BAHAGIAN PERKHIDMATAN FARMASI
KEMENTERIAN KESIHATAN MALAYSIA
Lot 36, Jalan Universiti, 46350 Petaling Jaya, Selangor Malaysia

SIRIM
CERTIFIED TO MS ISO 9001:2008
Reg No: AR 3596

Ruj. Tuan :

Ruj. Kami : KKM-55/BPF/103/001/09Jld15(32)

Tarikh : 25 April 2013

SEPERTI SENARAI EDARAN

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

Pindaan/Tambahan Kepada Formulari Ubat Kementerian Kesihatan Malaysia (FUKKM) – Bil 1/2013

Dengan hormatnya saya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Mesyuarat Panel Kajisemula Senarai Ubat KKM Bil. 1/2013 yang diadakan pada 1 April 2013 telah menimbangkan permohonan-permohonan yang diterima untuk pindaan/tambahan kepada FUKKM. Keputusan-keputusan pindaan/tambahan tersebut adalah seperti berikut:

2.1 Ubat-ubat baru yang diluluskan masuk ke dalam FUKKM (Lampiran 1). Penggunaan ubat-ubatan ini perlu dipantau dengan rapi dan sebarang kesan advers dilaporkan kepada MADRAC (Jawatankuasa Penasihat Kesan Advers Ubat Kebangsaan) di Biro Pengawalan Farmaseutikal Kebangsaan, Petaling Jaya dan satu salinan dihantar ke bahagian ini.

2.2 Ubat-ubat dalam FUKKM yang diluluskan untuk ditambah/pinda formulasi/kekuatan/kategori preskriber/bentuk dosej/indikasi (Lampiran 2).

2.3 Permohonan-permohonan yang tidak diluluskan untuk dimasukkan ke dalam FUKKM (Lampiran 3).

2.4 Permohonan-permohonan yang ditangguhkan dan akan dibentangkan dalam Mesyuarat Panel akan datang (Lampiran 4).

3. Untuk makluman, harga-harga yang terdapat di dalam senarai di lampiran adalah harga yang diberikan oleh pihak syarikat ke bahagian ini untuk penyenaraian ubat berkenaan ke dalam FUKKM. Sebarang perbezaan harga yang ditawarkan di peringkat hospital/institusi KKM hendaklah dilaporkan ke bahagian ini beserta bukti dengan kadar segera supaya tindakan selanjutnya dapat diambil.

Alamat Surat Menyurat :
Beg Berkunci No. 924, Pejabat Pos Jalan Sultan, 46790 Petaling Jaya, Selangor, Malaysia.
Tel : 603-78413200 / 3320 Faks : 603-79682222 http://www.pharmacy.gov.my

4. Sehubungan dengan itu, mohon kerjasama YBhg. Datuk/ Dato'/ Datin/ Tuan/ Puan untuk menyampaikan maklumat ubat-ubatan yang tersebut di atas kepada hospital/ institusi/ klinik kesihatan di negeri masing-masing.

5. Segala kerjasama yang diberikan amat dihargai dan didahului dengan ucapan terima kasih.

Sekian, terima kasih.

'BERKHIDMAT UNTUK NEGARA'

Saya yang menurut perintah,

b/p DR. SALMAH BINTI BAHRI
Pengarah Amalan Dan Perkembangan Farmasi
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

(DATO' EISAH BINTI A. RAHMAN)
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

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03-7841 3264 / 3357 / 3345

SENARAI EDARAN

1. Semua Ahli Panel Kajisemula Senarai Ubat-ubatan
   Kementerian Kesihatan Malaysia

2. Semua Pengerusi JKK Ubat-ubatan KKM

3. Pengarah
   Biro Pengawalan Farmaseutikal Kebangsaan
   Kementerian Kesihatan Malaysia

4. Semua Timbalan Pengarah Kesihatan Negeri (Farmasi)

5. Ketua Pegawai Farmasi
   Hospital Kuala Lumpur

6. Ketua Setiausaha
   Kementerian Kesihatan Malaysia

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

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

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

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

11. 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)

12. Pengarah
Pusat Perubatan Universiti Malaya
Lembah Pantai
59100 Kuala Lumpur
(u.p Ketua Pegawai Farmasi)

13. Pengarah
Pusat Perubatan Universiti Kebangsaan Malaysia
Jalan Yaacob Latif
Bandar Tun Razak
56000 Cheras, Kuala Lumpur
(u.p Ketua Pegawai Farmasi)

14. Pengarah
Hospital Universiti Sains Malaysia
Jalan Raja Perempuan Zainab II
16150 Kubang Kerian
Kelantan Darul Naim
(u.p Ketua Pegawai Farmasi)

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

16. Pegawai Farmasi
Bahagian Pembangunan Kesihatan Keluarga
Aras 5, Blok E6, Parcel E
Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
62509 Putrajaya

17. Pengarah
Pusat Darah Negara
Jalan Tun Razak
50400 Kuala Lumpur
(u.p Pegawai Farmasi)

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

19. Pegawai Farmasi
Bahagian Kesihatan dan Perubatan
Jabatan Hal Ehwal Orang Asli
KM.24, Jalan Pahang
53100 Gombak, Selangor

20. Penolong Pegawai Perpustakaan
Aras 4, Blok E7, Parcel E
Presint 1, Pusat Pentadbiran Kerajaan Persekutuan
62509 Putrajaya

21. Penolong Pegawai Perpustakaan
Kementerian Kesihatan Malaysia
Jalan Rumah Sakit
Off Jalan Bangsar
59100 Kuala Lumpur

22. Semua Ketua Unit
Bahagian Perkhidmatan Farmasi, KKM

PINDAAN BIL. 1/2013 KEPADA FORMULARI UBAT KKM

LAMPIRAN 1

1. UBAT–UBAT BARU YANG DILULUSKAN MASUK KE DALAM FORMULARI UBAT KKM

No	MDC	Generic Name Price quoted	Prescriber Category	Details
1	B01AC22110 T1002XXX	Prasugrel HCl 10mg Tablet Cost RM 6.50/tab of 10mg	A* (Only to be used in Cardiology Centre as third line treatment/ adjunctive therapy)	Indication Co-administered with aspirin, is indicated to reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndromes who are to be managed with percutaneous coronary intervention (PCI) as follows: • STEMI with or without diabetes • UA and NSTEMI with diabetes • Age <75yrs old • Weight >60kg • Without history of TIA stroke • Clinically suspected clopidogrel resistance subset Dose Initiate treatment with a single 60mg oral loading dose. Continue at 10mg/5mg once daily with or without food. Patients should also take aspirin (75 mg - 325 mg) daily. Precaution • CABG-related bleeding: Risk increases in patients receiving prasugrel who undergo CABG. • Discontinuation of prasugrel: Premature discontinuation increases risk of stent thrombosis, MI, and death. • Thrombotic thrombocytopenic purpura (TTP): TTP has been reported with prasugrel. Contraindication • Active pathological bleeding. • Prior transient ischemic attack or stroke. • Hypersensitivity to prasugrel or any component of the product. Interaction Increased risk of bleeding with warfarin and NSAIDs, cilostazol, citalopram, desirudin, escitalopram, fluoxetine, fluvoxamine, nefazodone, paroxetine and sertraline. Adverse effect Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction.
2	N06AX23999 T5002XXX	Desvenlafaxine succinate 50mg tablet (Extended Release)	A*	Indication For the treatment of major depressive disorder (MDD) Dose Recommended dose is 50mg once daily, with or

No	MDC	Generic Name Price quoted	Prescriber Category	Details
		Cost RM 3.46/tablet		without food Precaution Monitor for clinical worsening, suicidality or unusual change in behaviour. History of mania or hypomania. Patient w/ raised intraocular pressure, at risk of acute narrow-angle glaucoma or predisposed to bleeding. CV, cerebrovascular, lipid metabolism & seizure disorders. Underlying conditions that may be compromised by increases in BP. Avoid abrupt cessation of treatment. May impair ability to drive or operate machinery. Pregnancy & lactation. Childn <18 yr. Contraindication Hypersensitivity to desvenlafaxine succinate, venlafaxine or to any excipients in the desvenlafaxine formulation. Concomitant MAOI or w/in 14 days of discontinuing treatment w/ MAOI. Interaction Serotonergic Drugs eg lithium, sibutramine, tramadol, St. John's wort, MAOIs, linezolid, tryptophan supplements. CNS-active Drugs, alcohol. CYP3A4 inhibitors, Drugs metabolized by CYP2D6 & 3A4. Adverse effect Nausea, dry mouth, constipation, fatigue, headache, dizziness, insomnia, hyperhidrosis; palpitations, tachycardia, tinnitus, blurred vision, mydriasis, diarrhea, vomiting, chills, asthenia, feeling jittery, irritability, wt changes, increased BP & blood cholesterol, decreased appetite, musculoskeletal stiffness, somnolence, tremor, paraesthesia, dysgeusia, attention disturbance, anxiety, abnormal dreams, nervousness, decreased libido, anorgasmia, abnormal orgasm, urinary hesitation, erectile dysfunction, delayed ejaculation, ejaculation disorder/failure, yawning, hot flush.
3	L01DB01110 P3003XXX	Pegylated Liposomal Doxorubicin HCl 20 mg/vial (10 ml) Cost RM 1,845.00/vial	A*(Gyne Oncology Specialist only)	Indication 1. For patients with platinum-resistant ovarian cancer where the disease relapses within 6 months after completion of the initial platinum-based chemotherapy 2. For patients with platinum-sensitive ovarian cancer where the disease responds to first-line platinum-based therapy but relapses 12 months or more after completion of the initial platinum – based chemotherapy ***As third line therapy for very selected patients** Dose 50 mg/m2 IV every 4 weeks for as long as the disease does not progress & patient continues to tolerate

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				treatment. Administration For doses <90 mg: dilute in 250 ml Dextrose 5 % in Water. For doses >90 mg: dilute in 500 ml Dextrose 5 % in Water To minimize the risk of infusion reactions, the initial dose is administered at a rate no greater than 1 mg/minute. **Renal impairment**: • No dose adjustment required in patients with creatinine clearance 30-156 ml/min. • No pharmacokinetic data are available in patients with creatinine clearance of less than 30 ml/min. **Hepatic impairment**: At initiation of therapy: • Bilirubin 1.2 - 3.0 mg/dl, the first dose is reduced by 25 %. • Bilirubin > 3.0 mg/dl, the first dose is reduced by 50 %. Precaution CV disease, impaired cardiac function; patients who have received other anthracyclines, myelosuppression, diabetic patients Contraindication • Hypersensitivity reactions to any of the components of the product or to doxorubicin HCl. • Should not be used to treat AIDS-KS that may be effectively treated with local therapy or systemic α-interferon. • Pregnancy and Lactation Interaction • Caution should be exercised in the concomitant use of drugs known to interact with standard doxorubicin HCl • Other cytotoxic agents especially myelotoxic agents Adverse effect Infusion-associated reactions, stomatitis, palmar-plantar eryhtrodysesthesia, myelosuppression, leukopenia, anemia, neutropenia, peripheral edema, oral moniliasis, mouth ulceration
4	J07BD52963 P4002XXX	Measles and Rubella Virus Vaccine Live, Attenuated (Freeze-dried) 10 doses/vial	A*	Indication For active immunization against measles and rubella in infants, children, adolescents and young adults at risk. Immunization of susceptible non-pregnant adolescent and adult females is indicated if certain precautions are observed. The vaccine can be safely and effectively given simultaneously with DTP, DT, TT, Td, BCG,

No	MDC	Generic Name Price quoted	Prescriber Category	Details
		Cost RM63.75/vial of 10 doses		Polio Vaccine (OPV and IPV), Haemophilus influenza type B, Hepatitis B, Yellow fever vaccine and vitamin A supplementation. Dose The vaccine should be reconstituted only with the diluent supplied (sterile water for injection) using a sterile syringe and needle. With gentle shaking the dried cake is easily dissolved. After reconstitution the vaccines should be used immediately. A single dose of 0.5ml should be administered by deep SC injection into the anterolateral aspect of upper thigh in infants and upper arm in older children. If the vaccines is not used immediately then it should be stored in the dark at 2^0C and 8^0C for no longer than 6 hours. Precaution Diluent and reconstituted vaccine should be inspected visually for foreign particulate matter or variation of physical aspect prior to administration. In the event either is observed discard the diluents or the reconstituted vaccine. Contraindication Patients on corticosteroid, immune-suppressive drug or radio-therapy. Should be avoided in pregnancy because of the theoretical (but never been demonstrated) teratogenic risk. If pregnancy is being planned, then an interval of one (1) month should be observed after rubella immunization. No serious cases have been reported in more than 1000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Rubella vaccination during pregnancy is not an inidication for abortion. Interaction The vaccine should not be given within 6 weeks, and if it is possible within 3 months, after an injection of immunoglobulins or blood product containing immunoglobulins (blood plasma). For the same reason immunoglobulin should not be administered within two weeks after the vaccination Adverse effect Injection can cause mild pain and tenderness at site of injection. Measles component can cause a mild fever in 5 – 15% recipients and rash in 2% recipients. Encephalitis 1 in 1 million vaccines. Rubella component can cause low grade fever, lymphadenopathy, myalgia and paraesthesia.
5	N06AX22000 T1001XXX	Agomelatine 25mg Tablet Cost RM3.96/tablet	A*	Indication For the treatment of major depressive episodes in adult

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Dose The recommended dose is 25mg once daily at bedtime. If there is no improvement of symptoms, the dose maybe increased to 50mg once daily, i.e. 2(two) 25mg tablet, taken together at bedtime. Precaution • use in people with dementia or impaired liver function or by women who are breastfeeding • use in pregnant women and in people with kidney disease • History of mania or hypomania. Increased risk of suicidal tendencies; lactose intolerance • Perform liver function tests periodically. • May impair ability to drive or operate machinery • Pregnancy & lactation. Children <18 yr. Elderly Contraindication • with a history of previous hypersensitivity to the active ingredient or any of the excipients • with hepatic impairment (i.e. cirrhosis or active liver disease) • taking potent CYP1A2 inhibitors (e.g. fluvoxamine, ciprofloxacin) Interaction CYP2C9 & CYP1A2 inhibitors (eg fluvoxamine, ciprofloxacin, propranolol, grepafloxacin, enoxacin), oestrogens, alcohol. Adverse effect Headache, dizziness, somnolence, insomnia, migraine; anxiety; nausea, diarrhea, constipation, upper abdominal pain; hyperhidrosis; back pain; fatigue; increased ALAT &/or ASAT.
6	C09DB0693 5T1001XXX	Amlodipine Camsylate/ Losartan Potassium 5 mg/50 mg Tablet Cost RM 1.00/tab	A/KK	Indication Treatment of essential hypertension in adults patients whose blood pressure is not adequately controlled on either monotherapy Dose Amlodipine 5mg/losartan 50mg OR amlodipine 5mg/losartan 100mg orally once daily. MAXIMUM DOSE: amlodipine 5mg/losartan 100mg **Renal impairment**: No dosage adjustment in mild renal impairment. Not recommended in moderate to severe renal impairment or in patients on dialysis **Hepatic impairment**: Not recommended in patients who require lower dose of losartan (25mg) **Paediatric population**:
7	C09DB0693 5T1002XXX	Amlodipine Camsylate/ Losartan Potassium 5 mg/100 mg Tablet Cost RM 1.24/tab	A/KK	

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Not recommended in patients < 18 years as safety and efficacy is not established in this group Precaution Hypotension, liver impairment, renal impairment, hypersensitivity, electrolyte/fluid imbalance, use in heart failure patients, increase angina or myocardial infarction Contraindication Contraindicated in patients who are hypersensitive to any component of this product Interaction No interaction studies conducted with fixed-dose combination but studies have been done with individual components. Losartan: Rifampicin, ketoconazole, potassium-sparing diuretics, potassium supplements, NSAIDs Amlodipine: Rifampicin, ketoconazole, itraconazole, ritonavir, vardenafil, clarithromycin, isoniazid Adverse effect Dizziness, headache, asthenia, chest discomfort, chest pain, early satiety, oedema peripheral, pitting oedema, abdominal discomfort, dyspepsia, nausea, dyspnea, flushing, palpitation, urticaria
8	B01AC00000 T1002XXX	Cilostazol 100 mg tablet Cost RM 1.68/tablet	A*	Indication Improvement of the maximal and pain-free walking distances in patients with intermittent claudication, who do not have rest pain and who do not have evidence of peripheral tissue necrosis. Dose 100 mg BD Precaution • Concomitant therapy with platelet-aggregation inhibitors • Hematological events (thrombocytopenia or leukopenia progressing to agranulocytosis) have been reported • Renal impairment, severe (creatinine clearance less than 25 mL/min) Contraindication CHF, haemostatic disorders, active pathologic bleeding eg bleeding peptic ulcer & intracranial bleeding. Interaction

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Co-admin with drugs that affect CYP3A4 (erythromycin, other macrolides, diltiazem) or CYP2C19 (omeprazole) may influence the pharmacokinetics of cilostazol. Adverse effect Headache, dizziness, palpitations, diarrhea, abnormal stools; pain, infection, peripheral oedema, nausea, vomiting, other cardiac arrhythmias, chest pain, rhinitis, pharyngitis, ecchymosis and skin rash.
9	R03DX0500 0P3001XXX	Omalizumab 150mg (powder and solvent for solution) Cost RM1,133/vial	A*	Indication For adults and adolescents (≥12 years), for severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosetroids Dose *Adult & adolescent ≥12 yr*, 150-375 mg SC every 2-4 wk, according to body wt & baseline serum total IgE level.. For subcutaneous administration only. Do not administer by the intravenous or intramuscular route. Precaution Not for treatment of acute asthma exacerbations, acute bronchospasm or status asthmaticus. Renal or hepatic impairment, DM, glucose-galactose malabsorption syndrome, fructose intolerance or sucrose-isomaltase deficiency. Pregnancy & lactation. Contraindication Hypersensitivity to omalizumab or to any of the excipients Interaction No significant interaction observed in clinical trials Adverse effect Common: Injection site pain, swelling, erythema, pruritis, headache. Rare: Anaphylactic reactions, allergic conditions, allergic bronchospasm

No	MDC	Generic Name Price quoted	Prescriber Category	Details
10	P01BE03000 P3001XXX	Artesunate 60mg Injection Cost RM32.80/vial	A	Indication Treatment of severe malaria caused by Plasmodium falciparum in adults and children Dose 2.4mg of artesunate/kg body weight, by intravenous (iv) or intramuscular (im) injection, at 0, 12 and 24 hours, then once daily until oral treatment can be substituted. For adults and children with severe malaria or who are unable to tolerate oral medicines, artesunate 2.4 mg/kg body weight IV or IM given on admission (time = 0), then at 12 hrs and 24 hrs, then once a day for 5-7 days is the recommended treatment. Contraindication Artesunate is contraindicated in patients with hypersensitivity to artesunate or other artemisinins. Interaction Artesunate is rapidly and extensively converted to dihydroartemisinin (DHA), the active metabolite, primarily by plasma and erythrocyte esterases. DHA elimination is also rapid (half-life approximately 45 min) and the potential for drug-drug interactions appears limited. Adverse effect Transient and reversible reticulocytopaenia, drug fever, rash, bradycardia, transient 1st-degree heart block and reversible elevation of serum transaminases.

LAMPIRAN 2

2. TAMBAHAN DAN PINDAAN FORMULASI/KEKUATAN/KATEGORI PRESKRIBER/BENTUK DOSEJ/INDIKASI YANG DILULUSKAN UNTUK DIMASUKKAN KE DALAM FORMULARI UBAT KKM

A. Tambah Indikasi

No	MDC	Generic Name	Prescriber Category	Details
1	J05AF0799 9T1001XXX	Tenofovir disoproxil fumarate 300mg tablet	A*	Add indication Use as first line monotherapy for chronic hepatitis B or as a rescue therapy for patients with drug resistance hepatitis B virus (according to resistant profile or treatment guidelines).

B. Pinda Indikasi dan Dos

No	MDC	Generic name	Old Indication & dose	New Indication and dose	Other Details
1	L04AA04000P 3001001	Antithymocyte Immunoglobulin (From Rabbit) Injection 5 mg/ml (5ml Vial)	i) To be used when conventional anti-rejection therapy is not successful (patients who do not respond to horse serum) ii) Treatment of aplastic anaemia not responding to oxymetholone after 3 months, in which there is persistent pancytopenia with repeated attacks of septicaemia and bleeding. iii) Severe aplastic anaemia. iv) Graft-versus-host disease treatment Dose: Antirejection therapy: 2.5-5 mg/kg/day	i) Prophylaxis of acute graft rejection Dose: 1.0 – 1.5 mg/kg/day for 2 – 9 days after transplantation of a kidney, pancreas or liver, for 2 – 5 days after heart transplantation ii) Treatment of acute graft rejection Dose: 1.5 mg/kg/day for 3 – 14 days iii) Prophylaxis of acute and chronic graft versus host disease Dose: 2.5 – 5.0 mg/kg/day for 4 days iv) Treatment of steroid-resistant, acute graft versus host disease Dose: 2.5 – 5.0 mg/kg/day for 5 days v) Treatment of aplastic anemia Dose: 2.5 – 3.5 mg/kg/day for 5 days	As in MOH Formulary

C. Tambah Kekuatan/ Formulasi/Indikasi

No	Existing Drugs in MOH Drug Formulary	Add strength/ formulation/ indication	Prescriber Category	MDC
1	Oxycodone Hydrochloride 5, 10, 20 mg Immediate Release Capsules Oxycodone Hydrochloride 10, 20, 40 mg Prolonged Release Tablets	Add strength/ formulation Oxycodone hydrochloride 10mg/ml Injection Indication For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid. Other details As in MOH Drug Formulary	A*	N02AA05110P3001XXX
2	Rivaroxaban 10 mg Tablet	Add strength Rivaroxaban 15 & 20 mg Tablet Indications i) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as Congestive heart failure (CHF), hypertension, age ≥ 75 yrs, diabetes mellitus, prior stroke or transient ischaemic attack. ii) Treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.	A*	15MG: B01AX06000T1002XXX 20MG: B01AX06000T1003XXX

D. Pinda kategori Preskriber

No	MDC	Generic name	Old Category	New Category	Other Details
1	C07AB07000T1001XXX	Bisoprolol Fumarate 2.5 mg Tablet	A	B	As in MOH Formulary
2	C07AB07000T1002XXX	Bisoprolol Fumarate 5 mg Tablet			

LAMPIRAN 3

3. PERMOHONAN-PERMOHONAN YANG TIDAK DILULUSKAN

Proforma D

NO	REF	GENERIC NAME	REASON/S
1	D4	Tramadol 37.5mg + Paracetamol 325mg Tablet	i) Cost of one tablet of tramadol/paracetamol (fixed combination) is 12.72x higher than tramadol 50mg and paracetamol 500mg given separately. ii) Fixed-dose preparations reduce the scope for effective titration of the individual components in the management of pain of varying intensity. iii) Tramadol/paracetamol (fixed combination) is no more effective than ibuprofen in acute pain and no more effective than codeine plus paracetamol in post-surgical and chronic pain. In clinical practice, the tramadol/paracetamol combination offers patients little advantage in terms of efficacy, adverse effects or convenience compared with current standard analgesics.
2	D8	Fesoterodine Fumarate Prolonged Release 4 mg & 8 mg Tablet	Sufficient alternative in the MOH Drug Formulary
3	D10	Galsulfase 5mg/5ml vial, injection for intravenous use	The medicine is only used by 3 patients thus it can be bought by direct negotiation with the pharmaceutical company
4	D11	Cefixime 400mg tablet	i) Not enough evidence to convince the safety, efficacy, effectiveness and cost-effectiveness of cefixime. ii) Cost for 14-days drug treatment is higher with cefixime as compared to cefuroxime and amoxicillin+clavulanate. iii) Not supported by TDWC Antimicrobial iv) Proposer may have access to this medicine via special KPK approval.

Proforma B

NO	REF	GENERIC NAME	PROPOSED ALTERATION	CURRENT DRUG/S IN FUKKM	REASON/S
1	B4	Bisoprolol Fumarate 2.5 mg & 5 mg Tablet	To add indication (5mg strength): treatment of high blood pressure	Metoprolol, Atenolol, Propranolol	Sufficient alternative in the MOH Drug Formulary
2	B5	Oxaliplatin 5mg/ml inj	1. To add strength Current strength: 2mg/ml 2. To add indication Current indication: Only for patients with colorectal cancer who: i. have relapsed within 6 months after the end	1. <u>de Gramont regimen</u> i. Fluorouracil 250 mg/5 ml &1 g/20 ml Injection ii. Leucovorin Calcium 50 mg Injection 2. Capecitabine	Referring to The First Annual Report of the National Cancer Patient Registry-Colorectal Cancer 2007-2008 (report was published on November 2010), only 2.3% (3/131) and 2.9% (14/491) of the colorectal cancer patients in

NO	REF	GENERIC NAME	PROPOSED ALTERATION	CURRENT DRUG/S IN FUKKM	REASON/S
			of adjuvant chemotherapy with 5-fluorouracil-based regime ii. have progressive disease despite 5-fluorouracil chemotherapy for advanced disease iii. good performance status (WHO of 2 or less).	150&500mg Film-coated Tablet Irinotecan HCl Trihydrate 40 mg/2 ml &100 mg/5ml Injection	Malaysia were diagnosed with stage III colorectal cancer for 2007 and 2008 respectively. Thus, the proposal to add indication for adjuvant treatment of patients with stage III (Dukes's) colon cancer following surgery is only meant for a small group of population. Therefore, the usage of oxaliplatin for this indication may be requested by KPK approval only.

LAMPIRAN 4

4. PROFORMA YANG DITANGGUH

Proforma D & B

NO	REF	GENERIC NAME	REASON/S
1	D6	Gadoversetamide 0.5 mmol/ml Solution For Injection (10ml & 20 Ml Vial & Pre-Filled Syringe)	To get more information from applicant on the need for additional agent despite having several agents in the MOH Drug Formulary. Applicant to justify and consider deletion of any existing contrast agent.
2	B7	Docetaxel 20 mg/ml & 80 mg/4 ml Concentrate For Solution For Infusion	To get more information on formulation, packaging and tender pricing

NOTA:

Mesyuarat bersetuju untuk mengekalkan ubat Ipratropium Bromide 20 mcg and Salbutamol Base 100 mcg/dose Inhalation di dalam FUKKM kerana penggunaannya masih banyak dan telah dijadikan tender.