PHARMACY AND POISONS ORDINANCE

RESOLUTION

(Under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138))

RESOLVED that the following Regulations, made by the Pharmacy and Poisons Board on 29 September 2008, be approved –

- (*a*) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2008; and
- (*b*) the Poisons List (Amendment) (No. 4) Regulation 2008.

PHARMACY AND POISONS (AMENDMENT) (NO. 4) REGULATION 2008

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. First Schedule amended

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended, in Division A –

- (a) in the item relating to "Alkaloids", by repealing
 - "Nicotine (except chewing gum and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece)" and substituting –
 - "Nicotine (except when contained in (*a*) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (*b*) patches for external application, intended to be used in nicotine replacement therapy)";
- (b) by adding "Anidulafungin; its salts; its esters; their salts";
- (c) by adding "Etravirine";
- (*d*) by adding "Fosaprepitant; its salts";
- (*e*) by adding "Fulvestrant";
- (f) by adding "Idursulfase";
- (g) by adding "Palonosetron; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A -

- (a) by adding "Anidulafungin; its salts; its esters; their salts";
- (*b*) by adding "Etravirine";
- (c) by adding "Fosaprepitant; its salts";

- (*d*) by adding "Fulvestrant";
- (e) by adding "Idursulfase";
- (f) by adding "Palonosetron; its salts".

Chairman, Pharmacy and Poisons Board

29 September 2008

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulations") –

- (a) to relax the control of Nicotine under the First Schedule to the principal Regulations by providing for exceptions for the use of it in nicotine replacement therapy and –
 - (i) in the form of chewing gum or lozenges that contain not more than 4 mg of Nicotine per piece; or
 - (ii) in the form of patches for external application; and
- (b) to add 6 substances to the First and Third Schedules to the principal Regulations so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

POISONS LIST (AMENDMENT) (NO. 4) REGULATION 2008

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. The Poisons List

(1) The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in Division A –

- (*a*) in the item relating to "Alkaloids", by repealing
 - "Nicotine (except chewing gum and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece)" and substituting –
 - "Nicotine (except when contained in (*a*) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (*b*) patches for external application, intended to be used in nicotine replacement therapy)";
- (b) by adding "Anidulafungin; its salts; its esters; their salts";
- (c) by adding "Etravirine";
- (*d*) by adding "Fosaprepitant; its salts";
- (*e*) by adding "Fulvestrant";
- (*f*) by adding "Idursulfase";
- (g) by adding "Palonosetron; its salts".
- (2) The Schedule is amended, in Part II, in Division A, by repealing –
 "Nicotine: chewing gum and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece"

and substituting -

"Nicotine when contained in (*a*) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (*b*) patches for external application, intended to be used in nicotine replacement therapy".

> Chairman, Pharmacy and Poisons Board

29 September 2008

Explanatory Note

This Regulation amends the Poisons List Regulations (Cap. 138 sub. leg. B) ("principal Regulations") –

- (a) to relax the control of Nicotine under the Schedule to the principal Regulations by providing for exceptions for the use of it in nicotine replacement therapy and
 - (i) in the form of chewing gum or lozenges that contain not more than 4 mg of Nicotine per piece; or
 - (ii) in the form of patches for external application; and
- (b) to add 6 substances in Division A of Part I of the Poisons
 List set out in the Schedule to the principal Regulations so
 that, among other applicable requirements, poisons
 containing those substances can only be sold on registered

premises of an authorized seller of poisons by a registered pharmacist or in the pharmacist's presence and under the pharmacist's supervision.