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Tel : 2869 9205

Date : 25 February 2010

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 17 March 2010

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 March 2010 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) Regulation 2010; and

(b) the Poisons List (Amendment) Regulation 2010.

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 22 February 2010, be approved –

(*a*) the Pharmacy and Poisons (Amendment) Regulation 2010; and

(*b*) the Poisons List (Amendment) Regulation 2010.

PHARMACY AND POISONS (AMENDMENT) REGULATION 2010

(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 "Desvenlafaxine; its salts";

(b) by adding "Dronedarone; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(a) by adding "Desvenlafaxine; its salts";

(b) by adding "Dronedarone; its salts".

Chairman,
Pharmacy and Poisons Board

22 February 2010

Explanatory Note

This Regulation adds 2 substances to Divisions A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("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) REGULATION 2010

(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 "Desvenlafaxine; its salts";

(b) by adding "Dronedarone; its salts".

Chairman,
Pharmacy and Poisons Board

22 February 2010

Explanatory Note

This Regulation adds 2 substances to 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 MARCH 2010

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 1) Regulation 2010
Poisons List (Amendment) (No. 1) Regulation 2010

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 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 two pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following two substances to Part I of the Poisons List and

the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Desvenlafaxine; its salts

(b) Dronedarone; its salts.

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

6. We propose that these amendment regulations take immediate effect upon gazettal on 19 March 2010 to allow early control and sale of the relevant medicine.

7. 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 medicine concerned.

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

Poisons List (Amendment) (No. 1) Regulation 2010

Pharmacy and Poisons (Amendment) (No. 1) Regulation 2010

Supplementary Information to the Legislative Council

《2010年毒藥表（修訂）(第一號) 規例》
《2010年藥劑業及毒藥（修訂）(第一號) 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**
Desvenlafaxine; its salts (地文拉法辛；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 major depression in adults. Side effects include nausea, headache, dry mouth, sweating, dizziness, insomnia, constipation, loss of appetite, sleepiness, tiredness, anxiety, tremor, dilated pupils, decreased sex drive, delayed orgasm and ejaculation. Its use should be judged by a doctor. 此藥物用以治療患有重性抑鬱症的成人。副作用包括噁心、頭痛、口乾、流汗、暈眩、失眠、便秘、食慾不振、嗜睡、疲勞、焦慮、震顫、瞳孔擴張、性慾下降、延遲性高潮及射精。使用此藥物與否，應由醫生斷定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Dronedarone; its salts (屈奈達隆；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 an antiarrhythmic (heart rhythm and rate control) drug, use in patients with atrial fibrillation. Side effects include diarrhoea, nausea and vomiting, fatigue and asthenia. This drug should only be used upon medical judgment. 此藥是一種抗心律失常(控制心律和心速)的藥物，用於患有心房纖維性顫動的病人。副作用包括腹瀉、噁心和嘔吐、疲勞和虛弱。需經醫生診斷適用時，才能使用此藥物。