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REPORT OF THE ELEVENTH MEETING OF THE ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY (ACCSQ) PHARMACEUTICAL PRODUCT WORKING GROUP (PPWG)

8 - 10 March 2006, Hanoi, Viet Nam

The Eleventh Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held on 8 – 10 March 2006 in Hanoi, Viet Nam. The Meeting was preceded by the Focus Discussion Groups, followed by Vaccine Chapter on 6 March 2006, then the Dialogue with the Pharmaceutical Industry in ASEAN and the 6th Meeting of the Implementation Working Group (IWG) on 7 March 2006 at the same venue.

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The Meeting discussed the progress in implementing the ASEAN Harmonised Products in the following aspects:

1. **ASEAN BA/BE Studies**

   The Meeting considered the draft Terms of Reference (TOR) done on 6 March 2006 and was in view that the Draft TOR did not cover all mandates given to the Taskforce during the 10th PPWG Meeting held in Singapore. With regards to the above matter, the Meeting agreed that Indonesia with assistance by Malaysia will further improve the TOR and framework and submit for consideration and adoption at the next PPWG Meeting.

2. **Q & A for ASEAN Stability Guidelines and ACTD Quality**

   The Meeting agreed that a Q&A Forum should be established involving the group of experts at national level and/or regional level to resolve the implementation issues of the ACTD Quality and Stability Guidelines. Resolutions on technical issues would be included in the Q&A while the resolutions on implementation issues would be included in the country specific issues in the Q&A. In this aspect, Indonesia is to be the lead country.

3. **ASEAN Labelling Requirements - Possible Harmonisation**

   Out of 16 labelling requirements, 15 items have been harmonised amongst Member Countries, except for item number 13 (country specific requirements). The Meeting agreed not to pursue further the harmonisation of country specific requirements.

4. **Report of the 6th IWG Meeting**

   The Meeting considered the recommendations made by the IWG and made the following decisions:

   ACTD Implementation
   With regards to the flexibility over and above the ACTD for product applications for marketing authorisation, the IWG recommended that the flexibility would include accepting the ICH format for specific categories of products such as innovative therapeutic products and biologics, as well as consideration for national policies and specific needs of individual Member Countries.

   Establishment of the APAGEs Framework
   The formation of the APAGEs would be deferred to a later stage due to human and financial resource constraints.

   IWG Industry Dialogue
   Technical issues related to ACTD shall be handled by the lead country for the respective assigned areas and non-technical issues would be discussed at the national level between NRA and the industry.

   ASEAN Training Scheme
   PPWG will write to WHO for clarification on its future participation and support of the ASEAN Training Scheme. This is in view that Dr. Valerio Reggi, the WHO contact person has been reassigned to other responsibilities.

5. Other Activities Related to the ASEAN Healthcare Integration Roadmap

Mutual Recognition Arrangements (MRAs)
The Meeting endorsed the revised TOR as well as the draft outline of the ASEAN Sectoral MRA on GMP Inspection.

Post-Marketing Alert (PMA) System
The Meeting agreed that the PMA System could be considered as a formal system in the future to ensure the interactions and cooperation between Regulatory Authorities in ASEAN towards unsafe and defective pharmaceutical products. There should be separate glossaries for pharmaceuticals, cosmetics, traditional medicines and health supplements.

6. Cooperation with the Relevant International Organisations and Dialogue Partners

ACTD Implementation World Health Organisation (WHO) – ASEAN Harmonisation Project
Due to reassignment of work at the WHO Headquarters, the Draft ASEAN Guidance on Reference Drug Information which was prepared by the WHO would need to be deferred until the WHO nominates a new officer to be the contact person with the PPWG.

Vaccine Chapter
Due to limited resources in Member Countries, the Meeting decided that instead of establishing an ASEAN Vaccine Group (AVG), a regional focal point be appointed by the PPWG to coordinate with the WHO and Member Countries in organising these activities. The Meeting agreed to appoint Thailand as a regional focal point.

ASEAN WORKSHOP ON COMPULSORY LICENSING TO INCREASE ACCESS TO ANTIRETROVIRALS (ARVs) AND DIAGNOSTIC REAGENTS

23-24 May 2006, Kuala Lumpur, Malaysia

The ASEAN Workshop on Compulsory Licensing to Increase Access to Antiretrovirals (ARVs) and Diagnostic Reagents was held from 23 to 24 May 2006 in Kuala Lumpur, Malaysia. The workshop was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Thailand and Viet Nam. Representatives of WHO, ASEAN Secretariat, Family Health International, as well as resource persons from India, Philippines, USA and The Third World Network were also in attendance.

During the 11th Summit in December 2005, the ASEAN Leaders endorsed the ASEAN Work Programme on HIV and AIDS III (AWPIII) as the agenda for future action in addressing HIV transmission and AIDS treatment. In 2005, the Gleneagles and World Summit pledged support for scaling up comprehensive HIV prevention, treatment and care, with the aim of getting "as close as possible" to universal access

(UA) of treatment for all those who need it by 2010. The Workshop is one of a series of ASEAN activities/ workshops carried out under the ASEAN-USAID Project and coordinated by Indonesia in collaboration with Family Health International (FHI), ASEAN Secretariat, and the host countries.

The workshop was to delve into the following issues:

1. Whether there will be a need for Compulsory Licensing (CL), Government Use (GU) or Voluntary Licensing (VL) in order to enhance access to medicine into each of the ASEAN country.
2. Advantage(s) and disadvantage(s) of each of these options in the context of country/domestic situation of each of the country.
3. The realistic option.
4. Problems anticipated and ways to tackle them.

The workshop was concluded with the following outcome:

1. Cambodia and Lao PDR would not use any of the proposed options, but would continue to rely on importation of ARVs.
2. Rights of Government Use (GU) is the preferable option for Malaysia and the Philippines. However, VL and CL will be used also in the Philippines on case by case basis.
3. VL is preferred by Viet Nam; however Viet Nam is also ready to use GU and CL.
4. Indonesia and Thailand require all the options. However, they have to be used step by step starting with VL.

NEWS UPDATE ON THE 22ND MEETING OF THE ASEAN WORKING GROUP ON TECHNICAL COOPERATION IN PHARMACEUTICALS (AWGTCP)

25 – 27 May 2006, Kuala Lumpur, Malaysia

The 22nd Meeting of the ASEAN Working Group on Technical Cooperation in Pharmaceuticals (AWGTCP) was held from 25 – 27 May 2006 in Kuala Lumpur, Malaysia and was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, The ASEAN Secretariat as well as representatives from the World Health Organisation (WHO).

AWGTCP meetings, which have been held since 1979, plays an important role in strengthening cooperation amongst ASEAN member countries. During the recent meeting, the respective countries reported on the implementation of the activities from 2004 - 2006, summarised below:

1. **Training Centre for GMP Inspections/Auditors (Indonesia)**
Indonesia, with the support of WHO-SEARO, conducted a Global Training Network Workshop on GMP for Vaccines on 6 - 16 December 2005. The GMP training module for vaccines, developed in cooperation with WHO, was piloted at the workshop. Indonesia would follow-up on the availability of the ASEAN GMP guidelines in soft copy and would disseminate it to all Member Countries.

2. **Standardisation, Quality Control and Validation of Herbal Medicines (Indonesia/ Thailand)**
Volume II of Monographs of Standards of ASEAN Herbal Medicines (SAHM) has been published and distributed to ASEAN member countries.

3. **Training Centre for Strengthening of Quality Assurance and Non-Pharmacopoeial Analytical Methods (Malaysia)**
Malaysia has developed a test method for the detection of Cadmium in traditional medicines and analytical techniques for the detection of scheduled poisons in adulterated traditional medicines.

4. **Training Centre for Community and Clinical Pharmacy (Brunei Darussalam and Singapore)**
The Meeting requested Singapore / Brunei Darussalam to explore possible future training activities.

5. **Training Centre for the Production and Utilisation of Regional Standards and Reference Substances (ASEAN Reference Substances) (Thailand)**

- Production of ASEAN Reference Substances (Microbiological Assays), 14 - 25 February 2005.
- Production of ASEAN Reference Substances (Chemical Assays), 15 - 26 May 2006.

The Meeting also identified new areas of collaboration,discussed the agreed work plan / development for 2004 - 2008, as well as cooperation with dialogue partners and the related international agencies.

1. <u>New areas of collaboration in the following aspects:</u>

   i. **Building up and Strengthening ASEAN's Capacity on Good Clinical Practice (GCP) and Clinical Trials (Thailand)**
   A GCP Audit / inspection workshop was organised on 21 - 25 June 2005 with the support of Thai FDA and the private sector. There was participation from Cambodia, Indonesia and Malaysia.

   ii. **Pharmacoeconomics in Drug Regulatory Activities and Pharmaceutical Practice (Brunei Darussalam / Singapore)**
   To better reflect the role of pharmacoeconomics, Brunei Darussalam and Singapore proposed to amend the title of the project to "Pharmacoeconomics and Its Effective Applications".

   iii. **Strengthening ASEAN Collaboration on Combating Counterfeit Drugs (Indonesia)**
   Malaysia suggested that it would be useful to involve the industry in joint investigations when needed as from experience, the industry could provide timely and accurate information regarding counterfeit shipments.

2. Development / Formulation of Work Plan for 2004 - 2008

Issues discussed related to the agreed Work Plan included consideration to revise the time frame, prioritisation of the programmes / activities under the Work Plan as well as new proposals (from Cambodia, Lao PDR, Myanmar, Vietnam). The new proposals discussed are as below:

- Training in Biostatistics, National Reference Product Information, Drug Evaluation and Proficiency Testing (Cambodia).
- Technical assistance in Good Laboratory Practice and Good Manufacturing Practice, and assistance in strengthening networking and communications in pharmaceuticals within the country (Laos PDR).
- Collaboration (such as information sharing) in the areas related to drug pricing control and ethical practices (Viet Nam).

The above individual country needs to develop and submit proposals to the ASEAN Secretariat to seek funding.

3. Cooperation with Dialogue Partners and International Agencies

i. Informal ASEAN Consultation Meeting on the ASEAN-India Cooperation in Health and Pharmaceuticals

The Informal Consultation Meeting was held on 9 December 2005 in Jakarta. This was in conjunction with the 3rd Senior Officials Meeting on Health Development (SOMHD) to follow-up on the pending process of finalising the scope of cooperation and terms of reference under the draft Terms of Reference of the ASEAN-India Working Group on Health and Pharmaceuticals. Several activities proposed by India under the scope of cooperation of the draft TOR did not address ASEAN priorities for health. The informal consultation recommended that the proposed ASEAN-India Working Group on Health and Pharmaceuticals may not be the appropriate working mechanism to move forward with ASEAN-India cooperation on health. As such, Terms of Reference for such a mechanism would no longer be necessary to structure ASEAN-India cooperation on health.

ii. ASEAN-USAID Project on HIV and AIDS: Increasing Access to Antiretrovirals (ARVs) and Diagnostic Reagent

The ASEAN Workshop for Policy Makers for Establishing a Mechanism to Increase Access to Antiretrovirals and Diagnostic Reagents was held on 1 - 3 February 2006 in Bangkok. The proposed projects were as below:

- ASEAN Senior Officials Meeting with Pharmaceutical Companies and International Organisations on Increasing Access to ARVs and Diagnostic Reagents
- Communication and Information Management Using ATFOA.net
- Training workshop for Price Negotiators in Collective Procurement for ARVs
- Workshop of Drug Regulatory Authorities (DRA) to introduce fast-tract registration system.

- Update on intellectual property rights and access to ARVs and diagnostics for HIV and AIDS during the ASEAN Health Ministers Meeting in June 2006, Myanmar.
- ASEAN workshop on the implementation of compulsory licensing in order to increase access to ARVs.

iii. ASEAN-WHO Collaboration

(a) Rapid Alert System (RAS) on Combating Counterfeit Drugs

The meeting noted the WHO initiative to develop the RAS which would enhance the effectiveness of dissemination of information on counterfeit products to various countries. The availability of such mechanisms would enhance cooperation among agencies dealing with problems arising from counterfeit drugs.

(b) Development of Strategic Framework and 2 –year Operational Work Plan

The Meeting agreed to include the following 4 aspects: patent issues, promotion of ethical practices in pharmaceutical sector, combating counterfeit drugs and involving consumers in medicine surveillance under the priority area of Health Impact of the Trade Liberalisation in the work plan. The ASEAN Secretariat would follow up with WHO and finalise the operational work plan.

NEWS UPDATE ON THE SIXTH MEETING OF THE ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS AND QUALITY (ACCSQ) ASEAN COSMETIC COMMITTEE (ACC)

15 - 16 June 2006, Siem Reap, Cambodia

The Sixth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held on 15 - 16 June 2006 in Siem Reap, Cambodia. The Meeting was chaired by Drs. Ruslan Aspan, Deputy of Traditional Medicine, Cosmetic and Complementary Product Control, National Agency of Drug and Food Control, Republic of Indonesia. The Meeting was attended by representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, the ASEAN Secretariat and the ASEAN Cosmetic Association.

The agenda of the meeting included the following:

1. Follow-up from the 27th ACCSQ meeting (20 - 22 March 2006 - Penang, Malaysia)

- The ASEAN Leaders during their 11th ASEAN Summit held on 12 December 2005 in Kuala Lumpur, Malaysia signed the Kuala Lumpur Declaration on the establishment of ASEAN Charter. It is a landmark constitutional document embodying fundamental principles, goals, objectives and structures of ASEAN Cooperation. An Eminent Persons Group (EPG) has been established to examine and provide practical recommendations on the directions for ASEAN and nature of the ASEAN Charter.

- Progress in ASEAN FTAs negotiations with China, Japan, India, Korea and CER.
- Endorsement of the ASEAN Policy Guideline on Standards and Conformance which was recently endorsed by the ASEAN Economic Ministers.

2. Outcome of the ASEAN Regional Workshop on Cosmetic Good Regulatory Practice (13 - 15 March 2006)

The Regional Workshop on Cosmetic Good Regulatory Practice was held on 13 - 15 March 2006 in Jakarta, Indonesia.

The ACD requires that all cosmetic products be manufactured according to the ASEAN Cosmetic GMP Guideline and self-declaration of compliance by manufacturers is allowed. The Meeting noted the recommendations of the Workshop that the following products should be treated as cosmetics:

✓ Mouth wash
✓ Anti-caries toothpaste
✓ Anti-dandruff
✓ Skin wash
✓ Anti-bacterial including rinse-off
✓ Sunscreen
✓ Skin Whitening
✓ Anti-Acne
✓ Anti-Hair loss
✓ Anti-Cellulite
✓ Bust Contouring Cream

3. Implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRS)

(a) Progress of the ASEAN Cosmetic Scientific Body (ACSB)

The 5th ACSB Meeting was held on 14 June 2006 in Siem Reap, Cambodia.
The Meeting agreed that 14 ingredients will be deleted from the ASEAN Handbook of Cosmetic Ingredients and will be added to respective annexes of the ASEAN Cosmetic Directive while 6 ingredients required further review and discussion.

ACSB continues to review regulation of tooth whitening products containing more than 6% hydrogen peroxide for use by dentists. Member Countries would consult their Dentist Associations and submit their inputs on current use levels of hydrogen peroxide for tooth-whitening by dentist.

(b) Transposition of ASEAN Cosmetic Directive into National Legislation

Brunei Darussalam faces difficulty in terms of expertise and experience on the progress and problems encountered of Transposition of ACD.

In Cambodia, a survey to determine the extent of cosmetic products is being conducted. A mechanism to transpose the ACD into National Law in Cambodia is being undertaken with the support of the EU.
In Indonesia, deregulation on first stage had been conducted and it is now preparing for the second stage to amend the regulations to be in line with the ACD.

Phase 1 of AHCRS is now running smoothly in Malaysia and the GMP implementation for cosmetic manufacturers has been implemented since 1st January 2006.

Philippines informed the Meeting that the Philippines Bureau of Food and Drugs (BFAD) has adopted and implemented the ASEAN Cosmetic Directive with the issuance of the Administrative Orders (AOs) by the Department of Health (DOH). Philippines also informed that the existing National Law, the Consumer Act of Philippines is in conflict with the ASEAN Cosmetic Definition and its legal experts are currently working to amend the said legislation to be in line with the ASEAN Cosmetic Directive before 1 January 2008.

The transposition process is being undertaken in Singapore and new legislations which is in line with the ACD will be ready before 1st January 2008.

(c) Progress in ASEAN Cosmetic GMP

Cosmetic GMP Training Module

The Meeting agreed that the GMP training modules should be posted on the websites of the ASEAN Secretariat and the ASEAN Cosmetic Association for public reference.

Forthcoming Activities on GMP

The Regional Workshop will look into issues related to the implementation of the GMP Guideline. Malaysia and the ASEAN Secretariat together with GMP experts will work out the programme, the criteria to select participants to attend the Regional Workshop and circulate it for consideration and follow-up actions by Member Countries.

(d) Post-Marketing Surveillance (PMS)

PMS 1 – Strengthening of Cosmetic Laboratories Network

In selecting testing laboratories for regulatory purpose, Regulatory Authorities should consider using the accredited testing laboratories to the ISO / IEC 17025 by national accreditation bodies or by accreditation bodies which are signatories to the ILAC or APLAC MRAs.

PMS 2 & 3 – Safety and Efficacy Evaluation

(i) Outcome of regional workshop on Safety Evaluation Guideline.

The Regional Workshop on Development of Safety Evaluation Guideline meeting was held on 12 - 13 June 2006 in Siem Reap, Cambodia. Member Countries were given more time to consider the Draft Guideline and are to submit their comments to Singapore by 31 October 2006.

(ii) Outcome of the first series of training activities on PMS under the ITC project.

The Meeting agreed on the need to develop the following technical guidelines:

- Post-Market Surveillance Guideline including information that regulators should look for in the Product Information File (PIF).
- How to develop PIF.

Post Marketing Alert System (PMAS)

The approach for the PMAS implementation from Pharmaceutical PWG to start with one year trial for period from 16 June 2006 to 16 June 2007 will be adopted. The PMAS will be reviewed after a trial period before it can be officially adopted for the implementation at regional level.

(e) Consideration and Adoption of Notification Template and Guideline

The Regional Workshop on Cosmetic Products Notification was held on 16 - 17 March 2006 in Jakarta, Indonesia.

The draft of the Cosmetic Product Notification template was discussed. Following some amendments agreed upon by all parties involved, Singapore's report and the final Cosmetic Product Notification template was endorsed by the regional workshop.

DCA NEWS

Registration of Products Containing Gatifloxacin

With regards to the above matter, the DCA decided at its 181st meeting held on 29th May 2006 on the following:

i) To cancel all product registrations containing the active ingredient gatifloxacin.

ii) For products which have been registered and marketed, the registration license holder is given a period of 6 months from the effective date to withdraw all products from the market.

iii) Meanwhile, the license holder is required to issue a "Dear Healthcare Professional" letter to inform about the safety issue.

iv) The DCA will not consider registration of any new drugs containing the active ingredient gatifloxacin.

Warning on Label and Package Insert for Products Containing Promethazine Hydrochloride

The DCA at its 181st meeting held on 29th May 2006 agreed that the statement below must be included on labels and package inserts of **ALL** products containing Promethazine Hydrochloride (syrup, tablet, injection, solution and linctus) as 'Warning':

"THIS PRODUCT CONTAINS PROMETHAZINE HYDROCHLORIDE. IT SHOULD NOT BE USED IN PAEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE BECAUSE OF THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION".

PRODUCTS APPROVED FOR ADDITIONAL INDICATION
FROM JANUARY - JUNE 2006

(DCA 182 – 29 JUNE 2006)

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
1.	1.1 1.2 1.3 1.4	Temodal Capsule 5mg Temodal Capsule 20mg Temodal Capsule 100mg Temodal Capsule 250mg *(Temozolomide)*	Temodal Capsules are indicated for the treatment of patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and subsequently as adjuvant monotherapy treatment.	Schering-Plough Sdn. Bhd. Petaling Jaya, Selangor
2.	2.1 2.2	Cellcept Capsule 250mg Cellcept Tablet 500mg (*Mycophenolate mofetil)*	Cellcept is indicated for induction and maintenance treatment of lupus nephritis. Cellcept should be used concomitantly with corticosteroids.	Roche (Malaysia) Sdn. Bhd. 142, Jalan Ampang, Selangor

(DCA 181– 29 MAY 2006)

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
1.	1.1 1.2 1.3 1.4 1.5 1.6 1.7	Lipitor 10mg tablet Lipitor 20mg tablet Lipitor 40mg tablet Lipitor 80mg tablet Lipitor 10mg tablet Lipitor 20mg tablet Lipitor 40mg tablet *(Atorvastatin calcium)*	Prevention of Cardiovascular Disease i) In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, Lipitor is indicated to:	Pfizer (M) Sdn. Bhd. Level 3 & 4, Bangunan Palm Grove, Jln. Glenmarie, Shah Alam, Selangor.

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
			1. Reduce the risk of myocardial infarction 2. Reduce the risk of stroke 3. Reduce the risk for revascularization procedures and angina ii) In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, Lipitor is indicated to: 1. Reduce the risk of myocardial infarction 2. Reduce the risk of stroke	

(DCA 180– 20 APRIL 2006

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
1.	1.1	Aerius Syrup 0.5mg/ml *(Desloratadine)*	Aerius Syrup is indicated for the rapid relief of symptoms associated with seasonal allergic rhinitis, such as sneezing, nasal discharge and itching, congestion/stuffiness as well as ocular itching, tearing and redness. -Aerius Syrup is also indicated for the relief of symptoms associated	Schering Plough Sdn. Bhd. CP Tower, Pusat Dagang Seksyen 16, Petaling Jaya

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
			with chronic idiopathic urticaria such as the relief of itching and the size and number of hives. * To be used for children from age 1 year old.	
2.	2.1	Aromasin 25mg tablet	Aromasin is indicated for adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to Aromasin for completion of a total of five consecutive years of adjuvant hormonal therapy.	Pfizer (Malaysia) Sdn. Bhd. Level 3 & 4, Bangunan Palm Grove, Glenmarie, Shah Alam.

(DCA 178 – 23 FEB 2006)

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
1.	1.1 1.2	Emend 80mg capsule Emend 125mg capsule *(Aprepitant)*	Emend, in combination with other antiemetic agents, is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of: - moderately emetogenic cancer chemotherapy	Merck Sharp & Dohme, Menara Merais, 1 Jln.19/3, 46300 Petaling Jaya.

(DCA 177 – 26 JAN 2006)

NO.		PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORISATION HOLDER
1.	1.1 1.2	Oxis Turbuhaler 4.5mcg/dose Oxis Turbuhaler 9.0mcg/dose	Oxis is indicated as an add on therapy to maintenance treatment with inhaled corticosteroids, for the relief of broncho-obstructive symptoms and prevention of exercise-induced symptoms in patients with asthma when adequate treatment with corticosteroids is not sufficient.	AstraZeneca Sdn. Bhd. Wisma Prima 17, Jln. Sri Semantan Satu,
2.	2.1 2.2	Zyrtec Oral Solution 1mg/ml Zyrtec Oral Drops 10mg/ml	To be used for children of 1 year and above. Symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.	UCB Pharma Asia Pacific Sdn. Bhd. Level 2 & 3, Block B, Plaza Damansara, No. 45, Medan Setia 1, Bukit Damansara.

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(ii) Complementary Medicines & Cosmetic Section	-Natural Products Unit -Health Supplement Unit -Cosmetics Unit	Saleha Md. Ewan Mazuwin Zainal Abidin Anis Talib	238 278 333
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(iv) Regulatory Coordination Unit	-Regulatory Coordination Unit	Rosilawati Ahmad	245
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(ii) Laboratory Services Unit	Laboratory Services Unit	Tan Ann Ling	515
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