BAHAGIAN PERKHIDMATAN FARMASI
KEMENTERIAN KESIHATAN MALAYSIA
Beg Berkunci No. 924, Pejabat Pos Jalan Sultan,
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KKM-55/103/001/09 Bhg.3 (8)

5 Oktober 2005

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

Semua Pengarah Kesihatan Negeri.

Pengarah,
Biro Pengawalan Farmaseutikal Kebangsaan,
Petaling Jaya.

Semua Pengarah Institusi-Institusi Perubatan KKM

Y.Bhg. Dato'/Datin/Tuan/Puan,

Pindaan/Tambahan Kepada Formulari Ubat-ubatan
Kementerian Kesihatan Malaysia - Bil 2/2005

*** Adalah saya diarah merujuk perkara di atas dan sukacita memaklumkan bahawa Panel Kajisemula Senarai Ubat-ubatan Kementerian Kesihatan Malaysia telah pun menimbangkan permohonan-permohonan yang diterima dan seterusnya kelulusan Ketua Pengarah Kesihatan telah pun diperolehi. Keputusan-keputusan pindaan Formulari ubat-ubatan KKM adalah seperti yang dilampirkan.

2. Sukacita dapat Dato'/Datin/Tuan/Puan mengambil tindakan terhadap ubat-ubatan yang terlibat dan syarat-syarat terhadap penggunaannya dalam hospital/Institusi Kementerian Kesihatan. Kerjasama Dato'/Tuan/Puan adalah juga diminta untuk memastikan bahawa maklumat-maklumat mengenai pindaan/tambahan kepada Formulari Ubat-ubatan KKM diedarkan kepada semua hospital/Institusi/klinik kesihatan di negeri Dato'/Datin/Tuan/Puan.

3. Penggunaan ubat-ubatan yang baru ini perlu **dipantau** dengan rapi dan sebarang kesan advers dilaporkan kepada **MADRAC** (Jawatankuasa Penasihat Kesan Advers Ubat Kebangsaan) dan satu salinan ke Bahagian ini.

4. Penggunaan butiran-butiran yang telah **dibatalkan** seperti mana terdapat dalam lampiran boleh diteruskan **sehingga stoknya habis di hospital/Institusi masing-masing**.

5. **Harga-harga** yang terdapat didalam senarai dilampiran adalah harga ketika permohonan dibuat untuk memasukkan ubat berkenaan kedalam Formulari ubat KKM. Sebarang **kelainan harga** yang ditawarkan diperingkat hospital KKM hendaklah dilaporkan ke Bahagian ini beserta bukti dengan kadar segera supaya tindakan selanjutnya dapat diambil.

Sekian , harap maklum. Terima kasih.

'BERKHIDMAT UNTUK NEGARA'

Saya yang menurut perintah,

(DATO' CHE MOHD. ZIN BIN CHE AWANG)
Pengarah Perkhidmatan Farmasi,
Kementerian Kesihatan Malaysia.

s.k.

1. Ketua Setiausaha,
   Kementerian Kesihatan Malaysia.

2. Ketua Pengarah Kesihatan Malaysia.

3. Ketua-Ketua Bahagian, Kementerian Kesihatan Malaysia.

4. Semua Timbalan Pengarah Kesihatan Negeri (Farmasi)

5. Semua Timbalan Pengarah Kesihatan Negeri (Pergigian).

6. Ketua Pegawai Farmasi,
   Hospital Kuala Lumpur.

7. Pengarah,
   Pusat Perubatan Universiti Malaya,
   Petaling Jaya.

3. Penggunaan ubat-ubatan yang baru ini perlu **dipantau** dengan rapi dan sebarang kesan advers dilaporkan kepada **MADRAC** (Jawatankuasa Penasihat Kesan Advers Ubat Kebangsaan) dan satu salinan ke Bahagian ini.

4. Penggunaan butiran-butiran yang telah **dibatalkan** seperti mana terdapat dalam lampiran boleh diteruskan **sehingga stoknya habis di hospital/Institusi masing-masing**.

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   Hospital Kuala Lumpur.

7. Pengarah,
   Pusat Perubatan Universiti Malaya,
   Petaling Jaya.

PINDAAN BIL 2 TAHUN 2005 KEPADA FORMULARI UBAT KKM

1. BUTIRAN-BUTIRAN YANG **DIMANSUHKAN** DARI FORMULARI UBAT KKM

MDC	Generic Name	Trade Name	Category	Dosage	Remarks
G02AD01000P3001XX	Dinoprost (Prostaglandin F2) 5 mg/ml Injection	As in MOH Drugs Formulary			No longer used in hospital (use dinoprostone.)
G03FB06954T1003XX	Conjugated Oestrogen + Medrogestone Tablet (calendar pack of 31 tablets) (Prempak)	As in MOH Drug Formulary			Already phase out
N05CD07000C1001XX	Temazepam 10 mg capsule	As in MOH Drug Formulary			No longer used
N05BA01000T1003XX	Diazepam 10 mg Tablet	As in MOH Drug Formulary			This strength is not available in market Tablet 5 mg can be used.
N05CD08110T1002XX	Midazolam 15 mg tablet	As in MOH Drug Formulary			This strength has greater potential for abuse. Tablet 7.5 mg is available
S01AD01000D2001XX	Idoxuridine 0.1% Eyedrops (Herpidu ®)	As in MOH Drug Formulary			Can cause multiple ocular toxicity eg. puntal occlusion, anterior segment ischaemia etc.
S01AD01000G5101XX	Idoxuridine 0.1% eye ointment	As in MOH Drug Formulary			Can cause multiple ocular toxicity eg. puntal occlusion, anterior segment ischaemia etc.
V08AA04995P3001XX	Sodium Iothalamate 26% & meglumine	As in MOH Drug Formulary			No longer used

	Iothalamate 52% Inj.		
V08AC08520C1001XX	Sodium Ipodate 500 mg Capsule (Biloptin ®)	As in MOH Drug Formulary	No longer used
V09CX03995L9901XX	Sodium Iothalamate 60% (w/v) & Iodine 360 mg/ml Solution (Gastro-Conray ®)	As in MOH Drug Formulary	No longer used
V08AC02254P3001XX	Meglumine Iotroxinate Injection	As in MOH Drug Formulary	No longer used
V09CX03995P3001XX	Sodium Iothalamate 70% Inj. (Conray 420 ®)	As in MOH Drug Formulary	No longer used
S01EA01110D2001XX	Adrenaline (Epinephrine) 1 : 100,000 eyedrops	As in MOH Drug Formulary	Can cause systemic adverse reaction
S01EA01110D2002XX	Adrenaline (Epinephrine) 1 : 200,000 eyedrops		
S01EA01000D2003XX	Adrenaline (Epinephrine) 1 : 200 eyedrops		
S01EA01110D2004XX	Adrenaline (Epinephrine) 1 : 100 eyedrops		
G01AX03900S1001XX	Policresulen 90mg Suppository(Albothyl Supp)	As in MOH Drug Formulary	No longer used
G01AF02000S1001XX	Clotrimazole 100mg Pessary	As in MOH Drug Formulary	Replaced by Clotrimazole 200mg & 500mg vaginal Tablet

N03AX12000C1002XX	Gabapentin 400mg Capsule	As in MOH Drug Formulary	Replaced by Gabapentin 600mg Tablet
G04CA00196T1001XX	Doxazosin Mesylate 1 mg Tablet	As in MOH Drug Formulary	Replaced by Doxazosin Mesylate 4mg CR Tablet
G04CA00196T1002XX	Doxazosin Mesylate 2 mg Tablet	As in MOH Drug Formulary	Replaced by Doxazosin Mesylate 4mg CR Tablet
G04CA00196T1003XX	Doxazosin Mesylate 4 mg Tablet	As in MOH Drug Formulary	Replaced by Doxazosin Mesylate 4mg CR Tablet
S01HA02110D2001XX	Oxybuprocaine HCl 0.4 % Eye- Drops	As in MOH Drug Formulary	No more in the market
S01HA03110D2001XX	Amethocaine HCl 1 % Eye-Drops	As in MOH Drug Formulary	Replaced by Proparacaine 0.5% ophthalmic drops
J05AF03000T1001XX	Zalcitabine 0.75 mg Tablet	As in MOH Drug Formulary	Roche voluntarily withdraw the marketing license as not recommended in HIV treatment guidelines
J07BK00000P4001XX	Varicella Virus Vaccine Live 1350 PFU/0.5 ml Injection	As in MOH Drug Formulary	Same generic name as Varicella Virus Vaccine Live Attenuated Injection [J07BK01000P4001XX]- the only difference is the brand name. All approved indications for the two brand are included under the same generic name.

2. **Ubat –ubat BARU Yang Diluluskan Untuk Dimasukkan Ke Dalam Formulari Ubat KKM**

MDC	Generic Name/Price quoted in Proforma	Cate - Gory	Indication	Dosage	Contra Indication	Adverse Reaction	Precaution	Interaction
J05AF08 000T100 1XX	Adefovir Dipivoxil 10mg Tablet (Hepsera) RM374.40/30 tablets	A*	i)Treatment of active HBeAg positive and HBeAg negative CHB in adults with compensated liver function (lamivudine should be tried first) ii) Lamivudine-resistant chronic hepatitis B virus infection with either compensated or decompensated hepatitis function. (only by hepatologist and gastroenterologist for approved indications)	Adult over 18 yrs:10mg once daily	Breast-feeding, hypersensitivity.	Renal impairment and failure, increase serum creatinine, abdominal pain, flatulence, diarrhea, dyspepsia.	Monitor liver function and viral and serological markers for hepatitis B every 6months.Monitor renal function every 3 months, more frequently in renal impairment or in patients receiving nephrotoxic drugs; pregnancy	Aminoglycosides , ibuprofen, immunosuppressant,nephrotoxic agents, NSAIDs, vancomycin
S01HA0 4110D20 01XX	Proparacaine HCL 0.5% Ophthalmic Drops (Alcaine) RM7.16/15ml	B	Topical anaesthesia in ophthalmic procedures.	1-2 drops prn	Hypersensitivity	Transient stinging & burning, conjuctival redness, keratitis, systemic toxicity. Long term use may result in corneal damage, loss of vision and retard healing	Use cautiously in patients with cardiac disease and hyperthyroidism, prolonged use not recommended. Protect the eye from irritants, rubbing and foreign bodies during period of anaesthesia.	Hyaluronidase, St John's wort, increase effects of phenylephedrine , tropicamide

MDC	Generic Name/Price quoted in Proforma	Cate - Gory	Indication	Dosage	Contra Indication	Adverse Reaction	Precaution	Interaction
A02BC04520T1001XX	Rabeprazole Sodium 20mg Tablet (Pariet) RM2.30/20mg tablet	A*	1.Treatment and maintenance of erosive or ulcerative gastroesophageal reflux disease(GERD) 2. Duodenal ulcers	i) 10-20mg daily for 4-8 weeks, Maintenance:10-20mg daily ii) 20 mg daily in the morning for up to 4-8 wks	Hypersensitivity	Agranulocytosis, thrombocytopenia, hepatic dysfunction, jaundice, interstitial pneumonia, abdominal pain, diarrhea, edema , Headache, dizziness, rash	Liver disease, Hepatic impairment, elderly, pregnancy, lactation.	Ampicillin, digoxin, Iron, Itraconazole, ketoconazole, warfarin
G04CB02000C1001XX	Dutasteride 0.5mg Capsule (Avodart) RM4.20/tablet	A*	Benign prostatic hyperplasia in men with an enlarged prostate gland	0.5mg daily	Severe hepatic impairment, women, child and adolescent.	Impotence, decrease libido, ejaculation disorders, gynaecomastia, breast tenderness, allergic reactions including rash, prutitus, urticaria and localized edema.	Concurrent use of CYP3A4 enzyme inhibitors (e.g. ritonavir), capsules should not be handled by women who are pregnant or who may become pregnant due to the possibility of absorption of dutasteride through the skin and the potential risk of a fetal anomaly to a male	Verapamil, diltiazem, cimetidine, ciprofloxacin, ketoconazole, ritonavir.

MDC	Generic Name/Price quoted in Proforma	Cate - Gory	Indication	Dosage	Contra Indication	Adverse Reaction	Precaution	Interaction
							fetus; also, any woman should use caution whenever handling dutasteride capsules. Hepatic impairment, men treated with dutasteride should not donate blood until at least 6 months following their last dose, reduces total serum PSA concentration by approximately 40% after 3 months of treatment and 50% following 6 and 12 months of treatment; for interpretation of serial PSA's, a new baseline PSA concentration should be established after 3-6 months of treatment .	