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/103/001/09Jld.15(42)

Tarikh : 15 Ogos 2013

SEPERTI SENARAI EDARAN

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

Pindaan/Tambahan Kepada Formulari Ubat Kementerian Kesihatan Malaysia (FUKKM) – Bil 2/2013

Dengan hormatnya saya merujuk kepada perkara di atas.

2. Sukacita dimaklumkan bahawa Mesyuarat Panel Kajisemula Senarai Ubat KKM Bil. 2/2013 yang diadakan pada 25 Julai 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).

2.5 Produk untuk rawatan hemofilia, tambahan kekuatan ubat diphenhydramine HCl/ammonium chloride expectorant dan penukaran kekuatan ubat anti-RhD gamma-globulin injection (Lampiran 5).

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 dan ianya sah untuk tempoh setahun daripada tarikh pekeliling ini dikeluarkan. 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,

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

anis_talib@moh.gov.my/ masitah_h@moh.gov.my/ norhamizah_m@moh.gov.my
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. Pegawai Farmasi
    Institut Jantung Negara

23. Semua Ketua Unit
    Bahagian Perkhidmatan Farmasi, KKM

PINDAAN BIL. 2 TAHUN 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	J05AB14-110-T10-01-XXX	Valganciclovir 450 mg Tablet Cost RM115.83/Tablet	A*	Indication For the prevention of cytomegalovirus (CMV) disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor. For transplant physician only. Dose For adult patients who have received other than kidney transplant, the recommended dose is 900 mg (two 450 mg tablets) once a day starting within 10 days of transplantation until 100 days post-transplantation. For adult patients who have received a kidney transplant, the recommended dose is 900 mg (two 450 mg tablets) once a day starting within 10 days of transplantation until 200 days post-transplantation. Precaution Avoid direct contact of broken or crushed tablets with skin or mucous membranes (potential teratogen and carcinogen) Monitoring Ophthalmologic exam, renal function, complete blood count (CBC), including platelet counts Contraindication Valganciclovir is contraindicated in patients with known hypersensitivity to valganciclovir ,ganciclovir or to any component of the product. Due to the similarity of the chemical structure of valganciclovir and that of aciclovir and valaciclovir, a cross-hypersensitivity reaction between these drugs is possible. Interaction Drug interaction studies with valganciclovir have not been performed, but since it undergoes rapid conversion to ganciclovir, interactions are likely to be the same as with ganciclovir. Oral valganciclovir therapy is associated with a low incidence of viral resistance. Adverse effect Valganciclovir is a prodrug of ganciclovir, which is rapidly converted to ganciclovir after oral administration. The undesirable effects known to be associated with ganciclovir usage can therefore be expected to occur with valganciclovir. All of the adverse events observed in valganciclovir clinical studies have been previously observed with

No	MDC	Generic Name Price quoted	Prescriber Category	Details
2	G02CX01-122-P30-01-XXX	Atosiban 7.5mg/ml (solution for injection & concentrate for solution for infusion) Cost Atosiban 7.5mg/ml concentrate for solution for infusion: **RM 384.00 per vial of 5 ml** Atosiban 7.5mg/ml solution for injection: **RM 115.00 per vial of 0.9 ml**	A*	Indication To delay imminent preterm birth in pregnant women with: - Regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes - A cervical dilation of 1 to 3 cm (0 – 3 nulliparas) and effacement of ≥ 50% - Age ≥ 18 years - A gestational age from 28 until 33 completed weeks - A normal foetal heart rate Dose Initial intravenous bolus dose of 6.75mg (using 7.5mg/ml solution for injection). Immediately followed by a continuous high dose infusion (loading infusion 300 mcg/min using 7.5mg/ml concentrate for solution for infusion) during three hours, followed by lower infusion of 100mcg/min up to 45 hours. Duration of treatment should not exceed 48 hours. Total dose given during a full course should not exceed 330mg of the active substance. Precaution Renal & hepatic dysfunction, abnormally positioned placenta, multiple pregnancy or pregnancy between 24-27 wk, small for gestational age foetus. Treatment may be repeated up to 3 more times with uterine contractions & foetal heart rate monitored during use. May cause postpartum bleeding. Contraindication Pregnancy <28 wk or >33 wk, premature rupture of the membranes after 30 wk of pregnancy, intrauterine growth retardation or abnormal foetal heart rate, antepartum uterine haemorrhage that requires immediate delivery, eclampsia or severe pre-eclampsia requiring delivery, intrauterine foetal death, suspected intrauterine infection, placenta praevia, abruption placenta, abnormal or high-risk pregnancy, known hypersensitivity to active substance or excipients Interaction It is unlikely that atosiban is involved in cytochrome P-450 mediated drug-drug interactions, as *in vitro* investigations have shown that atosiban is not a substrate for the cytochrome P-450 system and does not inhibit the drug metabolising cytochrome P-450 enzymes. No clinically relevant interactions observed.

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Adverse effect Nausea & vomiting, headache, dizziness, hot flushes, tachycardia, hypotension, injection site reactions, hyperglycemia, fever, insomnia, itch, rash, allergic reaction, postpartum bleeding
3	G04BD08-000-T10-01-XXX	Solifenacin Succinate 5 mg Tablet Cost RM2.73/Tablet	A*	Indication Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Dose 5mg od. Dose can be increased to 10mg if necessary. Precaution • angioedema of the face, lips, tongue, and larynx, potentially life-threatening, has been reported • bladder outflow obstruction, clinically significant; risk of urinary retention • gastrointestinal motility, decreased • hepatic impairment, moderate (Child-Pugh B); dosage adjustment recommended • hepatic impairment, severe (Child-Pugh C); use not recommended • narrow-angle glaucoma, controlled • QT interval prolongation has been reported • renal impairment, severe (Creatinine clearance, CrCl less than 30 mL/min); dosage adjustment recommended Contraindication Solifenacin is contraindicated in: • patients with urinary retention • patients with uncontrolled narrow-angle glaucoma • patients who have demonstrated hypersensitivity to the drug substance or other components of the product • severe gastro-intestinal condition (including toxic megacolon and gastric retention) • myasthenia gravis • patients undergoing haemodialysis • patients with severe hepatic impairment • patients with severe renal impairment or moderate hepatic impairment and who are on treatment with a potent CYP3A4 inhibitor, e.g. ketoconazole Interaction Atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, potassium chloride, ritonavir, saquinavir, telithromycin Adverse effect Dry mouth, constipation, headache, and blurred vision

No	MDC	Generic Name Price quoted	Prescriber Category	Details
4	L03AA13-000-P50-01-XXX	Pegfilgrastim Pre-filled Syringe 6 mg/0.6 ml (60 mg/ml) Cost RM 1700/PFS of 0.6ml	A*	Indication Reduction in the duration of neutropenia, the incidence of febrile neutropenia and the incidence of infection as manifested by febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) Dose **Adults (≥18 years):** One 6 mg dose (a single pre-filled syringe) of pegfilgrastim for each chemotherapy cycle, administered as a subcutaneous injection approximately 24 hours following cytotoxic chemotherapy. **Renal impairment:** Pharmacokinetics of pegfilgrastim is not expected to be affected by renal impairment **Hepatic impairment:** Pharmacokinetics of pegfilgrastim is not expected to be affected by hepatic impairment **Paediatric population:** Insufficient data to recommend the use of pegfilgrastim in children and adolescents under 18 years of age. Precaution Splenic rupture or enlarged spleen have been reported; patients with left upper abdominal or shoulder tip pain should be evaluated for development of splenomegaly or splenic rupture. Acute respiratory distress syndrome (ARDS) may occur; monitor patients for pulmonary symptoms. Caution in patients with existing sickle cell disorders; as severe sickle cell crisis may occur. Not approved for myeloid malignancies and myelodysplasia. Monitor platelet count and haematocrit regularly. Contraindication Hypersensitivity to pegfilgrastim, filgrastim, *E. coli* derived proteins, or to any excipients Interaction Pegfilgrastim should not be given at the same time as cytotoxic chemotherapy due to the increased risk of myelosuppression. Adverse effect Bone pain, arthralgia, myalgia, and back, limb, musculo-skeletal, and neck pain, injection site pain and

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				erythema, chest pain (non-cardiac), headache, nausea; elevations in uric acid, alkaline phosphatase and lactate dehydrogenase; rare cases of splenic rupture, Sweet's syndrome, cutaneous vasculitis, angioedema, flushing, anaphylaxis
5	G03AC09-000-T10-01-XXX	Desogestrel 0.075 mg Tablet Cost RM 15.12 / pack of 28 tablets	A*	Indication Contraception. Only for women who should not take combined oral contraceptives (COCs) eg Obese, smoker, migraine, breast feeding Dose Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. One tablet is to be taken daily for 28 consecutive days. Each subsequent pack is started immediately after finishing the previous pack. How to start: **No Preceding Hormonal Contraceptive Use in the Past Month:** Tablet-taking has to start on day 1 of the woman's natural cycle (day 1 is the 1st day of her menstrual bleeding). Starting on days 2-5 is allowed, but during the 1st cycle, a barrier method is recommended for the first 7 days of tablet-taking. **Changing from a Combined Hormonal Contraceptive, Vaginal Ring or Transdermal Patch):** Start with Cerazette preferably on the day after the last active tablet (the last tablet containing the active substances) or on the day of removal of her vaginal ring or patch. In these cases, the use of an additional contraceptive is not necessary. The woman may also start at the latest on the day following the usual tablet-free, patch-free, ring-free or placebo tablet interval of her previous combined hormonal contraceptive, but during the first 7 days of tablet-taking an additional barrier method is recommended. **Changing from a Progestogen-Only-Method [Minipill, Injection, Implant or from a Progesterone-Releasing Intrauterine System (IUS)]:** The woman may switch any day from the minipill, (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due); an additional contraceptive method is not necessary. **Following 1st-Trimester Abortion:** After 1st-trimester abortion, it is recommended to start immediately; an additional contraceptive method is not necessary. **Following Delivery or 2nd-Trimester Abortion:**

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				The woman should be advised to start at day 21-28 after delivery or 2nd-trimester abortion. When starting later, she should be advised to additionally use a barrier method for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of Cerazette use or the woman has to wait for her first menstrual period. Precaution Liver cancer, hypertension, history of venous thromboembolism, diabetic, chloasma, glucose-galactose malabsorption, Lapp-lactase deficiency, galactose intolerance. Contraindication Hypersensitivity to desogestrel or to any of the excipients of Cerazette, Known or suspected pregnancy, Active venous thromboembolic disorder, Presence or history of severe hepatic disease as long as liver function values have not returned to normal, Known or suspected sex steroid-sensitive malignancies, Undiagnosed vaginal bleeding. Interaction Hydantoins, barbiturates, primidone, carbamazepine, rifampicin, oxcarbazepine, rifabutin, topiramate, felbamate, ritonavir, nelfinavir, griseofulvin, cyclosporine; St. John's wort & medical charcoal. Adverse effect Mood changes, decreased libido, headache, nausea, acne, breast pain, irregular menstruation, amenorrhoea, increased weight.
6	L01XE11-110-T10-01-XXX	Pazopanib Hydrochloride 200mg Tablet Cost RM47.58/Tablet (200mg)	A*	Indication For treatment of advanced and/or metastatic renal cell carcinoma (RCC) Dose Recommended dose is 800mg ORALLY once daily. Should be taken without food (at least one hour before or two hours after meal). The dose should not exceed 800mg. Precaution Monitor serum liver & thyroid function tests. Hypertension, QT prolongation, patient at increased risk of thrombotic events, haemorrhage, gastrointestinal perforation or fistula. Discontinue in wound dehiscence & nephrotic syndrome. Renal & hepatic impairment. Pregnancy & lactation. Children. Elderly. Contraindication Specific contraindications have not been determined
7	L01XE11-110-T10-02-XXX	Pazopanib Hydrochloride 400mg Tablet Cost RM95.15/Tablet (400mg)	A*	

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Interaction CYP3A4 inhibitors (ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole), CYP3A4 inducers (rifampin). Pgp & BCRP inhibitor eg lapatinib. Grapefruit juice, low-fat or high fat meal. Adverse effect Anorexia, headache, hypertension, gastrointestinal & hepatobiliary disorders, fatigue, asthenia, chest pain. Hair & skin depigmentation. Thrombocytopenia, neutropenia, hypothyroidism, decreased wt, transient ischaemic attack, dysguesia, myocardial ischaemia, QT prolongation, epistaxis, haematuria, rash, alopecia, palmar-plantar erythrodysaesthesia syndrome, proteinuria.
8	A06AD10-921-L99-01-XXX	Potassium Chloride 0.15% w/v & Sodium chloride 0.9% w/v intravenous infusion BP (500ml) Cost RM 2.30/bottle of 500 ml	B	Indication Prevention and treatment of potassium, sodium and chloride depletion Dose Dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient and concomitant therapy. Maximum recommended dose of potassium is 2 to 3 mmol/kg/24h **Administration** Solution containing potassium should be administered by slow intravenous infusion via central vein. Rapid infusion may be harmful. **Rate of infusion:** Max 10mmol/h of K^+ when serum K^+> 2.5 mmol/L Max 40mmol/h of K^+ when serum K^+< 2.5 mmol/L Precaution Potassium to be administered with care in patients with: - Cardiac disease - Conditions predisposing to hyperkalemia such as renal and adrenocortical insufficiency - Acute dehydration - Extensive tissue destruction as occurs with severe burns Sodium salts to be administered with care in patients with: - Hypertension - Heart failure - Peripheral or pulmonary edema - Impaired renal function - Preeclampsia - Other conditions associated with sodium retention

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Contraindication Hyperkalemia, severe renal impairment with oliguria, anuria or azotemia, hyperchloremia, acute ishaemic stroke, head trauma (first 24 hours) Interaction Solutions containing potassium should be used with caution in patients receiving drugs that increase serum potassium concentrations (potassium-sparing diuretics, ACE inhibitors, cyclosporine, and drugs that contain potassium such as potassium salts of penicillin). Corticosteroids are associated with the retention of sodium and water, with oedema and hypertension. Adverse effect Adverse reactions may be associated to technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia. Excessive administration of potassium may lead to development of hyperkalemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. Excessive administration of chloride salts may cause loss of bicarbonate with an acidifying effect.
9	N02AA55-900-T10-01-XXX	Oxycodone Hydrochloride and Naloxone Hydrochloride 5mg/2.5mg Dehydrate Tablet Cost RM3.00/Tablet (5mg/2.5mg)	A* (by pain specialist only)	Indication The management of moderate to severe chronic pain unresponsive to non-narcotic analgesics. The opioid antagonist naloxone in the fixed combination is added to counteract and/or prevent opioid-induced constipation Dose Adults and paediatric patients from 18 years of age: The usual starting dose for opioid-naïve patients or patients presenting with moderate to severe chronic pain uncontrolled by weaker opioids is one tablet 10mg/5mg at 12 hourly intervals, or one tablet 5mg/2.5mg 12-hourly for patients with mild hepatic impairment and patients with renal impairment. The dose should then be cautiously titrated, as frequently as every 1-2 days if necessary, to achieve pain relief. Precaution Mild hepatic impairment, renal impairment, severely impaired pulmonary function, opioid-dependent, substantially decreased resp reserve or preexisting resp depression, chronic obstructiove pulmonary
10	N02AA55-900-T10-02-XXX	Oxycodone Hydrochloride and Naloxone Hydrochloride 10mg/5mg Dehydrate Tablet Cost RM3.00/Tablet (10mg/5mg)		

No	MDC	Generic Name Price quoted	Prescriber Category	Details
11	N02AA55-900-T10-03-XXX	Oxycodone Hydrochloride and Naloxone Hydrochloride 20mg/10mg Dehydrate Tablet Cost RM5.75/Tablet (20mg/10mg)		disease (COPD), hypothyroidism, hypotension, hypertension, hypovolaemia, diseases of the biliary tract (eg cholelithiasis), pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency (Addison's disease), toxic psychosis, myxoedema, opioid-induced paralytic ileus, preexisting cardiovascular disease, epileptic disorders or predisposition to convulsions, pre-op use or w/in the 1st 12-24 hr post-op, peritoneal carcinomatosis, sub-occlusive syndrome in advanced stages of digestive & pelvic cancers, galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Long-term administration of higher opioid doses. Abrupt cessation of therapy. History of alcohol & drug abuse. May affect the ability to drive & operate machinery. Pregnancy & lactation. Children or adolescents <18 yr. Elderly, infirm or debilitated patients. Contraindication Hypersensitivity; moderate to severe hepatic impairment; severe resp depression with hypoxia; elevated carbon dioxide levels in the blood; cor pulmonale; cardiac arrhythmias; uncontrolled bronchial asthma; severe COPD; non-opioid-induced paralytic ileus; severe central nernous sytem (CNS) depression; increased cerebrospinal or intracranial pressure; brain tumour or head injury; uncontrolled convulsive disorders; suspected surgical abdomen; delayed gastric emptying; alcoholism; delirium tremens; concurrent administration of MAOIs & for 2 weeks after cessation. Pregnancy & lactation. Interaction Alcohol, Anticholinergic agents, antihypertensive agents, CNS depressants, coumarin derivatives, CYP2D6 & CYP3A4 inhibitors & inducers, metoclopramide, MAOIs, neuromuscular blocking agents, opioid agonist analgesics, opioid agonist-antagonist analgesics. Adverse effect Vertigo, abdominal pain, constipation, diarrhea, dry mouth, dyspepsia, nausea, vomiting, asthenic conditions, chills, increased hepatic enzymes, anorexia, muscle spasms, muscle twitching, myalgia, dizziness, headache, somnolence, insomnia, hyperhidrosis, pruritus, rash, decrease in BP & hot flush. For oxycodone HCl: resp depression, miosis, bronchial spasm & spasms of non-striated muscles, cough reflex suppression, gastritis, hiccup, drug w/drawal symptom, fever, faintness, agitation, mood changes, ureteric spasm, urinary abnormalities, urinary tract infection (UTI), bronchospasm, pharyngitis, voice alteration & orthostatic hypotension.
12	N02AA55-900-T10-04-XXX	Oxycodone Hydrochloride and Naloxone Hydrochloride 40mg/20mg Dehydrate Tablet Cost RM10.10/Tablet (40mg/20mg)		

<table>
<tr><th>No</th><th>MDC</th><th>Generic Name
Price quoted</th><th>Prescriber Category</th><th>Details</th></tr>
<tr><td>13</td><td>P01BF02-000-T10-01-XXX</td><td>Artesunate & Mefloquine HCl 25mg/55mg Tablet

<u>Cost</u>
RM1.50/Tablet</td><td rowspan="2">A</td><td rowspan="2"><u>Indication</u>
Treatment of acute uncomplicated Plasmodium falciparummalaria, resulting either from P. falciparum mono-infection or mixed infection with P. vivax.

<u>Dose</u>
<table>
<tr><th>Weight (kg)</th><th>Age</th><th>Recommended dose</th></tr>
<tr><td>5-8</td><td>6-11 months</td><td>One ASMQ FDC tab 25/55mg OD x 3 days (Artesunate 25mg +mefloquine 50mg)</td></tr>
<tr><td>9 - 17</td><td>1 – 6 years</td><td>Two ASMQ FDC tab 25/55mg OD x 3 days (Artesunate 50mg +mefloquine 100mg)</td></tr>
<tr><td>18 - 29</td><td>7 – 12 years</td><td>One ASMQ FDC tab 100/220mg OD x 3 days (Artesunate 100mg +mefloquine 200mg)</td></tr>
<tr><td>≥30</td><td>≥13 years</td><td>Two ASMQ FDC tab 100/220mg OD x 3 days (Artesunate 200mg +mefloquine 400mg)</td></tr>
</table>
* ASMQ FDC – Artesunate Mefloquine fixed dose combination

<u>Precaution</u>
• Patients with underlying cardiac conduction defects or known cardiac arrhythmias:
- In rare cases, treatment and prophylaxis with mefloquine have been associated with clinically significant adverse events related to cardiac conduction.
• Patients with a history of seizures.
• Patients with severe liver impairment, as mefloquine undergoes hepatic metabolism.
• Patients with thalassaemia, sickle cell anaemia or G6PD-deficiency. No studies have been done in persons with these conditions.

<u>Contraindication</u>
• Hypersensitivity to the active substances or to any of the excipients
• Known hypersensitivity to quinine, quinidine or any artemisinin
• The recovery period from severe malaria, as mefloquine has been shown to increase the risk of convulsions
• Concurrent or recent halofantrine therapy, due to the increased risk of prolongation of the QTc interval
• Concurrent or recent ketoconazole therapy, due to the increased risk of prolongation of the QTc interval</td></tr>
<tr><td>14</td><td>P01BF02-000-T10-02-XXX</td><td>Artesunate & mefloquine HCl 100mg/220mg Tablet

<u>Cost</u>
RM1.50/Tablet</td></tr>
</table>

No	MDC	Generic Name Price quoted	Prescriber Category	Details
				Interaction No drug-drug interaction studies have been conducted with the fixed dose combination of artesunate and mefloquine. Adverse effect The most frequent adverse events were headache, dizziness, vomiting, nausea, fatigue, pyrexia, arthralgias, myalgias, anorexia, sleep disorders, and palpitations.

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	Generic Name	Prescriber Category	Details
1	Rituximab 10mg/ml Injection	A*	Add indication Maintenance in relapsed/ refractory follicular lymphoma after response to induction therapy Dose 375mg/m^2 BSA once every 3 months (starting 3 months after the last dose of induction therapy) Others As in MOH Drug Formulary
2	Dexmedetomidine HCl 100mcg/ml	A*	Add indication For sedation of non-intubated patients prior to and/or during surgical and other procedures Dose Not to be infused for more than 24 hours, 1 mcg/kg over 10 minutes as loading dose. Maintenance dose: 0.2 - 0.7 mcg/kg/hr Others As in MOH Drug Formulary

B. Pinda kategori Preskriber

No	Generic name	Old Category	New Category	Other Details
1	Carvedilol 6.25mg Tablet	A*	A/KK	As in MOH Formulary
2	Carvedilol 25mg Tablet			
3	Budesonide + Formoterol 160mcg/4.5mcg Turbuhaler	A	A/KK	As in MOH Formulary
4	Budesonide + Formoterol 320mcg/9mcg Turbuhaler	A*	A/KK	As in MOH Formulary

LAMPIRAN 3

3. PERMOHONAN-PERMOHONAN YANG TIDAK DILULUSKAN

Proforma D

NO	REF	GENERIC NAME	REASON/S
1	T1	Gadoversetamide 0.5mmol/ml Solution for Injection (10ml & 20ml vial and Pre-filled Syringe)	Rejected as no relevant information/ feedback received from applicant. Proforma to be presented in the panel meeting in future when there is resubmission.
2	D5	Bevacizumab (humanized anti-VEGF monoclonal antibody) 100mg in 4ml, 400mg in 16ml	• Not supported by TDWC oncology • Number of applications under KPK special medication request for this drug is declining (for year 2011, 2012, 2013 Jan-Jun)
3	D7	Roflumilast 500mcg Tablet	Roflumilast is a new drug and due to high cost impact, it may only be used for certain patients who really need to be treated with the medication. Therefore, it is appropriate to try access the drug through KPK approval for a start
4	D13	Azacitidine 5 mg/ml Injection	Number of applications under KPK special medication request for this drug is declining (for year 2011, 2012, 2013 Jan-Jun).

Proforma B

NO	REF	GENERIC NAME	PROPOSED ALTERATION	CURRENT DRUG/S IN FUKKM	REASON/S
1	T2	Docetaxel 20mg/ml & 80mg/4ml concentrate for solution for infusion	To change strength from 20mg/0.5ml to 20mg/ml	Docetaxel 20 mg/0.5 ml & 80 mg /2 ml Injection	Submission rejected as contract for docetaxel (taxotere) has expired on 1/3/2013. New contract has been awarded to generic docetaxel (Docetax) effective from 4/3/2013 to 3/3/2015.
2	B1	Tegafur 100mg/Uracil 224mg capsule	Add indication: Follinate plus Tegafur-Uracil combination therapy is indicated for colorectal cancer	• Capecitabine tablet 150mg & 500mg • Flurouracil inj/Leucovorin calcium inj	Not supported by TDWC oncology and insufficient economic data to support listing of this drug for colorectal cancer
3	B4	Doripenem 500mg Injection	Add indication: Complicated intra-abdominal infection (cIAI)	1. Cefepime 500mg &1g Injection 2. Meropenem 1g & 500mg injection 3. Imipenem 500 mg and Cilastatin 500 mg Injection	• Doripenem is non-inferior to meropenem. • Cost of treatment with doripenem injection is (4.73-6.62 times) higher than meropenem injection. • The National Antibiotic Guidelines published in 2008 suggested the

NO	REF	GENERIC NAME	PROPOSED ALTERATION	CURRENT DRUG/S IN FUKKM	REASON/S
					selection of anti-infective agents for intra-abdominal infections. It does not recommend the use of carbapenem either as preferred treatment or alternative treatment neither for uncomplicated nor for complicated intra-abdominal infections • It is recommended that doripenem is administered as a one hour iv infusion while meropenem can be administered as either an intravenous bolus over 5 minutes, which may be an advantage in patients who have restricted fluid intake • Doripenem is not recommended for use in children below 18 years of age due to a lack of safety and efficacy data. • Doripenem is also not recommended for patients on any type of dialysis. Not supported by TDWC Antimicrobial Reason: There is no urgent need for the inclusion of cIAI indication at this point of time since doripenem is non-inferior to imipenem and meropenem and it is more costly as compared to the other 2 carbapenems
4	B7	Insulin Aspart 30% and Protaminated Insulin Aspart 70% 100 IU/ml Injection (3ml cartridge)	To change category of prescriber from A* to A/KK	1. Insulin Recombinant Synthetic Human, intermediate-acting 100 IU/ml Penfill and Refill (3ml cartridge) 2. Insulin Lispro 25% & Insulin Lispro Protamine 75% 100 IU/ml Injection in Prefilled syringe (3ml	• A cost-effectiveness evaluation of insulin analogues versus conventional insulins have shown that routine use of insulin analogues, especially long-acting analogues in type 2 diabetes, is unlikely to represent

NO	REF	GENERIC NAME	PROPOSED ALTERATION	CURRENT DRUG/S IN FUKKM	REASON/S
				cartridge)	an efficient use of finite health care resources • Usage of human insulin in health clinic is sub-optimal as shown in Drug Utilisation Study in the Treatment of Diabetes in MOH Facilities, 2011. It was reported that insulin alone therapy contributed to only 3.6% of overall anti-diabetic drug utilisation in health clinics, insulin + 1 OHA, 8.9%, insulin + 2 OHAs, 22.1%. These figures represent low rates of insulin use when compared to other countries. Most medical officers are reliant on OADs. 49.8% of patients are on OADs alone. • Need to identify the patient's barriers to insulin therapy and implement strategies to overcome or decrease these barriers as this will assist the patient in the decision-making process to accept and adhere to insulin therapy.
5	B8	Ranibizumab 10mg/ml (0.23 ml) Solution For Injection	To add indication: - Diabetic macular edema - Macular edema following Retinal Vein Occlusion (RVO)	NIL	High disease prevalence and high treatment cost with ranibizumab will have significant budget implication Submitted by TWDC of Ophthalmology

LAMPIRAN 4

4. PROFORMA YANG DITANGGUH

Proforma D & B

NO	REF	GENERIC NAME	REASON/S
1	D10	Golimumab 50mg (0.5ml) solution for injection in a pre-filled syringe Proposed indications: 1. Rheumatoid arthritis (in combination with MTX) 2. Psoriatic arthritis (alone or in combination with MTX) 3. Ankylosing spondylitis (alone)	To get more information from TDWC rheumatology on the willingness to delete one of the existing biologic DMARDs in the FUKKM to be replaced by golimumab.
2	B2	Gefitinib 250mg tablet Proposal to add indication: As first line treatment of adult patients with locally advanced or metastatic NSCLC who have activating mutations of the EGFR-TK	To get more information from TDWC oncology on the use of Gefitinib as first line in the treatment of NSCLC

LAMPIRAN 5

5.PRODUK HEMOFILIA YANG DISENARAIKAN KE DALAM FUKKM

i. Produk Baru

NO	GENERIC NAME	DETAILS
1	Factor IX, Factor II, Factor VII and Factor X In Combination Injection Prescriber category: A	Indication i)treatment and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required. ii)treatment and perioperative prophylaxis of bleeding in congenital deficiency of any of the vitamin K dependent coagulation factors only if purified specific coagulation factor product is not available. Dose Individualized dosage. Refer package insert. Precaution In patients with acquired deficiency of the vitamin-K dependent coagulation factors, this product should only be used when rapid correction of the prothrombin complex level is necessary. If allergic or anaphylactic-type reactions occur, the administration of this product has to be stopped immediately. There is risk of thromboembolic complications, closely monitor for patients with a history of coronary heart disease or myocardial infarction, liver disease, postoperative patients, neonates, patients at risk of thromboembolic phenomena or disseminated intravascular coagulation or simultaneous inhibitor deficiency and patients on a controlled sodium diet. Contraindication

NO	GENERIC NAME	DETAILS
		Known hypersensitivity to any of the components of the product. Risk of thrombosis, angina pectoris, recent myocardial infarction (exception: life-threatening haemorrhages following overdosage of oral anticoagulants, and before induction of fibrinolytic therapy). In the case of disseminated intravascular coagulation, prothrombin complex-preparations may only be applied after termination of the consumptive state. Known history of heparin-induced thrombocytopenia. Interaction No interactions with other medicinal products are known. Adverse effect Renal and urinary disorders: Nephrotic syndrome. Vascular disorders: Thromboembolic episodes. General disorders and administration site conditions: Increase in body temperature. Immune system disorders: Hypersensitivity or allergic reactions (angioedema, burning and stinging at injection site, chills, flushing, generalized urticaria, headache, hives, hypotention, lethargy, nausea, restlessness, tachycardia, angina pectoris, tingling, vomiting or wheezing. Development of heparin-induced thrombocytopenia, type II.
2	Factor VIII (Human blood coagulation factor) & Von Willebrand factor Injection Prescriber category: A	Indication i)The treatment and prophylaxis of haemorrhage or surgical bleeding in Von Willebrand Disease (VWD) when 1-deamino-8-D-arginine vasopressin (desmopressin, DDAVP) treatment alone is ineffective or contraindicated. ii)The treatment and prophylaxis of bleeding associated with factor VIII deficiency due to haemophilia A. Dose Individualized dosage. Refer package insert. Precaution Patients with a known allergy to factor VII concentrates, or human albumin. Allergic, anaphylactic reactions or fever are rarely observed in patients receiving factor VIII preparations. If any adverse event occurs while this product being administered, the rate of injection should be slowed or stopped to alleviate symptoms. The product contains blood group antibodies. If very high doses are used in patients with blood group A, B or AB, the patient should be monitored for signs of intravascular haemolysis. Contraindication Not known Interaction Has not been established in appropriate studies. Adverse effect Allergic, anaphylactic reactions or fever are rarely observed in patients receiving factor VIII preparations. Headache, back pain, anxiety, chest pain, arthralgia, skeletal pain, dizziness, flushing, fever, influenza-like symptoms, pharyngitis

ii. Tambah Indikasi

NO	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
1	Factor VIII (Recombinant) Octocog Alfa 250 IU & 500 IU Injection	Add indication: 1) Control and prevention of bleeding episodes in adults and children (0-16 years) with hemophilia A 2) Surgical prophylaxis in adults and children with hemophilia A 3) Routine prophylactic treatment to reduce the frequency of bleeding episodes and the risk of joint damage in children with no pre-existing joint damage Not indicated for the treatment of von willebrand's disease. Prescriber category: A*	Dose: Dosage and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding, and the patient's clinical condition. The expected in vivo peak increase in factor VIII level expressed as IU/dL (or % normal) can be estimated using thefollowing formulas: *Dosage (units) = body weight (kg) x desired factor VIII rise (IU/dL or % or normal) x 0.5 (IU/kg per IU/dL)* **OR** *IU/dL (or % normal) = Total Dose (IU)/body weight (kg) x 2 [IU/dL]/[IU/kg]* Doses administered should be titrated to the patinet's clinical response. Others: As in MOH Drug Formulary
2	Factor VIII Inhibitor Bypassing Activity Injection	Add indication: 1) Treatment and prophylaxis of hemorrhages in hemophilia A and B patients with inhibitors. 2) Treatment and prophylaxis of hemorrhages in non-hemophilic patients who have developed inhibitors to Factors VIII, IX and XI. 3) Treatment of patients with acquired inhibitors to Factors X and XIII. 4) In the combination with Factor VIII concentrate for a long-term therapy to achieve a complete and permanent elimination of the Factor VIII inhibitor so as to allow for regular treatment with Factor VIII concentrate as in patients without inhibitor. Prescriber category: A	Dose: As a general guideline, a dose of 50 – 100IU/kg body weight is recommended, not exceeding an individual dose of 100IU/kg bw and a maximum daily dose of 200IU/kg bw. Others: As in MOH Drug Formulary

6. PENAMBAHAN KEKUATAN UBAT DIPHENHYDRAMINE HCL AND AMMONIUM CHLORIDE EXPECTORANT YANG DISENARAIKAN KE DALAM FUKKM

NO	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
1	Diphenhydramine HCl **10mg/5ml** elixir Diphenhydramine HCl **14mg/5ml** and Ammonium Chloride 135mg/5ml Expectorant	Add strength: Diphenhydramine HCl **7mg/5ml** and Ammonium Chloride 67.5mg/5ml Expectorant Prescriber category: C	As in MOH Drug Formulary

7. PENUKARAN KEKUATAN UBAT ANTI-RHD GAMMA-GLOBULIN INJECTION DI DALAM FUKKM

NO	CURRENT DRUG IN FUKKM	AMENDMENT	DETAILS
1	Anti RhD Gamma Globulin 250 mcg/2 ml Injection (500 units=100 mcg)	Change strength: Anti RhD Gamma Globulin 300 mcg Injection Prescriber category: B	As in MOH Drug Formulary