



# BERITA UBAT-UBATAN

NEWSLETTER OF THE DRUG CONTROL AUTHORITY, MALAYSIA

VOLUME 41 • No. 19 • ISSN 0128-0627

September 2008

## National Regulatory Conference 2008 “Building Bridges Towards Excellence” 25th-27th August 2008 Sheraton Subang Hotel



The National Pharmaceutical Control Bureau (NPCB), together with the Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI), Malaysian Pharmaceutical Society (MPS), Chinese Medicine Manufacturers Association of Malaysia (PPUCM), Traditional Malay Medicine Manufacturers Association (PURBATAMA), Malaysian Dietary Supplement Association (MADSA) and Malaysian Biotechnology Corporation Sdn. Bhd. (BIOTECHCORP) jointly organised the National Regulatory Conference 2008 which was held on the 25th-27th August 2008. The theme for this conference, “Building Bridges Towards Excellence”, is very timely and in keeping with tradition, it continues to emphasize the practice of knowledge and information sharing between regulators, industry players and other stakeholders.

(CONTINUED NEXT PAGE)

IN  
THIS  
ISSUE

- National Regulatory Conference 2008 “Building Bridges Towards Excellence” 25th-27th August 2008 Sheraton Subang Hotel
- 15TH Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG)
- Organisational Chart National Pharmaceutical Control Bureau Ministry Of Health Malaysia
- DCA Policies
- News & Announcements

## DCA EDITORIAL TEAM

### ADVISORS:

Tan Sri Datuk Seri Dr. Haji Mohd. Ismail Merican  
Dato' Che Mohd. Zin Che Awang

### CHIEF EDITOR:

Selvaraja S. Seerangam

### EDITORS:

Dr. Sulaikah V. K. Moideen,  
Abida Syed M. Haq, Dr. Tajuddin Akasah,  
Tan Lie Sie, Anis Talib

BERITA UBAT-UBATAN IS PUBLISHED BY

THE NATIONAL PHARMACEUTICAL CONTROL BUREAU,  
MINISTRY OF HEALTH MALAYSIA, JALAN UNIVERSITI, P.O.  
BOX 319, 46730 PETALING JAYA, SELANGOR, MALAYSIA.  
TEL:60(3) 7883 5400 FAX: 60(3) 7956 2924  
WEB: WWW.BPFK.GOV.MY

MATERIAL PUBLISHED IN THIS NEWSLETTER MAY NOT BE REPRODUCED WITHOUT PERMISSION OR USED FOR ANY FORM OF ADVERTISING, SALES OR PUBLICITY.

(CONTINUED FROM PREVIOUS PAGE)

The conference focused on many issues and challenges faced by regulatory agencies and the pharmaceutical and related healthcare industries to facilitate product development and management. In view of that, the conference served as a platform for promoting continuous learning.



The National Regulatory Conference 2008 was officiated by Y.B. Tan Sri Dato' Seri Dr. Hj. Mohd. Ismail Merican, Director General of Health Malaysia, on behalf of Y.B. Dato' Liow Tiong Lai, Minister of Health Malaysia.

During the three-day conference, many interesting topics were delivered by both local and foreign speakers from UK, USA, Australia, Switzerland, Belgium, Singapore, Canada and Japan. The programmes were packed with morning plenary sessions, followed by four (4) different track sessions which covered a wide spectrum of topics that was carefully selected and tailored to the needs of 350 participants with different interests and scope of specialties.



Papers presented included subjects such as Regulatory Updates on ASEAN Harmonisation and Regulatory Initiatives in Malaysia, Biotherapeutics in the Era of Biosimilars, Pharmacovigilance, National Medicines Policy, Industrial Master Plan 3, GMP/PICS Update, Medicines Advertisement Board (MAB) Guidelines, Global Trends in the Regulation of Traditional Medicines Practices and Products as well as Good Manufacturing Practice for Biotechnology.



An official dinner was held on the first day of the conference and was attended by many officials from the Ministry of Health, members of the Drug Control Authority (DCA) and Malaysia Adverse Drug Reaction Advisory Committee (MADRAC) as well as the participants of the conference and representatives from their respective companies and agencies. Whilst the guests were enjoying their meal, they were entertained with a cultural show. The evening ended pleasantly with the guests from various agencies, bodies and companies bidding farewell to Y. Bhg. Dato' Che Mohd. Zin bin Che Awang, Senior Director of Pharmaceutical Services who will be going on his official retirement in September 2008.

The three-day conference not only provided participants with a wide range of knowledge but also served as a medium for networking and establishing new relationships among regulators, academia and industry players. In the light of the current regional and global wave, it is hoped that the proceedings of the conference will contribute immensely towards the improvement of current regulatory systems and practices in the country, and that the exchange of knowledge will further improve the access to safe and efficacious pharmaceuticals of high quality in this region.



It is heartening to see regulators, stakeholders, healthcare professionals and academia come together to build partnerships for health to facilitate and support the people of Malaysia in attaining their full potential in health. The expectations of practitioners, patients and the public must be met through the provision of excellence in healthcare. Indeed, without the sense of good partnership and shared responsibility amongst the relevant parties/ authorities, the vision for health may just remain as a vision that is beyond reach.

In conclusion, the NRC 2008 received good comments from participants for the various track sessions. It was deemed a success as the conference proceeded smoothly without any major incidents and achieved its objective in building relationships among the relevant parties, thus further paving the way for challenges to be met in a more effective manner.

Kudos to the organisers for their success and great work!





# 15<sup>th</sup> Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG)

The Fifteenth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held from 30-31 July 2008 in Jerudong, Brunei Darussalam. The Meeting was chaired by Mdm. Eishah Abd. Rahman, Director of Pharmaceutical Enforcement, Ministry of Health, Malaysia and co-chaired by Dr. Yuppadee Javroongrit, Assistant Director, Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand.

The Meeting was attended by representatives from the Drug Regulatory Authorities from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Vietnam and representatives from the ASEAN Secretariat. Representatives from the pharmaceutical associations and industries in ASEAN also attended the Meeting as observers.



The Meeting noted that the ASEAN MRA Taskforce had finalized the draft ASEAN Sectoral MRA on GMP Inspection of Manufacturers of Medicinal Products taking into consideration the comments from Member States especially on the entry into force of the MRA upon signing. Member States have agreed in principle that the MRA should enter into force upon signing but an article for deferral of implementation had been included taking into consideration the concerns of some Member States of not being able to fully implement the MRA upon signing.

The ASEAN BA/BE Taskforce discussed the Framework for Mutual Acceptance of the BA/BE Study Report in ASEAN and agreed on the following :

- a) ASEAN Bioequivalence Study Reporting Format
- b) Acceptable conformance standards on the clinical and bioanalytical aspects of BE studies as follows :
  - The clinical standards is ICH GCP E6 guidelines
  - The bioanalytical standard should follow applicable GLP principles
- c) To achieve the acceptable criteria for inspection on BA/BE studies, the following steps will be taken :
  - Establishment of minimum inspection criteria for Member States including checklist
  - Capacity building for inspection
  - Inspection by respective Drug Regulatory Agencies



The Meeting expressed its appreciation to WHO on its effort to assist ASEAN in the Vaccine Chapter which includes capacity building of the national Drug Regulatory Agencies in Vaccine Regulation, sharing of information and knowledge and strengthening Vaccine Regulations in the region through regulatory support mechanisms. The Meeting also requested Indonesia and Thailand to develop a proposal for the ASEAN-WHO collaboration in relation to capacity building by coordinating with Member States for feedback on two issues as proposed by WHO as follows :

- a) Support from WHO for an ASEAN Expert Review Committee
- b) Module 2 (ICH) Efficacy and Safety to be reviewed by one or two Member States

The Meeting noted that the the US Technical Assistance and Training Facility (US TATF) had a dialogue with the Heads of Delegation on the cooperation mechanism for technical assistance for the pharmaceutical products sector. Noting the concern raised by Lao PDR during the 14th ACCSQ PPWG Meeting, on the disparity in development among the ASEAN Member States and the need to have country-specific technical assistance and capacity building programmes, and the constraints of the US TATF to fund all Member States, the ASEAN Secretariat proposed the organization of country-specific technical assistance and capacity building programmes for Cambodia, Lao PDR and Vietnam.

Lastly, the Meeting accepted the gracious offer from Philippines to host the 16th PPWG Meeting tentatively in May 2009.



The Meeting was updated on the progress made in Operation Storm as a follow-up of its predecessor project, Operation Jupiter. Under this project, a SPOC (Single Point of Contact) network system is established involving seven ASEAN Member States and China to develop systematic partnership approach by collaborating with the national Drug Regulatory Agencies, customs and police of affected countries in order to disrupt the activities of transnational organized crimes in the trafficking of counterfeit medical products.

# Organisational Chart National Pharmaceutical Control Bureau Ministry Of Health Malaysia



# DCA NEWS

## **CLASSIFICATION OF AROMATHERAPY PRODUCTS**

The Drug Control Authority (DCA) at its 205th meeting held on the 29th of May 2008 has decided that the following cosmetic products (which were previously exempted from registration) will also be regulated through the cosmetic notification procedure :

- Essential oil on its own or essential oil mixture where a few drops are used in a bathtub filled with water.
- Essential oil on its own or essential oil mixture which is mixed with carrier oil and used for massage.

Based on the definition of cosmetic products, essential oil on its own or a mixture of essential oils for cosmetic purposes are included in the scope of cosmetic products. These essential oils are usually used with carrier oil for massage or added into bathing water to produce the desired aromatherapy effects. Some essential oils cannot be used directly on the skin as it may cause irritation and damage the skin. The notification procedure is in accordance with the harmonisation of cosmetic product regulation in ASEAN countries and aims to safeguard consumers.

What needs notification procedure / What does not :

- Aromatherapy materials which are brought in as bulk product (whether on its own or mixture of essential oils, carrier oil mixed with essential oils or on its own) do not require notification. However, once the bulk product has been through a manufacturing process and is produced as finished products, the resultant products then require notification.
- Aromatherapy materials in the finished product forms mentioned above, either with complete labeling or to be re-labeled require notification.

## **WARNING STATEMENT ON "INCIDENTS OF MYOCARDIAL ISCHAEMIA IN PREGNANT WOMEN WHO RECEIVE BETA-AGONIST TREATMENT TO DELAY PRE-MATURE BIRTH"**

The Drug Control Authority (DCA) at its 205th meeting held on the 29th of May 2008 has decided that a warning statement on "Incidents of myocardial ischaemia in pregnant women who receive beta-agonists treatment to delay pre-mature births' is required to be printed on the package insert of all groups of beta-agonist products used for the said treatment.

The warning statement is as follows :

For products in injection dosage form :

- As maternal pulmonary oedema and myocardial ischaemia have been reported during or following premature labour in patients receiving beta2-agonists, careful attention should be given to fluid balance and cardio-respiratory function, including ECG monitoring. If signs of pulmonary oedema and myocardial ischaemia develop, discontinuation of treatment should be considered.



- Due to the risk of pulmonary oedema and myocardial ischaemia that has been observed during the use of beta2-agonists in the treatment of premature labour, before these products are given to any patient with known heart disease, an adequate assessment of the patient's cardiovascular status should be made by a physician experienced in cardiology.
- Cautious use of salbutamol/terbutaline injections is required in pregnant patients when it is given for relief of bronchospasm so as to avoid interference with uterine contractility. During IV infusion of salbutamol/terbutaline, the maternal pulse should be monitored and not normally allowed to exceed a steady rate of 140 beats per minute.

For products in oral tablet and capsule dosage form :

- As maternal pulmonary oedema and myocardial ischaemia have been reported during or following premature labour in patients receiving beta2-agonists, careful attention should be given to fluid balance and cardio-respiratory function, including ECG monitoring. If signs of pulmonary oedema and myocardial ischaemia develop, discontinuation of treatment should be considered.
- Due to the risk of pulmonary oedema and myocardial ischemia that has been observed during the use of beta2-agonists in the treatment of premature labour, before these products are given to any patient with known heart disease, an adequate assessment of the patient's cardiovascular status should be made by a physician experienced in cardiology.

However, this warning statement is exempted for products in the form of syrup, suspension and inhalation dosage forms as such dosage forms are not used for the said purpose. In addition, no reports have stated that this adverse effect involves beta2-agonists inhalation products that are used for bronchospasm treatment.

### **REGISTRATION OF HEALTH SUPPLEMENT PRODUCTS WITH SINGLE ACTIVE INGREDIENT**

The Drug Control Authority (DCA) at its 205th meeting held on the 29th of May 2008 has decided to hasten the approval process for the registration of health supplement products with single active ingredient. The procedure involves vetting of the products by the NPCB Evaluation Committee at its biweekly meeting and once approval is obtained, the registration number will be issued. The DCA will then be notified at its meeting in the same month.

### **LOW MOLECULAR WEIGHT HEPARIN (LMWH) – CLEXANE PREFILLED SYRINGES (ENOXAPARIN)**

Following the increase in the number of adverse effect reports involving selected heparin sodium multi-dosage products, investigations carried out indicated that the said products were contaminated with over-sulphated chondroitin sulphate, where the crude heparin/active pharmaceutical ingredient is of porcine origin.

Currently, there are four Low Molecular Weight Heparin (LMWH) products registered in Malaysia, namely Clexane, Fraxiparine, Fragmin and Innoheap (porcine base) and one synthetic product Arixtra.

According to Sanofi-Aventis Sdn. Bhd., the product holder for Clexane, there are a few batches of Clexane globally which are contaminated with over-sulphated chondroitin sulphate (OSCS) and the level of contamination can be divided into the four categories as below :

- Category A – not detected : less than 1%
- Category B – detected and not quantified :  
1-2%
- Category C – quantitatively determined : 2-5%
- Category D – quantitatively determined : more  
than 5-7%

The Drug Control Authority (DCA) at a meeting held on the 29th of May 2008 decided to withhold usage of the products detected with contaminants (Category B, C, and D).

In the event that uncontaminated Clexane stocks cannot be obtained in the shortest time possible, other alternative LMWH products can be used provided that they are proven to be free of OSCS contaminants.



### **REPORT ON ADVERSE EFFECTS OF GAMAT BASED PRODUCTS**

The 207th Drug Control Authority (DCA) meeting held on the 4th of August 2008 has decided that the registration of two registered Gamat products from Healwell Pharmaceuticals will be suspended until a complete investigation is done. The products involved i.e. GAMAT EMULSION (MAL05061509TC) and GAMATOGEN (MAL20041083TCE are required to be recalled from the market. among applicants.

### **7TH BIOEQUIVALENCE REQUIREMENT LIST**

The Drug Control Authority (DCA) at its 207th meeting held on the 4th of August 2008 has agreed on the 7th list for bioequivalence studies. This list can be obtained from NPCB's webpage under the subtitle 'Bioequivalence - Generic Product for Bioequivalence studies – 7th Generic Immediate Release Product List'.

### **WARNING ON LABELS OF COSMETIC PRODUCTS CONTAINING ROYAL JELLY**

The Drug Control Authority (DCA) at its 207th meeting held on the 4th of August 2008 has decided to consider the exemption of warning statements regarding allergic reactions on the labels of cosmetic products containing royal jelly.

This exemption was given as the safety of consumers has been taken into consideration through the labeling requirement, whereby every ingredient in a particular cosmetic formulation (including royal jelly) must be stated on the product label using the globally used INCI (International Nomenclature for Cosmetic Ingredients) name. The aim of this requirement is to provide sufficient information to the consumer so as they can avoid the usage of cosmetic products which may cause them to suffer from allergic reactions.

# The 13<sup>th</sup> International Conference of Drug Regulatory Authorities (ICDRA)

16-19 September 2008, Bern, Switzerland

The International Conference of Drug Regulatory Authorities (ICDRAs) provides drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. The ICDRAs have been instrumental in guiding regulatory authorities, WHO and interested stakeholders and in determining priorities for action in national and international regulation of medicines, vaccines, biomedicines and herbals.

The conferences have been held since 1980 with the aim of promoting exchange of information and collaborative approaches to issues of common concern. As a platform established to develop international consensus, the ICDRA continues to be an important tool for WHO and drug regulatory authorities in their efforts to harmonize regulation and improve the safety, efficacy and quality of medicines.

Regulatory authorities are continually faced with new issues - such as globalization and extension of free trade - while increased responsibilities from expansion of the market and the improvement and sophistication of products place heavy demands on regulatory systems and knowledge bases. The development of cutting edge technologies and health care techniques and extensive use of the Internet impose further complex challenges.

The 13th International Conference of Drug Regulatory Authorities (ICDRA) took place in Bern, Switzerland, from 16-19 September 2008 and was organised by the Swiss Agency for Therapeutic Products (Swissmedic). Topics discussed during the four day conference included quality issues, herbal medicines, homeopathy, regulatory reforms, medicines safety, counterfeiting, access, regulation of clinical trials, harmonization and new technologies. At the end of the meeting, recommendations were proposed for action to be taken by drug regulatory agencies, WHO and related institutions.

The conference was attended by more than 300 regulators from all over the world representing the drug regulatory authorities of more than 100 countries, other agencies and the World Health Organization.

Malaysia was represented by 6 officers from the National Pharmaceutical Control Bureau and Pharmaceutical Services Division. Malaysia was invited to present papers during the plenary and workshops sessions and also to chair a session. The papers presented by Malaysia includes Strategies to fight counterfeit medicines (Eisah Abdul Rahman), Coping with increasing need for inspections: ASEAN initiatives (Abida Haq Syed M. Haq), Challenges in regulating radiopharmaceuticals: view of the International Consultancy Group affiliated to IAE (Kadariah Mohd Ali) and Involving consumers in medicines surveillance reporting (Tan Lie Sie).

The conference was programmed into 8 plenary session and 10 workshops sessions throughout the 4 days

The plenary sessions included the following topics:

- i) Update on 12th ICDRA.
- ii) Building Mutual trust as a key to access
- iii) Regulatory system in a changing environment
- iv) Crisis management: safeguarding health
- v) Current topics
- vi) Keynote presentation
- vii) Recommendations

The workshop sessions included the following issues:

- i) Regulatory aspects of paediatric medicines
- ii) Development of regulation for herbal medicines
- iii) Safety and pandemic preparedness
- iv) Regulatory approaches to proving interchangeability
- v) Strategies to fight counterfeit medicines
- vi) Emerging regulatory issues concerning biosimilars and biologicals
- vii) Emerging diseases: regulating blood products
- viii) Regulator's contribution to access
- ix) Update on harmonization initiatives
- x) Role of regulators in clinical trial approval
- xi) Building regulatory capacity: best practices for the future
- xii) GMP Inspections: impact on information sharing and risk management

The next ICDRA Conference is scheduled to be held in Singapore in 2010.

## **Report of the Tenth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC)**

The Tenth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held from 25-26 June 2008 in Bali, Indonesia.

The Meeting was chaired by Mr. Vongtavanh Chiemsourath, Director of Narcotics, Chemical and Cosmetic Control Division, Food and Drug Department, Ministry of Health, Lao PDR and co-chaired by Mrs. Anis Talib, Senior Principal Assistant Director, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia.

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

The Meeting noted Member Countries' progress in the implementation of the ASEAN Cosmetic Directive (ACD). To date, all Member Countries have implemented ACD at national level, except for Indonesia due to some considerations of several internal issues by the relevant regulatory authorities. Internal assessment has concluded that the small and medium enterprises (SMEs) are not ready to implement the ACD as they may not be able to fulfill the Good Manufacturing Practice (GMP) requirements of the ACD. Nevertheless, Indonesia has taken some action to make progress in supporting ACD implementation, which includes, among others, the following:

- Issuance of new regulation on Cosmetic Ingredients in February 2008, which is in line with the Annexes on ACD
- Mapping the industry capacity in implementing GMP
- Capacity Building for regulators in the field of GMP
- Training for safety assessor
- Strengthening the technical infrastructure

Malaysia had implemented the ACD starting on 1 January 2008. Up to September 2008, about 23,000 notifications have been received. The notification process is done via an electronic system. Other activities which have been conducted include PIF auditing, market sampled product testing as well as training and seminars.

On the subject of Post Marketing Surveillance (PMS 1), Singapore as the lead country for PMS 1, updated the Meeting on the progress on setting up the ASEAN Cosmetic Reference Laboratories (ACRL) Network. The Meeting noted the establishment of the ACRL was in order to give technical support to ASEAN regulatory authorities in conducting PMS activities. For this purpose, periodical assessment of ACRL would be conducted to monitor the performance of ACRL.

The Meeting agreed to endorse a proposal from Malaysia for Regional Workshop of GMP Experts. It was noted that the objective of the Workshop was to capture learning points from the implementation of ACD in relation to GMP as well as to formulate strategies and intervention for any technical assistance/ training for ASEAN Member States. Malaysia also informed the Meeting about a new GMP licensing scheme put in place after the implementation of ACD. In this regard, to increase the awareness and competence of the local cosmetic industry, ongoing trainings/ seminars will be conducted, by using the ASEAN GMP Training Modules.

Finally, the Meeting noted that the 11th ACC Meeting will be hosted by Singapore from 18-21 November 2008.

## News & Announcements

### **SUBMISSION OF VETERINARY PRODUCT REGISTRATION APPLICATIONS AND REVIEW OF FEES FOR REGISTRATION APPLICATIONS AND PRODUCT ANALYSIS**

The deadline for the submission of registration applications for “existing products” (i.e. veterinary products that have been manufactured or imported and marketed in the country before 1st August 2007) has been extended to :

- 31. 12 . 2008 for products containing scheduled poisons (prescription products)
- 30. 06 . 2009 for products that do not contain scheduled poisons (non prescription products which include health supplements and herbal/natural products).

The fees for processing of product applications (including fees for product analysis/ evaluation carried out during postmarket surveillance) are as follows:

- a) Prescription products, non prescription products and health supplements : RM1500
- b) Herbal/ natural products : RM1200
- c) For export only products, the fee is RM500 for each product containing scheduled poisons. For products that do not contain scheduled poisons, only a notification to the NPCB is required at RM100 per product.

The above new fee structure came into effect since 1st August 2008.

### **PROHIBITION ON THE USE OF SEMI-AUTOMATIC ENCAPSULATING MACHINES**

Semi-automatic encapsulating machines are not allowed to be used in the manufacture of registered pharmaceutical products due to quality issues whereby there exists a risk of contamination towards products manufactured using such machines.

Pharmaceutical manufacturers are therefore required to take appropriate measures to ensure that pharmaceutical products (poisons and non-poisons) are manufactured using machineries which comply with the Good Manufacturing Practice requirements. Traditional product manufacturers are also encouraged to take similar measures to minimize the risk of contamination that might exist with the use of existing machineries.

The prohibition on the use of semi-automatic encapsulating machines to manufacture pharmaceutical products (poison and non-poison) was implemented during the licensing of products in the Phase I and Phase II registration exercise (in the year 1987 and 1992 respectively).

## **REGISTRATION OF PRODUCTS IN ESSENCE FORM (E.G. : CHICKEN ESSENCE/ FISH ESSENCE/ OSTRICH ESSENCE/ DUCK ESSENCE)**

The NPCB has received several applications for the registration of products in the 'essence' form. The applications had to be rejected as the products were under the category of food. The processing fees paid are not refundable.

The classification of whether a certain product is under the purview of NPCB or the Food Safety and Quality Division is based on the ratio of 20:80. Products containing 80% or more food ingredients (chicken/fish/ostrich/duck essence) and 20% or less pharmaceutical or herbal ingredients are thus classified as food products and vice versa.

Please refer to the Classification Decision Tree which can be obtained from the NPCB's website, [www.bpfk.gov.my](http://www.bpfk.gov.my), under the subtitle Regulatory Information – Other Guidelines to ensure that such products are classified correctly.

## **NOTICE TO ALL PHARMACEUTICAL, TRADITIONAL MEDICINE AND COSMETIC INDUSTRIES/ ASSOCIATIONS**

The National Pharmaceutical Control Bureau (NPCB) has received some complaints regarding certain individuals claiming to be from the NPCB and these individuals purportedly approach members of the public/ organizations to make payment for sponsorship in the advertisement section of "Uniting Voice of National Pharmaceutical Control Bureau Pharmacy Assistants' Magazine".

The NPCB wish to inform the public that the said magazine is not related to NPCB and NPCB has never issued any orders or letters supporting the collection of payment for the said magazine. The NPCB is also not responsible for any issues that are related to the said publication.

All companies and organizations that have fallen victim to this group are strongly urged to make a police report as the irresponsible conduct of these individuals has tarnished NPCB's reputation.



# CONTACT & MAP

ORGANISATION	TEL-EXT
National Pharmaceutical Control Bureau	+ 603 - 7883 5400
Centre for Product Registration	5457
Section 1 Generic Medicines Section	5489
Section 2 Complementary Medicine & Cosmetics Section	5522
Section 3 New Drug Section	5514
Section 4 Biotechnology Section	5518
Section 5 Regulatory Coordination Section	5502
Centre for Post Registration	5538
Centre for Organisational Development	5553
Centre for Compliance and Licensing	5565
Centre for Quality Control	5429
(i) Reference Standard Unit	5468
(ii) Laboratory Services Unit	5431
(iii) Pharmaceutical Chemistry Testing Section	5450, 5456, 5462
(iv) Bio-Pharmaceutical Testing Section	5442, 5446
(v) Natural Product Testing Section	5471
Administrative Centre	5412

## National Pharmaceutical Control Bureau (NPCB) Biro Pengawalan Farmaseutikal Kebangsaan

Jalan Universiti,  
Peti Surat 319,  
46730 Petaling Jaya,  
Selangor Malaysia

Tel: + 603 - 7883 5400

Fax: + 603 - 7956 2924

Website:

<http://www.bpfk.gov.my>

