

Summary of Ticket Number and Requests for Special Drug Request Module – IWP

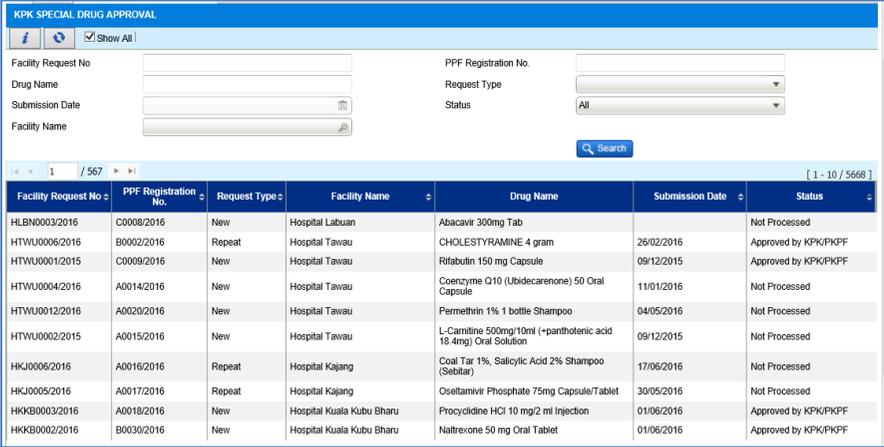
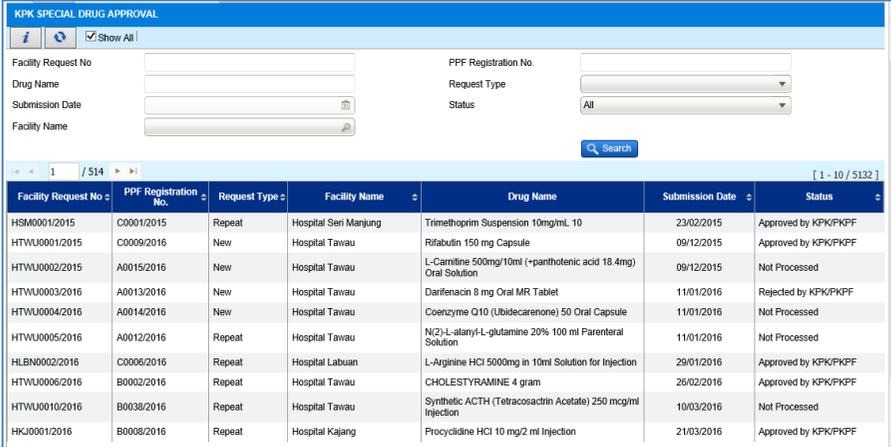
No.	Ticket #	Description	Requests	Solution
1.	I-PhIS0246 83118S	<u>Special Drug Request - Request date on form less than submission date</u> Add validity rule for date on the form (Pharmacy base) - should be less than submission date (discuss this during CR review 13Feb2018)	To validate on request date for each level	1) Validate on date entered for each level
2.	I-PhIS0246 83418S	<u>Special Drug Request - Request to sort based on submission date (older to newer)</u> Sorting of data at listing page upon search - submission date; older to newer	To sort the record by submission date in ascending order.	2) Sort the record by submission date in ascending order.
3.	I-PhIS0184 93817S	<u>Tasklist : notification not appear for Approve drug KPK</u> There's no notification appear on the first page for both Head of Department and pharmacy side to inform that KPK application was received for approval. We need to click in Order Management --> Special Drug Request then only know there's application pending for approval, which may cause delay in processing the application.	Task list for all user level.	3) Provide task list for all user level.
4.	I-PhIS0315 57118S	<u>Tasklist - Request to have notification approval KPK and Drug Info</u> Encik Syafuan request to have notification of approval for transaction Approval KPK and Drug Info. As of current version, his officer need to expend module to enter in each module for approval.	Task list for approval	
5.	I-PhIS0199 18017S	<u>Special Drug Request - Request to add field/checkbox to acknowledged KPK sample drug</u> User request to add field/checkbox sample drug to acknowledged KPK that drug is sample drug or put field/checkbox others and user able to fill in description/remark.	To add new field to capture request category	4) Added new field to capture request category
6.	I-PhIS0240 89218S	<u>Special Drug Request - Remarks not appear</u> User reported remarks not appear when print.	To display remarks in form.	5) Display remarks in form.
7.	I-PhIS0442	<u>Special Drug Request - Remarks not appear on report</u>	To display remarks in form.	

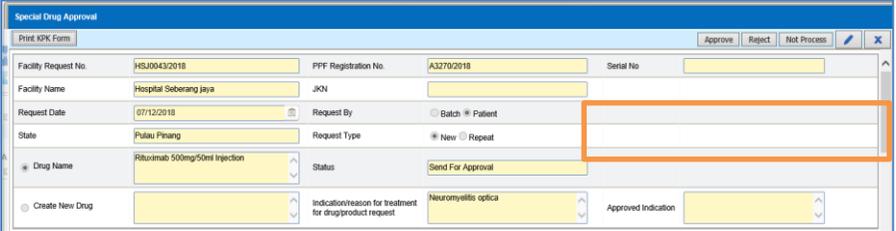
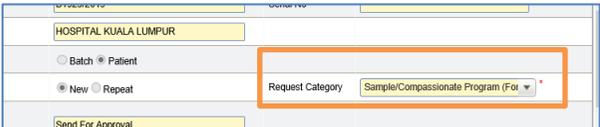
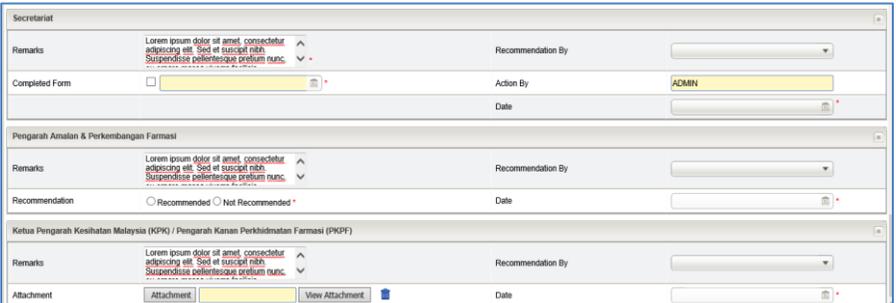
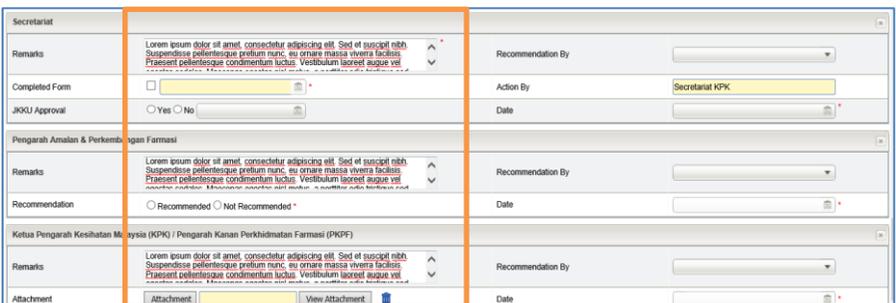
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	93418S	User reported that remarks that she key in in patient details not appear after she print KPK form report. User mention she received feedback from BPF informed that the dosage was not appear on her KPK form, so that BPF unable to proceed with KPK Approval. User explain that due to the dosage have range, she had key in dosage on Remarks field on Patient details. User check on system appear that Remarks, but after print KPK Form, the remarks does not appear.		
8.	I-PhIS0281 93118S	<u>Special Drug Request - Request changes for Request By Batch</u> User request changes for Request By : Batch. Current Situation When user print out SDR with status, Sending for KPK Approval. Print KPK Form. Patient Column still appear but blank. User request if tick to Request By Batch, the patient column do not need to be appear and replace with : Stock Hospital		6) To replace patient column with 'Stok Hospital' for Request By Batch.
9.	I-PhIS0443 43718S	<u>Special Drug Request: Patient list in KPK Form and permit</u> User request for module Special Drug Request: Patient list in KPK Form and permit, "Terms for name pesakit in KPK form page 3 & Permit 1. 5 patients and below; Show all patients name 2. More than 5 patients; Show total no of patients. E.g. 38 orang pesakit (seperti dalam lampiran) 3. Apply as batch; Stok Hospital		7) Patient list in KPK Form: a. If 5 patients or less- show all patients name b. More than 5 patients -Show total no of patients.
10.	I-PhIS0443 44118S	<u>Special Drug Request: Statistic Report</u> 1. Report to be displayed based on drug name instead of active ingredient. 2. Allow filter by BPF Register (A,B or C)		8) Statistic Report a. To display based on drug name instead of active ingredient. b. Allow filter by BPF Register (A,B or C) 9) Allow user to print 3 different permits after

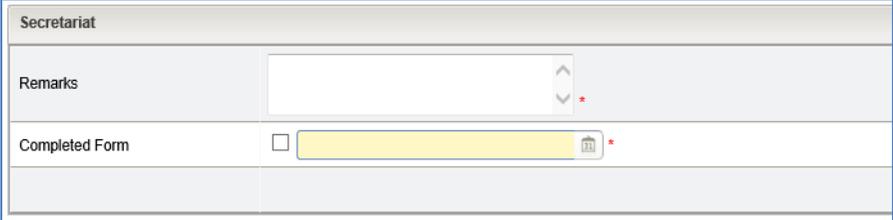
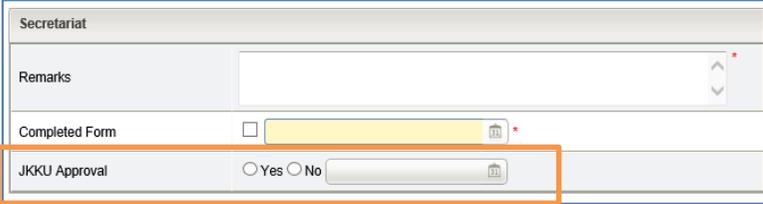
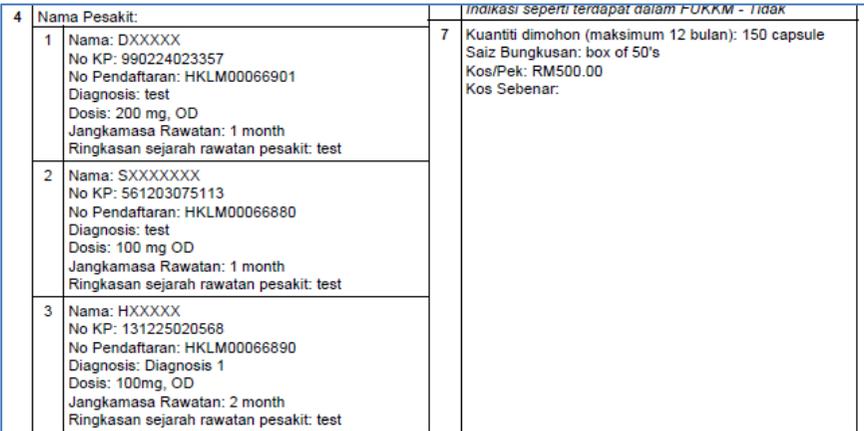
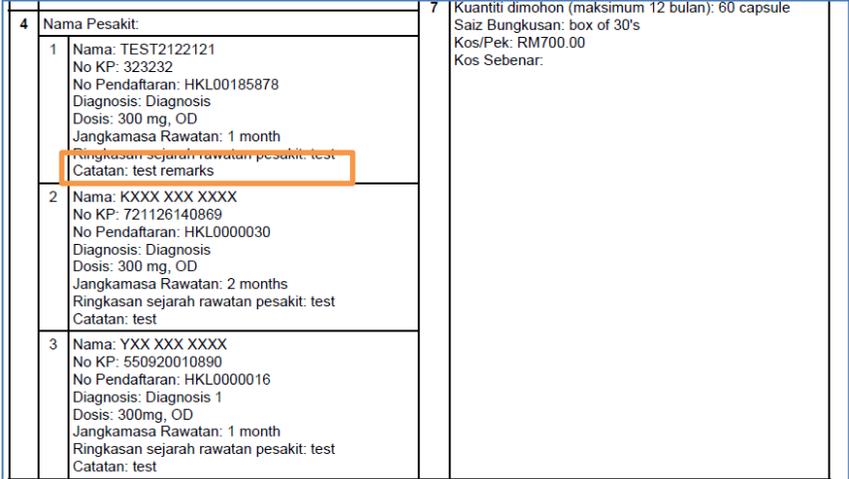
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				request is approved.
11.	I-PhIS0443 43818S	<p><u>Special Drug Request: Complete Registration Report</u></p> <p>User request for module Special Drug Request: Complete Registration Report: "Filter - to allow view All & Status 'Pending'"</p> <p>1. Calculation of total process time; Date Approval sent - Date Complete Application Received</p> <p>2. Tempoh Pemprosesan = To consider working days only"</p>		10) Complete Registration Report, Filter - to allow view All & Status 'Pending'.
12.	I-PhIS0492 62419S	<p><u>(UAT 2.1) Special Drug Request -KPK Form</u></p> <p>1. To add 'Request Category' information inside KPK Form under section '3. Jenis Permohonan'</p> <p>Amend section G heading: To change '(Untuk Permohonan....)' to '(Ruangan ini untuk kegunaan sekretariat sahaja)'</p>		<p>11) To add 'Request Category' information inside KPK Form under section '3. Jenis Permohonan'</p> <p>12) Amend section G heading: To change '(Untuk Permohonan.)' to '(Ruangan ini untuk kegunaan sekretariat sahaja)'</p>
13.	I-PhIS0492 62819S	<p><u>(UAT 2.1) KPK Special Drug Approval</u></p> <p>To add new radio button under 'Completed Form' field inside Secretariat section.</p> <p>JKKU Approval: •Yes •No ; Date:</p> <p>This will reflect into KPK form Bahagian 4</p>		<p>13) To add new radio button under 'Completed Form' field inside Secretariat section.</p> <p>a) JKKU Approval: •Yes •No</p> <p>b) Date:</p>
14.	I-PhIS0492 62619S	<p><u>(UAT 2.1) Special Drug Request - Dialog screen</u></p> <p>Allow expand field function for Remarks.</p>		14) To increase all 'Remarks' fields.
15.	I-PhIS0492	<p><u>(UAT 2.1) Special Drug Request -Permit report</u></p>		15) Permit format to add 'Jata Negara'

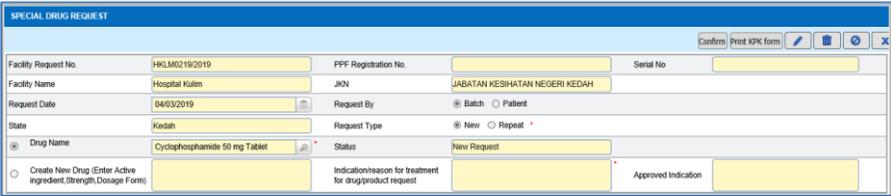
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	62719S	Permit format to add 'Jata Negara'		
16.	I-PhIS0492 62919S	<p>(UAT 2.1) Complete Registration report</p> <p>1. To allow filter by PPF Registration status:</p> <ul style="list-style-type: none"> a) All b) A c) B d) C 		<p>16) Allow filter by BPF Register (A,B or C). Compare with Registration status (T_SPL_DRUG_REQUES T_INT. REG_STATUS). Default to All.</p>
17.	I-PhIS0492 63019S	<p>(UAT 2.1) Statistic Report</p> <p>1. To check on Total Request value</p> <p>2. Request to be able to sort by KPK status inside Statistic report</p> <ul style="list-style-type: none"> a) ALL b) Approved by KPK/PKPF c) Rejected by KPK/PKPF d) Not Processed 		<p>17) Allow filter by BPF KPK status</p> <ul style="list-style-type: none"> a) ALL b) Approved by KPK/PKPF c) Rejected by KPK/PKPF d) Not Processed

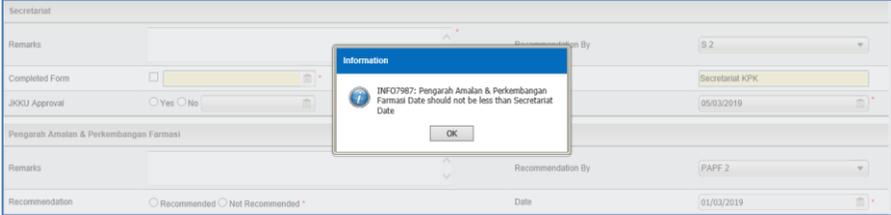
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Function Flow	Special Drug Request in current Version 2.0	Special Drug Request in new Version 2.1
<p>2. Task list</p>	<p>1. Login as secretariat 2. No task list for new request received</p> 	<p>1. Login as secretariat 2. New request will be displayed in task list. Click on transaction no to proceed with secretariat task.</p> 
<p>3. Approval list</p>	<p>1. Approval list not sorted in proper order</p> 	<p>1. By default, list will be sorted by submission date in ascending order.</p> 

Function Flow	Special Drug Request in current Version 2.0	Special Drug Request in new Version 2.1
<p>4. Request Category</p>	<p>1. Select request that still pending for approval. 2. No field to display request category.</p> 	<p>1. Select request that still pending for approval. 2. New field added to display 'Request category'. Field will be displayed based on value select by facility</p>  <p>3. Selection of value as below:</p> <ul style="list-style-type: none"> • Funded by Facility • 'Sample/Compassionate Program (For Fully Funded Only) • Pesara Persekutuan • Pesara Lain • Others – Free text.
<p>5. Remarks</p>	<p>1. User has to scroll to view more information in remarks fields.</p> 	<p>1. Remarks fields width has been increased.</p>  <p>2. Apply to remarks in the following section :</p> <ol style="list-style-type: none"> Specialist Recommendation by Head of Department Pharmacist Recommendation By Head of Pharmacy Department Recommendation By Hospital Director Secretariat Ketua Pengarah Kesihatan Malaysia (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF)

Function Flow	Special Drug Request in current Version 2.0	Special Drug Request in new Version 2.1
<p>6. JKKU Approval</p>	<p>2. No field to capture JKKU Approval information.</p> 	<p>3. New radio button added under 'Completed Form' field inside Secretariat section. This information is not mandatory.</p> <p>a) JKKU Approval: •Yes •No</p> <p>b) Date:</p>  <p>4. This will reflect into KPK Form when selected,</p> 
<p>7. KPK Form. Patient list</p>	<p>1. Select request with 'Request by'= Patient.</p> <p>2. List of all patient will be displayed in the form regardless no of patient.</p> 	<p>1. Select request with 'Request by'= Patient.</p> <p>2. If number of patients equal to 5 or less, all patients name will be displayed.</p> 

Function Flow	Special Drug Request in current Version 2.0	Special Drug Request in new Version 2.1														
		<p>3. Remarks from patient details also will be displayed in this form.</p> <p>4. If number of patients more than 5, it will display total number of patients only.</p> <table border="1" data-bbox="1216 368 2107 472"> <tr> <td data-bbox="1216 368 1659 440">4</td> <td data-bbox="1216 440 1659 472">Nama Pesakit: 6 orang pesakit (seperti dalam lampiran)</td> <td data-bbox="1659 368 2107 472">7</td> <td data-bbox="1659 472 2107 472">Kuantiti dimohon (maksimum 12 bulan): 60 capsule Saiz Bungkus: box of 30's Kos/Pek: RM700.00 Kos Sebenar:</td> </tr> </table>	4	Nama Pesakit: 6 orang pesakit (seperti dalam lampiran)	7	Kuantiti dimohon (maksimum 12 bulan): 60 capsule Saiz Bungkus: box of 30's Kos/Pek: RM700.00 Kos Sebenar:										
4	Nama Pesakit: 6 orang pesakit (seperti dalam lampiran)	7	Kuantiti dimohon (maksimum 12 bulan): 60 capsule Saiz Bungkus: box of 30's Kos/Pek: RM700.00 Kos Sebenar:													
<p>8. KPK Form - 'Stok Hospital' and Request category</p>	<p>1. Create new request and select 'Request by'= Batch.</p>  <p>2. Save the request and print KPK form. Section 4 will be displayed as 'Nama Pesakit' with blank value.</p> <table border="1" data-bbox="280 826 1171 1007"> <tr> <td data-bbox="280 826 728 887">3</td> <td data-bbox="280 887 728 922">Jenis permohonan: Baru</td> <td data-bbox="728 826 1171 922">Tidak berdaftar tetapi terdapat dalam Formulari Ubat KKM (FUKKM) <i>Indikasi seperti diluluskan oleh PBKD - Tidak Indikasi seperti terdapat dalam FUKKM - Ya</i></td> </tr> <tr> <td data-bbox="280 922 728 1007">4</td> <td data-bbox="280 1007 728 1007">Nama Pesakit:</td> <td data-bbox="728 922 1171 1007">7</td> <td data-bbox="728 1007 1171 1007">Kuantiti dimohon (maksimum 12 bulan): 60 tablet Saiz Bungkus: box of 30's Kos/Pek: RM600.00 Kos Sebenar:</td> </tr> </table> <p>Section 3 will display 'Jenis Permohonan' = Baru or Ulangan.</p>	3	Jenis permohonan: Baru	Tidak berdaftar tetapi terdapat dalam Formulari Ubat KKM (FUKKM) <i>Indikasi seperti diluluskan oleh PBKD - Tidak Indikasi seperti terdapat dalam FUKKM - Ya</i>	4	Nama Pesakit:	7	Kuantiti dimohon (maksimum 12 bulan): 60 tablet Saiz Bungkus: box of 30's Kos/Pek: RM600.00 Kos Sebenar:	<p>1. Create new request and select 'Request by'= Batch.</p>  <p>2. Save the request and print KPK form. Title for section 4 changed to 'Stok Hospital'</p> <table border="1" data-bbox="1216 826 2107 999"> <tr> <td data-bbox="1216 826 1659 903">3</td> <td data-bbox="1216 903 1659 903">a. Jenis permohonan:Baru b. Kategori Permohonan: Funded by Facility</td> <td data-bbox="1659 826 2107 903">Berdaftar MAL - <i>Indikasi seperti diluluskan oleh PBKD - Ya Indikasi seperti terdapat dalam FUKKM - Ya</i></td> </tr> <tr> <td data-bbox="1216 903 1659 999">4</td> <td data-bbox="1216 999 1659 999">Stok Hospital</td> <td data-bbox="1659 903 2107 999">7</td> <td data-bbox="1659 999 2107 999">Kuantiti dimohon (maksimum 12 bulan): 60 capsule Saiz Bungkus: box of 30's Kos/Pek: RM700.00 Kos Sebenar:</td> </tr> </table> <p>3. Section 3 will be splitted into 2:</p> <p>a) 'Jenis Permohonan' = Baru or Ulangan</p> <p>b) 'Kategori Permohonan'. In will refer to 'Request Category' value.</p> 	3	a. Jenis permohonan:Baru b. Kategori Permohonan: Funded by Facility	Berdaftar MAL - <i>Indikasi seperti diluluskan oleh PBKD - Ya Indikasi seperti terdapat dalam FUKKM - Ya</i>	4	Stok Hospital	7	Kuantiti dimohon (maksimum 12 bulan): 60 capsule Saiz Bungkus: box of 30's Kos/Pek: RM700.00 Kos Sebenar:
3	Jenis permohonan: Baru	Tidak berdaftar tetapi terdapat dalam Formulari Ubat KKM (FUKKM) <i>Indikasi seperti diluluskan oleh PBKD - Tidak Indikasi seperti terdapat dalam FUKKM - Ya</i>														
4	Nama Pesakit:	7	Kuantiti dimohon (maksimum 12 bulan): 60 tablet Saiz Bungkus: box of 30's Kos/Pek: RM600.00 Kos Sebenar:													
3	a. Jenis permohonan:Baru b. Kategori Permohonan: Funded by Facility	Berdaftar MAL - <i>Indikasi seperti diluluskan oleh PBKD - Ya Indikasi seperti terdapat dalam FUKKM - Ya</i>														
4	Stok Hospital	7	Kuantiti dimohon (maksimum 12 bulan): 60 capsule Saiz Bungkus: box of 30's Kos/Pek: RM700.00 Kos Sebenar:													

Function Flow	Special Drug Request in current Version 2.0	Special Drug Request in new Version 2.1								
<p>9. KPK Form – Section G</p>	<p>5. Section G display as (untuk permohonan ubat tidak ...)</p> <div data-bbox="280 300 1169 459"> <table border="1"> <tr> <td colspan="2"> G PENGESAHAN PENERUSI JKK UBAT-UBATAN KKM (untuk permohonan ubat tidak berdaftar (tiada dalam FUKKM) dan permohonan ubat diluar) </td> </tr> <tr> <td> Ulasan: <input type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG </td> <td> Tandatangan, nama & cop: Tarikh: </td> </tr> </table> </div>	G PENGESAHAN PENERUSI JKK UBAT-UBATAN KKM (untuk permohonan ubat tidak berdaftar (tiada dalam FUKKM) dan permohonan ubat diluar)		Ulasan: <input type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG	Tandatangan, nama & cop: Tarikh:	<p>1. Change on section G heading from '(Untuk Permohonan....)' to '(Ruangan ini untuk kegunaan sekretariat sahaja)'</p> <div data-bbox="1214 343 2105 502"> <table border="1"> <tr> <td colspan="2"> G PENGESAHAN PENERUSI JKK UBAT-UBATAN KKM (Ruangan ini untuk kegunaan sekretariat sahaja) </td> </tr> <tr> <td> Ulasan: <input type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG </td> <td> Tandatangan, nama & cop: Tarikh: </td> </tr> </table> </div>	G PENGESAHAN PENERUSI JKK UBAT-UBATAN KKM (Ruangan ini untuk kegunaan sekretariat sahaja)		Ulasan: <input type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG	Tandatangan, nama & cop: Tarikh:
G PENGESAHAN PENERUSI JKK UBAT-UBATAN KKM (untuk permohonan ubat tidak berdaftar (tiada dalam FUKKM) dan permohonan ubat diluar)										
Ulasan: <input type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG	Tandatangan, nama & cop: Tarikh:									
G PENGESAHAN PENERUSI JKK UBAT-UBATAN KKM (Ruangan ini untuk kegunaan sekretariat sahaja)										
Ulasan: <input type="checkbox"/> SOKONG <input type="checkbox"/> TIDAK DISOKONG	Tandatangan, nama & cop: Tarikh:									
<p>10. Validation on date entered for each level</p>	<p>1. Select date for Secretariat and 'Pengaruh Amalan & Perkembangan Farmasi' date.</p> <div data-bbox="280 598 1182 810">  </div> <p>2. No alert display if user enter date smaller than secretariat date</p>	<p>1. Select date for Secretariat and 'Pengaruh Amalan & Perkembangan Farmasi' date.</p> <div data-bbox="1214 598 2105 813">  </div> <p>2. Alert will be displayed if date entered is less than secretariat date</p> <p>3. Date should be same or more than previous level date by the following order:</p> <ol style="list-style-type: none"> Secretariat (Action Date) Pengaruh Amalan & Perkembangan Farmasi Ketua Pengarah Kesihatan Malaysia (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF) 								

11. Permit

1. Once request is approved, 'Print Permit' button will be displayed.

2. On click of 'Print Permit' button, permit will be displayed as below.

**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
(No.Siri:)**

KKM-55/BPF/103/001/_____

Pengecualian ini diberikan kepada (Nama Pemohon) : A/_____

Nama dan Alamat Hospital/Institusi : Hospital Kulim

Nama Keluaran : Cysteamine Bitartrate 50mg Capsule

Indikasi/ Tujuan :

Kuantiti : 220 capsule

Nama Pesakit :

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 adwers ubat akibat dari penggunaan keluaran tidak berdaftar ini adalah tanggungjawab pemohon sepenuhnya. Laporan Aduan produk dan kesan adwers ubat hendaklah

1. Once request is approved, 'Print Permit' button will be displayed.

2. On click of 'Print Permit' button, screen will be displayed as below.

Serial No	C0012/2019
Requester Name	DR CHAN Pegawai Perubatan Pelatih
Drug Name	Abacavir 300mg Tab
Approved Quantity	60 application
Manufacturer	Manufacturer ABC
Supplier	Syarikat XYZ Sdn Bhd
Date	

- a) Serial No – Default to Serial No. User not allow to change this value in this screen.
- b) Requester Name – Default the value to 'Requester Name and Designation'. User is allowed to change this value. Maximum 100 characters is allowed.
- c) Drug name - Default the value to 'Drug Name'. User is allowed to change this value. Maximum 100 characters is allowed.
- d) Approved Quantity - Default the value to 'Approved Quantity & Quantity UOM'. User is allowed to change this value. Maximum 100 characters is allowed.
- e) Manufacturer - Default the value to 'Manufactured by'. User is

		<p>allowed to change this value. Maximum 100 characters is allowed.</p> <ul style="list-style-type: none">f) Supplier – Default the value to 'Imported by'. User is allowed to change this value. Maximum 100 characters is allowed.g) Date – Default to blank. Maximum 100 characters is allowed. <ol style="list-style-type: none">3. Changes on above value will only apply to this screen and permit. User is allowed to change the value after save. (No changes on original value from the request screen)4. Permit value will refer to this screen. All fields are not mandatory. User is allowed to print the permit at any time (with blank value)5. User has option to print the following print.<ul style="list-style-type: none">a) Permit Standardb) Permit Lot Releasec) Permit Psychotropic Drugs6. Sample of permit as below:
--	--	---

a) Permit Standard


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 :C0012/2019)**

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

Nama Pemohon : DR CHAN Pegawai Perubatan Pelatih,
Hospital/Institusi : Hospital Kuala Lumpur
Nama Produk : Abacavir 300mg Tab
Kuantiti : 60 application

Pengecualian ini tertakluk kepada syarat-syarat yang berikut ;

- (1) Pengimportan ini dihaskan 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.

b) Permit Lot Release



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

PENGEUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN
PENYAKIT YANG MENGANCAM NYAWA (No.Siri :C0012/2019)

KKM-600-34/4/

Pengecualian ini diberikan kepada:

Nama Pemohon : DR CHAN Pegawai Perubatan Pelatih,
Hospital/Institusi : Hospital Kuala Lumpur
Nama Produk : Abacavir 300mg Tab
Kuantiti : 60 application
Nama Pembekal : Manufacurer ABC
Nama Pengilang : Syarikat XYZ Sdn Bhd

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.

c) Permit Psychotropic Drugs


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 (No.Siri :C0012/2019)

KKM-600-34/4/

Pengecualian ini diberikan kepada:

Nama Pemohon : DR CHAN Pegawai Perubatan Pelatih,
Hospital/Institusi : Hospital Kuala Lumpur
Nama Produk : Abacavir 300mg Tab
Kuantiti : 60 application

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 sesalinan 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: 05/03/2019

Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.

12. Statistic Report

Go to Report/Enquiry → KPK → Statistic report

1. Enter search criteria and click on search button

Drug Name	Total Request	Quantity	SKU	Total Cost (RM)
Atazanavir	1	111	capsule	4,884.00
Fluoxetine	1	111	capsule	5,359.00
Isotretinoin	1	111	capsule	1,221.00
Mercaptopurine bitartrate (Cysteamine bitartrate)	1	132	capsule	2,331.00
Paricalcitol	1	111	capsule	506.00
Vorinostat	1	111	capsule	7,429.00
Total	6	687		21,730.00

2. Drug name refer to active ingredient name
3. No filter by PPF Registration Status
4. No filter by Approval status

Go to Report/Enquiry → KPK → Statistic report

1. Enter search criteria and click on search button

Drug Name	Total Request	Quantity	SKU	Total Cost (RM)
Denosumab 120 mg solution for Injection	1	6	vial	7,483.80
Ibuprofen 100mg/5mL Oral Suspension	1	20	ml	38.00
Leuprolide Acetate 3.75mg Injection	1	12	prefilled syringe/pen	3,924.00
Mirabegron 50 mg prolonged-release tablet	1	360	tablet	1,977.60
Mycophenolate Mofetil 250 mg Capsule	1	800	capsule	1,968.24
Pamidronate Disodium 30mg Injection	1	42	vial	3,296.00
Papaverine HCl 60 mg/2ml Injection	1	40	each	2,633.40
Phenylephrine Hydrochloride 10mg/ml injection	1	50	ampoule	500.00
Sildenafil Citrate 100 mg Tablet	2	140	tablet	280.00
Tramadol 37.5mg, Paracetamol 325mg Tablet	2	720	tablet	1,080.00
Total	12	2190		23,181.04

2. Drug name will refer to drug name as in drug master
3. Allow to filter by PPF Registration Status (A, B or C)

PPF Registration status: All

Date To: All

Search

4. Allow to filter by Approval status

Approval Status: All

Approved by KPK/PKPF

Rejected by KPK/PKPF

Not Processed

13. Complete Registrati on Report

Go to Report/Enquiry → KPK → Complete Registration report

1. Enter search criteria

2. User not able to filter all status.
3. No filter by PPF Registration Status

Go to Report/Enquiry → KPK → Complete Registration report

1. Enter search criteria

2. Status will be defaulted to all. User able to filter by other status

5. Allow to filter by PPF Registration Status (A, B or C)