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By Fax

中華人民共和國香港特別行政區政府總部衞生福利局的信頭
Letterhead of Health and Welfare Bureau Government Secretariat, Government of the Hong Kong Special Administrative Region The People's Republic of China

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Our ref. (46) in HWB/M/1/5 Pt. 19(95) **Tel:** 2973 8119
Your ref: **Fax:** 2840 0467/2869 4376

5 February, 1999

By Fax:2524 3802

Clerk to Panel
Legislative Council
Legislative Council Building
8 Jackson Road
Central
Hong Kong

(Attn: Ms Doris Chan)

Dear Doris,

Legislative Council
Panel on Health Services
Meeting on 8 February 1999

Thank you for your letter dated 3 February 1999 attaching a submission from the Pharmaceutical Society of Hong Kong on the control of unregistered pharmaceutical products and seeking our comments on it. After consulting the Department of Health, we would like to offer the following comments -

The Pharmacy and Poisons Ordinance (Cap. 138) already allows the importation of unregistered pharmaceutical products for clinical trial purposes. According to Reg. 36B of the Pharmacy and Poisons Regulations (the Regulations), importation of a pharmaceutical product for clinical trial purposes will be allowed if a clinical trial certificate in respect of the product has been issued by a Committee formed under the Pharmacy and Poisons Board.

Reg. 36(1A)(a)(iii) of the Regulations also allows the importation of unregistered pharamceutical products for named patient treatment.

The Administration has no intention to change these provisions of the law in the context of tightening the controls on importation of unregistered pharmaceutical products.

As we have indicated in our paper for the Panel on Health Services, entitled "Control of Unregistered Pharmaceuticals and Blood/Blood Products in Hong Kong", illegal importation of pharmaceuticals into Hong Kong is an offence under the Import and Export Ordinance (Cap. 60) carrying a maximum penalty of $500,000 and 2 years' imprisonment.

Yours sincerely,

(Miss Ada Chan)
for Secretary for Health and Welfare