	Click on the 'Search' button to search the existing record: i. If user enters multiple search criteria, system will display the search results based on the specified criteria ii. If no criteria entered, system will display all transactions iii. System will display the records that match any keyword entered regardless of the letter type (uppercase or lowercase).

2.	Request list	List will display all request where Request status = 'Approved by KPK/PKPF'
		Double click on any record to view the record details.
		List will display the following information:
		i. Facility Request No
		ii. Facility Name
		iii. Drug Name
		    o If user request by drug name, it will show the drug name.
		    o If user request for new drug, it will show the new drug name entered. Once assign to new drug, display new drug created.
		iv. Approved Date
		v. Status – Pending/completed

3.	Refresh Listing	Click on the 'Refresh' button to reset all search criteria:

No.	Name	Description
		i. BPF Register No – Display as empty field
		ii. Drug Name – Display as empty field
		iii. Status – Display as empty field
		iv. Facility name – Display as empty field
		v. Approved Date – Display as empty field
		Search results will display all records based on above reset search criteria.

3.2.3.1.3   Input Validation Rules

No.	Name	Description	Manda tory	Format
1.	BPF Register No	User to enter free text value to search for BPF request no.	No	Text field
2.	Drug name	User to enter free text value to search for drug name	No	Text field
3.	Status	Value refer to reference code, domain = 'KPK_ITEM_APPROVED_STATUS' Default to <blank> however user can select specific value.	No	Drop down list
4.	Facility Name	List of facility from external facility master.	No	Searching field
5.	Approved Date	User to select date from the calendar. Click on the calendar icon to display the calendar.	No	Calendar

3.5.3.2   **Drug Assignment**

3.2.3.2.1   Screen Design

ID	SDR.SD6
Description	Drug Code Assignment screen
Diagram	

Drug Code Assignment			
Request Details			
Facility Request No.	HTMH0033/2018	BPF Register No.	B0643/2018
Facility Name	Hospital Tanah Merah	State	Kelantan
Request Date	08/06/2018	Request Type	● New ○ Repeat
● Drug Name	Acyclovir 400 mg Tablet	Status	Approved by KPK/PKPF
○ Create New Drug			
Drug Details			
Drug Description	Acyclovir 400 mg Tablet	Item Code	
		Packaging Description	

Notes	
Cross References	

3.2.3.2.2   Application Business Rules

No.	Name	Description
1.	Drug Assignment	• On click of the approved request, details screen will be displayed for admin to select the drug. • If user request by drug name, drug description value will be defaulted to the requested drug. • If user request for new drug, administrator need to select the drug to be used. Once the admin selects the drug, related item code will be displayed. • If only one item available, item code will be defaulted to that item. One item code must be selected. Packaging description will be displayed.
2.	Save record	Click on save button to save the request • Status will be changed to completed. • Once completed, user is not allowed to change the drug and item. • Updated details will be send back to requester.

3.2.3.2.3   Input Validation Rules

No.	Name	Description	Mand atory	Format
1.	Drug description	List of drugs from drug master where 'Special Approved Drug' flag is true.	Yes	Searching field
2.	Item Code	List of item code for the selected drug.	Yes	Drop down box
3.	Packaging description	Packaging description will be displayed for the selected item/	No	Read only

3.5.4   **Integration**

None

3.6 KPK Form

BPF/103-KPK01 (Pindaan 4)

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

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

NO. SIRI Series no
Hospital:
Bhg. Perkhidmatan Farmasi:

1	Hospital yang memohon: **Facility Name** Hospital Pakar Sultanah Fatimah, Muar	**5**	Nama ubat / keluaran dimohon: **Drug Name** Dexamethasone 4mg tablet	
2	Negeri: **State Name** Johor	**6**	Status pendaftaran Pihak Berkuasa Kawalan Dadah (PBKD: http://portal.bpfk.gov.my/) **Registration Status**	
3	Jenis permohonan: **Request Type** Ulangan (No. Siri Kelulusan A1234/2016)			

4	Nama Pesakit: **Patient Name**		**A**	Berdaftar MAL – ABC123 *Indikasi seperti diluluskan oleh PBKD - Tidak*
	1	Nama: Muhammad Razif Ahmad No KP: 800203023457 No Pendaftaran: HPSF12345678 Umur pesakit: 36 tahun 9 bulan Diagnosis: Low blood Dosis/regimen rawatan: 200 mg Berat pesakit: Jangkamasa rawatan: 30 Ringkasan sejarah rawatan pesakit :		**B**	Tidak berdaftar tetapi terdapat dallam Formulari Ubat KKM (FUKKM) *Indikasi seperti terdapat dalam FUKKM - Ya*
	2	Nama: No KP: No Pendaftaran: Umur pesakit: Diagnosis: Dosis/regimen rawatan: Berat pesakit: Jangkamasa rawatan: Ringkasan sejarah rawatan pesakit :		**C**	Tidak Berdaftar dan tiada dalam FUKKM * Nama Pengilang : ABC Sdn Bhd Nama Pengimport : XYZ Sdn Bhd

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

3	Nama: No KP: No Pendaftaran: Umur pesakit: Diagnosis: Dosis/regimen rawatan: Berat pesakit: Jangkamasa rawatan: Ringkasan sejarah rawatan pesakit :	**7**	Kuantiti dimohon (maksimum 6 bulan): **Request Quantity** Kos seunit: RM **Cost per unit** Kos sebenar : RM **Cost**

A	**INDIKASI/TUJUAN RAWATAN BAGI UBAT/KELUARAN YANG DIMOHON** Indication/reason for treatment

B	UBAT/KELUARAN ALTERNATIF SEDIA ADA DALAM FUKKM BAGI INDIKASI DIMOHON **Alternative/ Treatment**		
	UBAT/KELUARAN	**TEMPOH PENGGUNAAN**	**SEBAB-SEBAB TIDAK DAPAT DIGUNAKAN**
1			
2			
3			
4			

C	**MAKLUMAT PAKAR YANG MEMOHON Specialist Information**	
	Ulasan:	Nama: Tarikh:

D	**KETUA JABATAN Head of Department**	
	Ulasan:	Nama: Tarikh:

E	**KETUA PEGAWAI FARMASI Chief Pharmacist**	
	Ulasan:	Peruntukan yang diperlukan: Peruntukan sedia ada:
		Nama: Tarikh:

F	**PENGESAHAN PENGARAH HOSPITAL Hospital Director**	
	Ulasan:	Nama: Tarikh:

G	**PENGESAHAN PENGERUSI JKK UBAT-UBATAN KKM (Kegunaan Sekretariat Ubat Kelulusan Khas) Verification**	
	Ulasan: ☐ SOKONG ☐ TIDAK DISOKONG	Tandatangan, nama & cop : Tarikh:

pharmaniaga

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

	Hospital	Facility Name		No. Siri: BPF Register No
	Nama Ubat	Drug Name		
	Kuantiti Ubat	Request Quantity		Kos Ubat: RM Cost
	Nama Pesakit	Patient Name (Patient Name 1, Patient Name 2)		
	Nama Pemohon Jawatan (Pakar)	Specialist name		
H	URUSETIA Secretariat			
	Ulasan:		Nama :	
			Tarikh:	
I	PENGARAH AMALAN & PERKEMBANGAN FARMASI PKPF			
	Ulasan:		Tandatangan, nama & cop :	
	☐ SOKONG ☐ TIDAK DISOKONG		Tarikh:	
J	KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF) KPK/PKPF			
	Sila maklum bahawa permohonan tuan/puan:		Tandatangan, nama & cop :	
	☐ LULUS ☐ TIDAK LULUS			
	Ulasan:		Tarikh:	

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 telak diberikan dan bukan sebagai alasan untuk memehon peruntukan tambahan.

No.	Name	Description
1.	Series No	• Facility Request No. • BPF Register No ➢ Display in form Hospital: Facility Request No Bhg. Perkhidmatan Farmasi: BPF Register No E.g.: ***Hospital:*** *HPSF0003/2016* ***Bhg. Perkhidmatan Farmasi:*** *A0005/2016*
2.	Facility Name	Facility Name
3.	State	State
4.	Request Type	N = New, R = Repeat o Display in form, N = Baru, R = Ulangan, o For R, display previous request no E.g.: *Ulangan (No. Siri Kelulusan A1234/2016)*
5.	Patient name	• Patient Name(Nama) • Patient ID (No KP) • Age (Umur Pesakit) Format : <u>YY</u> tahun <u>MM</u> bulan E.g.: Request date = 1/10/2015, Patient DOB = 1/1/1980 → *35 tahun 9 bulan* • MRN No (No Pendaftaran) • Diagnosis • Dose (Dosis) • Treatment Duration (Jangkamasa Rawatan) • Summary of patient indication history(Ringkasan sejarah rawatan pesakit) ➢ Display in form, Nama: Patient name No KP: Patient ID Umur pesakit: ___ tahun ___ bulan No Pendaftaran: MRN No Diagnosis: Diagnosis Dosis /regimen rawatan: Dose and Dose UOM Berat pesakit: Jangkamasa Rawatan: Treatment Duration Ringkasan sejarah rawatan pesakit : *repeat the number of patient record based on number of patient per request. If no patient record show as 'Not Available'
6.	Drug name	• If user request by drug name, it will show the drug name. • If user request for new drug, it will show the new drug name

No.	Name	Description
7.	Registration Status	1) If 'Registered MAL'= True, Show **A** • Registered MAL (*Berdaftar MAL*) • Indication approved by PBKD (*Indikasi seperti diluluskan oleh PBKD*), If True then show 'Ya', else show 'Tidak' ➢ Display in form, Berdaftar MAL - (Registration No) *Indikasi seperti diluluskan oleh PBKD - Ya* 2) If 'MOH Drug Formulary' = True and 'Registered MAL' = False, Show **B** • FUKKM Indication (Indikasi seperti terdapat dalam FUKKM) If True then show 'Ya', else show 'Tidak' ➢ Display in form, Tidak berdaftar tetapi terdapat dalam Formulari Ubat KKM (FUKKM) *Indikasi seperti terdapat dalam FUKKM - Ya* 3) If 'MOH Drug Formulary' = False and 'Registered MAL' = False, Show **C** • Manufactured by (Nama Pengilang) • Imported by (Nama pengimport) ➢ Display in form, Tidak Berdaftar dan tiada dalam FUKKM * Nama pengilang - Manufactured by Nama pengimport - Imported by **Show A, B or C only*
8.	Request Quantity	Request Quantity
9.	Cost per unit	Cost per Pack
10.	Cost	Total Cost
11.	Indication/reason for treatment	Indication/reason for treatment for drug/product request
12.	Alternative/ Treatment	• Item (Ubat/Keluaran) • Duration (Tempoh Penggunaan) • Reason/Comment (Sebab-sebab tidak dapat digunakan) ➢ Display in form, Ubat/Keluaran : Item Tempoh Penggunaan : Duration Sebab-sebab tidak dapat digunakan : Reason/Comment *repeat the number of alternative/treatment record based on number of record per request.
13.	Specialist Information	• Remarks (Ulasan) – Specialist remarks • Name (Nama) – Specialist Name

No.	Name	Description
		• Request Date (Tarikh) – Request by specialist date
14.	Head of Department	• Remarks (Ulasan) – HOD Remarks • Name (Nama) – HOD Name • Date (Tarikh) – Recommendation by HOD Date
15.	Chief Pharmacist	• Allocation Required • Existing Allocation • Remarks (Ulasan) – Chief Pharmacist remarks • Name (Nama) – Chief Pharmacist name • Date (Tarikh) - Recommendation by Chief Pharmacist Date
16.	Hospital Director	• Remarks (Ulasan) – Hospital Director remarks • Name (Nama) - Hospital Director name • Date (Tarikh) – Recommendation by HD Date
17.	Verification	• Remarks (Ulasan) • Date (Tarikh) • Nama • Status - Status = 'R', SOKONG, Status = 'N', TIDAK DISOKONG
18.	Secretariat	• Remarks (Ulasan) • Date (Tarikh) • Nama
19.	PKPF	• Remarks (Ulasan) • Date (Tarikh) • Nama • Status - Status = 'R', SOKONG, Status = 'N', TIDAK DISOKONG
20.	KPK/PKPF	• Remarks (Ulasan) • Name (Nama) • Date (Tarikh) – KPK/PKPF approval date • Status - Status = 'APP', LULUS, Status = 'REJ', TIDAK LULUS

3.7   Print Permit

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

PENGECUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI
TUJUAN RAWATAN PENYAKIT YANG MENGANCAM NYAWA
1. No Siri   **(No. Siri: XXXXX/XX)**

KKM-55/BPF/103/001/_____

Pengecualian ini diberikan kepada (Nama Pemohon) : **2. Requester Name**

Nama dan Alamat Hospital/Institusi : **3. Facility Name**

Nama Keluaran :   **4. Drug Name**

Kuantiti :   **5. Quantity**

Indikasi/ Tujuan Rawatan : **6. Indication**

Nama Pesakit : **7. Patient Name**

Pengecualian ini tertakluk kepada syarat-syarat yang berikut:

1) Pengimportan ini dikhaskan bagi kegunaan ke atas pesakit seperti dinyatakan dalam permohonan sahaja.
2) Rekod dan dokumen mengenai pembekalan keluaran ini kepada pesakit berkenaan hendaklah disimpan untuk tujuan audit.
3) Aduan produk dan kesan advers ubat akibat dari penggunaan keluaran tidak berdaftar ini adalah tanggungjawab pemohon sepenuhnya. Laporan Aduan produk dan kesan advers ubat hendaklah dikemukakan kepada Bahagian Perkhidmatan Farmasi dan JKN (Farmasi) negeri masing-masing.
4) Pegawai perubatan yang merawat pesakit hendaklah memberikan nasihat supaya pesakit boleh memilih ubatnya dan memberikan persetujuannya.
5) Perundangan yang berkaitan dengan keluaran hendaklah dipatuhi khasnya mengenai pengimportan, penyimpanan, pembekalan dan kesan advers.
6) Adalah menjadi tanggungjawab syarikat yang mengimport untuk memastikan produk yang diimport tidak melanggar mana-mana hak milik paten atau/dan data exclusivity.
7) Dalam tempoh 30 hari dari tarikh pengimportan, pemohon hendaklah:
    a. memulangkan semula pengecualian ini dan.
    b. menghantar sesalinan borang import Kastam
    kepada Pengarah Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
8) Pengecualian ini sah untuk pengimportan dalam tempoh satu (1) tahun dari tarikh ia dikeluarkan.

Tarikh: **8. Date**

Pengarah Kanan Perkhidmatan Farmasi

Kementerian Kesihatan Malaysia

No.	Name	Description
1.	No. Siri	BPF Register No
2.	Requester Name	Requester Name and Designation
3.	Facility Name	Facility Name
4.	Drug Name	Drug Name
5.	Quantity	Approved Quantity & Quantity UOM
6.	Indication	Indication/reason for treatment for drug/product request
7.	Patient Name	Patient Name
8.	Date	Approval Date

4. References

Document	Description/ Expansion
garispanduan-permohonan-ubat-kpk-2016-final-040816.pdf	Garis Panduan Permohonan Memperolehi dan Menggunakan Ubatubatan Yang Memerlukan Kelulusan Khas Ketua Pengarah Kesihatan (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF)
	Edisi Pertama, Ogos 2016

5. Acronyms

Item	Description
HD	Hospital Director
HOD	Head of Department
KPF	Ketua Pegawai Farmasi (Chief Pharmacy Officer)
KPK	Ketua Pengarah Kesihatan
FUKKM	Formulari Ubat Kementerian Kesihatan Malaysia.
	List of medicines that have been approved for use in the Ministry of Health (MOH) facilities.

6. Appendix

6.1 Request Validation

No	KKM Drug List	Registered MAL	Indication Approved By PBKD	Indication as listed in FUKKM	Status	Remarks
1.	Yes	Yes	No	No	Valid	Off label PBKD & FUKKM
2.	Yes	Yes	No	Yes	Not Valid	To be listed in FUKKM, indication must be approved by PBKD
3.	Yes	No	Yes	Yes	Valid	Listed FUKKM but not registered
4.	Yes	No	Yes	No	Valid	Listed FUKKM but not registered
5.	Yes	No	No	No	Valid	Listed FUKKM but not registered
6.	Yes	No	No	Yes	Valid	Listed FUKKM but not registered
7.	No	Yes	Yes	No	Valid	Not listed FUKKM but registered
8.	No	Yes	Yes	Yes	Valid	Not listed FUKKM but registered
9.	No	No	No	No	Valid	Not listed and not registered
10.	No	No	No	Yes	Valid	Not listed and not registered
11.	No	Yes	No	No	Valid	Not listed FUKKM but registered
12.	No	Yes	No	Yes	Valid	Not listed FUKKM but registered
13.	Yes	Yes	Yes	No	Valid	Off label FUKKM
14.	Yes	Yes	Yes	Yes	Not Valid	
15.	No	No	Yes	No	Not Valid	
16.	No	No	Yes	Yes	Not Valid	

6.2 Request Status

No	Action	Status	Code	Full Based	Pharmacy Based
Facility					
1.	Apply for special drug (by Specialist/HOD/Pharmacist)	New Request	NEW	Y	Y
2.	Confirm request (by Specialist)	Pending	PEN	Y	-
3.	Confirm request (by HOD)	Pending Review by Pharmacist	PRP	Y	-
4.	Confirm request (by Pharmacist)	Pending Recommendation by KPF	PRKPF	Y	Y
5.	Recommendation by HOD – No	Not Recommended by HOD	NRHOD	Y	-
6.	Recommendation by HOD – Yes	Pending Review by Pharmacist	PRP	Y	-
7.	Review by Pharmacist	Pending Recommendation by KPF	PRKPF	Y	-
8.	Recommendation by KPF – No	Not Recommended by KPF	NRKPF	Y	Y
9.	Recommendation by KPF – Yes	Recommended by KPF	RKPF	Y	*
10.	Recommendation by Hospital Director – No	Not Recommended by HD	NRHD	Y	-
11.	Recommendation by Hospital Director – Yes ** Recommendation by KPF – Yes (for Pharmacy Based)*	Send for Approval	SENT	Y	Y
IWP					
12.	Secretariat receive Special Drug application - Check on 'Completed Form'	Pending for KPK Approval	PKPK	Y	Y
13.	Secretariat receive Special Drug application – Not Process	Not processed	NP	Y	Y
14.	Approval by Secretariat – Approve	Approved by KPK/PKPF	APP	Y	Y
15.	Approval by Secretariat – Reject	Rejected by KPK/PKPF	REJ	Y	Y

6.3   Sample of KPK Form

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

NO. SIRI
Hospital:

PERHATIAN : *Permohonan yang tidak lengkap* **TIDAK** *akan diproses.*   **Bhg. Perkhidmatan Farmasi:**

1	Hospital yang memohon:		5	Nama ubat / keluaran dimohon:
2	Negeri:		**6**	Status pendaftaran Pihak Berkuasa Kawalan Dadah (PBKD: http://portal.bpfk.gov.my/)
3	Jenis permohonan:			
4	Nama Pesakit:			Berdaftar MAL *Indikasi seperti diluluskan oleh PBKD*

4 Nama Pesakit:

1	Nama: No KP: No Pendaftaran: Umur pesakit: Diagnosis: Dosis/regimen rawatan: Berat pesakit: Jangkamasa rawatan:Ringkasan sejarah rawatan pesakit :
2	Nama: No KP: No Pendaftaran: Umur pesakit: Diagnosis: Dosis/regimen rawatan: Berat pesakit: Jangkamasa rawatan:Ringkasan sejarah rawatan pesakit :
3	Nama: No KP: No Pendaftaran: Umur pesakit: Diagnosis: Dosis/regimen rawatan: Berat pesakit: Jangkamasa rawatan: Ringkasan sejarah rawatan pesakit :

6 (samb.):

Berdaftar MAL
Indikasi seperti diluluskan oleh PBKD

Tidak berdaftar tetapi terdapat dallam Formulari Ubat KKM (FUKKM)
Indikasi seperti terdapat dalam FUKKM

Tidak Berdaftar dan tiada dalam FUKKM *
Nama Pengilang :
Nama Pengimport :

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

7	Kuantiti dimohon (maksimum 12 bulan): Kos seunit: RM Kos sebenar: RM

A	**INDIKASI/TUJUAN RAWATAN BAGI UBAT/KELUARAN YANG DIMOHON**

B	UBAT/KELUARAN ALTERNATIF SEDIA ADA DALAM FUKKM BAGI INDIKASI DIMOHON		
	UBAT/KELUARAN	**TEMPOH PENGGUNAAN**	**SEBAB-SEBAB TIDAK DAPAT DIGUNAKAN**
1			
2			
3			
4			

C	MAKLUMAT PAKAR YANG MEMOHON

Ulasan:	Nama:
	Tarikh:

D	KETUA JABATAN

Ulasan:	Nama:
	Tarikh:

E	KETUA PEGAWAI FARMASI

Ulasan:	Peruntukan yang diperlukan:
	Peruntukan sedia ada:
	Nama:
	Tarikh:

F	PENGESAHAN PENGARAH HOSPITAL

Ulasan:	Nama:
	Tarikh:

G	PENGESAHAN PENGERUSI JKK UBAT-UBATAN KKM (Kegunaan Sekretariat Ubat Kelulusan Khas)

Ulasan: ☐ SOKONG ☐ TIDAK DISOKONG	Tandatangan, nama & cop : Tarikh:

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

	Hospital		**No. Siri:**	
	Nama Ubat			
	Kuantiti Ubat		**Kos Ubat: RM**	
	Nama Pesakit			
	Nama Pemohon Jawatan (Pakar)			
H	**URUSETIA**			
	Ulasan:		Nama: Tarikh:	
I	**PENGARAH AMALAN & PERKEMBANGAN FARMASI**			
	Ulasan: ☐ SOKONG ☐ TIDAK DISOKONG		Tandatangan, nama & cop : Tarikh:	
J	**KEPUTUSAN KETUA PENGARAH KESIHATAN MALAYSIA (KPK) / PENGARAH KANAN PERKHIDMATAN FARMASI (PKPF)**			
	Ulasan: ☐ SOKONG ☐ TIDAK DISOKONG		Tandatangan, nama & cop : Tarikh:	

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 telak diberikan dan bukan sebagai alasan untuk memehon peruntukan tambahan.