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REGIONAL EXPERT CONSULTATION ON THE ESTABLISHMENT OF AN ASEAN SUMMARY OF PRODUCT CHARACTERIATICS

The Regional Expert Consultation on the Establishment of an ASEAN Summary of Product Characteristics was held in Manila on 22-24 June 2005. It was organised in cooperation with the EC-ASEAN Economic Cooperation Program, the Bureau of Product Standards (BPS), the Bureau of Food and Drugs (BFAD), and the World Health Organization (WHO).

The meeting was chaired by Ms. Charunee Krisanaphan of Thailand, co-chaired by Ms. Lee Hui Keng of Singapore. Ms. Josephine K. Sarau of the Philippines was the rapporteur of the meeting. Attendees of the said consultative meeting were namely, 1 WHO expert, 4 ASEAN Experts, 10 ASEAN and 15 local participants from their respective drug regulatory agency. Malaysia was represented by Ms. Mazuwin Zainal Abidin and Ms. Fuziah Abdul Rashid.

In This Issue

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The meeting was convened with the following objectives:

a) Design a practical approach for improved drug information (DI) in ASEAN member countries

b) Draft a template for the application of the approach proposed

c) Identify reliable sources of information to be used as preferred reference in the marketing authorisation process;

d) Identify suitable technical solutions for making DI easily accessible through the web sites.

The meeting discussed possible practical approaches which aim to enable ASEAN regulators to produce and publish drug information in order to:

- avoid inconsistency and inaccuracy in the information provided to patients and health professionals,

- help patients and health professionals to achieve rational and safe use of drugs,

- improve the image of regulators as a reliable source of information,

- minimize the workload implied by assessment of Package Insert/Patient Information Leaflet (PI/PIL)

The two days meeting have achieved the expected results as follows:

- participants improved their understanding of drug information issues,

- a concrete strategy was outlined for possible immediate implementation by ASEAN Drug Regulatory Agencies (DRAs),

- a proposed format for reference drug information,

- a list of preferred sources of information to be used in the assessment of drug information materials submitted in applications for Marketing Authorisation (MA),

- number of support measures necessary for the effective implementation of the proposed strategy.

The meeting recommended that all recommendations proposed will be submitted by the Chair or one of the experts who attended this meeting to the next Pharmaceutical Product Working Group (PPWG) meeting planned for 23-26 August 2005 in Singapore.

NEWS UPDATE ON ASEAN CONSULTATIVE FOR STANDARDS AND QUALITY (ACCSQ) ASEAN COSMETICS COMMITTEE (ACC)

The Fourth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held on 2 – 3 June 2005 in Kuala Lumpur, Malaysia

The Meeting was chaired by Mrs. Werawan Tangkeo, Deputy Secretary General, Food and Drug Administration, Ministry of Public Health, Thailand, and co-chaired by Drs. Ruslan Aspan, MM, Deputy, Traditional Medicine, Cosmetic and Complementary Product Control, National Agency of Drug and Food Control, Republic of Indonesia.

The Meeting was attended by the representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, the ASEAN Secretariat and the ASEAN Cosmetic Association. Representatives from ASEAN Cosmetic Industry also attended the Meeting as observers.

The Meeting discussed and agreed with the following outcomes of the 25th ACCSQ Meeting:

i) Products to be marketed in ASEAN have to fully meet the requirements of the ASEAN Cosmetic Directive regardless of the country of origin of the products.

ii) Suppliers/ Manufactures that would like to place their products in any ASEAN Member Countries will have to declare their compliance with the ASEAN Cosmetic Directive and notify the regulatory authority in the respective country.

iii) Member Countries shall use the ASEAN Cosmetic Directive as the platform for any trade negotiations for cosmetic sector with other countries/ sub-region.

With regards to the implementation of the ASEAN Cosmetic Good Manufacturing Practice (GMP), the Meeting also agreed on the following:

i) Regulatory authorities continue to disseminate information that complies with the ASEAN Cosmetic GMP Guideline.

ii) Cosmetic industry in ASEAN and outside ASEAN who intend to place their cosmetic products in ASEAN market should make an effort to comply with the ASEAN Cosmetic GMP Guideline and the targeted date for compliance is by 1st January 2008.

iii) With regard to the Post Marketing Surveillance approach, there is no requirement for the GMP Certification from 1 January 2008.

iv) The Regulatory Authorities in Member Countries will conduct a survey on the level of GMP compliance by cosmetic industry in ASEAN in January 2007.

The Meeting also discussed on ASEAN Post Marketing Surveillance/Safety Evaluation and adopted the revised Guide Manual for the Industry and the revised Template for Notification. The Meeting then considered and agreed to adopt the Draft Post Marketing Surveillance Alert System proposed by Singapore as ASEAN Alert System for Unsafe and Defective Cosmetic Products.

The Meeting noted the training course done and will discuss the possibility of running a short summary course conducted locally by EU industry experts.

Besides that the Meeting has discussed on safety issue of cosmetic products and the content of Information Booklet on the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) and ACC websites.

The fifth ACC Meeting will be held in Brunei Darussalam tentatively on 6 – 8 December 2005.

DCA NEWS

Amendment of statement on label and package insert for Traditional Product containing GINSENG

The Drug Control Authority (DCA) at its 169th meeting which was held on the 28th April, 2005 decided to amend the statement 'Continuous use exceeding three months is not advisable' which is mandatory on label and package insert for all products containing Ginseng (including Panax genus) amended to **'Safety on long term use has not been established'.**

Other than that, the following statement also need to be included on label and package insert for all products containing ginseng:

- Safe use of ginseng in pregnant women and children has not been established
- Do not exceed the stated dose
- Safety on long term use has not been established

Restriction on the usage of products containing Thioridazine

At the same meeting, the DCA agreed not to allow the registration of products containing THIORIDAZINE based on safety issue. All registered product holders will be asked to withdraw their products voluntarily.

Regularoty actions towards Cox-2 Inhibitors: Celecoxib and Etoricoxib.

The DCA also decided at its 169th meeting, all the informations stated below need to be inserted in all package insert for **COX-2 Inhibitor** products containing **Celecoxib** and **Etoricoxib.**

i) Limiting the usage of COX-2 Inhibitors as a "2nd line therapy".

ii) Contraindication for patient who have risk of cardiovascular disease (ischeamic heart disease and stroke).

iii) Warning to prescriber when prescribing COX-2 Inhibitors to patients with risk factors of heart disease, hypertension (high blood pressure), hyperlipidemia, diabetes, smoking patient and patient with "peripheral arterial disease".

iv) Statement on limiting the period and dosing is written as "Given the association between cardiovascular risk and exposure to COX-2 Inhibitors, doctors are advised to use the lowest effective dose for the shortest possible duration of treatment".

v) Contraindication for patient using Etoricoxib is written as "Contra-indication for etoricoxib in patients with hypertension (high blood pressure) whose blood pressure is not under control".

Warning statement on the label and package insert for all products containing Propolis (Topical form), Royal Jelly (All forms) and Ginkgo Biloba/Ginkgo Extract

The Drug Control Authority (DCA) at its 170th meeting held on the 26th May, 2005 made the decision that the following warning statement need to be included on the label and package insert of products containing PROPOLIS, ROYAL JELLY and GINKGO BILOBA/GINKGO EXTRACT:

(i) For all topical form of propolis products:
- ***Propolis may cause allergic skin reactions.***

(ii) For all royal jelly products:
- ***This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals.***
- ***Asthma and allergy sufferers may be at the greater risks.***

iii) For all products containing Ginkgo Biloba/Ginkgo Extract;
- ***As the use of Ginkgo may increase the tendency of bleeding, please consult your physician pharmacist if you are on or intend to start using any other medicines and before you undergo any surgical/dental procedure***

Withdrawal of the registration termination of DYNASTAT INJECTION (Parecoxib)

The DCA at its 171st meeting held on the 30th June, 2005 agreed to withdraw the registration termination of IM/IV Parecoxib. Parecoxib is now allowed to be marketed with the following amendments:

i) The indication of IV/IM Parecoxib is restricted to the following condition:
"Management of post operative pain in the immediate post operative setting only with the exception of patients undergoing coronary bypass grafting (CAB) procedures and in those patients with cardiovascular risk".

ii) Limitation of usage
"Use should be limited to two (2) days only with a maximum dose of 80mg per day"

iii) To include box warning as follows:
"Contraindicated in patients undergoing coronary bypass grafting (CABG) procedures and in those patients with cardiovascular risk".

All these three amendments must be included in the package insert.

The withdrawal to the registration termination of parecoxib is only effective for the following products.

PRODUCT NAME : DYNASTAT INJECTION 20MGVIALS
REGISTRATION NO : MAL20033925AR

PRODUCT NAME : DYNASTAT INJECTION 20MGVIALS WITH DILUENT
REGISTRATION NO : MAL20033927AR

However the termination of the registration of the product **IV/IM BEXTRA** by DCA still remains even though it contains Parecoxib.

Poisons Act 1952, Poisons Regulations (amendment) 2003 : Label for 'Controlled Medicine or Ubat Terkawal'

At the same meeting, the DCA has agreed to the amendment of the word 'Poison' which is mandatory as a labelling requirement to all products containing scheduled poisons as listed in Poison List 1952 to **'Controlled Medicine or Ubat Terkawal'.**

The word 'Controlled Medicine or Ubat Terkawal' must be printed in Bahasa Melayu or English in any colour, font and font size. Sticker labels are also allowed.

As of **1st January, 2006,** all registered products containing scheduled poisons are required to comply with this labeling requirement.

Study Requirement and Implementation Date of Bioequivalence (BE) Study Report for the Application of New Products and Registered Products.

With regards to the above matters, at the same meeting the DCA has also agreed to the following:

No.	Active Substances	Decision	Implementation
1)	Comparator product is not available in local market		
	◗ Lithium Carbonate ◗ Dexamethasone ◗ Verapamil ◗ Prednisolone	These active Substances have been listed out from the List of BE study requirement for Generic Product 'Immediate Release' Requirement to present the report of BE study is not compulsory. However, applicant should present:- a) Validation process report for 2 consecutive batches b) Comparative dissolution Profile for 3 consecutive batches at time points: 0, 5, 15, 30 and 45 minute.	1 December 2005
2)	Comparative product which is not in the market/different dosage form		
	◗ **Omeprazole** ◗ **Piroxicam**	**Dosage Form: Capsule/Tablet** Identified product comparator: • **Losec Mups Tablet** **(i) Dosage Form: Capsule** Registered generic product identified as a product comparator:-	1 July 2006 1 July 2006

No.	Active Substances	Decision	Implementation
		• **Uphaxicam 20 Capsule (MAL19861112A)** • **Uphaxicam 10 Capsule (MAL19861109A)** **(Manufacturer: Upha Pharm Mfg. Sdn. Bhd.)** • **Felxicam 20 Capsule (MAL19920515A)** • **Felxicam 10 Capsule (MAL19920514A)** **(Manufacturer: Hovid Sdn. Bhd.)** • **Roxim Capsule 20mg (MAL19950262A)** • **Roxim Capsule 10mg (MAL19950261A)** **(Manufacturer: Prime Pharmaceutical Sdn. Bhd.)** • **Axcel Piroxicam-10 Capsule (MAL19910832A)** **(Manufacturer: Kotra Pharma (M) Sdn. Bhd.)** **(ii) Dosage Form: Dispersable Tablet** Identified Product Comparator:- • **Feldene Dispersible Tablet (MAL19962549A)**	
3)	Comparator product that has different dissolution profile with the test product		
	◗ **Phenytoin sodium**	Suggest formulating generic product based on 'innovator' product specification. Identified product comparator:- • **Dilantin Capsule 100mg (MAL 19860935AR)** • **Dilantin Capsule 100mg (MAL 19860940AR)**	1 July 2006

PRODUCTS APPROVED FOR ADDITIONAL INDICATION FROM JANUARY – JUNE 2005.

DCA 171– 30 JUNE 2005

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2	Taxotere 20mg/0.5ml vial Taxotere 80mg/2ml vial	**Prostate cancer** Taxotere in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostatic cancer. **Breast cancer** Taxotere in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.	Aventis Farma SA (Malaysia) Sdn. Bhd. 8th. Floor, No. 19, PNB Damansara, Lorong Dungun, Damansara Heights, 50490 KUALA LUMPUR

DCA 170– 26 MAY 2005

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2	Valtrex tablets 250mg Valtrex tablets 500mg (Valaciclovir hydrochloride)	Valtrex can reduce transmission of genital herpes when taken as suppressive therapy and combined with safer sex practices (particularly the use of condoms).	GlaxoSmithKline Pharmaceutical Sdn. Bhd. 8th Floor, Menara Lien Hoe, 8 Persiaran Tropicana, 47410 Petaling Jaya, Selangor.
2.	2.1 2.2	Eloxatin 50mg freeze dried powder for infusion Eloxatin 100mg freeze dried powder for infusion (Oxaliplatin)	Oxaliplatin in combination with 5 -fluorouracil and folinic acid is indicated in: i) the adjuvant treatment of stage III colon cancer (Dukes stage C) following complete resection of the initial tumour ii) the treatment of metastatic colorectal cancer	Sanofi Synthelabo (Malaysia) Sdn. Bhd. 8th Floor, No. 19, PNB Damansara, Lorong Dungun, Damansara Heights
3.	3.1 3.2	Nexium 20mg tablet Nexium 24mg tablet (Esomeprazole Magnesium Trihydrate)	Patients requiring continued NSAID therapy - healing of gastric ulcers associated with NSAID therapy - prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk.	AstraZeneca Sdn. Bhd. PO Box 1122 50740 Kuala Lumpur

4.	4.1 4.2 4.3	Atacand Tablet 4 mg Atacand Tablet 8 mg Atacand Tablet 16 mg (Candesartan Cilexetil)	Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction = 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated.	AstraZeneca Sdn. Bhd. PO Box 1122 50740 Kuala Lumpur
5.	5.1 5.2	Proscar 5mg tablet Proscar 5mg tablet (Finasteride)	Full indications: Proscar is indicated for the treatment and control of benign prostatic hyperplasia (BPH) and for the prevention of urologic events to: - reduce the risk of acute urinary retention - reduce the risk of surgery including ransurethral resection of the prostate (TURP) and prostatectomy. Proscar causes regression of the enlarged prostate, improves urinary flow and improves the symptoms associated with BPH. Patients with enlarged prostate are the appropriate candidates for therapy with Proscar. Proscar administered in combination with the alpha-blocker doxazosin is indicated to reduce the risk of symptomatic progression of BPH (a confirmed 4 point increase in AUA symptom score).	Merck Sharp & Dohme (I.A) Corp. Letter Box 1502, 15th Floor, Menara Merais, 1, Jalan 19/3, 46300 Petaling Jaya.
6.	6.1 6.2 6.3	Vfend IV 200mg/30ml Vfend 50mg Tablet Vfend 200mg Tablet (Voriconazole)	- Treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall and wounds.	Pfizer (M) Sdn. Bhd., Level 3 & 4, Bangunan Palm Grove, No. 14, Jalan Glenmarie, (Persiaran Kerjaya), Section U1, 40150, Shah Alam, Selangor.

DCA 169– 28 April 2005

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2 1.3	Videx Paediatric Oral Suspension 2g Videx Paediatric Oral Suspension 4g Videx tablet 25mg	For treatment of HIV-infected pediatric patients from 2 weeks of age and older in appropriate antiretroviral regimens in combination with other nucleoside analogues, non-nucleoside reverse-transcriptase inhibitors and HIV protease inhibitors.	Bristol-Myers Squibb (M) Sdn. Bhd. 16th Floor, Menara Lien Hoe, 8, Persiaran Tropicana, 47410 Petaling Jaya.

	1.4 1.5 1.6	Videx tablet 50mg Videx tablet 100mg Videx tablet 200mg (Didanosine)		
2.	2.1 2.2 2.3 2.4 2.5	Epilim Chrono 500mg tablet Epilim 200 enteric coated tablet Epilim 500 enteric coated tablet Epilim Syrup 200mg/5ml Epilim Liquid 200mg/5ml (Sodium valproate, valproic acid)	Treatment and prevention of mania associated with bipolar disorders.	Sanofi Synthelabo (Malaysia) Sdn. Bhd. 3.02 Level 3, Wisma Academy, Lot 4A, Jln 19/1, 46300 Petaling Jaya
3.	3.1	Valcyte tablet 450mg (Valganciclovir hydrochloride)	Valcyte is indicated for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.	Roche (Malaysia) Sdn. Bhd. The Selangor Dredging, 142, Jalan Ampang, 50450 Kuala Lumpur.
4.	4.1	Femara 2.5mg film-coated tablet (Letrozole)	Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy).	Novartis Corporation (Malaysia) Sdn. Bhd. Lot 9 Jalan 26/1, Seksyen 26, Kaw. Perindustrian HICOM, 40400 Shah Alam.

DCA 168– 21 March 2005

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.		Prevacid capsules 30mg (Lansoprazole)	Treatment and prophylaxis of NSAID-associated benign-gastric ulcers, duodenal ulcers and relief of symptoms in patients requiring continued NSAID treatment.	Level 3A, Block B, No. 10, Jalan Bersatu 13/4, 46200 Petaling Jaya.

2.	2.1 2.2 2.3	Imigran tablet 100mg Imigran tablet 50mg Imigran injection 6mg/0.5ml (Sumatriptan succinate)	Sumatriptan remains effective in treating menstrual migraine ie. migraine without aura that occurs between 3 days prior and up to 5 days post onset of menstruation. Sumatriptan should be taken as soon as possible in an attack.	GlaxoSmithKline Pharmaceutical Sdn. Bhd. 7th & 8th Floor, Menara Lien Hoe, No. 8, Persiaran Tropicana, 47410 Petaling Jaya.

DCA 166– 31 January 2005

NO		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 1.2	Gemzar for Injection 200mg Gemzar for Injection 1g (Gemcitabine)	Gemcitabine, in combination with carboplatin, is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma, who have relapsed >6 months, following platinum-based therapy.	Eli Lilly (Malaysia) Sdn. Bhd. Unit 18.1, Level 18, CP Tower, No. 11, Jalan 16/11, Pusat Dagang Seksyen 16, 46350 Petaling Jaya.
2.	2.1 2.2 2.3 2.4	Lamictal 5mg dispersible tablet Lamictal 25mg dispersible tablet Lamictal 50mg tablet Lamictal 100mg tablet (Lamotrigine)	**Bipolar disorder** Adults (18 years of age and over) Lamotrigine is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.	GlaxoSmithKline Pharmaceutical Sdn. Bhd. 7th & 8th Floor, Menara Lien Hoe, No. 8, Persiaran Tropicana, 47410 Petaling Jaya.
3.	3.1 3.2	Cancidas Injection 50mg/vial Cancidas Injection 70mg/vial (Caspofungin acetate)	Cancidas is indicated for empirical therapy for presumed fungal infections in febrile, neutropenic patients.	Merck Sharp & Dohme (I.A) Corp. Letter Box 1502, 15th Floor, Menara Merais, 1 Jalan 19/3, Petaling Jaya.

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(ii) Complementary Medicines & Cosmetic Section	-Natural Products Unit -Health Supplement Unit -Cosmetic Unit	Saleha Md. Ewan Abdullah Hisham Ahmat Yaya Anis Talib	238 233 333
(iii) Investigational & New Drug Section	-New Drug Unit -Clinical Trial Regulatory Unit -Biotechnology Unit	Fudziah Ariffin Dr. Kamaruzaman Saleh Arpah Abas	242 371 241
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