Year 2003

DCA News Update (DCA 154 23/12/2003)

NEW LIMITS OF VITAMINS AND MINERALS ALLOWED IN DIETARY SUPPLEMENTS PER DAY FOR ADULT.

The Drug Control Authority (DCA) at its 154th meeting held on 23rd December 2003 has agreed to the new limits of three (3) vitamins and five (5) minerals allowed in dietary supplement per day for adult as shown below.

No. Ingredient Limit (daily maximum dose for adult)

1. Iodine 300mcg

2. Iron 20mg;

    (note: for pre and antenatal use, as part of multivitamin and mineral preparations, levels higher than 20mg limit established for adults may be permitted at the discretion of the DCA)

3. Manganese 5mg

4. Selenium 300mg

5. Zinc 25mg

6. Vitamin B5 (pantothenic acid) 200mg

7. Vitamin B6(pyridoxine) 100mg

8. Vitamin E 400 i.u (~270mg)

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DCA News Update (DCA 152 28/10/2003)

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

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

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

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

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

Please take note that full evaluation will be done on applications for additional indication which do not fulfil all the criterias as mentioned above. This procedure will be effective beginning November 2003.

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DCA News Update (DCA 151 25/09/2003)

CONTROL ON THE PACK SIZE OF COUGH MIXTURES CONTAINING PHOLCODEINE

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

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

CONTROL ON THE PACK SIZE OF ALL LIQUID COUGH PREPARATIONS

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

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

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

WARNING LABEL ON THE USAGE OF THE INGREDIENT Chelidonium majus

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

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

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

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

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

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DCA News Update (DCA 149 24/07/2003)

Products Containing Dopaminergic Active Ingredients :Additional Warning Regarding Sudden Sleep Onset

The DCA in its 149th meeting which was held on the 24th of July 2003 made the decision and agreed that a warning regarding Sudden Sleep Onset be placed on the package inserts of all products containing dopaminergic active ingredients to reduce the risk of serious adverse effects to consumers.

Products containing dopaminergic active ingredients include:

a. Levodopa (termasuk kombinasi dengan carbidopa/benserazide/entacapone).
b. Apomorphine.
c. Bromocriptine.
d. Cabergoline.
e. Alpha-dihydroergocryptine.
f. Lisuride.
g. Pergolide.
h. Piribedil.
i. Pramipexole.
j. Quinagolide.
k. Ropinirole.

The warnings which are to be included on the package insert is as below:

i) Special warnings & Special Precautions For Use :
.....has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinsons disease. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported very rarely. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with &&.. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore a reduction of dosage or termination of therapy may be considered.

ii) Effects on Ability to Drive and Use Machines:
Patients being treated with &&&. and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved (see also section on special warnings and special precautions for use).

iii) Undesirable Effects:
&&.. is associated with somnolence and has been associated very rarely with excessive daytime somnolence and sudden sleep onset episodes.

EXTENSION OF TIME TO CHANGE THE PRODUCT REGISTRATION NUMBER FROM PBKD TO MAL.

The DCA had previously given a grace period until the 30th of June 2003 for all companies to update their product labels as stated above.

However, following many appeals received from applicants for the extension of this grace period, the DCA

has agreed to extend this grace period until the 31st of December 2003.

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DCA News Update (DCA 148 24/06/2003)

Registration of Herbal Teas in The Form of Teabags

The Drug Control Authority (DCA) through its 148th meeting which was held on the 19th of June 2003 agreed that only herbal teas in the form of teabags with medical claims will still be controlled by the DCA & thus requires registration.

Applicants who wish to submit their applications are advised to refer to the Guidelines for Application of Registration of Traditional Medicines (Garispanduan Permohonan Pendaftaran Keluaran Ubat Tradisional).

Proposal to further strengthen the conditions of usage of products containing CISAPRIDE

DCA agreed that the usage of Cisapride is limited to hospitals and a patient register must be kept. Cisapride will be controlled under Group A of Poison Act 1952.

Registration Suspension Of Product Containing Nimesulide Due To Safety Issue

The registration of all products containing Nimesulide will be suspended until further notice from Committee for Proprietary Medicinal Products (CPMP).

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DCA News Update (DCA 147 29/05/2003)

Registration of Products Containing Nimesulide

The marketing authorization holder of registered products containing Nimesulide must ensure that intensive monitoring on the adverse effects of such products is carried out.

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