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藥物評審及進出口管制科
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG EVALUATION AND
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(來函請敘明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

11 October 2021

To: All holders of licences and certificates issued under the Pharmacy and Poisons Ordinance
Dear Sirs / Madams,

**Strengthening the Sales Control of
Pharmaceutical Products containing “Trospium chloride”**

The Drug Office of the Department of Health, an executive arm of the Pharmacy and Poisons Board (“the Board”) reminds you that strengthening the sales control of pharmaceutical products containing trospium chloride indicated for the treatment of symptoms associated with involuntary loss of urine (wetting) and/or increased frequency of urination and imperative urge of urination in adult patients with hyperactive urinary bladder (involuntary urge of urination and voiding problems of unknown origin or due to nervous system disorders) will become effective on **11 December 2021**.

You can refer to the letter previously issued by the Board on 11 December 2020 for more details:

https://www.drugoffice.gov.hk/eps/upload/eps_news/42442/EN/1/PRC%20Letter%20to%20Cert%20Holders%20trospium%20chloride_Eng_2020.12.11_final.pdf

In this connection, the registration certificate holders of the above affected products should comply with the labelling requirements by including a bilingual statement of “**Prescription Drug** 處方藥物” on the sales pack of the products.

I wish to draw your attention that any illegal sale of Schedule 1, Schedule 3 and Part 1 of Schedule 10 poisons without a prescription, and sale of medicine not complying with the above labelling requirements is an offence under the Pharmacy and Poisons Ordinance and its Regulations. The maximum penalty of each offence is a fine at level 6 (currently \$100,000) and two years’ imprisonment upon conviction.

The Department of Health will take enforcement actions for contravention of the labelling requirements after the effective date of the amendments. You are therefore advised to take note of the above and to comply with the legal requirements accordingly.

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*

For further enquiry of the above issue, please contact Ms. Queenie CHAN at 3974 4147.

Yours faithfully,



(Danny KONG)
for Director of Health