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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 17 December 2008

Proposed resolution under the Pharmacy and Poisons Ordinance

I forward for Members' consideration a proposed resolution which the Secretary for Food and Health will move at the Council meeting of 17 December 2008 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2008; and

(b) the Poisons List (Amendment) (No. 5) Regulation 2008.

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 English and Chinese versions, which the Secretary will deliver when moving the proposed resolution, and the supplementary information provided by the Secretary, are also attached.

(Mrs Justina LAM)
for Clerk to the Legislative Council

Encl.

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 25 November 2008, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2008; and

(*b*) the Poisons List (Amendment) (No. 5) Regulation 2008.

PHARMACY AND POISONS (AMENDMENT) (NO. 5) 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*) by adding "Dabigatran etexilate; its salts";

(*b*) by adding "Laropiprant; its salts";

(*c*) by adding "Vildagliptin; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Dabigatran etexilate; its salts";

(*b*) by adding "Laropiprant; its salts";

(*c*) by adding "Vildagliptin; its salts".

Chairman,
Pharmacy and Poisons Board

25 November 2008

Explanatory Note

This Regulation adds 3 substances to the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("the principal Regulations") respectively 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. 5) 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

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

(*a*) by adding "Dabigatran etexilate; its salts";

(*b*) by adding "Laropiprant; its salts";

(*c*) by adding "Vildagliptin; its salts".

Chairman,
Pharmacy and Poisons Board

25 November 2008

Explanatory Note

This Regulation adds 3 substances in Division A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) 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.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 17 DECEMBER 2008

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2008
Poisons List (Amendment) (No. 5) Regulation 2008

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 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, dentist or veterinary surgeon.

4. Arising from an application for registration of three pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following three substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Dabigatran etexilate; its salts ;
(b) Laropiprant; its salts; and
(c) Vildagliptin; its salts.

Pharmaceutical products containing these three substances must then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

5. We propose that these amendment regulations take immediate effect upon gazettal on 19 December 2008 to allow early control and sale of the relevant medicines.

6. The two Amendment Regulations are 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 amendments necessary in view of the potency, toxicity and potential side effects of the medicines concerned.

7. With these remarks, Mr President, I move the motion.

Poisons List (Amendment) (No. 5) Regulation 2008

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2008

Supplementary Information to the Legislative Council

《2008年毒藥表（修訂）(第 5 號) 規例》
《2008年藥劑業及毒藥（修訂）(第 5 號) 規例》
提交立法會的補充資料

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Dabigatran etexilate; its salts 達比加群酯; 其鹽類	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used in adults to prevent the formation of blood clots in the veins who have had an operation to replace a hip or knee. Its use should be decided by a doctor. 此藥用於成人，以作預防接受置換髖或膝關節手術的血塊形成。使用該藥與否，須由醫生決定。
Laropiprant; its salts 拉羅匹侖; 其鹽類	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Laropiprant together with Niacin is used in addition to diet and exercise in patients with dyslipidaemia (abnormally high levels of fat in the blood). Its use should be decided by a doctor based on the patient's condition. 拉羅匹侖與菸鹼酸並用，加上配合節食和運動，用於治療患血脂異常 (血液中有異常高水平的脂肪含量)。使用該藥與否，須由醫生按病人的病情決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Vildagliptin; its salts 維格列汀; 其鹽類	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat type 2 diabetes mellitus (non-insulin-dependent diabetes). It is used together with another antidiabetes medicine (as 'dual therapy') when the patient's diabetes is insufficiently controlled by other medicine taken alone. Its use should be decided by a doctor based on the patient's condition. 此藥用以治療二型糖尿病 (非胰島素依賴型糖尿病)。在病人單靠另一種藥物不足以控制糖尿病時，此藥與另一種抗糖尿病藥物並用(作'雙重治療')。使用該藥與否，須由醫生按病人的病情決定。