

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 6) REGULATION 2015

INTRODUCTION

The Pharmacy and Poisons Regulations (Cap. 138A) (“the Regulations”) was made under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (“the Ordinance”). The Pharmacy and Poisons (Amendment) (No. 6) Regulation 2015 (“the Amendment Regulation”) at Annex is to amend Schedules 2 and 10 to the Regulations.

JUSTIFICATIONS

General Background

2. Under section 29(1B) of the Ordinance, the Pharmacy and Poisons Board (“the Board”) set up under section 3 of the Ordinance is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Regulations, subject to section 31 of the Ordinance and to the approval of the Secretary for Food and Health.

Proposal of the Pharmacy and Poisons Board

3. Arising from a recent review on the control of nicotine-containing products in Hong Kong, the Board proposes to:

- (i) amend Group II, Division B of Schedule 2 to the Regulations by repealing “preparations in aerosol dispensers containing not more than 0.2% of nicotine, weight in weight; other liquid preparations and solid preparations with a soap base, containing not more than 7.5% of nicotine, weight in weight”; and

- (ii) amend Division A of Part 2 of the Poisons List set out in Schedule 10 to the Regulations to the effect that only “Nicotine when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4mg of nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy” are classified as Part 2 poisons.

4. The Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the substances.

THE AMENDMENT REGULATION

5. It is noted that nicotine is a highly toxic substance and fatal oral dose for an adult could be as low as 40mg. The Amendment Regulation is to, among others, tighten up the control of nicotine-containing products as proposed in paragraph 3(ii) above in order to protect the public health. On the other hand, the Amendment Regulation will also remove certain nicotine-containing preparations currently exempted from the Ordinance since they are considered as substances for use in pesticides, which are being regulated under the Pesticides Ordinance (Cap. 133) (Section 21 of the Pesticides Ordinance provides that the Ordinance shall not apply to any pesticide to which the Pesticides Ordinance applies).

6. In sum, the effects of the Amendment Regulation are that pesticides will be regulated by Pesticides Ordinance; certain chewing gum, lozenges and patches for nicotine replacement therapy will remain as Part 2 poisons under the Regulations; tobacco will remain exempted from the Ordinance; and all other nicotine-containing products would be classified as Part 1 poisons under the Regulations.

LEGISLATIVE TIMETABLE

7. The legislative timetable will be –

Publication in the Gazette	11 December 2015
Date of Commencement	11 December 2015

IMPLICATIONS OF THE PROPOSAL

8. The proposal will impose appropriate control on pharmaceutical products consisting of the above substances so that they can be sold in the market upon fulfillment of the relevant regulations.

ENQUIRY

9. For any enquiries on the brief, please contact Mr Chow Tat-wing, Assistant Secretary for Food and Health, at 3509 8956.

Food and Health Bureau

December 2015

Pharmacy and Poisons (Amendment) (No. 6) Regulation 2015

(Made by the Pharmacy and Poisons Board under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Secretary for Food and Health)

1. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2 and 3.

2. Schedule 2 amended (articles exempted by regulation 8 from the provisions of the Ordinance and of these regulations)

Schedule 2, Group II, Division B, item relating to “Nicotine”—

Repeal

“; preparations in aerosol dispensers containing not more than 0.2% of nicotine, weight in weight; other liquid preparations and solid preparations with a soap base, containing not more than 7.5% of nicotine, weight in weight”.

3. Schedule 10 amended (Poisons List)

Schedule 10, section 2, Table, Part 2, Division A, item relating to “Pharmaceutical products retailed in the form as supplied by the manufacturer”, paragraph (e), after item “Nicocodine; its salts”—

Add

“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)”.



Chairman,
Pharmacy and Poisons Board

4 December 2015

Explanatory Note

This Regulation amends—

- (a) Schedule 2 to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (*principal Regulations*) so that certain preparations containing nicotine are no longer exempt from the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations; and
- (b) Division A of Part 2 of the Poisons List set out in Schedule 10 to the principal Regulations to tighten the control over pharmaceutical products containing nicotine.