

PHARMACY AND POISONS ORDINANCE

RESOLUTION

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

RESOLVED that -

(a) the Pharmacy and Poisons (Amendment) Regulation 2002;
and

(b) the Poisons List (Amendment) Regulation 2002,
made by the Pharmacy and Poisons Board on 8 March 2002 be
approved

PHARMACY AND POISONS (AMENDMENT) REGULATION 2002

(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. Substances falling within the Poisons List
to which special restrictions apply
under regulations 3 and 5**

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

(a) in the item relating to "Alkaloids" -

(i) by repealing "Nicotine" and
substituting -

"Nicotine, except chewing gum intended
to be used in nicotine replacement
therapy which contains not more than
2 mg of Nicotine per piece";

(ii) by adding -

"Galantamine";

(b) by adding -

"Eletriptan; its salts
Gatifloxacin; its salts; its esters
Imatinib; its salts
Tenecteplase; its salts
Tiagabine; its salts; its esters; their salts".

2. Substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon

The Third Schedule is amended in part A -

(a) in the item relating to "Alkaloids", by adding -
"Galantamine";

(b) by adding -

"Eletriptan; its salts

Gatifloxacin; its salts; its esters

Imatinib; its salts

Tenecteplase; its salts

Tiagabine; its salts; its esters; their salts".

(Dr P Y LAM)

Chairman,
Pharmacy and Poisons Board

8 March 2002

Explanatory Note

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) -

- (a) to relax the control of Nicotine where it is intended to be used in nicotine replacement therapy and in the form of chewing gum containing not more than 2 mg of Nicotine per piece; and
- (b) to add 6 substances to the First and Third Schedules

POISONS LIST (AMENDMENT) REGULATION 2002

(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

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg.)
is amended -

(a) in Part I, in part A -

(i) in the item relating to "Alkaloids" -

(A) by repealing "Nicotine" and
substituting -

"Nicotine, except chewing gum
intended to be used in nicotine
replacement therapy which
contains not more than 2 mg of
Nicotine per piece";

(B) by adding -

"Galantamine";

(ii) by adding -

"Eletriptan; its salts
Gatifloxacin; its salts; its esters
Imatinib; its salts
Tenecteplase; its salts
Tiagabine; its salts; its esters; their
salts";

(b) in Part II, in part A, by adding -

"Nicotine: chewing gum intended to be used in nicotine replacement therapy which contains not more than 2 mg of Nicotine per piece".

(Dr P Y LAM)

Chairman,
Pharmacy and Poisons Board

8 March 2002

Explanatory Note

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) -

- (a) to relax the control of Nicotine where it is intended to be used in nicotine replacement therapy and in the form of chewing gum containing not more than 2 mg of Nicotine per piece; and
- (b) to add 6 substances to part A of Part I of the Poisons List.

**SPEECH BY
THE SECRETARY FOR HEALTH AND WELFARE
AT THE LEGISLATIVE COUNCIL
ON 24 APRIL 2002
Pharmacy and Poisons Ordinance (Cap 138)**

**Poisons List (Amendment) Regulation 2002
Pharmacy and Poisons (Amendment) Regulation 2002**

Madam President,

I move that the Poisons List (Amendment) Regulation 2002 and the Pharmacy and Poisons (Amendment) Regulation 2002 as set out under my name in the paper circulated to Members be approved.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and inspection system set up in accordance with the Pharmacy and Poisons Ordinance. The Ordinance maintains a Poisons List under the Poisons List Regulations and several Schedules under the Pharmacy and Poisons Regulations. Pharmaceutical products put on different parts of the Poisons List and different Schedules are subject to different levels of control in regard to the conditions of sale and keeping of records.

3. For the protection of public health, some pharmaceutical products can only be sold in pharmacies under the supervision of registered pharmacists and in their presence. For certain pharmaceutical products, proper records of the particulars of the sale must be kept, including the date of sale, the name and address of the purchaser, the name and quantity of the medicine and the purpose for which it is required. The sale of some pharmaceutical products must be authorized by prescription from a registered medical practitioner, a registered dentist or a registered veterinary surgeon.

4. The Amendment Regulations now before Members seek to amend the Poisons List in the Poisons List Regulations and the Schedules to the Pharmacy and Poisons Regulations, for the purpose of imposing control on a number of new medicines.

5. The Pharmacy and Poisons Board proposes to add six new medicines to Part I of the Poisons List, and the First and Third Schedules to the Pharmacy and Poisons Regulations so that pharmaceutical products containing any of them must be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. In addition, the Pharmacy and Poisons Board proposed to re-classify Nicotine, where it is intended to be used in nicotine replacement therapy and in the form of chewing gum containing not more than 2 mg of Nicotine, from Part I of the Poisons List to Part II of the Poisons List to allow its sale by an authorized seller of poisons or by a listed seller of poisons. These products can relieve nicotine craving and withdrawal symptoms, thereby facilitating smoking cessation in smokers. The proposed relaxation of control would make these products more accessible to smokers who intend to quit smoking.

7. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under section 3 of the Ordinance to regulate the registration and control of pharmaceutical products. The Board comprises members engaged in the pharmacy, medical and academic professions. The Board considers the proposed amendments necessary in view of the potency, toxicity and potential side-effects of the medicines concerned.

8. With these remarks, Madam President, I move the motion.