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NEWS UPDATE
ON ASEAN PHARMACEUTICAL HARMONISATION

8th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG).

The Eighth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held on 21 – 23 July 2004 in Bangkok, Thailand.

The Meeting was chaired by Dato' Che Mohd Zin Che Awang, Director of Pharmaceutical Services, Ministry of Health, Malaysia and co-chaired by Dr. Yuppadee Javroongrit, Senior Pharmacist, Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand.

Almost 300 delegates and observers comprising of both regulatory and industry representatives from the ASEAN member countries except Myanmar attended the meeting. Staff of the ASEAN Secretariat and a representative from the World Health Organization (WHO) were also present.

The objective of the Meeting was to develop harmonisation schemes of pharmaceutical regulations of the ASEAN member countries to complement and to facilitate the objective of ASEAN Free Trade Area (AFTA), particularly the elimination of technical barriers to trade posed by these regulations without compromising on drug quality, safety and efficacy.

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The following documents were deliberated and adopted at the 8th Meeting.

- ASEAN Common Technical Dossier (ACTD) on Quality.
- ASEAN Guidelines on Stability Studies
- ASEAN Guidelines on Bioavailability Bioequivalence (BA/BE) Studies

Pertaining to the Guidelines on Bioavailability/Bioequivalence (BA/BE) Studies, Malaysia has been assigned to form a sub-working group to review and address issues on selection of ASEAN comparator products and active substances for BA/BE studies.

As for the pending and new ACTD-Efficacy Guidelines, Thailand as the coordinating country will form a working group to address all relevant issues. On the full implementation of ACTD, member countries have agreed to the following datelines:

- Singapore — January 2005
- Malaysia and Thailand — December 2005
- Viet Nam — January 2006
- Brunei Darussalam and Philippines — December 2006
- Indonesia — December 2007
- Cambodia, Lao PDR and Myanmar — December 2008

As Chair and Co-Chair of the Implementation Working Group (IWG), Singapore and Indonesia will coordinate a training needs analysis to support member countries in implementing the ACTD. The Meeting noted concerns of the pharmaceutical industry regarding labelling requirements in different member countries. Malaysia was assigned to lead a task force on labelling to resolve the relevant issues.

The roadmap for integration of the healthcare sector in ASEAN as proposed by SEOM was also discussed during the Meeting. The Meeting recommended that two separate Product Working Groups be established under the ACCSQ. One working group will handle medical devices and equipment and the other traditional medicines and health supplements.

The Meeting also discussed on possible Mutual Recognition Arrangements (MRA) for Pharmaceutical Sector in ASEAN. Nevertheless, the meeting felt that mutual recognition amongst ASEAN member countries on approval processes could only be worked out after all member countries have successfully implemented the ACTD. The meeting however agreed that there are some potential areas for mutual recognition that member countries could start exploring without waiting for the full implementation of the ACTD. This includes GMP Inspection reports, QC testing methods and results, BE studies and Product assessment reports.

With regards to cooperation with the relevant international organizations and dialogue partners, the PPWG will continue to work with the WHO on the proposed ASEAN Summary on Product Characteristics (SmPC). Pertaining to the EC-ASEAN Regional Economic Cooperation Programme on Standards, Quality and Conformity Assessment, the Meeting encouraged member countries to work closely with the respective country coordinators to ensure suitable participants and experts are selected to take part in the respective activities.

As for training assistance to new members (Cambodia, Lao PDR, Myanmar and Vietnam), the Meeting noted that several training courses in ACTD/ACTR, stability studies, BA/BE and clinical data assessments have successfully been conducted.

Overall, the ACCSQ-PPWG has made considerable progress despite limitations in the existing capability and capacity of the regulatory authorities of ASEAN member countries.

The 9th ACCSQ-PPWG Meeting will be held in Manila, Philippines in late February 2005.

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NEWS UPDATE
ON ASEAN COSMETIC HARMONISATION

2nd Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC).

The Second Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) ASEAN Cosmetic Committee (ACC) was held on 7 – 8 June 2004 in Bangkok, Thailand. The Meeting was chaired by Mrs. Werawan Tangkeo, Executive Director, Bureau of Cosmetic and Hazadous Substances Control, Food and Drug Administration (FDA), Ministry of Public Health, Thailand and co-chaired by Drs. Ruslan Aspan, MM, Deputy, Traditional Medicine, Cosmetic and Complementary Product Control, National Agency of Drug and Food Control (NADFC), Republic of Indonesia.

The Meeting was attended by 88 delegates and observers comprising of both regulatory and industry representatives from ASEAN member countries except Vietnam and Myanmar. Staff Member of the ASEAN Secretariat, CEN Leader team, EU and ASEAN Officers were also present.

The Chair presented to the Meeting the main outcomes of the 1st ACC Meeting held in Hanoi, Vietnam on 18-19 December 2003 as follows:

(i) The role of ACC is to oversee the implementation of the Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS), and will operate under the TERMS OF REFERENCE of the ASEAN Cosmetic Committee adopted during the 1st ACC Meeting in Hanoi, Vietnam.

(ii) Member Countries had indicated their participation in the Mutual Recognition Arrangement (MRA) and Directive as follows:
- Schedule A (MRA) – Lao PDR, Malaysia and the Philippines
- Schedule B (Directive) – Brunei Darussalam, Cambodia, Indonesia, Singapore, Thailand and Vietnam

(iii) The Meeting adopted the following:
- Guidelines for the implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme.
- Requirements for Notification under Schedule B, the ASEAN Cosmetic Directive.
- ASEAN Cosmetic GMP – Programme proposed by Malaysia.
- Establishment of ASEAN Cosmetic Scientific Body.

The roadmap for the integration of 11 priority sectors in ASEAN as proposed by SEOM was also discussed during the meeting. The Meeting was informed of the draft roadmap for the integration of healthcare sector, which covers cosmetic products. The Meeting considered the recommendation on acceleration of the implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme by 31 December 2005 and the following concerns were raised :

(i) Since Member countries are required to transpose the ASEAN Cosmetic Directive into their national legislation, it would take time for Member Countries to do so.

(ii) Early implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme would affect a number of small and medium enterprises in ASEAN as they would need time to put in place the system in compliance with the requirements of the ASEAN Cosmetic Directive.

Report/ Discussion on the EC-ASEAN Cosmetic Sub- Programme

The Team Leader for the EC-ASEAN Regional Economic Cooperation Program presented to the Meeting on the activities and time frame for the implementation of the sub-programme on Cosmetic. The Meeting noted the total budget of 1.3 million Euros has been allocated for the following activities to be organized in 2004-2005 :

Regional Activities :

(i) **ASEAN GMP**
- To understand, implement and interpret uniformly, among Member States, the guidelines on Cosmetic GMP

(ii) **Post Marketing Surveillance and Product Safety Evaluation.**
- To provide assistance on Capacity Building for Laboratory Expertise (PMS / PSE 1) to establish testing methods and assess the chemical components of cosmetic products for safety evaluation.
- To provide assistance on Capacity Building for Safety and Efficacy Evaluation (PMS / PSE 2) to perform testing methods to evaluate the safety of the products to consumers.
- To provide assistance on Capacity Building for Management of Adverse Events and non-conforming products(PMS / PSE 3) to set up procedures on sampling methods, adverse cosmetic product reporting, management and dissemination of this information through electronic networking.

(iii) **Institutionalising ASEAN Cosmetic Scientific Body**
- To set up system, procedures and management of ASEAN Cosmetic Scientific Body and to review the ingredients listing.

National Activities :

(i) Accreditation for Bureau of Food and Drug (BFAD) (Philippines), NADFC (Indonesia), FDA Laboratories (Thailand)
(ii) National Testing Laboratory for indigenous materials (Philippines, Indonesia, Thailand)
(iii) National Assistance Centre (Philippines)

Report of country progress in preparation for the implementation of the ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRS)

Member countries except Myanmar and Vietnam reported to the Meeting on the status of the implementation of the AHCRS. The Meeting noted the progress and concerns by Member Countries:

Progress Made :

(i) Dissemination of information on the AHCRS to stakeholders has been carried out in most countries.
(ii) Working groups comprising of authorities and industries were formed to prepare for the implementation of the AHCRS.
(iii) Singapore has introduced an e-system to support the Notification of Cosmetic Products.

Concerns :

(i) The resources required in transposing ASEAN Cosmetic Directive into National Laws and Regulations.

(ii) SMEs need more time to prepare for the implementation of the ASEAN Cosmetic GMP and PMS / PSE.
(iii) Cambodia and Laos PDR have expressed concern of the lack of expertise and resources to implement the AHCRS.

With the above concerns, Member Countries, namely Brunei Darussalam, Cambodia, Indonesia, Laos PDR, Malaysia, Philippines, Singapore and Thailand confirmed their readiness of full compliance with the AHCRS by 2008. The Meeting,however, encouraged Member Countries to put extra effort to accelerate the implementation of the AHCRS.

The Meeting further expressed the concern about the accurate transposition of the ASEAN Cosmetic Directive in National Legislation. The Meeting suggested that regulators in Member Countries should work closely with industries, consumer associations and government legal officers to ensure accuracy and consistency.

The Action Plan / Work Programme for the ASEAN harmonisation of the ASEAN Cosmetic Regulation has been discussed and adopted during the meeting. The third ACC Meeting will be held in Indonesia in late November / early December 2004.

DIRECTIVE ON THE USE OF THE HOLOGRAM SECURITY DEVICE (MEDITAG™) AND FREQUENTLY ASKED QUESTIONS

The Drug Control Authority (DCA) at its 161st meeting held on the 5 August 2004 acknowledged the decision of Our Honorary Health Minister to approve the proposal to use hologram labels on registered products.

This is due to the concerns of the Government in respect of counterfeit, imitation and unregistered products being manufactured or imported and sold, and in an effort to streamline the manufacture, import and sale of genuine products.

The requirement for the affixation of this security device (called the MeditagTM) to product labels, is only applicable to **pharmaceuticals, including OTC external personal care products, traditional products and health supplements.** Cosmetics are currently excluded from the exercise. Implementation on the use of the hologram label will be carried out in 2 phases.

1. Phase 1 beginning **1st May 2005** for products which are **non-parenterals**
2. Phase 2 from **1st July 2005** for **parenterals / injectables**

However, products like vaccines and biologicals which are temperature sensitive and require cold chain maintenance are exempted from the requirement.

With the affixation of the hologram security device onto the product label, **the requirement to label OTC products with "diluluskan oleh KKM" does not remain and may be considered optional.**

The directive can be referred under the Section on Circular in the following website (www.bpfk.gov.my).

FREQUENTLY ASKED QUESTIONS (FAQ)

No.	Question	Answer
1.	What is the size and shape of the hologram label?	The size of Meditag™ is **8mm x 16mm.** It is rectangular in shape.
2.	What is the price of Meditag™ ?	Each label costs **RM0.056.** The price is not inclusive of delivery charges, nor insurance charges, tax and sales duties. The minimum order is 1 roll or 2 sheets. Each roll consists of 15,000 labels and is usually used with labelling machines. The sheets each contains 100 labels and is suitable for manual labelling.
3.	What is the size of the roll form?	Each roll is 220mm in diameter. Roll width is 10mm. Core diameter is 76mm. Space in between each Meditag™ is 4mm. The backing of the Meditag™ is glassine.
4.	Where is the hologram label to be applied?	The hologram shall be affixed onto the outer packaging of the product on the **front panel of the product label.** Where there is no outer packaging, the label shall be appplied to the immediate packaging, i.e. the bottle label. The hologram label **cannot be applied onto the outer shrink wrap.** The customer purchasing a product should be able to locate the presence of the hologram without having to open the packaging. None of the product particulars on the label shall be covered over by the security device.
5.	Where should the security label be affixed for promotional packs containing 2 or more items?	Each individual item that is a product registered with the DCA will have to bear the security label.
6.	If manufacturers and importers pack and sell their products in a box of one dozen to their dealers must they apply the hologram label onto the box of one dozen or on each individual pack/bottle?	The hologram label is to be applied to each individual **unit of sale to the level of the end customer.** It is not however required that each blister strip be affixed with a hologram label. The unit of sale for blister/strip packed products would be the box or sachet of 4's, 8's, 10's or 20's that they are packed in. A similar situation applies for injectables. The box unit pack for sale is to be labelled and not the individual ampoules in each box.

No.	Question	Answer
7.	Are registered importers allowed to send the hologram labels to their manufacturers who are located outside Malaysia?	Yes, the labels can be sent to the overseas manufacturer and the product is then imported fully labelled. The importer to whom the labels have been sold will remain the responsible party.
8.	Who is suposed to buy and apply the security label if both principals and distributors are companies in Malaysia as well as registered with BPFK?	The company that is on record with the DCA as the importer for a particular product will be the party responsible for the security labels on the product in question. Even if the registered importer outsources the actual process of stickering the labels onto the physical stock to another agent, the importer will still be accountable. SOP's for the labelling procedure, including documentation and reconciliation records should be maintained.
9.	How detailed should the security label reconciliation record be?	Reconciliation records should be as required under GMP requirements as for any other type of product label.
10.	When will DCA begin inspection or enforcement on the use of the labels?	Enforcement will be at the **point of sale,** and can begin any time after implementation. The implementation will be in 2 phases, with the 1st phase for all non-injectable products starting 1st May 2005. All non-injectables which are imported or manufactured on or after 1st May 2005 should carry the security label. The 2nd phase of implementation for parenteral preparations will begin 1st July 2005.
11.	What happens to those products already available for sale or on the shelves? Will a recall need to be done?	A recall need not be instituted for products already on the market. Companies are advised to project and plan realistically to ensure that there is no overstocking of products without the security label. Products placed on shelves after the implementation dates should preferably bear the hologram labels. It is possible that consumers may exercise their choice immediately after implementation and purchase only those products that have the hologram label.

No.	Question	Answer
12.	Would food supplements and plaster products require security label?	All products registered with the DCA, with the exception of cosmetic products, will need to be affixed with the security label. Please refer back to Q8 on the implementation phases.
13.	Are registered importers and manufacturers of cosmetic products allowed to purchase and apply Meditag™ onto their products?	Currently the requirement for security label does not apply to cosmetics. It is **NOT** recommended that cosmetic products carry the Meditag™ label as it may lead to confusion.
14.	If manufacturers and importers are unable to get sufficient stocks, can they be allowed to sell their products without the label?	No, all products manufactured and imported after the stated implementation date(s) will need to bear the label. Forecast of orders for the security labels are needed by the supplier to understand requirement needs. As demand is dynamic, the information supplied is vital to ensure adequate stocks are kept to fulfil customer orders.
15.	Will registered manufacturers and importers be liable if their assigned Meditag™ (serial number) is found in counterfeit products?	There are security features, both overt (visible) and covert (hidden) that can be used for verification of label authenticity. The Meditag™ labels supplied to registered importers and manufactureres will carry unique serialised numbers. As such each label can be traced to its "owner". If genuine Meditag™ labels are found on counterfeit products, the owner would definitely have some explanations to do.
16.	Who can buy the Meditag™ labels?	Only **licensed** manufacturers and importers of pharmaceutical, traditional medicine and health supplement products can purchase the labels.
17.	How do I ensure an authentic purchase of Meditag™ labels?	The only agent authorized by the Government to supply the hologram security device is Mediharta Sdn Bhd. Should more information be required on the technical and supply aspects, please contact Mediharta. Tel: +6(03) 2093 3075 Fax: +6(03) 2093 9763 Website: www.mediharta.com.my Email: enquiries@mediharta.com.my

DCA NEWS

Use of Thiomersal in Vaccines – An Update

The Drug Control Authority (DCA) at its 124th meeting has decided not to allow thiomersal as a preservative in vaccines. A new proposal has emerged requesting a review of that decision based on latest findings of the safety of thiomersal.

DCA has taken into account that the latest epidemiological research showed no relations of thiomersal-containing-vaccine causing specific neurodevelopmental disorders.

Therefore, the DCA at it 161st meeting held on the 5 August 2004 has decided the following:

i) Thiomersal can be considered in being used as a preservative in vaccines.

ii) Vaccines registration application, which has thiomersal content, will be evaluated case by case while taking into account product efficacy and general health needs.

iii) Products with thiomersal content have to be accompanied with a label and warning stating **'risk of sensitization in relation to thiomersal and other preservatives'.**

iv) In accordance with the global aim of reducing exposure to mercury, vaccines preparations without thiomersal or minimum thiomersal content is encouraged.

Cadmium (Cd) in the Toxic Metal Tests for Traditional Products

The Drug Control Authority (DCA) at its 161st meeting held on the 5 August 2004 has agreed on the following:

(i) **Cadmium** test is included in the test of traditional products whereby the limit for the test is **0.3mg/kg.** This rule will come into effect from **1 January 2005.**

(ii) To accept the limit stated in Appendix 1 as the latest specification for Quality Control of Traditional Medicine Products.

Appendix 1

Quality Control Test Specifications for Traditional Medicine Products

1. Limit Test for Heavy Metals

Maximum limit for heavy metals

1.1	Lead	:	≤ 10.0 mg/kg or mg/litre (≤ 10.0ppm)
1.2	Arsenic	:	≤ 5.0 mg/kg or mg/litre (≤ 5.0ppm)
1.3	Mercury	:	≤ 0.5 mg/kg or mg/litre (≤ 0.5ppm)

2. Disintegration Test (for tablets, capsules and pills)

Disintegration time

2.1	Uncoated tablets	:	≤ 30 minutes
2.2	Film-coated tablets	:	≤ 30 minutes
2.3	Sugar-coated tablets	:	≤ 60 minutes
2.4	Enteric-coated tablets	:	≥ 120 minutes in an acid solution ≤ 60 minutes in buffer solution
2.5	Capsules	:	≤ 30 minutes
2.6	Pills	:	≤ 120 minutes

3. Test for Uniformity of Weight (tablets and capsules only)

≤ 2 capsules / tablets exceed the limit by ± 10% from the average weight.
No tablet / capsule exceed the limit by ± 20% from the average weight.

4. Test for Microbial Contamination

4.1 Preparations for topical use and for use in the respiratory tract except where required to be sterile and transdermal patches

4.1.1	Total viable aerobic count (aerobic bacteria and fungi)	:	≤ 5×10^2 cfu/gram cfu/ml
4.1.2	Enterobacteria and certain other Gm-negative bacteria	:	≤ 5×10^1 cfu/gram or cfu/ml
4.1.3	Pseudomonas aeruginosa	:	Absent in 1 gram or 1 millilitre
4.1.4	Staphylococcus aureus	:	Absent in 1 gram or 1 millilitre

4.2 Transdermal Patches

4.2.1	Total viable aerobic count (aerobic bacteria and fungi)	:	≤ 5×10^2 cfu/patch
4.2.2	Enterobacteria and certain other Gm-negative bacteria	:	Absent in 1 patch
4.2.3	Pseudomonas aeruginosa	:	Absent in 1 patch
4.2.4	Staphylococcus aureus	:	Absent in 1 patch

4.3 Preparations for oral administration containing raw materials of natural origin (animal, vegetable or mineral) for which antimicrobial pre-treatment is not feasible, and for which the competent authority accepts a microbial contamination of the raw material exceeding 5 x 10^3 viable microorganisms per gram or per millilitre (excluding herbal remedies described in 4.4)

4.3.1	Total viable aerobic count	:	Bacteria : ≤ 5 x 10^4 cfu / gram or cfu / ml Fungi : ≤ 5 x 10^2 cfu / gram or cfu / ml
4.3.2	Enterobacteria and certain other Gm-negative bacteria	:	≤ 5 x 10^2 cfu / gram or cfu / ml
4.3.3	Salmonella	:	Absent in 10 gram or 10 ml
4.3.4	Escherichia coli	:	Absent in 1 gram or 1 ml
4.3.5	Staphylococcus aureus	:	Absent in 1 gram or 1 ml

4.4 Herbal medicinal products consisting solely of one and more herbal drugs (whole, reduced or powdered)

4.4.1 Herbal medicinal products to which boiling water is added before use

4.4.1.1	Total viable aerobic count	:	Bacteria : ≤ 5 x 10^7 cfu / gram or cfu / ml Fungi : ≤ 5 x 10^5 cfu / gram or cfu / ml
4.4.1.2	Escherichia coli	:	≤ 5 x 10^2 cfu / gram or cfu / ml

4.4.2 Herbal medicinal products to which boiling water is not added before use

4.4.2.1	Total viable aerobic count	:	Bacteria : ≤ 5 x 10^5 cfu / gram or cfu / ml Fungi : ≤ 5 x 10^4 cfu / gram or cfu / ml
4.4.2.2	Enterobacteria and certain other Gm-negative bacteria	:	≤ 5 x 10^3 cfu / gram or cfu / ml
4.4.2.3	Escherichia coli	:	Absent in 1 gram or 1 ml
4.4.2.4	Salmonella	:	Absent in 10 gram or 10 ml

References:-

Test 1 : Akta Racun 1952

Tests 2, 3 & 4 : BP 2002*

* The specifications for tests 2,3 and 4 will depend on the changes in the pharmacopoeia. The latest edition of the British Pharmacopoeia is followed if there are changes.

CORRECTION

In the last page of Berita Ubat-Ubatan, June 2004, Volume 24, No. 2, " Centre for Product Classification " should read as **" Centre for Product Registration ".**

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Application for registration of :			
(i) Generic Medicines Section	-Prescription Unit	Noorizam Ibrahim	239
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	-Dosage Performance Unit	Muhd Nasir Hashim	613
	-Spectroscopy / General Chemistry Unit	Tan Chuan Ai	614
	-Chemistry Research Unit		521
(ii) Pharmaceutical Biology Testing Section	-Pharmacology / Toxicology Unit	Faridah Ab. Malek	605
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	-Tissue Culture & Biological Research Unit		605
(iii) Natural Product Testing Section	-Herbal Monograph Unit	Jaafar Lassa	250
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	-Toxic Compound Detection Unit		250
(iv) Reference Standard Unit	Reference Standard Unit	Abdul Aziz Mansor	510
(v) Laboratory Services Unit	Laboratory Services Unit	Tan Ann Ling	515