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BERITA ubat-ubatan

NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

PRESS STATEMENT BY Y.B. DATO' CHUA JUI MENG, MINISTER OF HEALTH MALAYSIA ON ANNOUNCEMENT OF EFFECTIVE DATE OF ENFORCEMENT OF CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984 FOR COSMETIC

It is hereby announced that the Honourable Minister of Health Malaysia through *His Majesty's Government Gazette* has specified **1st January 2004** as the effective date of enforcement of paragraph 7(1)*(b)* and regulation 30, Control of Drugs and Cosmetics Regulations 1984 for the registration of cosmetic products.

2. Under these Regulations, no person shall manufacture, sell, supply, import or possess for sale any cosmetic product unless :-

2.1. the product is a registered product ;

and

2.2. the person holds the appropriate licence as required and issued under these Regulations.

3. Paragraph 7(1)*(b)* relates to relevant licence holders whereas Regulation 30 addresses violations and penalties. Any person who commits an offence

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against these Regulations shall be liable on conviction to a fine not exceeding RM 25,000 or to imprisonment for a term not exceeding 3 years or to both, and for a second or subsequent offence shall be liable on conviction to a fine not exceeding RM 50,000 or to imprisonment for a term not exceeding 5 years imprisonment or to both. Any body corporate shall be liable on conviction to a fine not exceeding RM 50,000, and for a second or subsequent offence it shall be liable on conviction to a fine not exceeding RM100,000.

4. Registration of cosmetic products is carried out "on-line" and application forms can be obtained from the National Pharmaceutical Control Bureau's website at www.bpfk.gov.my. Applicants can also obtain the Cosmetic Registration Guidelines, Cosmetic Good Manufacturing Practice Guidelines and Cosmetic Advertisement Code from the website.

   Applications for registration of cosmetic products must be submitted before **1st January 2004.**

5. However, to avoid disruption in supplies to consumers, cosmetic products may continue to be marketed in Malaysia until **30th June 2004** subject to the following conditions:

   5.1 There is evidence to show that application for registration of the particular product has been submitted before **1st January 2004**, by obtaining the Registration Reference Number and payment voucher which has been certified receipt by the National Pharmaceutical Control Bureau. This includes locally manufactured as well as imported products.

   5.2 Manufacturers are given a grace period of **six (6) months** to comply with labelling requirements as specified in the Cosmetic Registration Guidelines.

6. Products that do not comply with the above requirements shall not be manufactured, imported, sold or supplied.

7. Definition of Cosmetic :

   7.1. A cosmetic product shall mean "any substance or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair system, nails, lips, external genital organs and others) or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".

8. All cosmetic products shall be registered under Phase 4:

   For the purpose of registration, cosmetic products are divided into two (2) categories:

   8.1. **Category 1**
   This category covers products have a potential of being absorped through the skin or mucous membrane. The products include:

   - Products that are used around the eyes *(except eye brow).*
   - Products that are used on the lips.
   - Products that are used in the oral cavity.

- Hair dyes containing phenylenediamine, toluenediamine, salt and its derivatives.

- Products for sun tanning that contain topical dyes.

8.2. **Category 2**
Other types of cosmetics that are not listed under Category 1 (examples: moisturizing cream, liquid face cleanser and others).

9. All cosmetic products under Category 1 must be registered effectively from **1st February 2002.** For Category 2, applications must be submitted effectively from **1st January 2003.**

10. A step by step registration was implemented by the Drug Control Authority (DCA) since 1991. Two types of cosmetic products which have been registered earlier are hair-dyes, implemented since **1st August 1991** and tooth whiteners since **1st February 1996.**

11. Application forms for cosmetic product registration can be acquired from the National Pharmaceutical Control Bureau's website at www.bpfk.gov.my and any enquiries can be referred to the following address:

Cosmetic Unit,
Product Evaluation and Safety Division,
National Pharmaceutical Control Bureau,
Ministry of Health Malaysia,
Jalan Universiti,
Peti Surat 319,
46730 Petaling Jaya

Tel : 03-79573611 (ext 333/334/335)
Fax: 03-79556772

Officers to contact:
Puan Anis Talib (Unit Head)
Cik Zuraida Abdullah
Puan Nik Shamsiah Nik Salleh

PROGRESS REPORT

(March 2002 – September 2003)

Country **:** MALAYSIA

Coordinator **:** Training Centre for Strengthening of Quality Assurance and Non-Pharmacopoeial Analytical Methods

1. Introduction

As a Collaborating Centre for WHO in Pharmaceutical Regulatory Control, the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia continues to provide training services to fellows from other countries. During the period from March 2002 until August 2003, greater emphasis of the activity was placed on training as evident from the increase in the number of fellows from abroad receiving training in NPCB. In addition, officers from NPCB are now involved in conducting inspections and training abroad in areas related to Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).

The development of reference substances was also given due consideration. NPCB had obtained special funding and was allocated RM 0.5 million for the purchase of new analytical equipment and RM 1 million for the purchase of primary reference standards in an effort to further strengthen the activities of the Reference Standard Unit.

This report provides information on the status of activities undertaken by Malaysia from March 2002 until September 2003.

2. Activities Coordinated by Malaysia - Training Centre for Strengthening of Quality Assurance

2.1 Training conducted in Malaysia.

2.1.1 Malaysia received a total of 37 fellows from various countries namely Bangladesh, Sri Lanka, Nepal, Republic of Seychelles, Lao PDR, Zimbabwe, China, Vietnam, Sudan and Bhutan. The number of trainees showed a marked increase as compared to the figure reported in the last meeting (9 participants). The courses provided under this program are designed specifically to cater to the needs of the individual fellows. For personnel with laboratory background the courses include training in pharmaceutical analysis. The areas covered include dosage performance testing, chemical, microbiological, pharmacological and toxicological method of testing, testing of traditional medicines as well as preparation and handling of reference standard. Other areas of training include aspects pertaining to GMP requirement and licensing system, drug registration, pharmacovigilance and post-marketing surveillance.

2.1.2. Malaysia hosted the 7th ASEAN Consultative Committee on Standards and Quality (ACCSQ)

Pharmaceutical Product Working Group (PPWG) meeting from the 1st until 3rd of July 2003. The meeting was represented by delegates and observers from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand and Vietnam. A one-day Validation Seminar attended by ASEAN participants was held prior to the meeting.

2.1.3. Malaysia recently hosted an International Course on Regulatory Drug Evaluation from 28th July until 1st August 2003. Twenty participants from Indonesia, Malaysia, Philippines, Singapore and Thailand attended the workshop. The course which was funded and facilitated by the WHO offered elements for a standardized evaluation of new drugs that takes into account the specific national situation and therapeutic needs.

2.1.4 Concurrent with the above-mentioned International Course on Regulatory Drug Evaluation, another meeting involving one participant each from the same 5 ASEAN member countries namely Indonesia, Malaysia, Philippines, Singapore and Thailand was held on the 30th and 31st of July 2003. The aim of the meeting was to review the existing Manual for a Drug Regulatory Authority. The WHO manual on ***"Marketing Authorisation of Pharmaceutical Product with Special Reference to Multisource (Generic Product)"*** and proposed changes were discussed. Several pertinent recommendations were put forward by the group for consideration. The two-day meeting was also funded and facilitated by the WHO.

2.2 Training and assessment undertaken by NPCB officers abroad.

Malaysia, as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) since 1st January 2002 has been appointed the task of conducting training overseas. Selected experts from NPCB had successfully conducted trainings in the Philippines, United Arabic Emirates (UAE) and Vietnam in areas pertaining to GMP, GLP and quality assurance in general.

A GMP expert from NPCB had also participated in a PIC/S joint assessment to evaluate the quality system of GMP inspection and licensing system for Chinese Taipei, who had applied to become a member of PIC/S.

2.3 Planning for future training and assessment.

Efforts have been initiated to send officers involved in the evaluation and analysis of biotechnology products to the Therapeutic Goods Administration (TGA), Australia for relevant attachment training on the evaluation of analytical methods and validation data for quality control of biotechnology-derived products. Subsequently, these officers will provide training to other officers of NPCB.

Two NPCB officers were appointed as WHO short-term consultants to conduct an assessment of Nepal's regulatory system

in aspects pertaining to GMP and GLP requirements for three weeks in December 2003. In addition, a GMP auditor was also invited to participate in a PIC/S joint assessment to review the GMP and licensing system in Greece from the 12th until the 19th of September 2003.

A workshop on Evaluation of Analytical Method Validation Data was conducted in NPCB for the local pharmaceutical industry as well as regulatory officers from 6th to 8th October 2003. The training was jointly organised with the local pharmaceutical industry organisation.

3. Activities Coordinated By Other Countries/Organisation And Participated By Malaysia - *Production and Utilisation of ASEAN Reference Standards*

The NPCB which represents Malaysia as a member in this collaborative project has sent to Singapore (Health Sciences Authority) and the Philippines (Bureau of Food and Drugs) in mid 2002, portions of the 3 proposed ASEAN Reference Substances (ARS) bulk material, namely Riboflavin, Methylparaben, Propylparaben and their respective primary standards and protocols of analysis required for the studies. The completed analytical reports from these 2 laboratories along with the one from Malaysia as the coordinating country, were then compiled and collated for the purpose of submission to the adoption meeting, held in Thailand in February 2003.

Malaysia was invited by other ASEAN member countries to participate as the analysis partner for the production of ARS. Malaysia completed the analytical reports for Dextromethorphan, Phenylpropanolamine, Dequalinium Chloride and Vancomycin Hydrochloride ARS, which were submitted to Singapore by October 2002. The completed report on Tetracycline hydrochloride ARS was submitted to Thailand in September 2002.

The 12th Meeting on the Production and Utilisation of ASEAN Reference Substances was held on the 11-13th February 2003 at the Department of Medical Sciences, Ministry of Public Health, Thailand. Malaysia was represented by Mr. Muhammad Nasir Hashim from the NPCB. At the meeting, Methylparaben and Riboflavin were adopted as ASEAN Reference Substances, while Propylparaben was put on hold pending further test results from the Philippines, which at the time of this report writing, has been made available. Eleven (11) substances with a mixture of new and 2nd/ 3rd batches were suggested by Malaysia at the meeting for the next coming production and collaborative studies and they are as follows:

1. Betamethasone Dipropionate
2. Prednisolone
3. Norfloxacine
4. Guaifenesin
5. Prednisone
6. Cephalexin
7. Cyanocobalamine
8. Erythromycin
9. Nystatin
10. Lignocaine
11. Diphenhydramine Hydrochloride

By early June 2003, Malaysia completed the collaborative analysis on the Proposed ASEAN Reference Substance (PARS), ibuprofen, which was handed by the coordinating country Philippines during the 12th Meeting, held in February 2003 in Bangkok.

In July 2003, 5 vials each containing Hyoscine Butylbromide and Hyoscine Hydrobromide ARS were delivered to Thailand. The Japan Pharmaceutical Manufacturers Association (JPMA), through the Society of Japanese Pharmacopoeia (SJP) had sent Prednisolone (200g) and Nystatin (300g) raw materials to Malaysia for the next coming PARS collaborative studies.

4. Other Pharmaceutical Related Activity/ Training

4.1 In relation to the ASEAN Harmonisation of Regulatory Requirements, a delegation led by the WHO visited NPCB from 21st until 25th October 2002 to review Malaysia's current regulatory system.

4.2 Malaysia will join a WHO-led delegation to visit the Bureau of Drug and Cosmetic, Ministry of Health, Cambodia, to review its present regulatory system. This forth-coming visit which is funded by the WHO has been scheduled from 2nd until 8th November 2003.

4.3 Malaysia also participated in the Consultation Meeting on Improving Access to Essential Medicines in the Western Pacific Region organised by the WHO. The meeting was held on 15-17 July 2003 in Penang, Malaysia.

4.4 Malaysia was also selected to participate in the 6th International Training Course on the Use of Pharmacoeconomics in Drug Selection which was held on 13-23 September 2003 in Bangkok, Thailand. The course was also funded by the WHO.

DCA UPDATES

CONTROL ON THE PACK SIZE OF COUGH MIXTURES CONTAINING PHOLCODEINE

The Drug Control Authority (DCA) at its 151st meeting held on 2nd October 2003 agreed that the pack size for all liquid cough preparations containing Pholcodeine would be set at a pack size of ***not more than 90ML.***

The importation and manufacturing of liquid Pholcodeine cough preparations with the pack size of more than 90ml should be stopped starting from the 1st of January 2004. All the existing stocks of liquid Pholcodeine cough preparations in pack sizes exceeding 90 ml must be recalled from the market by 1st April 2004.

CONTROL ON THE PACK SIZE OF ALL LIQUID COUGH PREPARATIONS

The Drug Control Authority (DCA) at its 151st meeting held on 2nd October 2003 agreed that the pack size for all liquid cough mixtures be fixed at a ***maximum pack size of 120ML.***

This new policy will be effective as of 1st April 2004 and thus the manufacturing and importation of all such cough preparations in pack sizes exceeding 120ml must cease to be carried out as of this date.

Please note that this new policy is not applicable to liquid traditional medicine cough preparations and liquid cough preparations containing Pholcodeine.

CHANGING OF PRODUCT REGISTRATION NUMBER FROM PBKD TO MAL

Due to the confusion that arose following the Drug Control Authority (DCA) Circular Bil (12) dlm BPFK/02/5/1.3 dated 6th August 2003, the DCA would like to clarify again on the stated policy:

- ***All registered products manufactured and / or imported as of 1st January 2004 must have the registration number MAL.***
- ***Registered products in the market bearing the registration number PBKD is allowed to be marketed until the said stock is finished.***

Should further information be required, kindly contact the National Pharmaceutical Control Bureau at 03-79573611 ext. 270 or 242.

ABRIDGED EVALUATION PROCEDURE FOR THE APPLICATION OF ADDITIONAL INDICATION FOR PRODUCTS REGISTERED WITH THE DCA

The Drug Control Authority (DCA) at its 152nd meeting held on 28th October 2003 made the decision that abridged evaluation is applicable to applications for additional indication for registered products that fulfil the following criteria:

- The said additional indication has been approved by European Union countries (EU - United Kingdom, Sweden and France) **AND** also one of the following countries namely America, Australia, Canada and Japan.

- Approval letter for the said additional indication from the Regulatory Authority as well as the approved product information (Approved Product Data Sheet / SmPC) or the approved package insert in the countries mentioned above must be submitted.

- Approval of the said additional indication in the **country of manufacture** is no longer a criterion for the approval of the application as long as the applicant is able to provide a strong justification.

Please note that full evaluation will be carried out on applications for additional indications which do not fulfil all the criteria as mentioned above. This procedure will be effective beginning November 2003.

WARNING LABEL ON THE USAGE OF THE INGREDIENT *Chelidonium majus*

The Drug Control Authority (DCA) at its 151st meeting held on 2nd October 2003 made the decision that a warning regarding the usage of the ingredient *Chelidonium majus* be included on the label of all products containing this ingredient. This is due to the fact that the said ingredient has been linked to hepatic failure.

Therefore, for all products containing the ingredient as mentioned above, the following warning **must** be printed on the product label in two languages (Bahasa Malaysia **AND** English).

Bahasa Malaysia:
"Amaran: Produk ini mungkin boleh menyebabkan kesan sampingan pada hepar (hati)."

English:
"Warning: This product may cause adverse reaction to the liver".

In accordance to this, all product registration holders are advised to comply with the said decision.

COMING SOON

ON-LINE REGISTRATION COURSE – INTRODUCTION TO COMPUTERS

This course is introduced with the purpose of familiarizing computer illiterate users of the Quest 2 System to peripherals such as computers, scanners and the smart card reader. Participants will also be taught to handle files, images and how to use the internet browser.

Further details regarding the training course can be obtained from NPCB's website at www.bpfk.gov.my.

TRAINING COURSE – ON-LINE SUBMISSION FOR COSMETIC PRODUCT REGISTRATION

Organised by: ***NPCB, Ministry of Health***
Supported by: ***CTFA-FMM-MCTIG***
Conducted by: ***Technology Innovation Resources Sdn. Bhd.***

Information on the course

This training course covers the administrative and technical aspects of the on-line submission for cosmetic product registration. Conducted via classroom instructions, demonstrations and hands-on practical sessions, it provides participants with full knowledge for effective on-line submission. A set of courseware will be included in the training package.

CEOs, Managing Directors, Product Managers, Consultants and anyone involved in the registration of cosmetic products should attend this course.

The course will be conducted at Bilik Dokumentasi, 1st Floor, Block C1, National Pharmaceutical Control Bureau, Jalan Universiti, 46730 Petaling Jaya, Selangor. For more information, please visit NPCB's website at www.bpfk.gov.my.

NEWSLETTER OF THE DRUG CONTROL AUTHORITY MALAYSIA

TRAINING COURSE – ON-LINE SUBMISSION FOR PHARMACEUTICAL PRODUCT REGISTRATION

Organised by: ***Technology Innovation Resources Sdn. Bhd.***
Supported by: ***NPCB, Ministry of Health***

Information on the course

This training course is designed as a gauge for pharmaceutical companies to evaluate their knowledge and skills in conducting submissions for pharmaceutical product registration via online. The aim is to ensure that learning actually takes place in the context of business. Hence, priority is placed on effective learning strategies.

Those attending the course will participate in theory sessions, live demonstrations and practical sessions throughout the two-day program.

CEOs, Managing Directors, Product Managers, Consultants and anyone involved in the registration of pharmaceutical products will benefit from attending this course.

Further details regarding the training course can be obtained by visiting NPCB's website at www.bpfk.gov.my.

TRAINING COURSE – ON-LINE SUBMISSION FOR TRADITIONAL PRODUCT REGISTRATION

Organised by: ***Technology Innovation Resources Sdn. Bhd.***
Supported by: ***NPCB, Ministry of Health***

Information on the course

This course is designed for traditional medicine companies that intend to obtain information regarding the on-line registration of traditional products. It is suitable for and should be attended by all CEOs, Managing Directors, Product Managers, Consultants and anyone involved in the registration of traditional products.

The course will be carried out through lectures and practical training sessions. Notes will also be provided. For further details, please browse through NPCB's website at www.bpfk.gov.my.

NATIONAL PHARMACEUTICAL CONTROL BUREAU

Ministry of Health Malaysia
Jalan Universiti, P. O. Box 319, 46730 Petaling Jaya.
(Telephone: 603-79573611, Fax: 603-79562924)

Homepage http://www.bpfk.gov.my

OFFICERS TO CONTACT

ISSUE/AREA	DIVISION/UNIT	NAME OF OFFICER	TEL-EXT
National Pharmaceutical Control Bureau	Director		301
Product Evaluation and Safety Division	Deputy Director	Eisah Abdul Rahman	270
– Certificate of free sale – General information regarding registration	Secretariat Unit	Ramli Zainal	242
Application for Registration of - Poisons - Non Poisons - Traditional Medicines - New Chemical Entities - Cosmetics / Nutritional Supplements	 – Poisons Unit – Non Poisons Unit – Traditional Medicines Unit – New Chemical Entity Unit – Cosmetics Unit	 Noorizam Ibrahim (Head) Tan Lie Sie (Head) Saleha Md. Ewan (Head) Fudziah Ariffin (Head) Anis Talib (Head)	 239 245 238 233 333
- Manufacturer's Licence - Import Licence - Wholesaler's Licence	GMP and Licensing Division	Dr. Tajuddin Akasah (Head)	201
- Clinical Trial Import Licence	New Chemical Entities Unit	Fudziah Ariffin (Head)	233
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Drug Analysis Division	Deputy Director	Datin Hasiah Abdullah	204
- Request/Purchase of Reference Standards	Reference Standard Unit	Nasir Hashim (Head)	510
- Payment for Laboratory Tests	Laboratory Services Unit	Choy Khye Moon	512
- Submission of Samples for Stage 2 of Registration Application	Laboratory Officers on Duty	(according to schedule)	512
- Submission of Letters for Product Evaluation and Safety Division	Receiving Counter	Administrative Assistant	
- Collection of Application Forms - Purchase of NPCB Publications/Guidelines	Administrative Division	Rosnani Mhd. Yusoff (Head)	502
- Drug Information - Library - Classification of Products	Organisational Development & Information Technology Division	Abida Haq (Acting Head)	217
- General Inquiries and Technical Information - Classification of Products	Public Affairs Unit	Azlina Ismail	223