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Date : 23 February 2015

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 18 March 2015

Proposed resolution under the Pharmacy and Poisons Ordinance

The Secretary for Food and Health will move, at the Council meeting of 18 March 2015, a proposed resolution under section 29(1) of the Pharmacy and Poisons Ordinance (Cap. 138). The proposed resolution is attached for Members' consideration. The President has directed that it be printed in the terms in which it was handed in on the Agenda of the Council.

2. The speech, in both Chinese and English, which the Secretary will deliver when moving the proposed resolution is also attached.

(Odelia LEUNG)
for Clerk to the Legislative Council

Encl.

Pharmacy and Poisons Ordinance

Resolution

(Under section 29(1) of the Pharmacy and Poisons Ordinance (Cap. 138))

Resolved that the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2015, made by the Pharmacy and Poisons Board on 9 February 2015, be approved.

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2015

(Made by the Pharmacy and Poisons Board under section 29(1) of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. Pharmacy and Poisons Regulations amended

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

2. Fifth Schedule amended (indication of statement prescribed by regulation 15 for the purposes of section 27(c) of the Ordinance)

Fifth Schedule, paragraph 8, after "Astemizole,"—

Add

"Bilastine,".



Chairman,
Pharmacy and Poisons Board

9 February 2015

Explanatory Note

This Regulation amends paragraph 8 of the Fifth Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) so that the container of a medicine containing Bilastine, its salts or its compounds with any other substance is not required to be labelled with the warning statement prescribed in that paragraph.

**SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 18 MARCH 2015**

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No.2) Regulation 2015

Mr President,

I move that the motion under my name, as printed on the Agenda, be passed.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and monitoring system set up in accordance with the Pharmacy and Poisons Ordinance. The Ordinance maintains several Schedules, including a Poisons List, under the Pharmacy and Poisons Regulations. Pharmaceutical products put under 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, dentist or veterinary surgeon.

4. Arising from an application for registration of one pharmaceutical product, the Pharmacy and Poisons Board proposes to add the following substance to paragraph 8 of the Fifth Schedule to

the Pharmacy and Poisons Regulations:

- (i) Bilastine.

The container of a medicine containing the above substance, its salts or its compounds with any other substance is not required to be labelled with the warning statement prescribed in that paragraph.

5. For amendment regulations concerning the adding of the above one substance to the Fifth Schedule to the Pharmacy and Poisons Regulations, we propose them to take immediate effect upon gazettal on 20 March 2015, to allow legitimate and early sale of the relevant medicines.

6. The Amendment Regulation is made by the Pharmacy and Poisons Board, which is a statutory authority established under the Ordinance to regulate pharmaceutical products. The Board comprises members engaged in the pharmacy, medical and academic professions. The Board considers the proposed amendment necessary in view of the potency, toxicity and potential side effects of the medicine concerned.

7. With these remarks, Mr President, I hope members could support the motion.

8. Thank you.