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14th April 2014

Dear Sirs,

Legal requirements to register pharmaceutical products and proprietary Chinese medicines

This letter serves to remind all traders about the legal requirements to register pharmaceutical products or proprietary Chinese medicines under the Pharmacy and Poisons Ordinance (Cap 138) and the Chinese Medicine Ordinance (Cap 549) respectively.

According to Cap 138, all pharmaceutical products must be registered with the Pharmacy and Poisons Board of Hong Kong before they can be sold legally in the market. Illegal sale and possession of unregistered pharmaceutical products for sale or distribution are both criminal offences. The maximum penalty for each offence is a fine of \$100,000 and two years' imprisonment. "Pharmaceutical product" means any substance or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in-

- (a) the diagnosis, treatment, mitigation, alleviation or prevention of disease or any symptom thereof;
- (b) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or any symptom thereof;
- (c) altering, modifying, correcting or restoring any organic function, in human beings or in animals.

According to Cap 549, all proprietary Chinese medicines must first be registered by the Chinese Medicines Board before they can be imported, manufactured and sold in Hong Kong. Illegal sale, import or possess any unregistered proprietary Chinese medicines are criminal offences. The maximum penalty for each offence is a fine at level 6 (i.e. \$100,000) and two years' imprisonment. "Proprietary Chinese medicine" means any proprietary product-

- (a) composed solely of the following as active ingredients-
 - (i) any Chinese herbal medicines; or
 - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
 - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;

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- (b) formulated in a finished dose form; and
- (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

In general, products containing medicinal ingredient, e.g. medicated oil products or creams containing methyl salicylate or wintergreen oil, are considered as either pharmaceutical products or proprietary Chinese medicines. Further guidelines on application for registration of pharmaceutical product and proprietary Chinese medicines could be downloaded from the following websites respectively:

1) pharmaceutical products

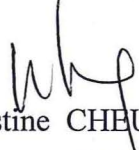
http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html

2) proprietary Chinese medicines

http://www.cmchk.org.hk/pcm/chi/#main_down02.htm

You are hereby reminded that the above above-mentioned legal requirements should be complied and you should refrain from selling and/ or possessing unregistered pharmaceutical products or unregistered proprietary Chinese medicines.

Yours faithfully,


(Ms Christine CHEUNG)
for Director of Health