BERITA UBAT-UBATAN

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Congratulations Mdm Hasnah Ismail

The Editorial Board extends its congratulations to Madam Hasnah Ismail, for being appointed as the new Director of National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia on 1st August 2007.

Madam Hasnah graduated with a Degree in Pharmacy in 1977 from Institut Teknologi Bandung, Indonesia. She then embarked on her career as a pharmacist in Hospital Kota Bharu, Kelantan in 1978. Seven year later, in 1985, she received her Masters in Science (M. Sc in Pharm Sci.) from University of Aston in Birmingham, United Kingdom.

In January 1989, Madam Hasnah and NPCB's path crossed. Madam Hasnah was promoted as the Head of Traditional Products Unit, Centre for Product Registration, NPCB. She then assumed the duties of the Head of Non-Drug Unit from May 1989 to 1995. Subsequently for 8 years, Madam Hasnah headed the Secretariat Unit in NPCB.

In 2002, Madam Hasnah's career was greeted with greater heights and responsibilities as she was appointed Deputy Director of Pharmaceutical Care in the Pharmaceutical Services Division (PSD) and Secretary to the MOH Drug List Committee. Madam Hasnah then climbed the rank as Director of NPCB today.

Having been with the hospital, NPCB and PSD, Madam Hasnah is very knowledgeable on matters pertaining to clinical and regulatory pharmacy. She has participated and served as an expert in various seminars, meetings, forums, etc related to pharmacy matters. She has also presented many papers pertaining to clinical and regulatory pharmacy both locally and internationally as well.

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DCA EDITORIAL TEAM

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News Update on ASEAN-EU Programme for Regional Integration Support (APRIS 2)

Report of the second Regional Meeting for Heads of Delegations of ASEAN Cosmetic Committee (ACC) 3 – 4 September 2007, Jakarta, Indonesia

The 2nd Regional Meeting for Heads of Delegations of ASEAN Cosmetic Committee (ACC) was held on 3 – 4 September 2007 in Jakarta, Indonesia. The Meeting was attended by representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam, representatives from the APRIS 2, the ASEAN Secretariat and the ASEAN Cosmetic Association. The Meeting was chaired by Mr. Ruslan Aspan, Deputy of Traditional Medicine, Cosmetic and Complementary Product Control, National Agency of Drug and Food Control of Indonesia.

With regard to the ASEAN Cosmetic Directive (ACD), the Meeting noted the following:

Uniform Labelling Regulation
The Meeting agreed to allow country specific requirement for Brunei Darussalam, Indonesia and Malaysia, taking into consideration their religious issue and to allow Indonesia, Thailand and Viet Nam to require certain information to be printed in local languages.

Consistent Validity of Notification Period and Notification Fee
Noting the different situation among countries in terms of infrastructure and human resource, the Meeting agreed that decision on this matter will be left for each country.

Grace Period For PIF and Labelling Compliance
Grace period and labelling compliance is given for the existing products. New products manufactured on or after 1 January 2008 will have to comply with the ACD requirements.

Issue on Readiness of the Industry
Given consideration that the Industry especially SMEs will not be fully compliant with the ACD requirements by 1st January 2008 especially in GMP, safety assessment and PIF, the Meeting agreed that it should be a continuing learning process for both regulators and industry after 1st January 2008. Hence, regulators are encouraged to give some consideration and flexibility to industry when conducting post market surveillance if there is no critical issue on product safety and to continue to guide the industry towards compliance.

Readiness of the National Legislation To Support the Implementation of the Asean Cosmetic Directive
Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore and Viet Nam presented their draft legislation transposing the ACD requirements for consideration and discussion of the meeting. The Meeting considered and gave substantial comments to the draft legislation of each country. The Meeting decided on the following:

(i) Member Countries to continue to study the draft legislations and submit their comments, if any, to the respective Member Country within the following specific timeframe.

(ii) Legislation of all Member Countries to be in line with the ACD requirements should be ready by **31 November 2007**

(iii) Member Countries should observe 3 fundamental principles in the transposition process: (a) mandatory notification; (b) labelling requirements and (c) safety assessment; and

(iv) The ASEAN Cosmetic Handbook of Ingredients should not be transposed since it will soon be eliminated.

World Health Organisation Collaborating Centre Redesignation

In tandem with the contributions made by the National Pharmaceutical Control Bureau to the advances in the WHO programme on regulatory control of pharmaceuticals, the Regional Office for the Western Pacific of World Health Organization in Manila, Philippines, has redesignated the National Pharmaceutical Control Bureau as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals for a further period of four (4) years from 1 August 2007. The terms of reference of the Centre are as follows:

1. To act as a reference centre and support for matters pertaining to pharmaceutical quality assurance and regulatory affairs.

2. To continue to collaborate in the current ongoing collaborating projects among quality control laboratories of ASEAN countries to produce pharmaceutical reference standards.

3. To provide training in all aspects of pharmaceutical quality assurance programme.

4. To carry out product analysis for reference purposes or on behalf of countries lacking quality control laboratories.

5. To establish a co-coordinating network for monitoring regulatory matters pertaining to product recall, product defects and other related matters.

6. To provide training on computerization on handling drug regulatory matters.

7. To collaborate closely with WHO in drug regulatory matters, especially in the field of inspection.

8. To provide support for training and capacity building of other regional national Drug Regulatory Authorities.

9. To collaborate with WHO in the evaluation of dossiers received from manufacturers expressing interest in the supply of drugs for the treatment of HIV/AIDS, malaria and tuberculosis.

10. To provide training on regulatory matters pertaining to pharmacy enforcement activities; and

11. To provide training on regulatory matters pertaining to the sale and advertisement of medicines.

This redesignation has given the National Pharmaceutical Control Bureau much encouragement and affirmation as it continues to strive for continuous improvement of the organisation to serve the people better.

(CONTINUED FROM PAGE 1, "CONGRATULATIONS MDM HASNAH ISMAIL")

Those who have met and worked with her know that she is a very warm and pleasant person. Her personality endears her to the staff of all levels and she always makes her staff feel very comfortable working with her.

Looking back on her past achievements and with her vast experience and knowledge, NPCB is confident that Madam Hasnah's capabilities will shine as the new Director of NPCB. For your dedication and efforts, Madam Hasnah, we wish you the very best in your new position. Once again, Welcome Back and Congratulations!

Prohibited Visual / Graphics on Label of Natural Products

No.	Issue	Example	Note
1.	Logos or trademarks which contains letters and digits	***Example:-*** *ABCD™ , 1234™, Pagoda Logo etc.*	Only large logos and registered trademarks need to be included as a product name
2.	Marketing strategy	***Example:-*** *"Money back guarantee"* "*Buy 1 free 1"* "*Backed by RM5 million product Liability Insurance"*	Such statements are prohibited on labels (as per Medicines (Advertisement and Sale) Act 1956 requirements
3.	Usage guide which promotes use of other product(s)	***Example:-*** "After consumption of this product (Product A), for better results, it is recommended to take Product B"	This is allowed if all products are registered with the DCA
4.	Consumer testimonial		Prohibited on product label
5.	Clinical Trial results or any information on clinical trial done on product	***Example :-*** *"Clinically Tested"* "*Randomized Double Blind Placebo Control Clinical Study"*	Such statements are prohibited on labels (as per Medicines (Advertisement and Sale) Act 1956 requirements
6.	Photograph of product pioneer		Allowed to be used on product label
7.	Reference to Hadith/ Al-Quran/ Bible/ Religious books		Prohibited on product label
8.	Opinion of prominent figure(s) on product or its active ingredient/ content	***Example :-*** *Opinion of product/ formulation inventor*	Prohibited on product label
9.	Label design (graphic and color) similar to labels from another company		Prohibited on product label
10.	Statement on herbal origin	***Example:-*** Source from the Mountains of Alps	Allowed if proven true
11.	Introduction of founder/ manufacturer		Prohibited on product label
12.	Logo with certification	***Example :-*** *SIRIM / ISO / GMP / HACCP*	Prohibited on product label if certification renewal is on a yearly basis

13.	Name/ Statement / Logo/registered trademark which does not satisfy the specifications of the Traditional Unit	***Example:-*** "Dr.ABC's Formula" "Nothing like it"	Prohibited on product label
14.	Patency claim/ Patency number/ Special technique used/ superiority in ingredients (example: capsule coat)	***Example:-*** *Patented technique*	Allowed if proven true
15.	Nutritional claims with analysis certificate attached	***Example:-*** *Calorie, Fat, Protein and others*	Prohibited on product label
16.	Negative remarks	***Example:-*** *"NO ANIMAL INGREDIENT"* *"NO LAXATIVE"* *"EPHEDRINE FREE"* *"SUGAR FREE"* *"CAFFEIN FREE"*	Prohibited on product label
17.	Graphics or picture of internal organs	***Example:-*** *Kidney, Heart, Nerves.*	Prohibited on product label
18.	Photograph of celebrities	***Example :-*** *Artiste, Sports person(s), Politician*	Prohibited on product label
19.	Sex symbol (male or female)	(♀ and / or ♂)	Prohibited on product label
20.	Indecent photographs/ pornography		Prohibited on product label
21.	Graphics which are incoherent with the indication	***Example:-*** *- Noted indication is for constipation, but graphics on label shows a slim-looking lady which denotes indication for weight loss* *- Indication for urination but label graphics contains picture of a water hose.*	Prohibited on product label
22.	Highlighting unnecessary body parts	***Example:-*** *Indication is for general health but graphics on label highlights male and female sexual organ parts*	Prohibited on product label
23.	Graphics of plants or animal which may cause confusion	***Example:-*** *Radix Ginseng which is improvised as a male sexual part*	Prohibited on product label
24.	Other statements	***Example:-*** *- This product is blended with premium quality* *- Certified chemical residue free*	Prohibited on product label

* *THIS LIST IS NOT EXHAUSTIVE.*
* *IT MAY BE REVIEWED AS AND WHEN IT IS DEEMED NECESSARY*
* *DCA RESERVES THE RIGHT TO DISALLOW ANY OTHER WORDS, PHRASES OR GRAPHICS FOR PRODUCT LABEL WHICH IN ITS OPINION IS MISLEADING, IMPROPER OR NOT FACTUAL*

Prohibited Use of Product Names for Natural Products

No.	Issue	Example
1.	**Prohibited use of disease names as stated in the Medicines (Advertisement and Sale) Act 1956 (Revised 1983)**	***Example :-*** *Diabetes, Asthma, Cancer*
2.	**Prohibited use of a single active ingredient as a product name in products containing more than one active ingredient unless product name contains words such as 'Plus, Compound, Complex, Herbanika**	***Example :-*** *Tongkat Ali Capsule ----* *But product contains tongkat ali, ginseng, ect.*
3.	**Prohibited use of superlative - Names which indicates superiority in efficacy**	***Example :-*** *Power, Superior, Pure, Mustajab, Safe, Healthy, Penawar, VIP, Good*
4.	**Prohibited use of spelling of words which may cause confusion** Words which involve names of/part thereof: i) 20 disease names prohibited in the Medicines (Advertisement and Sale) Act 1956 (Revised 1983) ii) Other diseases without scientific proof iii) Prohibited indication	***Example:-*** *a) Go Out = GOUT (label)* *b) UTix*
5.	**Prohibited use of names which may cause ambiguity** Ambiguous product name	***Example:-*** *B For Energy ?*
6.	**Prohibited use of names which may be offensive or indecent**	***Example:-*** *SENXBIG=SEnXBIG(label)* *Sexy, Enjoy, Paradise, Heavenly, Blue boy, Casanova, Desire*
7.	**Prohibited use of product names which are incoherent with the approved indication** Name containing a product claim whereas product is indicated for more than the approved indication	***Example:-*** *Cough Syrup X= Approved indication for cough, dizziness, flu and itch*
8.	**Prohibited use of product names which has elements of ludicrous belief** Statements referring to ancient believe/ negative spirits/ supernatural power	***Example :-*** *Words such as miracle, magic, magical, miraculous, saintly, heavenly*
9.	**Prohibited use of product names similar to the existing approved product names** Product names similar to the spelling and pronunciation of words of the existing product names	***Example:-*** *Tenormin vs Tenormine vs Tenormy* *Re-Liv vs Re-Lif*
10.	**Prohibited use of product names which may cause ambiguity in the nature of product (drug/food/beverage)** Product names similar to a food/beverage product	***Example:-*** *Juice, Health drink, Beverage, Kooky*
11.	**Prohibited use of product names which represents professional advice or opinion**	***Example:-*** *Dr Sunny, Dr Noortier Rooibose Tea, Professor*
12.	**Other prohibited product names**	***Example :-*** *Slim, Langsing, Trim, Minda*

* *THIS LIST IS NOT EXHAUSTIVE.*
* *IT MAY BE REVIEWED AS AND WHEN IT IS DEEMED NECESSARY*
* *DCA RESERVES THE RIGHT TO DISALLOW ANY OTHER WORDS OR PHRASES FOR PRODUCT NAME WHICH IN ITS OPINION IS MISLEADING, IMPROPER OR NOT FACTUAL*

Drug Control Authority Statement on Cardiac Safety of Rosiglitazone (AVANDIA)

An article recently published in the New England Journal of Medicine has raised concern about an increased risk of myocardial infarction (heart attack) and cardiovascular death in patients with type 2 diabetes treated with Avandia. This article was based on a review of 42 clinical studies. However the degree of risk of Avandia related to ischaemic cardiovascular events is not yet positively confirmed because some of the studies in the New England Journal of Medicine included patients who were not treated for the indication approved in the European Union and Malaysia.

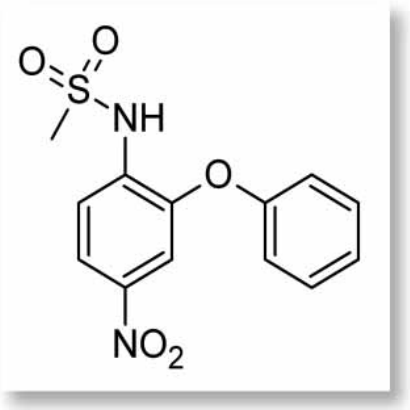
In Malaysia, AVANDIA is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus as a monotherapy or in combination with a sulfonylurea or metformin. Myocardial ischemic events are currently described in the WARNINGS section. Prescribers are reminded to adhere to the restrictions for use in patients with cardiac disease as stated in the product information leaflet. Patients are advised not to stop treatment with rosiglitazone and to discuss the medication with their doctors.

The US Food & Drug Administration (USFDA) on 6th June, 2007 has issued letters to the manufacturers of Avandia and another drug in the same therapeutic class, requesting to include a boxed warning to strengthen the existing warnings. The manufacturer of Avandia is in discussion with the US FDA to review and revise the US prescribing information for Avandia relating to congestive heart failure. The Drug Control Authority (DCA) will continue to monitor the safety of rosiglitazone and any action taken by other regulatory agencies on this matter. DCA will review the labelling of Avandia and strengthen the warnings section so that the risk of congestive heart failure associated with the use of this drug is prominently displayed.

Suspension of Sales of All Products Containing Nimesulide

The Drug Control Authority of Malaysia has suspended the sales of all products containing nimesulide with effect from 30 August, 2007 until further regulatory decision is observed.

The decision was made based on new safety information released from the Irish Medicines Board (IMB) pertaining to cases of idiosyncratic and irreversible fulminant hepatic failure associated with the use of nimesulide.



N-(4-Nitro-2-phenoxyphenyl)methanesulfonamide

Nimesulide has anti-pyretic and analgesic property and is a prescription medicine which is indicated in the treatment of various painful inflammations.
Nimesulide-containing products that have been suspended from the market are as follows:

- Mesulid tablet 100mg
- Nimotas-CD
- Nimegesic 100 Tablet
- Nidol 100 mg Tablet
- Nimed Tablet 100mg
- Precoxi Tablet 100mg

Patients currently on this medication are advised to consult their healthcare providers for alternative therapy available.

New Improved Oral Rehydration Salts (ORS)

With diarrhoea as a major cause of childhood mortality, numerous studies have been undertaken to develop an 'improved' Oral Rehydration Salts (ORS). The goal was to develop a product that would be safe and effective as standard ORS in addition to reducing stool output or have other important clinical benefits. One approach was done by reducing the solution's glucose and salt concentration to produce a new solution of 245mOsm/L. Because of the improved effectiveness of reduced osmolarity of ORS solution, The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) now recommend that countries use and manufacture the following formulation in place of the previously recommended ORS solution with a total osmolarity of 311 mOsm/L.

Each new formulation of ORS sachet contains:

Glucose anhydrous Food Grade	13.5 g
Sodium chloride BP98	2.6 g
Trisodium citrate dehydrate BP98	2.9 g
Potassium chloride BP98	1.5 g
Net Weight	20.5 g
Total Osmolarity	245 mmol/L

In tandem with the recommendation put forth by WHO and UNICEF on the new improved formula of ORS which contains less sodium, glucose and osmolarity, all product registration holders in Malaysia are required to abide by the new ORS formulation . Product registration holders must furnish the Drug Control Authority (DCA) Secretariat with the following details:

a) Product name
b) Product r egistration number
c) Original formulation (ingredients and quantity of all active ingredients and excipient)
d) Suggested new formulation (ingredients and quantity of all active ingredients and excipient, electrolyte and glucose contents in mmol/l)

The respective product holders must submit their variation applications and produce all documents such as Batch Manufacturing Formula (BMF), Batch Manufacturing Record (BMR), label and product inserts to the Variation Unit, Centre for Post Registration of Products, National Pharmaceutical Control Bureau.

Voluntary Withdrawal of Clobutinol (Silomat Syrup 20mg/5mg -MAL19990593A) From the Market

Boehringer Ingelheim (Malaysia) Sdn. Bhd., after consultation with the Drug Control Authority, has voluntarily withdrawn **Clobutinol** *(Silomat Syrup 20mg/5ml)* from the market based on new safety information as of 31st August 2007.

Preliminary results from a recent clinical trial with Clobutinol in healthy adult volunteers have shown that the potential risk of causing cardiac arrhythmia cannot be exempted.

Healthcare professionals are advised to discontinue prescribing and dispensing, and all patients to discontinue the use of **Clobutinol** *(Silomat Syrup 20mg/5ml)* immediately as there are alternative drugs indicated for similar use in the market.

Image: www.boehringer-ingelheim.at/img/Silomat_Range.jpg © 2007 Boehringer Ingelheim Austria GmbH.

Suspected adverse reaction associated with the use of

Clobutinol
(Silomat Syrup 20mg/5ml)

Should be notified to:
Drug Control Authority
Tel : 03 - 7957 3611 ext 225 / 209

1) Warning Statement on Package Insert of Gadolinium-based Contrast Agents Used in Magnetic Resonance Imaging

The DCA at its 195th meeting held on 7 August 2007 agreed that the following warning statements should be included under 'WARNING' and 'PRECAUTIONS' on package insert of products containing gadolinium-based contrast agents (GBCAs) for the purpose of magnetic resonance imaging.

a) Warning on product package

- Exposure to gadolinium-based contrast agents (GBCAs) increases the risk for Nephrogenic Systemic Fibrosis (NSF) in patients with:
    - Acute or chronic severe renal insufficiency (glomerular filtration rate <30 mL/min/ 1.73m^2, or
    - Acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period.
- NSF is a debilitating and sometimes fatal disease affecting the skin, muscle, and internal organs.
- Avoid use of GBCAs unless the diagnostic information is essential and not available with non-contrast enhanced magnetic resonance imaging (MRI).
- Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests.

When administering a GBCA, do not exceed the dose recommended in product labelling.
Allow sufficient time for elimination of the GBCA prior to any re-administration.

b) New warnings

- Among the factors that may increase the risk for NSF are repeated or higher than recommended doses of a GBCA.
- For patients receiving hemodialysis, healthcare professionals may consider prompt hemodialysis following GBCA administration in order to enhance the contrast agent's elimination. However, it is unknown if hemodialysis prevents NSF.
- Determine the renal function of patients by obtaining a medical history of laboratory tests that measure renal function prior to using GBCA.

- The risk, if any, for developing NSF among patients with mild to moderate renal insufficiency or normal renal function is unknown.

- Post-marketing reports have identified the development of NSF following single and multiple administrations of GBCAs.

- The list of registered contrast medium agents used in Magnetic Resonance Imaging that require affixation of such warnings is as follow:

Gadoxetic acid	(1 product)
Gadoversetamide	(3 products)
Gadoteric acid	(2 products)
Gadolinium oxide	(11 products)
Gadodiamide	(8 products)
Gadobutrol	(1 product)
Gadobenic acid	(1 product)

2) Warning Statement on Package Insert of Additional List of Oral Products Indicated for Insomnia

The DCA at its 195th meeting held on 7 August 2007 agreed that the following warning statements should be included under 'WARNING' and 'PRECAUTIONS' on package insert of products indicated for insomnia:

- Anaphylaxis (severe allergic reaction) and angioedema (severe facial swelling) which can occur as early as the first time the product is taken.

- Complex sleep-related behaviours which may include sleep driving, making phone calls, preparing and eating food while asleep.

The above warning statement are to be used for all registered sedatives-hypnotics products which include the following:

Nitrazepam	(2 products)
Zopiclone	(4 products)
Lorazepam	(9 products)
Diazepam	(18 products)
Bromazepam	(4 products)
Alprazolam	(13 products)
Clobazam	(1 product)

3) Suspension of Sales of Products Containing Nimesulide Due to Safety Issues

The DCA at its 195th meeting held on 7 August 2007 decided to suspend the sales of all products containing nimesulide in Malaysia until further information on the study carried out by the European Medicines Agency (EMEA) and feedback from local medical practitioners regarding the usage of nimesulide are obtained.

4) Veterinary Products Registration Guidelines

The DCA at its 195th meeting held on 7 August 2007 has accepted and approved the guidelines for veterinary products registration. The guidelines can be accessed through the BPFK website at

www.bpfk.gov.my

5) Additional Warning Statement on Package Insert of Products Containing Ceftriaxone

The DCA at its 196th meeting held on 30 August 2007 agreed that the potential risks of concomitant usage of Ceftriaxone with calcium or calcium-containing products must be added under 'WARNING' and 'PRECAUTIONS' on package insert of products containing Ceftriaxone.

i) The following warning statements should be affixed under 'WARNING' :

- Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines.

- Calcium-containing solutions or products must not be administered within 48 hours of last administration of Ceftriaxone.

- Cases of fatal reactions with calcium-Ceftrixone precipitates in lung and kidneys in both term and premature neonates have been described. In some cases, the infusion lines and times of administration of calcium-containing solutions differed.

ii) Warning statement that must be affixed under 'Dosage and Administration: Direction for use' is as follow:-

"Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute Ceftriaxone. Particulate formation can result."

iii) The product registration holder, Roche (M) Sdn. Bhd. has been ordered to issue a letter to notify medical practitioners regarding the change in prescription information.

6) USE OF PREMIX ITEMS IN TRADITIONAL PRODUCTS

The DCA at its 193rd meeting held on 24 May 2007 has agreed not to allow the use of premix items in traditional product formulations based on the following grounds:

a) Existing manufacturers for traditional products containing premix items will be given an allowance period of six (6) months from 1 June 2007 to find alternative source (single blended herbs) in replacement of the premix items.

b) Existing manufacturers will be given an allowance period of three (3) months to make necessary changes on active ingredients information through variation application via the online system.

c) Effective 1 December 2007, all new products consisting of premix as raw material will not be registered.

d) Appeal to delay period of execution will be considered on a case to case basis.

The DCA at its 194th meeting held on 21 June 2007 has agreed to allow local manufacturers with premix producing facilities to supply premix items commercially to other local manufacturers.

CONTACT & MAP

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