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

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7 March 2000

Ms Doris Chan Clerk to Panel on Health Services Legislative Council Legislative Council Building 8 Jackson Road, Hong Kong

Dear Ms Chan,

Control of Importation of Unregistered Pharmaceutical Products

Further to my letter of 15 July 1999, I wish to inform you that the Pharmacy and Poisons Board has reviewed its earlier decision regarding the new licensing requirements proposed to tighthen the control of importation of unregistered pharmaceutical products for re-export purposes.

After consideration of the feedback from various interested parties, the Board has decided to revise the original proposal to the effect that an application for import licence for any unregistered pharmaceutical products for re-export purposes will only be endorsed by the Board for approval by the Director-General of Trade if the applicant is able to fulfill condition (b) as set out in the aforesaid letter. That is to say, application for import licence must be accompanied by application for export licence for same, together with production of documentary evidence, such as purchase order or Letter of Credit, to show that the unregistered pharmaceutical product to be imported will actually be re-exported. Condition (a) providing for the production of a letter of authorization from the manufacturer is no longer an option.

To allow time for traders to prepare for the revised licensing requirement, the Board has decided to allow a further grace period for its implementation. All applications must comply with the new requirement with effect from <u>2 January 2001</u>.

All licensed importers of pharmaceutical products have been notified of the revised requirement.

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The new requirement will not apply to pharmaceutical products which are bulk drug substances (i.e. active pharmaceutical ingredients).

I should be grateful if you would convey the above information to all Panel Members.

Yours sincerely,

(Miss CHOW Yan-yan) Secretary, Pharmacy and Poisons Board