Year 2001

Change of Product Registration Code from PBKD to MAL

At its 131st meeting held on 28th December 2001, the DCA agreed that:-
i. the product registration code of all products be changed from PBKD to MAL
i. the validity period for registration of products without expiry dates (ie. Pendaftaran hak) will be 5 years
There will be a smooth transition to ensure that 'PBKD' codes are updated to "MAL". This was started in phases with effect from March 2002. At present, "PBKD" codes are changed to "MAL" upon the re-registration of products.

A six-month grace period is given for this change in the registration code to allow registration holders to finish their stocks of old labels. A further extension of the grace period to 12 months will be given upon request.

As at December 2001, the number of products registered with 'PBKD' codes are shown in the table below:-
Year of registration
Total number of products registered with 'PBKD' code

1987
1249

1988
270

1989
496

1990
510

1991
1729

1992
4

Total
4818

For registered products without validity period, the proposed expiry dates as indicated below will enable all such products to be re-checked during the process of re-registration.
Year of registration
Total number of products registered with 'PBKD' code

1987
2005

1988
2006

1989

2006

1990
2006

1991
2007

1992
2007

The implementation of these changes will also ensure that when the new computerized system (QUEST 2) is launched, it will provide the user with the current information.

DCA News Update (DCA 130 29/11/2001)

Review on the Cancellation of the Traditional Products that contain 'Aristolochic Acid'

The NPCB has received many appeals regarding the products that have been cancelled during the 127th DCA Meeting, which contain 'Aristolochic Acid'.

Their appeals can be considered if they can proof that the product does not contain 'Aristolochic Acid'. The same registration number will be retained, provided that the registration period is still valid.

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DCA News Update (DCA 131 28/12/2001)

Suspension of Products that contain Kava-Kava (DCA 131 -28/12/2001)

Kava-Kava (Piper Methysticum) is a herb that has been promoted for relieving anxiety, diseases of the gall bladders and gastric tube. Recently, 30 cases of hepatotoxicity which are associated with the use of products that contain Kava-Kava have been reported. There are 13 registered products that contain Kava-Kava in Malaysia.

Due to the serious adverse effects that are associated with the use of the herb, the DCA has decided that:

i. To suspend the registration of products containing Kava-Kava until more safety data available.
ii. The registration holders need to submit data on the sources and methods used in Kava-Kava extraction. (Method using Acetone-extract has been associated with the serious adverse effects).
iii. The registration holders are given 30 days to submit data on the procedures and methods of Kava-Kava extraction that are being used. Products that are using acetone-extracted Kava-Kava, are to be withdrawn form the market immediatel

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DCA News Update (DCA 129 26/10/2001)

- None -

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DCA News Update (DCA 128 20/09/2001)

Revision on the Additional Statement to be put on the Labels for all Registered Pharmaceutical Products; "Diluluskan oleh KKM"

The DCA has agreed that the previous statement "Diluluskan oleh PBKD, Kementerian Kesihatan Malaysia" to be shortened to "Diluluskan oleh KKM"

Cancellation of Products that contain Fenfluramine and Dexfenfluramine

All studies that have been conducted on products, which contain fenfluramine and Dexfenfluramine, have shown evidence in association with cardiac valve abnormalities. The DCA has agreed to cancel the registration of those products containing the fenfluramine and dexfenfluramine.

Aspirin : Additional Warnings on the Labels

The DCA has looked into the suggestion regarding the additional warning on the use of aspirin for children aged less than 16 years:

- Warnings in 4 languages
- Warnings in graphical form

Due to the widespread market of aspirin, it is worried that the aspirin might be misused in children. This could be due to the consumers perception that the product is safe and the appearance of the product is more resembling the traditional medicine.

Therefore, the DCA has agreed that:

- "Warning: Not to be taken for children aged less than 16 years" should be written in four languages i.e. Malay/English/Chinese/Tamil and the graphic form is need to explain that the product is not meant for children on the immediate label.

Patent Act 1983

Patent Act 1983 (Revised 2000) has been implemented by 1st August 2001. The amendment allows local manufacturers to submit their applications for patented products for the registration purposes. The DCA has agreed that the submission of patented products for registration can be made 24 months before patent expires.

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DCA News Update (DCA 127 23/08/2001)

Herbal Products Containing Aristolochic Acid

Herbs that contain Aristolochic acid are associated with adverse effects towards the kidney such as nephropathy and end-stage renal failure. In USA, consumers are advised to stop using "Bragantia" and "Asarum" because they also contain Aristolochic acid.

The DCA has decided to cancel the registration of all products, which contain herbs that are associated with Aristolochic acid. The registration holders are required to recall their products from the market.

Famotidine: Dosage Adjustment in Moderate or Severe Renal Impairment

The DCA has looked into the proposal regarding the amendments on the label for product-containing famotidine. This is due to the scientific evidence that it causes adverse effects on the central nervous system such as changing the mental status of patient who suffers from renal failure.

The DCA has agreed on the proposal and the amendments that are to be imposed on the package insert are:

- Under the Dosage section, this statement must be stated:
  Dosage adjustment is required for patients with moderate to severe renal insufficiency.
    - Since CNS adverse effects have been reported in patients with moderate to severe renal insufficiency, to avoid excess accumulation of the drug, the dose of famotidine may be reduced to half the recommended dose or the dosing interval may be prolonged to 36-48 hours as indicated by the patients clinical response.

2. Under the Precaution section, this statement must be stated:
   As elderly patients are more likely to have decreased clearance of famotidine, care should be taken in dose selection and it may be useful to monitor renal function.

Evaluation for Homeopathic Products

There are about 530 homeopathic products, which are submitted by 15 registration holders throughout Malaysia. Some of the products may contain scheduled poisons, heavy metals, extracts from organs/glands, bacterial and viral enzymes in very diluted form (homeodiluted) such as 1X 6X, D1 D30, IC 30C.

The DCA has agreed that:

1. To allow the homeopathic products to contain ingredients such as scheduled poisons, heavy metals, extracts from organs/glands, bacterial and viral enzymes in very diluted form (homeopathic strengths).
2. Indication must starts with "Traditionally used as homeopathic medicines for&&&."
3. Statement "Homeopathic Medicines" must be printed on the label.

Additional Statement to be printed on the labels for all registered pharmaceutical products; "Diluluskan oleh Kementerian Kesihatan"

The DCA has agreed that the said statement to be printed on the labels for all registered pharmaceutical products. The registration holders are also encouraged to include the hologram of the DCA logo.

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DCA News Update (DCA 126 26/06/2001)

- None -

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DCA News Update (DCA 125 28/06/2001)

Vaccines containing Thiomersal as preservatives

The registration holders are advised to remove the preservative from their formulation. The list of vaccines that do not contain thiomersal will be distributed to hospitals and website.

Blister packing for Chemotherapeutic products

The DCA has agree to allow chemotherapeutic products which could not be packed into blister packing, to use amber bottle in condition that the product need not to be repacked again. It should be dispensed as patients pack.

HALAL logo for Cosmetic Products

The DCA has agreed that:

i. HALAL logo is considered as an additional information for the consumer and does not affect the quality and safety of the product.

ii. The issuing body/institution for the HALAL logo must be recognised by the Government of Malaysia e.g JAKIM (Jabatan Kemajuan Islam Malaysia)

iii. HALAL logo is not a mandatory requirement for a cosmetic product

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DCA News Update (DCA 124 07/06/2001)

Review on the use of Colourants in Pharmaceutical Products

Colourants that are allowed to be used in pharmaceutical products are based on their safety and the status of their use in other countries. The DCA has agreed that Erytrosine is now allowed to be used in pharmaceutical products since it is still being used in other countries such as Europe, USA, Australia and other ASEAN countries.

Colourants such as FD & C Green 3 and D & C Yellow are also allowed to be used. However, the use Tartrazine is still restricted on external preparations only.

Additional Flavour/Colourant for Effervescent Powder/Tablet and Chewable Tablet for Non-Poison products

Currently, the DCA allows only 2 flavours to be used in effervescent tablet, granules/powder, lozenges and chewable tablet for Non-Poison products. Consumer will have more selection of products in the market if more flavours/colourants are allowed to be used.

Hence, the DCA has agreed to allow the said products to have 5 flavours/colourants in condition that the flavours or colourants used are approved by the DCA.

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DCA News Update (DCA 123 17/05/2001)

Registration of Traditional Products

The DCA has agreed on the implementation of the new approach in evaluating traditional products to ensure the quality and safety of the products. Focus should be aimed on the use of new active ingredient and product containing combination of ingredients.

1. Additional data that need to be submitted:

Product containing new single ingredient:

a) Extract form

i. Information on the taxonomy of the ingredient

ii. Techniques and methods in preparing/processing the extract and subsequently the product

iii. Information on the use and safety of the ingredient and the product

iv. Quality standard

b) Powder/Granules

i. Information on the taxonomy of the ingredient

ii. Techniques and methods in preparing/processing the extract and subsequently the product

iii. Information on the use and safety of the ingredient and the product

- Product containing multiple ingredients (contains ingredients which are known to be used traditionally):

i. The source of the product formulation

e.g. Chinese Pharmacopoeia

ii. Proof or evidence of the use, traditionally

Product containing multiple ingredients (contains ingredients which are not known to be used traditionally):

i. Information on the use and safety of every new ingredient

ii. Safety data on the new formulation

2. Quality Testing

Sample for testing should be submitted together with application form at the stage 3 submission.

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DCA News Update (DCA 122 24/04/2001)

Warning on interaction of intravaginal Miconazole preparations

There are several reports on adverse effects associated with increased risks of international normalized ratio (INR) and prothrombin time in patients on warfarin and vaginal miconazole preparation.

The DCA has agree that for all miconazole intravaginal preparations, that are registered with the DCA to include the warning as listed below on their labels and package inserts;

Sila dapatkan nasihat doktor atau ahli farmasi sebelum menggunakan keluaran ini jika anda mengambil ubat warfarin, iaitu sejenis ubat antipembekuan darah, kerana lebam/pendarahan pada gusi/hidung boleh berlaku secara spontan.

(Please consult your physician/pharmacist before using this product if you are on the anticoagulant medicine warfarin, because bleeding from the nose/gums or bruising may occur spontaneously)

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