

DCA 154 (23/12/2003)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1	Loette 21 tablet (Levonorgestrel 100mcg & Estradiol 20mcg)	Also indicated for the treatment of mild to moderate acne vulgaris in postmenarchal, premenopausal women who accept contraception.	Wyeth (M) Sdn. Bhd. 701&801, Blok C, Menara Glomac, Kelana Jaya Business Centre, No. 97 Jln SS 7/2, Kelana Jaya
2.	2.1	Arimidex 1mg (Anastrozole 1mg)	Is indicated for adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. The effectiveness of Arimidex in early breast cancer is based on an analysis of recurrence-free survival in patients treated for a median of 31 months. Further follow-up of study patients will be required to determine long-term outcomes.	AZ Pharmaceuticals (M) Sdn. Bhd. 2nd. Floor, Wisma Prima, 17 Jln Sri Semantan 1, Damansara Heights, KL
3.	3.1 3.2 3.3	Aprovel 75mg Aprovel 150mg Aprovel 300mg (Irbesartan)	Nephropathy in Type 2 Diabetic patients Is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300mg/day) in patients with type 2 diabetes and hypertension. In this population, irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation)	Sanofi-Synthelabo (M) Sdn. Bhd. 3.02 Level 3, Wisma Academy, Lot 4A Jln 19/1, 46300 PJ
4.	4.1	Visudyne injection (Verteporfin 15mg/vial)	Is indicated for the treatment of patients with occult subfoveal choroidal neovascularization due to subfoveal choroidal neovascularization caused by other macular disease. The final indication will be as follows : Is indicated for the treatment of patients with predominantly classic or occult subfoveal choroidal neovascularization due to age-related macular degeneration or with subfoveal choroidal neovascularization caused by other macular	Novartis Corporation (M) Sdn. Bhd. Lot 9, JLn 26/1, Seksyen 26, Kaw. Perindustrian HICOM, 40400 Shah Alam

5.	5.1 5.2	Cancidas injection 50mg/vial Cancidas Injection 70mg/vial (Caspofungin acetate 55.5mg & 77.7mg)	disease. Indicated for the treatment of : i) Oesophageal candidiasis. ii) Invasive candidiasis, including candidemia.	Merck Sharp & Dohme (I.A) Corp. Letter Box 1502, 15th floor, Menara Merais, 1 Jln 19/3, PJ
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DCA 153 (18/11/2003)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2	Luvox 50mg film- coated tablet Luvox 100mg film- coated tablet (Fluvoxamine maleate)	Treatment of symptoms of obsessive compulsive disorder (OCD).	JDH Pharmaceutical S/B, Li Fung Centre, Lot 6, Persiaran Perusahaan Seksyen 23, 40300 Shah Alam
2.	2.1	Zometa 4mg powder for infusion (Zolendronic acid anhydrous)	Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone or tumour induced hypercalcemia) in patients with advanced malignancies involving bone.	Novartis Corporation (M) Sdn. Bhd. Lot 9, JLn. 26/1, Seksyen 26, Kawasan Perindustrian HICOM, 40400 Shah Alam

DCA 152 (23/10/2003)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1	1.1	Plavix 75mg (clopidogrel hydrogen sulphate 97.875mg)	Indicated for the prevention of atherothrombotic events in: - patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. - Patients suffering from non-ST segment	Sanofi-Synthelabo (M) Sdn. Bhd. 3.02, Level 3, Wisma Academy, Lot 4A Jalan 19/1, 46300 PJ

		elevation acute coronary syndrome (unstable angina or non-Q wave myocardial infarction) in combination with acetyl salicylic acid (ASA).	
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DCA 151 (2/10/2003)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1	1.1	Symbicort Turbuhaler 80/4.5µg/dose (Budesonide 80µg + Formoterol fumarate 4.5µg)	To be used in children for 6 to 12 years old. Dosage : 1-2 inhalations twice daily	AZ Pharmaceuticals (M) Sdn. Bhd. 2nd floor, Wisma Prima, 17 Jln Sri Semantan 1, Damansara Heights, 50490 KL
2.	2.1	Telfast 180mg tablet (Fexofenadine HCL 180mg)	Indicated for the relief of symptoms associated with allergic rhinitis in adults and children 12 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itch nose/palate/throat, itchy/watery red eyes	Aventis Farma SA (M) S/B No.74,Jln Universiti, 46200petaling Jaya Selangor
3.	3.1 3.2 3.3	Cipram tablet 10mg Cipram tablet 20mg Cipram tablet 40mg (Citalopram 10mg,20mg & 40mg)	-Prevention of relapse/recurrence of depression -Obsessive Compulsive Disorder -Panic Disorder with or without agoraphobia	JDH Pharmaceutical S/B, Li Fung Centre, Lot 6, Persiaran Perusahaan Seksyen 23, 40300 Shah Alam
4.	4.1	Botox (Botulinum toxin Type A) IM Injection (Clostridium botulinum toxin type A)	It is indicated for temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.	Diethelm (M) Sdn. Bhd 74, Jalan Universiti, 46200 Petaling Jaya.

DCA 149 (July 2003)

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1	1.1	Aerius 5mg tablet (Desloratadine)	Indicated for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives.	Schering-Plough Sdn. Bhd. Petaling Jaya, Selangor

2	2.1	Minirin 0.1mg tablet	Treatment of nocturia associated with nocturnal polyuria in adults.	United Italian Trading (M) Sdn. Bhd. Petaling Jaya, Selangor
	2.2	Minirin 0.2mg tablet (Desmopressin acetate)		

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NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1	1.1	Decapeptyl CR Injection (Triptorelin)	Treatment of confirmed central precocious puberty (preterm sexual development) (girls under 9 years, boys under 10 years of age).	United Italian Trading (M) Sdn Bhd. No. 1, 1ST Floor, The Highway Centre, Jalan 51/205, 46050 PJ
2	2.1	Fosamax 70mg tablet (Alendronate sodium)	Fosamax is indicated for treatment of osteoporosis in men to prevent fractures.	Merck Sharp & Dohme (I.A) Corp. Malaysia branch
3	3.1 3.2	Cutivate cream 0.05% w/w Cutivate ointment 0.005% w/w (Fluticasone Propionate)	Reduce of the risk of relapse of chronic recurrent atopic eczema once an acute episode has been treated effectively.	Glaxosmithkline Pharmaceutical Sdn. Bhd, 7th Floor, Menara Lien Hoe, No. 8, Persiaran Tropicana, 47410 Petaling Jaya. Selangor.
4	4.1	Botox IM Injection 100unit/vial (Clostridium botulinum toxin type A)	Botox is indicated in the management of focal spasticity including wrist and hand disability due to upper limb spasticity associated with stroke in adult.	Diethelm Malaysia Sdn. Bhd. 74, Jln. University, 46200 P. Jaya

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NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1	1.1	Zoloft 50 mg tablet	Treatment of post-traumatic stress disorder	Pfizer (M)

	1.2	Zoloft 100mg tablet(Sertraline)	(PTSD).	Sdn.Bhd,Lot 4,Jln.13/6,P.O Box333,Jln Sultan,46740Petaling Jaya,Selangor.
2	2.1	Lipanthyl Supra 160mg Film-coated tablet (Fenofibrate)	The treatment of secondary hyperlipoproteinaemias is indicated if the hyperlipoproteinaemia persists despite effective treatment of the underlying disease (e.g. dyslipidaemia in diabetes mellitus).	Antah Pharma S/B, No. 3, Jalan 19/1,46300, Petaling Jaya,Selangor.
3	3.1 3.2	Taxotere 20mg/0.5ml injection dan Taxotere 80mg/2ml injection (docetaxel)	i) Taxotere in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. ii) Indicated for the treatment of metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy.	Aventis Farma SA (M) S/B,74, Jln Universiti, PO Box 77, 46700, P.Jaya,Selangor.
4	4.1	Xenical Capsule 120 mg (Orlistat)	n type 2 diabetic patients who are overweight (BMI = 28 kg/m ²) or obese (BMI = 30 kg/m ²). XENICAL, in conjunction with a mildly hypocaloric diet, provides additional glycemic control when used in combination with antidiabetic such as metformin, sulfonylurea and/or insulin.	Roche (M) Sdn. Bhd.,The Selangor Dredging,142 Jalan Ampang, 50450,K. Lumpur.

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NO	LOI NUMBER	PRODUCT NAME	ACTIVE SUBSTANCE	MARKETING AUTHORIZATION HOLDER	MANUFACTURER
1	1997040824A	Oxis Turbuhaler 4.5 µg/dose	Formoterol fumarate dihydrate	AZ Pharmaceuticals (M) Sdn. Bhd. 2nd Floor, Wisma Prima, 17,Jln. Sri Semantan Satu, Damansara Heights, 50490 KL	Astra Zeneca AB, Sweden
2	1997051075A	Oxis Turbuhaler 9 µg/dose	sda	sda	D

INDIKASI YG DILULUSKAN

Prevention of exercise-induced symptoms in asthmatics when adequate treatment with corticosteroids is not sufficient.

NO	LOI NUMBER	PRODUCT NAME	ACTIVE SUBSTANCE	MARKETING AUTHORIZATION HOLDER	MANUFACTURER
1	1999041123A	Vioxx 12.5mg tablet	Rofecoxib	Merck Sharp & Dohme (I.A) Corp. Malaysia Branch, Letter Box 1502, 15th floor, Menara Merais, 1 Jalan 19/3, 46300 PJ	Merck Sharp & Dohme USA
2	1999041124A	Vioxx 25mg tablet	sda	sda	sda
3	1999041121A	Vioxx Oral Suspension 12.5mg/5ml	sda	sda	sda
4	1999041122A	Vioxx Oral Suspension 25mg/5ml	sda	sda	sda

INDIKASI YG DILULUSKAN

For acute and chronic treatment of the signs and symptoms of rheumatoid arthritis.

NO	LOI NUMBER	PRODUCT NAME	ACTIVE SUBSTANCE	MARKETING AUTHORIZATION HOLDER	MANUFACTURER
1	1995060272A	Eposin, concentrate for infusion 20mg/ml (5ml)	Etoposide	United Italian Trading (M) Sdn. Bhd. No.1, 1st floor, The Highway Centre, Jln 51/205, 46050 PJ	Pharmachemie B.V, The Netherlands

INDIKASI YG DILULUSKAN

Monoblastic leukemia (AML M5) and acute myelomonoblastic leukemia (AML M4) when standard therapy has failed (in combination with other chemotherapeutic agents).

NO	LOI NUMBER	PRODUCT NAME	ACTIVE SUBSTANCE	MARKETING AUTHORIZATION HOLDER	MANUFACTURER
1	1991110052A	Seroxat 20mg tablet	Paroxetine	GlaxoSmithKline Pharmaceuticals Sdn. Bhd. 7th & 8th floor, Menara Lien Hoe, 8,Persiaran	Smithkline Beecham Pharmaceuticals, Manor Royal,

Tropicana, 47410 PJ

Crawley, West
Sussex,
UK,RH102QJ**INDIKASI YG DILULUSKAN**

Treatment of symptoms and prevention of relapse of Generalized Anxiety Disorder.

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BIL.	No RUJUKAN	NAMA PRODUK	BAHAN AKTIF	PENGILANG	PEMOHON
1.	LOI 1998071498A	Xeloda tablet 150mg	Capecitabine	Hoffman-La Roche Inc., USA	. Roche (M) Sdn. Bhd. Kuala Lumpur
2.	LOI 1998071499A	Xeloda tablet 500mg	sda	sda	sda

INDIKASI YG DILULUSKAN

'Use in combination with docetaxel for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.'

BIL.	No RUJUKAN	NAMA PRODUK	BAHAN AKTIF	PENGILANG	PEMOHON
1.	LOI 2001044096A	Glivec 100mg capsule	Imatinib	Novartis Pharma Stein AG, Switzerland	Novartis Corporation (M) Sdn. Bhd.

INDIKASI YG DILULUSKAN

'Treatment of adult patients with unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST).'

BIL.	No RUJUKAN	NAMA PRODUK	BAHAN AKTIF	PENGILANG	PEMOHON
1.	LOI 1996050553A	Roferon-A 3miu/0.5ml PFS	Interferon alfa-2a	F. Hoffman-La Roche Ltd, Basel, Switzerland	Roche (M) Sdn. Bhd.Selangor Dredging, Jln. Ampang, KL
2.	LOI 1996050476A	Roferon-A 4.5miu/0.5ml PFS	sda	sda	sda
3.	LOI 1996050475A	Roferon-A 6miu/0/5ml PFS	sda	sda	sda

4.	LOI 1996050474A	Roferon-A 9miu/0/5ml PFS	sda	sda	sda
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INDIKASI YG DILULUSKAN:

'Adjuvant therapy of surgically resected malignant melanoma of AJCC stage II (Breslow tumour thickness > 1.5mm) in patients who have no clinically detectable nodal or distant metastases.'

Dosage and Administration:

Roferon-A should be administered subcutaneously or intramuscularly at a dose of 3 million IU three times a week. Patients should be treated for 18 months, starting no later than six weeks post surgery. If tolerance develops, the dose should be lowered to 1.5million IU three times a week.

BIL.	No RUJUKAN	NAMA PRODUK	BAHAN AKTIF	PENGILANG	PEMOHON
1.	MAL 19950380A	Clexane 20 mg/10.2 ml Pre-filled syringe	Enoxaparin	Laboratoires Bellon 15, rue de la Vanne MONTROUGE CEDEX France	Aventis Farma SA(M) Sdn. Bhd., PO Box 77,46700 Petaling Jaya, Selangor, Malaysia.
2.	MAL 19950379A	Clexane 40 mg/0.4 ml Pre-filled syringe	Enoxaparin	- sama -	- sama -
3.	MAL 19973597A	Clexane 60 mg/0.6 ml Pre-filled syringe	Enoxaparin	- sama -	- sama -
4.	MAL 19973598A	Clexane 80 mg/0.8 ml Pre-filled syringe	Enoxaparin	- sama -	- sama -
5.	MAL 19973599A	Clexane 100 mg/ml Pre-filled syringe	Enoxaparin	- sama -	- sama -

INDIKASI YG DILULUSKAN

"Prophylaxis of venous thromboembolic disease in medical patients bedridden due to acute illness".

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BIL.	No RUJUKAN	NAMA PRODUK	BAHAN AKTIF	PENGILANG	PEMOHON
1.	MAL 19963142A	Cozaar 50mg	Losartan	Merck Sharp & Dohme	Merck

& Dohme Corp., (LOI 1996010203A)	Tablet	potassium	Ltd., United Kingdom	Sharp Selangor.
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NDIKASI YANG DILULUSKAN:

Nephropathy in Type 2 Diabetic Patients

Cozaar is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio = 300mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, Cozaar reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation).