KEMENTERIAN KESIHATAN MALAYSIA
(Ministry of Health Malaysia)
Pejabat Pengarah Kanan Perkhidmatan Farmasi
(Office of the Senior Director of Pharmaceutical Services)
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Ruj. Tuan :
Ruj. Kami : KKM.600-34/4/04 Jld. 2 (2)
Tarikh : 17 April 2018

SEPERTI SENARAI EDARAN

YBhg. Datuk/Dato'/Datin/Tuan/Puan,

PEKELILING PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT-UBATAN KEMENTERIAN KESIHATAN MALAYSIA BILANGAN 1/2018

Saya dengan segala hormatnya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Mesyuarat Panel Kaji Semula Senarai Ubat KKM Bil. 1/2018 yang diadakan pada 27 Mac 2018 telah mempertimbangkan permohonan-permohonan pindaan/tambahan kepada Formulari Ubat KKM (FUKKM). Keputusan pindaan/ tambahan tersebut adalah seperti berikut:

2.1 Pindaan/Tambahan kepada FUKKM yang diluluskan (Jadual A):
- Lampiran 1: Penyenaraian ubat baru ke dalam FUKKM.
- Lampiran 2: Tambahan indikasi bagi ubat-ubatan dalam FUKKM.
- Lampiran 3: Tambahan kekuatan baru ke dalam FUKKM.
- Lampiran 4: Pindaan kategori preskriber bagi ubat-ubatan dalam FUKKM
- Lampiran 5: Pemansuhan ubat-ubatan daripada FUKKM.
- Lampiran 6: Pengemaskinian maklumat bagi ubat-ubatan dalam FUKKM.

2.2 Permohonan-permohonan yang tidak diluluskan (Jadual B).

2.3 Permohonan yang ditangguhkan (Jadual C).

3. Penggunaan ubat-ubatan yang terdapat dalam FUKKM perlu dipantau dengan rapi dan sebarang kesan advers hendaklah dilaporkan kepada Jawatankuasa Penasihat Kesan Advers Ubat Kebangsaan (MADRAC) di Bahagian Regulatori Farmasi Negara (NPRA) dan sesalinan dihantar ke Bahagian ini.

4. Sebagai makluman, harga yang terdapat dalam senarai di lampiran adalah harga yang diisytiharkan oleh pihak syarikat kepada Bahagian ini untuk penyenaraian ubat berkenaan ke dalam FUKKM. Sebarang perbezaan harga (melebihi harga yang ditawarkan) di peringkat hospital/ institusi KKM hendaklah dilaporkan beserta bukti dengan kadar segera supaya tindakan selanjutnya dapat diambil.

5. Sehubungan dengan itu, diharapkan YBhg. Datuk/Dato'/Datin/Tuan/Puan dapat menyampaikan maklumat ini kepada fasiliti yang berkaitan di negeri atau jabatan masing-masing. Segala kerjasama yang diberikan amatlah dihargai.

Sekian, terima kasih.

'BERKHIDMAT UNTUK NEGARA'

Saya yang menurut perintah,

(DR. SALMAH BINTI BAHRI) RPh.783
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

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SENARAI EDARAN

1. **Timbalan Pengarah Kesihatan Negeri (Farmasi)**
   Johor/ Kedah/ Kelantan/ Melaka/ Negeri Sembilan/ Pahang/ Perak/ Pulau Pinang/ Perlis/ Sabah/ Sarawak/ Selangor/ Terengganu/ Wilayah Persekutuan Kuala Lumpur dan Putrajaya/ Wilayah Persekutuan Labuan

2. **Ketua Pegawai Farmasi**
   Hospital Kuala Lumpur

3. **Ketua Pegawai Farmasi**
   Institut Kanser Negara

4. **Pegawai Farmasi y/m**
   Institut Perubatan Respiratori.

5. **Pegawai Farmasi y/m**
   Pusat Darah Negara

s.k.

1. **Ketua Setiausaha**
   Kementerian Kesihatan Malaysia

2. **Ketua Pengarah Kesihatan**
   Kementerian Kesihatan Malaysia

3. **Setiausaha Bahagian (Perolehan & Penswastaan)**
   Kementerian Kesihatan Malaysia
   Aras 7, Blok E7, Parcel E
   Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
   62509 Putrajaya
   (u.p Pegawai Farmasi)

4. **Pengarah Kanan (Kesihatan Pergigian)**
   Kementerian Kesihatan Malaysia
   Aras 5, Blok E10, Pusat Pentadbiran Kerajaan Persekutuan
   62590 Putrajaya

5. **Pengarah**
   Bahagian Perkembangan Perubatan
   Aras 5-7, Blok E1, Parcel E
   Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
   62509 Putrajaya

6. **Pengarah**
   Bahagian Pembangunan Kesihatan Keluarga
   Aras 5, Blok E6, Parcel E
   Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
   62509 Putrajaya

7. **Pengarah**
   Bahagian Kawalan Penyakit
   Kementerian Kesihatan Malaysia
   Aras 3, Blok E10, Parcel E
   Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
   62509 Putrajaya

8. **Semua Pengarah Kesihatan Negeri**
   Kementerian Kesihatan Malaysia

9. **Semua Pengerusi JK Kerja Ubat-ubatan**
   Kementerian Kesihatan Malaysia

10. **Semua Ahli Panel Kaji Semula Senarai Ubat-ubatan**
    Kementerian Kesihatan Malaysia

11. **Pengarah**
    Agensi Regulatori Farmasi Negara
    Kementerian Kesihatan Malaysia

12. **Semua Timbalan Pengarah**
    Bahagian Amalan & Perkembangan Farmasi
    Kementerian Kesihatan Malaysia

13. **Ketua Penolong Pengarah Kanan**
    Sektor Bekalan Farmasi
    Cawangan Dasar Polisi Perkhidmatan
    Bahagian Perkembangan Kesihatan Awam
    Kementerian Kesihatan Malaysia

14. **Timbalan Pengarah**
    Cawangan Teknologi Maklumat & Informatik Farmasi
    Bahagian Dasar dan Perancangan Strategik Farmasi
    (bagi tujuan pengemaskinian sistem PhIS).

15. **Ketua Pustakawan**
    Kementerian Kesihatan Malaysia
    Aras 4, Blok E7, Parcel E
    Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
    62509 Putrajaya

16. **Penolong Pegawai Perpustakaan**
    Institut Pengurusan Kesihatan
    Kementerian Kesihatan Malaysia
    Jalan Rumah Sakit
    Off Jalan Bangsar
    59100 Kuala Lumpur

17. **Unit Teknikal Bantuan Perubatan**
Pejabat Timbalan Ketua Pengarah Kesihatan (Perubatan)
Aras 7, Blok E1, Parcel E
Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
62509 Putrajaya.

18. **Ketua Pegawai Farmasi**
Pusat Perubatan Universiti Malaya
Lembah Pantai
59100 Kuala Lumpur

19. **Ketua Jabatan Farmasi**
Hospital Canselor Tuanku Muhriz
Pusat Perubatan Universiti Kebangsaan Malaysia
Jalan Yaacob Latif
Bandar Tun Razak
56000 Cheras, Kuala Lumpur

20. **Ketua Pegawai Farmasi**
Hospital Universiti Sains Malaysia
Jalan Raja Perempuan Zainab II
16150 Kubang Kerian, Kelantan

21. **Pengarah Farmasi**
Bahagian Perkhidmatan Kesihatan
Kementerian Pertahanan Malaysia
Jalan Padang Tembak
50634 Kuala Lumpur

22. **Pegawai Farmasi**
Institut Jantung Negara

PINDAAN/TAMBAHAN KEPADA FORMULARI UBAT KKM (FUKKM) BIL. 1 TAHUN 2018

A. PERMOHONAN PINDAAN/TAMBAHAN KEPADA FUKKM YANG DILULUSKAN

BIL	NAMA UBAT	PINDAAN	LAMPIRAN
1.	Dexlansoprazole 30 mg and 60 mg delayed release capsule	D1 – penyenaraian ubat baru	1
2.	Teriflunomide 14 mg tablet		
3.	Pimecrolimus 1% cream		
4.	Febuxostat 80 mg tablet		
5.	Sacubitril/Valsartan 50 mg, 100 mg and 200 mg tablet		
6.	Micafungin 50 mg injection	D1 – tambahan indikasi *(treatment of invasive candidiasis in children)*	2
7.	Insulin glargine 300 units/ml injection (pre-filled pen)	D2 – tambahan kekuatan	3
8.	Potassium Chloride 1 g/15 ml mixture	Pindaan kekuatan kepada Potassium Chloride 1 g/10 ml mixture	
9.	Vildagliptin 50 mg tablet	D3 – pindaan kategori preskriber (A* kepada A/KK)	4
10.	Vildagliptin/Metformin HCl (50 mg/500 mg) tablet		
11.	Vildagliptin/Metformin HCl (50 mg/850 mg) tablet		
12.	Vildagliptin/Metformin HCl (50 mg/1000 mg) tablet		
13.	Bromhexine HCl 8 mg tablet	D3 – pindaan kategori preskriber (B kepada C)	
14.	Hyoscine N-Butylbromide 10 mg tablet		
15.	Mefenamic acid 250 mg capsule		
16.	Miconazole 2% cream		
17.	Linagliptin 5 mg tablet	D5 – pemansuhan daripada FUKKM	5
18.	Glibenclamide 5 mg tablet		
19.	Rabeprazole sodium 20 mg tablet		
20.	Chloramphenicol 125 mg/5 ml suspension		
21.	Diphenhydramine hydrochloride 10 mg/5 ml oral solution		
22.	Ethosuximide 250 mg/5 ml syrup		
23.	Pneumococcal polysaccharide conjugate vaccine (adsorbed) 13-valent injection	Pindaan *prescribing restriction*	6
24.	Empagliflozin 10 mg and 25 mg tablet		

B. PERMOHONAN PINDAAN/TAMBAHAN KEPADA FUKKM YANG <u>TIDAK DILULUSKAN</u>

BIL	NAMA UBAT	CADANGAN PINDAAN	JUSTIFIKASI
1.	Fulvestrant 250 mg/5 ml injection	D1 – penyenaraian ubat baru	Cost and formulation/route of administration are not favourable as compared to the available alternatives in FUKKM.
2.	Ibrutinib 140 mg capsule	D1 – penyenaraian ubat baru	High cost implication that is not sustainable to MOH.
3.	Micafungin 50 mg injection	D1 – tambahan indikasi *(Prophylaxis of Candida infection in children and adult patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia).*	High cost implication that is not sustainable to MOH.
4.	Eltrombopag 25 mg tablet	D1 – tambahan indikasi	High cost implication that is not sustainable to MOH.
5.	Chlorpheniramine maleate 10mg/ml injection	D3 – pindaan kategori preskriber (B kepada C)	Medical officer assessment and prescription are mandatory when require IV formulation for moderate to severe hypersensitivity.
6.	Multivitamin tablet	D3 – pindaan kategori preskriber (B kepada C)	High cost implication to MOH.

C. PERMOHONAN PINDAAN KEPADA FUKKM YANG DITANGGUHKAN

BIL	NAMA UBAT	CADANGAN PINDAAN	JUSTIFIKASI PENANGGUHAN
1.	Fluticasone furoate/ vilanterol (100/25mcg & 200/25mcg) Inhalation powder	D1 – penyenaraian ubat baru	To defer until review on the respiratory inhalers for the management of asthma and chronic obstructive pulmonary disease (COPD) in the FUKKM is completed.
2.	Vortioxetine 10 mg tablet	D1 – penyenaraian ubat baru	To gather more information from relevant stakeholders on the selection of medicines in treatment of multiple depression disorder (MDD).
3.	Tegafur 100 mg & uracil 224 mg capsule	D1 – tambahan indikasi	To gather more information from relevant stakeholders on the preference of medicines in the treatment of colorectal cancer.
4.	Leucovorin Calcium (Calcium Folinate) 15 mg tablet	D1 – tambahan indikasi	

LAMPIRAN 1

UBAT-UBATAN BARU YANG DILULUSKAN UNTUK DISENARAIKAN DALAM FUKKM

NO.	*MDC*	*GENERIC NAME & QUOTED PRICE*	*PRESCRIBER CATEGORY*	*DETAILS*
1.	i) A02BC06-000-C30-01-XXX; ii) A02BC06-000-C30-02-XXX.	i) Dexlansoprazole 30 mg delayed release capsules ii) Dexlansoprazole 60 mg delayed release capsules <u>Cost:</u> RM1.50/tablet for all strengths.	A*	<u>Approved Indication(s):</u> i) Treatment of erosive esophagitis (EE) ii) Maintenance of healed erosive esophagitis (EE) iii) Symptomatic treatment of non-erosive gastroesophageal reflux disease. **<u>Prescribing Restriction(s):</u>** As a second-line therapy for: i) Patients with refractory EE; ii) Geriatrics; iii) Patients with polypharmacy. <u>Dose:</u> i) Treatment of EE – 60 mg once daily for 8 weeks ii) Maintenance of healed EE – 30 mg once daily for 6 months iii) Symptomatic non-erosive gastroesophageal reflux disease – 30 mg once daily for 4 weeks. <u>Precaution(s):</u> Gastric malignancy, Clostridium difficile associated diarrhoea, bone fracture, influence on vitamin B-12 absorption, interference with laboratory tests, hypomagnesemia, concomitant use with methotrexate <u>Contraindication(s):</u> Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation Hypersensitivity and anaphylaxis have been reported with dexlansoprazole use <u>Interaction(s):</u> Drugs with pH-dependent absorption pharmacokinetics (e.g. atazanavir, nelfinavir, ampicillin esters, digoxin, iron salts, ketoconazole), warfarin, tacrolimus,

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
				methotrexate Adverse reaction(s): Most common ≥2%: Diarrhoea, abdominal pain, nausea, upper respiratory tract infection, vomiting, flatulence.
2.	L04AA31-000-T32-01-XXX	Teriflunomide 14 mg tablet Cost: RM 119.46/tablet	A*	Approved Indication(s): Treatment of adult patients with relapsing remitting multiple sclerosis (MS) Dose: 14mg once daily. Precaution(s): Monitor and assess BP, alanine aminotransferase & CBC i.e., differential WBC & platelet count prior to & during treatment. Assess liver enzymes prior to & every 2 wk during 1st 6 mth treatment & every 8 wk thereafter. Discontinue use if liver injury is suspected, pulmonary symptoms e.g., persistent cough & dyspnoea, severe haematological reactions i.e., pancytopenia, ulcerative stomatitis, skin &/or mucosal reactions, peripheral neuropathy occurs. Pre-existing liver disease, hypoproteinaemia, active acute or chronic infections, latent TB, history of interstitial lung diseases. Delay initiation in patients w/ severe active infection until resolution. Avoid use of live attenuated vaccines. Concomitant with leflunomide, interferon β or glatiramer acetate, alcohol. Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. May affect ability to drive & use machines. Children 10-18 yr. Elderly ≥65 yr. Contraindication(s): Hypersensitivity to the active substance or to any of the excipients. Interaction(s): Rifampicin, carbamazepine, phenobarbital,

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
				phenytoin, St John's Wort, warfarin, cholestyramine, activated charcoal, repaglinide, paclitaxel, pioglitazone, rosiglitazone, ethinylestradiol, levonorgestrel, caffeine, cefaclor, benzylpenicillin, ciprofloxacin, indometacin, ketoprofen, furosemide, cimetidine, methotrexate, zidovudine, methotrexate, topotecan, sulfasalazine, daunorubicin, doxorubicin, simvastatin, atorvastatin, pravastatin, and nateglinide. Adverse reaction(s): Diarrhoea, nausea; alopecia; increased alanine aminotransferase. Influenza, upper respiratory tract infection, UTI, bronchitis, sinusitis, pharyngitis, cystitis, viral gastroenteritis, oral herpes, tooth infection, laryngitis, tinea pedis; neutropenia, anaemia; mild allergic reactions; anxiety; paraesthesia, sciatica, carpal tunnel syndrome; hypertension; upper abdominal pain, vomiting, toothache; rash, acne; musculoskeletal pain, myalgia; pollakiuria; menorrhagia; pain; increased γ-glutamyltransferase & aspartate aminotransferase, decreased weight, neutrophil & white blood cell counts.
3.	D11AH02-000-G10-01-XXX	Pimecrolimus 1% cream Cost: RM63.45/tube of 15gm	A*	Approved Indication(s): Short-term and intermittent long-term therapy of mild to moderate atopic dermatitis in non-immunocompromised patients aged 2 years and older, in whom the use of alternative, conventional therapies are deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative, conventional therapies. **Prescribing Restriction(s):** • First line for periorbital eczema; • Second line for facial eczema. Dose: Apply a thin layer of the cream to the affected

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
				skin twice daily. Precaution(s): None Contraindication(s): Known hypersensitivity to Pimecrolimus or to any of the excipients (Eg: triglycerides, oleyl alcohol, propylene glycol, stearyl alcohol, cetyl alcohol, mono and diglycerides, sodium cetostearyl sulphate, benzyl alcohol, citric acid, sodium hydroxide, purified water). Interaction(s): Potential interactions between pimecrolimus 1% cream and other drugs have not been systematically evaluated. Based on its minimal extent of absorption, interactions with systematically administered drugs are unlikely to occur. Adverse reaction(s): **Very rare:** Application site burning **Rare:** Alcohol intolerance; Allergic reactions (e.g. rash, urticarial, angioedema), skin discoloration (hypopigmentation, hyperpigmentation); Malignancy including cutaneous and other types of lymphoma, skin cancers.
4.	M04AA03-000-T32-01-XXX	Febuxostat 80 mg tablet Cost: RM7.56/tablet	A*	Approved indication(s): Treatment of chronic hyperuricaemia in adult patients, in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). **Prescribing restriction(s):** As second line for patients who are allergic or intolerant to allopurinol. Dose: The recommended oral dose is 40 mg or 80 mg once daily without regard to food. The recommended starting dose is 40 mg once daily. If serum uric acid is > 6.0 mg/dL (357 µmol/L) after 2-4 weeks, 80 mg once

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
				daily may be considered. The 80 mg tablet can be divided into equal halves. In order to provide a 40 mg dose, the tablet should be split just before use. Prescribers should advise patients on how to break the tablets in half and to keep the other half for the next dose. <u>Precaution(s):</u> Not recommended in patients with cardio-vascular disorders, xanthine deposition (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), treatment with mercaptopurine/azathioprine, rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption and in patients who are organ transplant recipients. Caution in patients with medicinal product allergy/ hypersensitivity, acute gouty attacks (gout flare), liver disorders (continuation of treatment is based on clinical judgment) and thyroid disorders. <u>Contraindication(s):</u> Hypersensitivity to the active substance or to any of the excipients. <u>Interaction(s):</u> Concomitant use of mercaptopurine/ azathioprine, cytotoxic chemotherapy is not recommended. No dose adjustment needed if use with rosiglitazone/ CYP2C8 substrates, theophylline, naproxen and other inhibitors of glucuronidation, colchicine/ indomethacin/ hydrochlorothiazide/ warfarin, Desipramine/ CYP2D6 substrates and antacids. Monitoring of uric acid is needed if use with inducers of glucuronidation. <u>Adverse reaction(s):</u> Gout flares, liver function abnormalities, diarrhoea, nausea, headache, rash and oedema.

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
5.	i) C09DX04-000-T32-01-XXX; ii) C09DX04-000-T32-02-XXX; iii) C09DX04-000-T32-03-XXX	i) Sacubitril/ Valsartan 50 mg tablet; ii) Sacubitril/ Valsartan 100 mg tablet; iii) Sacubitril/ Valsartan 200 mg tablet. Cost: RM 4.48/tablet for all strengths	A*	Approved Indication(s): Treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction. **Prescribing Restriction(s):** • NYHA class II-IV; • Patients who are symptomatic despite being on optimized treatment with an ACEi / ARB, a beta blocker, a diuretics and an mineralocorticoid receptor agonist (MRA). Dose: **1a. Adult dosing:** • The recommended starting dose of sacubitril/valsartan is one tablet of 100 mg twice daily. The dose should be doubled at 2-4 weeks to the target dose of one tablet of 200 mg twice daily, as tolerated by the patient • For the following patients, initiate with sacubitril/valsartan 50 mg twice daily, double the dose at every 3-4 weeks to achieve the target dose of 200 mg twice daily as tolerated by the patient: – Not currently on ACEI/ ARB; – Switching from low dose of ACEI/ ARB; – In patients with systolic BP ≥100 to 110 mmHg; – In patients with moderate renal impairment (eGFR 30-60 ml/min/1.73 m2); – In patients with moderate hepatic impairment (Child-Pugh B classification). **1b. Dose in renal impairment** • Mild Renal Impairment: No dose adjustment is required in patients with mild (Estimated Glomerular Filtration Rate [eGFR] 60-90 ml/min/1.73 m2) renal impairment. • Moderate (eGFR 30-60 ml/min/1.73 m2)

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
				& severe (eGFR <30 ml/min/1.73 m2) renal impairment: A starting dose of 50 mg twice daily. • End-stage renal disease: There is no experience in patients with end-stage renal disease and use of sacubitril/valsartan is not recommended. **1c. Dose in liver failure** • Mild hepatic impairment: No dose adjustment is required (Child-Pugh A classification). • Moderate hepatic impairment: In patients with moderate hepatic impairment (Child-Pugh B classification) or with AST/ALT values more than twice the upper limit of the normal range, the recommended starting dose is 50 mg twice daily. • Severe hepatic impairment: Sacubitril/valsartan is contraindicated in patients with severe hepatic impairment, biliary cirrhosis or cholestasis (Child-Pugh C classification) <u>Precaution(s):</u> • Dual blockade of renin-angiotensin-aldosterone system; • Hypotension, with systolic blood pressure less than 100mg; • Impaired renal function; • Worsening renal function; • Hyperkalaemia; • Angioedema; • Renal artery stenosis; • NYHA functional classification IV; • B-type natriuretic peptide; • Hepatic impairment. <u>Contraindication(s):</u> • Hypersensitivity to the active substance, sacubitril, valsartan, or to any of the excipients. • Concomitant use with ACEIs. Sacubitril/valsartan must not be administered until 36 hours after discontinuing ACEI therapy due to the

NO.	MDC	GENERIC NAME & QUOTED PRICE	PRESCRIBER CATEGORY	DETAILS
				risk of angioedema. • Known history of angioedema related to previous ACEI or ARB therapy. • Hereditary or idiopathic angioedema. • Concomitant use with aliskiren in patients with type 2 diabetes or in patients with renal impairment (eGFR <60 ml/min/1.73 m2). • Severe hepatic impairment, biliary cirrhosis and cholestasis. • Pregnancy. <u>Interaction(s):</u> • ACEi, Aliskiren. • ARB containing product. • OATP1B1 and OATP1B3 substrates (e.g. statins), PDE5 inhibitors including sildenafil, Potassium, NSAIDs, including selective COX-2 inhibitors, Lithium, Furosemide, Nitrates, OATP and MRP2 transporters, Metformin. <u>Adverse reaction(s):</u> **Very common (≥1/10):** Hyperkalaemia, Hypotension, Renal impairment **Common (≥1/100 to <1/10):** Anaemia, Hypokalaemia, Hypoglycaemia, Dizziness, Headache, Syncope, Vertigo, Orthostatic hypotension, Cough, Diarrhoea, Nausea, Gastritis, Renal failure, acute renal failure, Fatigue, Asthenia **Uncommon (≥1/1,000 to <1/100):** Hypersensitivity, Dizziness postural, Pruritus, and Rash. Angioedema.

LAMPIRAN 2

TAMBAHAN INDIKASI YANG DILULUSKAN BAGI UBAT-UBATAN YANG TERSENARAI DALAM FUKKM.

NO.	*CURRENT DRUG IN FUKKM*	*AMENDMENT*	*DETAILS*
1.	Micafungin sodium 50mg injection	**Approved to add indication(s):** Treatment of invasive candidiasis in children. Cost: RM 169.00/vial	Category of Prescriber: A* Dose: i. Body weight ≤ 40kg: 2mg/kg/day ii. Body weight > 40kg: 100mg/day Precaution(s): Hypersensitivity: Anaphylactic / anaphylactoid reactions including shock may occur. Skin and subcutaneous tissue disorder: Exfoliative cutaneous reactions, such as Steven-Johnson syndrome and toxic epidermal necrosis have been reported. Haemolysis: Isolated cases of haemolysis including acute intravascular haemolysis or haemolytic anaemia have been reported. Hepatic effects: Early discontinuation in the presence of significant and persistent elevation of ALT / AST is recommended. Micafungin treatment should be conducted on a careful risk/benefit basis, particularly in patients having severe liver function impairment or chronic liver diseases. Use in pregnancy: There are no adequate or well-controlled studies of micafungin in pregnant women. Use in lactation: Micafungin and its metabolites were excreted in the milk of lactating rats. However, it is not known whether micafungin is excreted in human breast milk. Therefore, caution should be exercised when micafungin is administered during breastfeeding. Use in the elderly: No dose adjustment is necessary for the elderly. Contraindication(s): Micafungin is contraindicated in patients with hypersensitivity to any component of

NO.	*CURRENT DRUG IN FUKKM*	*AMENDMENT*	*DETAILS*
			this medication or to other echinocandins. Interaction(s): Micafungin has a low potential for interactions with medicines metabolised via CYP3A mediated pathway. However, patients receiving sirolimus, nifedipine or itraconazole in combination with micafungin should be monitored for toxicity and the dosage of sirolimus, nifedipine or itraconazole should be reduced if necessary. Adverse reaction(s): Diarrhoea, nausea, vomiting, constipation, abdominal pain, dyspepsia, pyrexia, mucosal inflammation, rigors, peripheral oedema, fatigue, hypokalaemia, hypomagnesaemia, hypocalcaemia, anorexia, hyperglycaemia, fluid overload, bacteraemia, sepsis, cough, dyspnea, epitaxis, thrombocytopenia, neutropenia, anaemia, febrile neutropenia, rash, pruritus, headache, insomnia, anxiety, hypotension, hypertension, phlebitis, back pain, tachycardia.

LAMPIRAN 3

TAMBAHAN/PINDAAN KEKUATAN YANG DILULUSKAN UNTUK DISENARAIKAN DALAM FUKKM.

NO.	*CURRENT DRUG IN FUKKM*	*AMENDMENT*	*DETAILS*
1.	Insulin glargine 100units/ml injection (pre-filled pen).	**Approved to add new strength:** Insulin glargine 300units/ml injection (pre-filled pen). Cost: RM 254.06 (box of 5 pens) or; RM 50.81/pen MDC: A10AE04-000-P50-02-XXX	Approved Indication(s): Diabetes mellitus type I and II in adults Category of prescriber: A* **Prescribing Restriction(s):** Treatment of diabetes mellitus type I and II in adults only; who are: i) On insulin not reaching treatment

NO.	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
			goals defined as high fasting plasma glucose (FPG ≥ 7 mmol/L) and/or HbA1c ≥ 6.5% after 6 months of therapy and/or; ii) With a high risk of hypoglycaemia as determined by the following risk factors: a) Advancing age b) Severe cognitive impairment c) Poor health knowledge d) Increased A1c e) Hypoglycaemia unawareness f) Low standing insulin therapy g) Renal impairment h) Neuropathy ***can only be prescribed / dispensed to patients in diabetic clinic / registered under DMTAC program.*** <u>Dose:</u> **Initiation:** • Patient with type 1 diabetes: Once daily with mealtime insulin and requires individual dose adjustments. • Patient with type 2 diabetes: 0.2units/kg followed by individual dose adjustment **Switch between insulin glargine 100 units/ml and insulin glargine 300units/ml:** Insulin glargine 100 units/ml and insulin glargine 300units/ml and are not directly interchangeable. - When switching from insulin glargine 100 units/ml to insulin glargine 300units/ml, this can be done on a unit-to-unit basis, but a higher insulin glargine 300units/ml dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels. - When switching from insulin glargine 300units/ml to insulin glargine 100 units/ml, the dose should be reduced

NO.	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
			(approximately by 20%) to reduce the risk of hypoglycaemia. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. **Switch from other basal insulins to insulin glargine 300units/ml:** When switching from a treatment regimen with an intermediate or long-acting insulin to a regimen with insulin glargine 300units/ml, a change of the dose of the basal insulin may be required and the concomitant anti-hyperglycaemic treatment may need to be adjusted (dose and timing of additional regular insulins or fast-acting insulin analogues or the dose of non-insulin anti-hyperglycaemic medicinal products). - Switching from once-daily basal insulins to once-daily insulin glargine 300units/ml can be done unit-to-unit based on the previous basal insulin dose. - Switching from twice-daily basal insulins to once-daily insulin glargine 300units/ml, the recommended initial T insulin glargine 300units/ml dose is 80% of the total daily dose of basal insulin that is being discontinued. **Switch from insulin glargine 300units/ml to other basal insulins:** Medical supervision with close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. Please refer to the prescribing information of the medicinal product to which the patient is switching. <u>Precaution(s)</u>: Insulin glargine 300 units/ml solution for injection is not the insulin of choice for the treatment of diabetic ketoacidosis. Since insulin glargine 300units/ml and insulin glargine 100units/ml are not bioequivalent and not interchangeable,

NO.	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
			switching may result in the need for a change in dose and should only be done under strict medical supervision. Contraindication(s): Hypersensitivity to the active substance or to any of the excipients (zinc chloride, metacresol, glycerol, hydrochloric acid, sodium hydroxide) Interaction(s): Antihyperglycaemic medical products, ACE inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase (MAO) inhibitors, pentoxifyline, propoxyphene, salicylates and sulphonamide antibiotics, corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazide, oestrogens and progestogens, phenothiazine derivatives, sompatropin, sympathomimetic medical products, thyroid hormones, atypical antipsychotic medical products, beta-blockers, clonidine, lithium salts or alcohol, pentamidine, guanethidine, reserpine. Adverse reaction(s): Hypoglycemia, lipohypertrophy, injection site reactions, lipoatrophy.
2.	Potassium Chloride 1 g/15 ml mixture	**Approved to amend the strength to:** Potassium Chloride 1 g/10 ml mixture	Amendment is based on available strength used in most MOH facilities.

LAMPIRAN 4

PINDAAN KATEGORI PRESKRIBER BAGI UBAT-UBATAN DALAM FUKKM YANG DILULUSKAN.

NO.	*CURRENT DRUG IN FUKKM*	*AMENDMENT*	*DETAILS*
1.	Bromhexine 8mg tablet	Approved to amend category of prescriber from B to C.	Approved Indication(s): Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucous secretion and impaired mucous transport **Prescribing Restriction(s):** To be prescribed by Medical Assistant in health settings without Medical Officer – for adult only. Others: As in FUKKM.
2.	Hyoscine N-Butylbromide 10 mg Tablet	Approved to amend category of prescriber from B to C.	Approved Indication(s): Gastrointestinal tract and genito-urinary tract spasm, dyskinesia of the biliary system **Prescribing Restriction(s):** To be prescribed by Medical Assistant in health settings without Medical Officer – for adult only. Others: As in FUKKM.
3.	Mefenamic acid 250mg capsule	Approved to amend category of prescriber from B to C.	Approved Indication(s): Mild to moderate pain Others: As in FUKKM.
4.	Miconazole 2% cream	Approved to amend category of prescriber from B to C.	Approved Indication(s): i) Fungal infections: Tinea pedis, Tinea corporis, Tinea capitis and other dermatophyte infections caused by Trichophyton and Epidermophyton species. ii) Antifungal agent that has been in various candida infections including

NO.	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
			vaginal candidiasis. **<u>Prescribing Restriction(s):</u>** To be used as 2nd line treatment at health facilities without medical officer <u>Others:</u> As in FUKKM.
5.	Vildagliptin 50mg tablet	Approved to amend category of prescriber from A* to A/KK.	<u>Approved Indication(s):</u> i) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of metformin monotherapy and high risk of hypoglycaemia. ii) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of sulphonylurea and intolerant/contraindicated for metformin therapy. iii) As third line therapy in type 2 diabetes patients inadequately controlled with dual OAD combination therapy with sulphonylurea and metformin. iv) As a monotherapy in type 2 diabetes mellitus patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. v) An adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus: As a dual therapy in combination with insulin in patients with insufficient glycaemic control. Insulin dose and regimen should be optimized before addition of vildagliptin. FUKKM restriction: As add-on therapy for patient who failed therapy and/or contraindicated/unable to tolerate metformin and/or sulphonylurea.

NO.	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
			Others: As in FUKKM.
6.	i) Vildagliptin/Metformin HCl (50mg/500mg) Tablet ; ii) Vildagliptin/Metformin HCl (50mg/850mg) Tablet ; iii) Vildagliptin/Metformin HCl (50mg/1000mg) Tablet	Approved to amend category of prescriber from A* to A/KK.	Approved Indication(s): i) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of metformin monotherapy and high risk of hypoglycaemia. ii) As second line therapy in type 2 diabetes patients inadequately controlled on maximal tolerated dose of sulphonylurea and intolerant/contraindicated for metformin therapy. iii) As third line therapy in type 2 diabetes patients inadequately controlled with dual OAD combination therapy with sulphonylurea and metformin. iv) As a monotherapy in type 2 diabetes mellitus patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. v) An adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus: As a dual therapy in combination with insulin in patients with insufficient glycaemic control. Insulin dose and regimen should be optimized before addition of vildagliptin. FUKKM restriction: As add-on therapy for patient who failed therapy and/or contraindicated/unable to tolerate metformin and/or sulphonylurea. Cost: RM 0.98/tablet for all strengths Others: As in FUKKM.

LAMPIRAN 5

UBAT-UBATAN YANG DILULUSKAN UNTUK DIMANSUHKAN DARIPADA FUKKM

(Pemansuhan ini hanya berkuatkuasa apabila tempoh kontrak bagi perolehan ubat-ubatan tersebut tamat atau stok habis digunakan di fasiliti masing-masing).

NO.	*GENERIC NAME*	*REASON(S)*
1.	Linagliptin 5 mg tablet	Sufficient alternatives are available in FUKKM.
2.	Glibenclamide 5 mg tablet	i) Risk of hypoglycaemia particularly in elderly. ii) Sufficient alternatives are available in FUKKM.
3.	Rabeprazole sodium 20 mg tablet	Low volume of acquisition/utilization in MOH facilities
4.	Chloramphenicol 125 mg/5 ml suspension	No usage and there are alternatives available in FUKKM.
5.	Diphenhydramine hydrochloride 10 mg/5 ml oral solution	
6.	Ethosuximide 250 mg/5 ml syrup	

LAMPIRAN 6

PENGEMASKINIAN MAKLUMAT KEPADA UBAT-UBATAN DALAM FUKKM

NO.	*GENERIC NAME*	*AMENDMENT*	*DETAILS*
1.	Pneumococcal polysaccharide conjugate vaccine (adsorbed) 13-valent injection.	Prescribing restriction (addition of prescribing restriction for children)	Active immunization for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1,3,4,5,6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in these population with associated risk in Invasive Pneumococcal Disease (IPD): **a) Infants/children from 2 months of age and adult with one of the following conditions:** i. Functional or anatomical asplenia; ii. Cochlear implant; iii. Congenital immune-deficiency; iv. Haematopoietic and solid organ transplant. **b) High risk infants/children (from 2 months old) with one of the following conditions:** i. Immunosuppression (including asymptomatic HIV) ii. Nephrotic syndrome iii. Chronic lung or heart disease (Adapted from Paediatric Protocols for Malaysia Hospital, 3rd Edition).

NO.	GENERIC NAME	AMENDMENT	DETAILS
			c) Adults aged 60 years and above with one of the following conditions: i) Chronic lung diseases, including chronic obstructive pulmonary disease (COPD), emphysema & asthma (requiring frequent hospital visit & use of multiple medications); ii) Chronic liver disease including cirrhosis, biliary atresia, chronic hepatitis; iii) Chronic cardiac disease, including congestive heart failure, congenital heart disease, and cardiomyopathies.
2.	i) Empagliflozin 10mg tablet; ii) Empagliflozin 25mg tablet.	Prescribing restriction [removal of criteria - secondary prevention of cardiovascular disease (patient that has previous cardiovascular event)]	Updated indication and prescribing restriction for Empagliflozin: Indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as: Add-on combination therapy: In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control; <u>Prescribing restriction (patient must fulfil all criteria):</u> i) HbA1c not more than 8.5% on dual combination anti-diabetic therapy; ii) Creatinine clearance 60ml/min or eGFR 60ml/min/1.73m2 and above; iii) BMI: 30kg/m2 and above.