



Pihak Berkuasa Kawalan Dadah  
Drug Control Authority  
KEMENTERIAN KESIHATAN MALAYSIA  
MINISTRY OF HEALTH MALAYSIA

Ruj Kami : (38) dlm. BPFK/PPP/07/1  
Tarikh : 06 Ogos 2008

**SEMUA PEMEGANG PENDAFTARAN PRODUK**

Tuan,

**SENARAI KETUJUH KAJIAN BIOEKUIVALENS (BE) BAGI PRODUK GENERIK "IMMEDIATE RELEASE"**

Dengan hormatnya saya merujuk kepada keputusan Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) kali ke 207 yang telah diadakan pada 05hb. Ogos 2008 mengenai perkara di atas.

2. PBKD telah bersetuju dengan cadangan Jawatankuasa Kajian BE menyenaraikan dua puluh tujuh (27) bahan aktif tertentu untuk ditambahkan kepada senarai sedia ada. Keperluan untuk mengemukakan Laporan Kajian BE untuk produk dalam senarai baru ini akan dilaksanakan secara berperingkat dalam tempoh dua tahun (Tahun 2008 – 2009).
3. Adalah dimaklumkan bahawa asas pemilihan masih berdasarkan kajian atas pelbagai aspek berpandukan kriteria-kriteria World Health Organisation ( WHO ) serta aduan-aduan pengguna daripada segi keberkesanan dan keselamatan produk.
4. Berikut adalah senarai produk generik "immediate release" yang mengandungi bahan aktif yang memerlukan kajian BE :-

- |                    |                    |
|--------------------|--------------------|
| 1. Atorvastatin    | 15. Quinapril      |
| 2. Methotrexate    | 16. Clopidogrel    |
| 3. Azathioprine    | 17. Valaciclovir   |
| 4. Tacrolimus      | 18. Fluconazole    |
| 5. Sirolimus       | 19. Pyrazinamide   |
| 6. Mycophenolate   | 20. Isoniazid      |
| 7. Etoposide       | 21. Topiramate     |
| 8. Flutamide       | 22. Alendronate    |
| 9. Chlorambucil    | 23. Amitriptylline |
| 10. Raloxifene HCl | 24. Clomipramine   |
| 11. Valsartan      | 25. Fluvoxamine    |
| 12. Irbesartan     | 26. Fluoxetine     |
| 13. Perindopril    | 27. Sertraline     |
| 14. Ramipril       |                    |

5. Tarikh berkuatkuasa keperluan untuk mengemukakan Laporan Kajian BE bagi produk mengandungi bahan aktif di atas adalah seperti berikut :-

- Permohonan Baru  
Mulai pada **01 Disember 2008**
  
- Produk Berdaftar  
Import : Diberi tempoh sehingga **01 Jun 2009**  
  
Tempatan : Diberi tempoh sehingga **31 Disember 2009**
  
- Sila rujuk Senarai 'Test Products, Comparator Products and Effective Submission Date for Bioequivalence Study Report for Year 2008 – 2009' seperti yang disertakan.

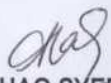
6. Sila ambil maklum bahawa sekiranya Tuan gagal untuk mengemukakan Laporan Kajian BE bagi produk-produk berdaftar pada tarikh yang telah ditetapkan, maka produk-produk akan dibentangkan ke Mesyuarat PBKD untuk dibatalkan pendaftarannya. Tuan juga dinasihatkan supaya merujuk kepada "ASEAN Guideline for the Conduct of Bioavailability and Bioequivalence Studies" sebagai panduan.

Kerjasama Tuan dalam memastikan arahan ini dipatuhi amatlah dihargai.

Sekian, terima kasih.

**"BERKHIDMAT UNTUK NEGARA"**

Saya yang menurut perintah,

  
**(ABIDA HAQ SYED M. HAQ)**  
Setiausaha  
Pihak Berkuasa Kawalan Dadah,  
Kementerian Kesihatan Malaysia.

- s.k.
1. Pengarah Kanan Perkhidmatan Farmasi, KKM
  2. Pengarah Regulatori Farmasi, BPFK
  3. Timbalan Pengarah Pusat Kawalan Kualiti (PKK), BPFK
  4. Timbalan Pengarah Pusat Pendaftaran Produk (PPP), BPFK
  5. Ketua Pusat Komplians dan Perlesenan (PKP), BPFK
  6. Ketua Pusat Pembangunan Organisasi (PPO), BPFK
  7. Ketua Pusat Pasca Pendaftaran Produk (PPPP), BPFK
  8. Pharmaceutical Association of Malaysia (PhAMA)
  9. Malaysian Organisation of Pharmaceutical Industries (MOPI)



**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE STUDY  
REPORT FOR YEAR 2008 - 2009**

**7 TH LIST**

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products		Effective Date for Submission of BE Study Report	Closing Date for Submission of BE Study Report of Registered Products	
		Trade Mark/Registration No.	Manufacturer	New Application	Imported Products	Local Products
1.	<b>Atorvastatin</b>	i) Lipitor Tablet 10mg (MAL19985090A) ii) Lipitor Tablet 10mg (MAL20034210ARS) iii) Lipitor Tablet 20mg (MAL19985091A) iv) Lipitor Tablet 20mg (MAL20034211ARS) v) Lipitor Tablet 40mg (MAL19985092A) vi) Lipitor Tablet 40mg (MAL20034212ARS) v) Lipitor Tablet 80mg (MAL20040226AR)	Godecke GmbH, Germany  Pfizer Ireland Pharmaceuticals Drug Product Plant, Ireland  Godecke GmbH, Germany  Pfizer Ireland Pharmaceuticals Drug Product Plant, Ireland  Godecke GmbH, Germany  Pfizer Ireland Pharmaceuticals Drug Product Plant, Ireland  Pfizer Pharmaceuticals LLC, USA	01/12/08	01/06/09	31/12/09
2.	<b>Methotrexate</b>	i) Emthexate Tablet 2.5mg (MAL19920203A) ii) Emthexate Tablet 10mg	Pharmachemie B.V, Netherland	01/12/08	01/06/09	31/12/09

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Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products		Effective Date for Submission of BE Study Report	Closing Date for Submission of BE Study Report of Registered Products	
		Trade Mark/Registration No.	Manufacturer	New Application	Imported Products	Local Products
1.	<b>Atorvastatin</b>	i) Lipitor Tablet 10mg (MAL19985090A) ii) Lipitor Tablet 10mg (MAL20034210ARS) iii) Lipitor Tablet 20mg (MAL19985091A) iv) Lipitor Tablet 20mg (MAL20034211ARS) v) Lipitor Tablet 40mg (MAL19985092A) vi) Lipitor Tablet 40mg (MAL20034212ARS) v) Lipitor Tablet 80mg (MAL20040226AR)	Godecke GmbH, Germany  Pfizer Ireland Pharmaceuticals Drug Product Plant, Ireland  Godecke GmbH, Germany  Pfizer Ireland Pharmaceuticals Drug Product Plant, Ireland  Godecke GmbH, Germany  Pfizer Ireland Pharmaceuticals Drug Product Plant, Ireland  Pfizer Pharmaceuticals LLC, USA	01/12/08	01/06/09	31/12/09
2.	<b>Methotrexate</b>	i) Emthexate Tablet 2.5mg (MAL19920203A) ii) Emthexate Tablet 10mg	Pharmachemie B.V, Netherland	01/12/08	01/06/09	31/12/09

		(MAL19890308A)	“			
3.	<b>Azathioprine</b>	i) Imuran 50mg Tablet (MAL04103439ACR)	Heumann PCS GmbH, Germany	01/12/08	01/06/09	31/12/09
4.	<b>Tacrolimus</b>	i) Prograf Capsule 0.5mg (MAL20031738A)  ii) Prograf Capsule 1mg (MAL19990220A)  iii) Prograf Capsule 5mg (MAL19990221A)	Astellas Ireland Co. Ltd, Ireland  “  “	01/12/08	01/06/09	31/12/09
5.	<b>Sirolimus</b>	i) Rapamune Tablet 1mg (MAL20032403AR)  ii) Rapamune Tablet 2mg (MAL07031064AR)	Wyeth Pharma Co., Puerto Rico, USA  Wyeth Pharmaceuticals Co., Puerto Rico, USA	01/12/08	01/06/09	31/12/09
6.	<b>Mycophenolate</b>	i) Cellcept Capsule 250mg (MAL19986427A)  ii) Cellcept Capsule 250mg (MAL06030803AS)  iii) Cellcept Tablet 500mg (MAL19986428A)  iv) Cellcept Tablet 500mg (MAL06030804AS)	ICN Dutch Holdings B.V, USA  Roche S.P.A., Italy  ICN Dutch Holdings B.V, USA  Roche S.P.A., Italy	01/12/08	01/06/09	31/12/09
7.	<b>Etoposide</b>	i) Vepesid Capsule 50mg	R.P Scherer GMBH & Co. KG,	01/12/08	01/06/09	31/12/09



		(MAL19972952A)	Germany			
8.	<b>Flutamide</b>	i) Fugerel Tablet 250mg (MAL19872265A)	Schering Canada Inc, Canada	01/12/08	01/06/09	31/12/09
9.	<b>Chlorambucil</b>	i) Leukeran Tablets 2mg (MAL04125474ACR)	Heumann PCS GmBH, Germany	01/12/08	01/06/09	31/12/09
10.	<b>Raloxifene HCl</b>	i) Evista Film Coated Tablet 60mg (MAL19992672A)  ii) Evista Tablet 60mg (MAL04125481A)	Eli Lilly and Company Limited, UK  Lilly S.A., Spain	01/12/08	01/06/09	31/12/09
11.	<b>Valsartan</b>	i) Diovan 40mg Film Coated Tablet (MAL06051320A)  ii) Diovan 80mg Film Coated Tablet (MAL20021002A)  iii) Diovan 160mg Film Coated Tablet (MAL20021003A)  iv) Diovan 320mg Film Coated Tablet (MAL07050032A)	Novartis Pharma Stein AG, Switzerland  "  "  "	01/12/08	01/06/09	31/12/09
12.	<b>Irbesartan</b>	i) Aprovel Tablet 75mg (MAL19990970A)  ii) Aprovel Tablet 150mg	Sanofi Winthrop Industrie, France  "	01/12/08	01/06/09	31/12/09

		(MAL19990971A) iii) Aprovel Tablet 300mg (MAL19990972A)	“			
13.	<b>Perindopril</b>	i) Coversyl 2mg Tablet (MAL19900369AR) ii) Coversyl 4mg Tablet (MAL19900370A) iii) Coversyl 4mg Tablet (MAL04103437AC) iv) Coversyl 8mg Tablet (MAL05061534A)	Les Labs Servier Industrie, France “ Kotra Pharma (M) Sdn. Bhd., Malaysia Les Labs Servier Industrie, France	01/12/08	01/06/09	31/12/09
14.	<b>Ramipril</b>	i) Tritace 2.5mg Tablet (MAL19986949A) ii) Tritace 5mg Tablet (MAL19986948A) iii) Tritace 10mg Tablet (MAL20031929A)	Sanofi-Aventis S.P.A, Italy “ “	01/12/08	01/06/09	31/12/09
15.	<b>Quinapril</b>	i) Accupril 5mg Tablets (MAL 19962575A) ii) Accupril 10mg Tablets (MAL19962573A) iii) Accupril 20mg Tablets (MAL19962574A)	Pfizer GmbH, Arzneimittelwerk Godecke, Germany “ “	01/12/08	01/06/09	31/12/09
16.	<b>Clopidogrel</b>	i) Plavix Tablet 75mg	Sanofi Winthrop Industrie, France	01/12/08	01/06/09	31/12/09

		(MAL19992344A)				
17.	<b>Valaciclovir</b>	i) Valtrex 250mg Tablet (MAL20020133A)  ii) Valtrex Tablet 500mg (MAL19962817A)	Glaxo Wellcome Operations UK Ltd, UK  Glaxo Wellcome S.A, Spain	01/12/08	01/06/09	31/12/09
18.	<b>Fluconazole</b>	i) Diflucan Capsule 50mg (MAL19913229A)  ii) Diflucan Capsules 50mg (MAL19984004AS)  iii) Diflucan Capsule 100mg (MAL19920034A)  iv) Diflucan Capsule 150mg (MAL19913230A)  ii) Diflucan Capsule 150mg (MAL19984003AS)	Pfizer PGM, France  Pfizer Australia Pty. Ltd, Australia  Pfizer PGM, France  Pfizer Australia Pty. Ltd, Australia	01/12/08	01/06/09	31/12/09
19.	<b>Pyrazinamide</b>	i) PZA-CIBA 500mg Tablet (MAL20041254)	Novartis Bangladesh Ltd, Bangladesh	01/12/08	01/06/09	31/12/09
20.	<b>Isoniazid</b>	i) Rimaectazid 300 Sugar Coated Tablet (MAL19871621A)	Novartis South Africa (Pty) Ltd, South Africa	01/12/08	01/06/09	31/12/09
21.	<b>Topiramate</b>	i) Topamax Tablet 25mg (MAL20013558A)	Cilag AG, Switzerland			



		ii) Topamax Tablet 25mg (MAL19988437AR)  iii) Topamax Tablet 50mg (MAL 20013560A)  iv) Topamax Tablet 50mg (MAL19988438AR)  v) Topamax Tablet 100mg (MAL20013561A)  vi) Topamax Tablet 100mg (MAL19988439AR)  vii) Topamax Tablet 200mg (MAL20013559A)  viii) Topamax Tablet 200mg (MAL19988440AR)	Jansen Cilag Farmaceutica Lda, Portugal  Cilag AG, Switzerland  Janssen Cilag Farmaceutica Lda, Portugal  Cilag AG, Switzerland  Janssen Cilag Farmaceutica Lda, Portugal  Cilag AG, Switzerland  Janssen Cilag Farmaceutica Lda, Portugal	01/12/08	01/06/09	31/12/09
22.	<b>Alendronate</b>	i) Fosamax Tablet 5mg (MAL20000248AR)  ii) Fosamax 10mg Tablet (MAL19971268AR)  iii) Fosamax Tablet 70mg (MAL20013990AR)	Merck Sharp & Dohme De Mexico S.A. De C.V., Mexico  Merck Sharp & Dohme (Italia) SPA, Italy  “	01/12/08	01/06/09	31/12/09
23.	<b>Amitriptylline</b>	i) Tryptanol 25mg Tablet (MAL19940012AS)	Merck Sharp & Dohme (Australia) Pty Ltd.	01/12/08	01/06/09	31/12/09
24.	<b>Clomipramine</b>	i) Anafranil 25mg Tablet (MAL20000270AC)	Merck Sharp & Dohme (Australia) Pty Ltd., Australia	01/12/08	01/06/09	31/12/09

25.	<b>Fluvoxamine</b>	i) Luvox 50mg Film Coated Tablet (MAL20021412A)  ii) Luvox 100mg Film Coated Tablet (MAL20021413A)	Solvay Pharmaceuticals SAS, France  "	01/12/08	01/06/09	31/12/09
26.	<b>Fluoxetine</b>	i) Prozac Capsule 20mg (MAL19900141A)  ii) Prozac Capsule 20mg (MAL07031127ACS)	Eli Lilly and Company Limited, United Kingdom  Patheon France S.A, France	01/12/08	01/06/09	31/12/09
27.	<b>Sertraline</b>	i) Zoloft Tablet 50mg (MAL19971291A)  i) Zoloft Tablet 100mg (MAL19971290A)	Pfizer Australia Pty Ltd, Australia  Pfizer Pty Ltd, Australia	01/12/08	01/06/09	31/12/09