

PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

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貴處檔號

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31 DEC 2015

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Regulatory Control of Products containing Vitamins and Glucosamine

On 4 December 2015, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the control of products containing vitamins and glucosamine in the US, EU, UK, Australia, Canada, Singapore and Taiwan together with scientific information related to the properties and effects of vitamins and glucosamine. After deliberation, the Committee decided that the following new regulatory control of products containing vitamins and glucosamine should be implemented in Hong Kong with immediate effect:

- a. Vitamin products will not be considered as pharmaceutical products **unless** -
 - i. they are indicated for parenteral use;
 - ii. they have medicinal claims for treating or preventing disease; or
 - iii. they belong to the following categories:
 - a. pharmaceutical product containing vitamin A with not less than 10,000 I.U. daily dose;
 - b. pharmaceutical product containing vitamin B3 (nicotinic acid) with more than 200 mg daily dose;
 - c. pharmaceutical product containing vitamin D with more than 1,000 I.U. daily dose;
 - d. pharmaceutical product containing alfalcidol;

- e. pharmaceutical product containing calcitriol; and
 - f. pharmaceutical product containing vitamin K in oral dose form (except vitamins K1 or K2 with 120 mcg or less daily dose).
- b. Glucosamine products will not be considered as pharmaceutical products **unless** -
- i. they are indicated for parenteral use; or
 - ii. they have medicinal claims for treating or preventing disease.

In light of the above, you are required to review the products containing vitamins or glucosamine registered by your company. If they are not considered as pharmaceutical products, please delete the registration numbers from the labels and return the registration certificates to Drug Office for cancellation. In addition, you should observe other legislative requirements applicable to the products concerned for compliance.

For those considered as pharmaceutical products, they will need to comply with the Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice standards in the applications for renewal of registration with effect from 1 January 2017.

You may visit the following Drug Office website for the updated *Guidance notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138)* on the above new control.

http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html

For further enquiries, please contact the Drug Office on registration matters of pharmaceutical products at 2319 8458.

Yours faithfully,



(Clive CHAN)
Secretary

Pharmacy and Poisons (Registration of Pharmaceutical
Products and Substances: Certification of Clinical Trial/
Medicinal Test) Committee

c.c. 7-15/3, Product Files
SYM/CC