BERITA UBAT-UBATAN

NEWSLETTER OF THE DRUG CONTROL AUTHORITY, MALAYSIA

VOLUME 47 • No. 25 • ISSN 0128-0627 March 2010

MS ISO/IEC 17025:2005 Accreditation

The Centre for Quality Control, National Pharmaceutical Control Bureau has been working towards MS ISO/IEC 17025:2005 accreditation since 2006. During this time, the staff of the Centre for Quality Control underwent a series of training on the requirements of the standard and conducted intensive work to validate as well as to estimate the measurement of uncertainty of the methods in the scope of accreditation. The required audits and assessments by the Department of Standards Malaysia were completed in August 2010 and subsequently, on the 14th of January 2010, the Centre for Quality Control was granted the MS ISO/IEC 17025: 2005 accreditation (No: SAMM 450) under the MALAYSIAN LABORATORY ACCREDITATION SCHEME (SAMM) in the fields of chemical and microbiological testing.

The scope of accreditation includes:

- Tests for Microbial Contamination (Total Viable Aerobic Count and Specified Microorganisms) for Medical Plant Preparations (Finished Products)

- Test for the Determination of Toxic Metals namely Arsenic (As), Lead (Pb) and Cadmium (Cd) in Medical Plant Preparations (Finished Products)

- Disintegration and Uniformity of Weight Tests for Medical Plant Preparations (Finished Products) - Tablets & Capsules

The Centre for Quality Control intends to further expand the scope of the accreditation under MS ISO/IEC 17025 to include the following tests:

- Test for the Determination of Mercury (Hg) in Medical Plant Preparations (Finished Products)

(CONTINUED NEXT PAGE)

ISI KANDUNGAN

DCA EDITORIAL TEAM

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

- Test for the Test for the Determination Lead (Pb) and Mercury (Hg) in Cosmetics

- Test for the Detection of Lovastatin in Medical Plant Preparations (Finished Products)

The accreditation is indeed an affirmation of the commitment to quality and service rendered by the NPCB to all its stakeholders. It is also an acknowledgement that the Centre for Quality Control, NPCB is competent in performing the tests accredited, having suitably trained and qualified staff, proper equipment management as well as the commitment to do things right. It is envisaged that with the accreditation, the customers would be confident that the tests carried out are conducted according to the stated specifications, test methods and correct test environment and that the test data are valid and the test reports accurately describe the test results.

Arepanrix® (MAL20091981A) : Rubber Coring Particles After Reconstitution

On February 15th 2010, the product registration holder of Arepanrix®, GlaxoSmithKline Pharmaceutical Sdn. Bhd. (GSK) was alerted by the Ministry of Health, Brunei, regarding the discovery of the presence of black particles in several batches of the reconstituted H1N1 vaccine (lot A80CA91A, A80CA114A , A80CA145A, A80CA146A and A80CA157A).

This first discovery spurned subsequent investigations by GSK in Singapore and Belgium and it was found that the black particles were a result of coring from the rubber stopper. Coring refers to small pieces of stopper material that are sheared off as a result of the repeated needle insertions through the stopper. The risk of abnormal level of stopper coring may be increased by the piercing of cold stopper because the effect of the temperature on the elasticity of the rubber closure material. Coring is more likely to occur when reconstitution is performed immediately after removal of the vaccine from the refrigerator and usage of the needles with larger borings or inadequate needle insertion technique. On quality aspect, the multidose rubber stopper used follows the latest standard of European Pharmacopeia (Monograph 3.2.9).

GSK further confirmed that the presence of black particles did not affect the quality and safety of the vaccine. GSK has also updated the instructions for use in Arepanrix® Product Information Leaflet (PIL) as below:-

Arepanrix™ International Product Information Instructions for Use/Handling

1. Before mixing the two components, the emulsion (adjuvant) and suspension (antigen) should be allowed to reach room temperature. Whitish sediments may be observed in the suspension vial; these sediments are part of the normal physical appearance of the suspension. The emulsion presents as a whitish to yellowish appearance.

2. Each vial should be shaken and inspected visually for any foreign particulate matter (other than the white sediments described above) and/or abnormal physical appearance. In the event of either being observed (including rubber particles from the stopper), discard the vaccine.

3. The vaccine is mixed by withdrawing the entire contents of the vial containing the

adjuvant by means of a 5 ml syringe and by adding it to the vial containing the antigen. It is recommended to equip the syringe with a 23-G needle. The vial containing the adjuvant should be maintained in upside down position to facilitate the withdrawal of the full content.

4. After the addition of the adjuvant to the antigen, the mixture should be well shaken. The mixed vaccine is a whitish to yellowish (milky) homogeneous emulsion. In the event of other variation being observed, discard the vaccine.

5. The volume of Arepanrix™ H1N1 vial after mixing is at least 5 ml. The vaccine should be administered in accordance with the recommended posology (see section Dosage and Administration).

6. The vial should be shaken prior to each administration and inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed (including rubber particles from the stopper), discard the vaccine.

7. Each vaccine dose of 0.5 ml (full dose) or 0.25 ml (half dose) is withdrawn into a 1 ml syringe for injection and administered intramuscularly. It is recommended to equip the syringe with a needle gauge not larger than 23-G

8. After mixing, use the vaccine within 24 hours. The mixed vaccine can either be stored in a refrigerator (2°C - 8°C) or at room temperature not exceeding 25°C. If the mixed vaccine is stored in a refrigerator, it should be allowed to reach room temperature before each withdrawal.

Any unused product or waste material should be disposed of in accordance with local requirements.

On March 11th, 2010 Malaysia has received the first complaint of black particles that were observed in several vials of the reconstituted H1N1 vaccine (lot A80CA152A) and investigation by GSK is still pending.

Reference: GSK Investigation Report 19th January 2010 and 25th February 2010

Complaints On Lack Of Efficacy Of Marcain Spinal 0.5% Heavy 4ml (MAL19991712A)

From 2004 till 2009 the National Pharmaceutical Control Bureau (NPCB) has received forty-one (41) reports in the span of five years (2004-2009) concerning lack of efficacy of the product containing Bupivacaine Hydrochloride as the active ingredient .The reports were not batch specific and twenty-three (23) batches were affected. Marcain Spinal 0.5% Heavy 4ml injection is a drug used for spinal anaesthesia given intrathecally for surgical and obstetrical procedures. The products, including all samples from the complainant were tested by the NPCB and the manufacturer in Sweden and were found to comply with the specifications. Astrazeneca (AZ) as the Marketing Authorisation Holder (MAH) has given its assurance that the quality of the product will be consistently monitored.

Failure of spinal anaesthesia has been reported at a frequency of up to 2-3% possibly due to factors such as inactive local anaesthetic, insufficient dose, insufficient intrathecal distribution of local anaesthetic, unintended extrathecal injection (technique) and/or poor local anaesthetic effect due to inflammatory processes. The change in injection technique and/or the change in the design of needles used may also contribute to the increase in number of failed spinal anaesthesias.

AZ has conducted road shows to the hospitals concerned explaining the possible factors mentioned. Since then, the number of complaints has decreased by more than 50%. The reason for the lack of efficacy to date is not conclusive. Since 2009, AZ has stopped the replacement and exchange of batches since analysis of returned samples has not shown any deviation from the approved specifications. Health Sciences Authority (HSA) Singapore also received lack of efficacy reports in 2009 and early 2010 and similar steps have been taken. The NPCB is working closely with AZ in monitoring the quality and efficacy of the product.

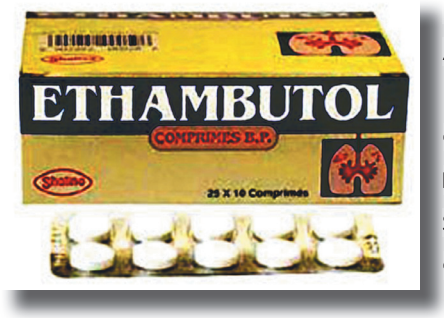
References:

1. Astrazeneca's Investigation Report 23rd May 2006 &12th Sept 2008.

2. Astrazeneca's Presentation entitled Failed Spinal Anesthesia Marcain Heavy Inj. 22nd April 2009.

3. J.Hoppe and P.Popham. Complete failure of spinal anaesthesia in obstetrics. International Journal of Obstetric Anesthesia (2007) 16, 250-255.

Physical Changes Of Ethambutol Tablet 400Mg (MAL19860806A)



The Drug Control Authority (DCA) has to date approved the registration of six products containing Ethambutol Hydrochloride as the active ingredient. Ethambutol is a bacteriostatic antimycobacterial drug prescribed to treat tuberculosis.

The National Pharmaceutical Control Bureau (NPCB) received a number of complaints on Ethambutol Tablet 400mg® (MAL19860806A) from several hospitals since 2009 involving 4 batches (0809175, 0809176, 0901238 and 0907259). All the complaints were with regard to change of product colour from white to yellowish/brownish colour.

Investigation reports from the manufacturer have ascertained that the change in colour was due to moisture absorption through blisters compounded by the hygroscopic nature of Ethambutol. Test results from the Quality Control Centre, NPCB and the manufacturer showed that the product was still within the specification despite the change in colour of the tablets.

Discussions were held between the NPCB and Upha Pharmaceutical Mfg. (M) Sdn Bhd which was the marketing authorisation holder as well as the manufacturer for the product. Short term measures taken by the company were as follows:

i) To supply the product in smaller pack sizes of 5 blisters x 10 tablets as compared to previous packs of 50 blisters x 10 tablets
ii) To pack in aluminium pouch with silica gel.

For long term action, the company would work to improve on the product formulation or packaging involved. The issue would be closely monitored by the NPCB and should the problem persist, users may be advised to purchase from alternative source(s).

Products Notified as Cosmetics but Advertised and Recommended for Medicinal Purposes

The public is advised to avoid buying and using eye toner products notified as cosmetics but recommended instead to be used in the eyes (instilled as eye drops). These products were originally notified as cosmetic products for external applications around the eye area for the purpose of reducing the appearance of dark circles, wrinkles and moisturizing the area around the eyes. However, the products have been exploited for the purpose of treating eye conditions/disorders and directed to be instilled into the eyes. Besides that, some cosmetic products are also being recommended to be used in the nasal cavity with the intention to treat running nose and bad breath.

Claims used for these products such as improving vision, short sightedness or long sightedness and refreshing the eye nerves are categorized as medicinal claims and are disallowed for cosmetics. Similarly, other medicinal claims such as reducing eye redness and itchiness, removing foreign materials from the eyes and curing conjunctivitis are also prohibited.

Cosmetics are preparations for use on external parts of the body, including the skin, hair, nails, lips and also on the teeth and in the oral cavity for the purpose of cleaning, perfuming, changing/improving appearance, protecting/keeping in good condition and correcting body odours.

Products intended for medicinal use in the eyes or nose are NOT cosmetics. They are classified as pharmaceutical products which must be manufactured in licensed manufacturing premises that comply with Good Manufacturing Practices for pharmaceutical products, which include, in the case of eye drops, the appropriate facilities for the manufacture of sterile products. Products notified as cosmetics do not meet these requirements. These products are prohibited to be imported/manufactured/distributed/sold and the responsible companies have been directed to withdraw these products from the local market.

Cosmetic Products Containing Scheduled Poisons

No.	Product Name	Notification Number	Scheduled Poison	Product Holder	Manufacturer
1	**Temulawak Whitening Pearl Cream Papaya**	NOT03090150K	Tretinoin	Zenith Ventures Sdn.Bhd.	Re-x Products Co. Ltd. Thailand
2	**Ratna Sari Whitening Night Cream**	NOT080700826K	Tretinoin	Sky Resources Sdn. Bhd.	Sky Resources Sdn. Bhd.
3	**Atika Beauty Renewal Night Cream**	NOT04082451KE	Hydroquinone	Pearl Elegance Hygiene Beauty Products Sdn. Bhd.	Chemi Lab Cosmetic Industries
4	**Chantique-Whitening Night Cream**	NOT04121404KE	Tretinoin	Sky Resources Sdn. Bhd.	Sky Resources Sdn. Bhd.

No.	Product Name	Notification Number	Scheduled Poison	Product Holder	Manufacturer
5	**NV Toner Treatment No.1**	NOT05010130KE	Hydroquinone & Tretinoin	Maxbeauty Industries Sdn. Bhd.	Maxbeauty Industries Sdn. Bhd.
6	**NV Toner Treatment No.2**	NOT05010129KE	Hydroquinone & Tretinoin	Maxbeauty Industries Sdn. Bhd.	Maxbeauty Industries Sdn. Bhd.

The notifications of cosmetic products mentioned above have been cancelled due to detection of scheduled poisons; tretinoin or hydroquinone in these products.

Tretinoin and hydroquinone are not allowed in cosmetics because they can cause side effects to users if used without advice from doctors. Tretinoin can cause skin irritation such as redness, skin peeling and hypersentitivity to the sun while hydroquinone can cause redness, change of skin colour and hypersensitive skin. The use of hydroquinone can prevent the pigmentation process (depigmentation) which reduces the skin's protection from ultraviolet rays leading to an increase risk of skin cancer if exposed to excessive sunlight.

The public is advised to be very cautious when purchasing cosmetics as there is a wide range of brands available in the market. Consumers should be more knowledgeable and informed when making decisions and should not be easily influenced by advertisements and testimonials promoted by cosmetics companies.

Warning to Registration Holders/Manufacturers of Medicines Making Unapproved Changes that Affect Product Quality and Efficacy

The Ministry of Health Malaysia has enforced the registration of medicines through its regulatory body, the Drug Control Authority (DCA). As stipulated under the Control of Drugs and Cosmetics Regulations 1984, all medicines must be registered with the DCA before they can be manufactured, imported, distributed or used in Malaysia. In line with international standards, all medicines, regardless of whether they are innovators or generic medicines undergo a scientific evaluation process to establish their safety, quality and efficacy before they are marketed in Malaysia.

Generic medicines contain the same active ingredient and are indicated for the same use as the innovator medicines and therefore must be the same in all respects to ensure that they can be used interchangeably.

As generic medicines contain well documented active ingredients, it is the global practice to accept bioequivalence studies on generic medicines as a mandatory requirement for registration since 1999. To date, there are 112 active ingredients for which bioequivalence studies are required as a pre-requisite for registration in Malaysia.

Bioequivalence studies are conducted to compare generic medicines against innovator medicine using human volunteers as subjects to prove that the generic medicines are equivalent to the innovator medicine in terms of providing the same therapeutic effects to patients. In view of the importance of bioequivalence studies to the effectiveness of generic medicines, the DCA has always taken a serious view on matters related to this requirement. Since its implementation,

a total of 213 registered medicines have been cancelled and suspended due to failure to comply with this requirement. In 2008 and 2009, the DCA rejected a total of 66 new applications for registration as applicants failed to submit adequate and satisfactory bioequivalence study data.

After a medicine has been registered with the DCA, it is possible that the manufacturer may make some changes on the source of active ingredients used; manufacturing process involved and so on. As all these changes may have implications on the quality and efficacy of the registered product, it is mandatory for companies to seek prior approval from the DCA before making any changes to these registered products. Data must be provided to substantiate that the quality, safety and efficacy have not been compromised through these changes. Punitive actions can be taken against any company that does not conform to these requirements/directives.

All registration holders and manufacturers of medicines are again reminded to ensure that medicines being marketed are in accordance with the formulation, quality standards and regulatory requirements as specified and approved by the DCA. Any modifications to the product that can affect the quality of the medicines are not allowed and prior approval must be sought from the DCA before any critical changes are made.

In order to ensure that all marketed medicines in Malaysia comply with these regulatory requirements, all registered medicines are continuously monitored through the Post-Market Surveillance Program and the Adverse Reactions Reporting Program. The DCA wishes to bring to the attention of all registration holders and manufacturers that it will not hesitate to suspend or cancel the registration of any unsafe or substandard medicines apart from instituting immediate recalls of such products.

The DCA also wishes to bring to the attention of all medical practitioners, health professionals, consumers and the public that they can report directly to the DCA of any complaint(s) regarding the quality of medicines particularly if they experience adverse reactions or any other problem with the medicines.

Further Information On New Specifications For Microbial Limit Test

In line with the harmonisation efforts on methods and specifications of Microbial Limit Test by European Pharmacopoiea, United States Pharmacopoiea and Japanese Pharmacopoiea, the National Pharmaceutical Control Bureau (NPCB) has been using Harmonised Method specifications for testing of microbial contamination for pharmaceutical and traditional products since July 2009.

The table below shows 'Interpretation of the Results' for specifications and 'Maximum acceptable count' which is currently used by the NPCB (Reference: British Pharmacopoiea 2009).

Route of administration	TAMC (CFU/g or CFU/ml)	TYMC (CFU/g or CFU/ml)	Specified microorganisms
Non-aqueous preparations for oral use	10^3	10^2	Absence of *Escherichia coli* (1g or 1ml)
Aqueous preparations for oral use	10^2	10^1	Absence of *Escherichia coli* (1g or 1ml)

Route of administration	TAMC (CFU/g or CFU/ml)	TYMC (CFU/g or CFU/ml)	Specified microorganisms
Rectal use	10^3	10^2	-
Oromucosal use Gingival use Cutaneous use Nasal use Auricular use	10^2	10^1	Absence of *Staphylococcus aureus* (1g or 1ml) Absence of *Pseudomonas aeruginosa* (1g or 1ml)
Vaginal use	10^2	10^1	Absence of *Staphylococcus aureus* (1g or 1ml) Absence of *Pseudomonas aeruginosa* (1g or 1ml) Absence of *Candida albicans* (1g or 1ml)
Transdermal patches (limits for one patch including adhesive layer and backing)	10^2	10^1	Absence of *Staphylococcus aureus* (1 patch) Absence of *Pseudomonas aeruginosa* (1 patch)
Inhalation use (special requirements apply to liquid preparations for nebulisation)	10^2	10^1	Absence of *Staphylococcus aureus* (1g or 1ml) Absence of *Pseudomonas aeruginosa* (1g or 1ml) Absence of bile-tolerant gram-negative bacteria (1g or 1ml)
Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 103 CFU per gram or per millilitre	10^4	10^2	Not more than 10^2 CFU of bile-tolerant gram-negative bacteria (1g or 1ml) Absence of *Salmonella* (10g or 10ml) Absence of *Escherichia coli* (1g or 1ml) Absence of *Staphylococcus aureus* (1g or 1ml)
Special Ph. Eur. provision for herbal medicinal products consisting solely of one or more herbal drugs (whole, reduced or powdered): -herbal medicinal products to which boiling water is added before use -herbal medicinal products to which boiling water is not added before use	10^7 10^5	10^5 10^4	Not more than 10^2 CFU of *Escherichia coli* (1g or 1ml) Not more than 10^2 CFU of bile-tolerant gram-negative bacteria (1g or 1ml) Absence of *Escherichia coli* (1g or 1ml) Absence of *Salmonella* (10g or 10ml)

Note: The specifications in the table above is in line with the specifications stipulated in the Drug Registration Guidance Document (December 2009), paragraph 12.6 Quality Control Test Specifications for Traditional Medicine Products- Test for Microbial Contamination (page 191). The specifications for 'Non-aqueous Preparations for Oral Use' and 'Aqueous Preparations for Oral Use' are only for pharmaceutical products.

Interpretation of the Results:
When an acceptance criterion for microbiological quality is prescribed it is interpreted as follows:

- 10^1 CFU: maximum acceptable count = 20;
- 10^2 CFU: maximum acceptable count = 200;
- 10^3 CFU: maximum acceptable count = 2000;

and so forth.

(Reference: British Pharmacopoiea 2009)

Report Of The Thirteenth Meeting Of Asean Cosmetic Committee (ACC)

The 13th Meeting of the ASEAN Cosmetic Committee was held on 2-3 December 2009 in Chiang Mai, Thailand. The Meeting was preceded by the 12th ASEAN Cosmetic Scientific Body (ACSB) Meeting held on 1 December 2009 at the same venue. The Meeting was chaired by Ms. Sameerah Bt. Shaikh Abdul Rahman, Senior Principal Assistant Director, Centre for Post Registration of Products, National Pharmaceutical Control Bureau, Ministry of Health Malaysia and co-chaired by Ms. Maria Theresa M. Gutierrez, Food and Drug Regulation Officer IV, Supervisor – Regulation Division 1, Philippines Food & Drugs Administration, Department of Health, Philippines.

On the status of implementation of the notification system for placement of cosmetic products by ASEAN Member States, the Meeting noted that all Member States except Cambodia, Indonesia and Myanmar had effectively put in place procedures and systems to support the notification for placement of cosmetic products by manufacturers as stipulated in Article 1 paragraph 3 of the ASEAN Cosmetic Directive (ACD).

Malaysia raised concern on the requests made by the regulatory authorities of Indonesia for documents and evidences of compliance which were not in line with the ACD as well as the concern raised by the local industries on the lengthy registration process. The Meeting noted that the local industries of Indonesia enjoyed the benefits accrued from the entry into force of the ACD when placing their products in the markets of the other Member States and urged Indonesia to accord the same treatment to the industries from the other Member States.

The Meeting noted that great efforts were taken by Member States to ensure a common interpretation of the ACD and raising consumer awareness on the implication of ACD as well as the use of safe cosmetic products which includes among others, training courses, expositions, road-shows, media coverage and consumer empowerment.

The Meeting discussed the national initiatives taken to enhance the capability of the Small and Medium Enterprises (SME) to comply with the ACD and noted that all Member States have established several programmes to assist the SME. The Meeting further noted the recommendations made to engage the industry, in particular the SME, in the integration initiatives of the cosmetic sector for consideration by the Member States such as below:

a) Exchange information among ASEAN Member States on national strategies and initiatives to enhance SME capability

b) Establish a regional work programme or action plan for SME development in the cosmetic sector with close cooperation with the SME to consider the following:
   (i) Dissemination of information on the integration initiatives in the cosmetic sector;

   (ii) Enhance coordination with other related ASEAN bodies on SME development; and

   (iii) Public-Private Partnerships.

The Meeting noted that the post market surveillance activities which included Product Information File (PIF) audits on products that have been notified are being carried out. Actions are taken on products that have been found to be not in compliance with the ACD and product recalls have also been carried out as deemed necessary. Singapore updated the Meeting that all Member States are participating in the Post Market Alert System, which has been put in place for the healthcare sector covering cosmetic products, medical devices, pharmaceutical products, traditional medicines and health supplements. The Meeting was informed that for the period of January 2009 to November 2009, 69.3% of the total alerts were on cosmetic products out of the total of 251 product alerts that were received through the Post Market Alert System.

The Meeting also discussed on matters such as achieving free movement of cosmetic products in ASEAN and technical assistance as well as capacity building programme for the cosmetic sector.

DATE OF ENFORCEMENT FOR LICENSING OF VETERINARY PRODUCTS OF LOCAL MANUFACTURERS

The Drug Control Authority (DCA) meeting held on 29th January 2010 agreed that:

a. The date of enforcement for licensing of local veterinary products will be from 1st January 2012.
b. During the interim period, registration of product will only be considered if the manufacturer has Good Manufacturing Practice (GMP) status for sterile products. For non-sterile products, registration can be considered even if the manufacturer has not acquired GMP status.
c. To cancel the registration of products of manufacturers who have not fulfilled GMP requirement after 1st January 2012.

The Meeting suggested that the industries be informed of these through awareness programmes such as seminars, circulars and newspaper statements.

PROPOSAL TO INCLUDE DESCRIPTION OF SIBUTRAMINE CARDIOVASCULAR OUTCOME (SCOUT) STUDY IN PACKAGE INSERT OF PRODUCT CONTAINING SIBUTRAMINE

The DCA meeting held on 29th January 2010 agreed that:

a. description of SCOUT study information be included in package inserts of all Sibutramine products in order to reinforce the safety data of the products.
b. all registration holders of Sibutramine products are required to send out letters to all medical practitioners in Malaysia to inform them about this new information.

REVIEW OF REGISTRATION OF PRODUCTS CONTAINING CAFFEINE IN MALAYSIA

The DCA meeting held on 25th February 2010 agreed to postpone the proposed review of registration of products containing caffeine as the following needs to be presented before any decision can be made:

a. Study data to support the safety of products containing a combination of analgesic and caffeine (as the DCA in previous meetings had decided not to approve this because of several safety issues).
b. Justification for maximum limit of single adult dose

The meeting was informed that the National Pharmaceutical Control Bureau (NPCB) was in the process of collecting relevant information and this matter would be deliberated on in its upcoming policy meeting.

PRESS RELEASE REGARDING WARNING ON CHANGE OF INFORMATION OF REGISTERED MEDICINE

The DCA was informed of a press release on 22nd January 2010 regarding warning to registration holders and product manufacturers in the country to disallow changing any information of registered products without the approval from the DCA.

Appropriate action will be taken on companies which do not comply with this ruling because failure to adhere to this can affect the quality and efficacy of the registered products. All products, whether innovator or generic, are evaluated scientifically to prove their safety, quality and efficacy before they are marketed in Malaysia. This is in accordance with international standards.

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 Veterinary Section	5520
Section 3 New Drug Section	5522
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	5564
Centre for Quality Control	5429
(i) Reference Standard Unit	5468
(ii) Laboratory Services Unit	5477
(iii) Pharmaceutical Chemistry Testing Section	5450, 5456, 5462
(iv) Bio-Pharmaceutical Testing Section	5442, 5443
(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