

立法會
Legislative Council

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Tel : 2869 9205

Date : 27 November 2007

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 19 December 2007

**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 19 December 2007 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2007; and
- (b) the Poisons List (Amendment) (No. 5) Regulation 2007.

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 November 2007, be approved –

- (a) the Pharmacy and Poisons (Amendment)(No. 5) Regulation 2007; and
- (b) the Poisons List (Amendment)(No. 5) Regulation 2007.

PHARMACY AND POISONS (AMENDMENT)(NO. 5) REGULATION 2007

(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 “Diacerein; its salts; its esters”;
- (b) by adding “Exenatide”;
- (c) by adding “Lapatinib; its salts”;
- (d) by adding “Paliperidone; its salts”.

2. Third Schedule amended

The Third Schedule is amended, in Division A –

- (a) by adding “Diacerein; its salts; its esters”;
- (b) by adding “Exenatide”;
- (c) by adding “Lapatinib; its salts”;
- (d) by adding “Paliperidone; its salts”.

Chairman,
Pharmacy and Poisons Board

22 November 2007

Explanatory Note

This Regulation adds 4 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 2007

(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 “Diacerein; its salts; its esters”;
- (b) by adding “Exenatide”;
- (c) by adding “Lapatinib; its salts”;
- (d) by adding “Paliperidone; its salts”.

Chairman,
Pharmacy and Poisons Board

22 November 2007

Explanatory Note

This Regulation adds 4 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 poisons containing those substances can only be sold on premises of authorized sellers of poisons by a registered pharmacist or in his presence and under his supervision.

**SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 19 DECEMBER 2007**

Pharmacy and Poisons Ordinance (Cap. 138)

**Pharmacy and Poisons (Amendment)(No. 5) Regulation 2007
Poisons List (Amendment)(No. 5) Regulation 2007**

Madam 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 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, dentist or a veterinary surgeon.

4. Arising from four applications for registration of pharmaceutical products, the Pharmacy and Poisons Board proposes to add four substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations. Pharmaceutical products containing any of these 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 21 December 2007 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, Madam President, I move the motion.

Poisons List (Amendment) (No. 5) Regulation 2007

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2007

Supplementary Information to the Legislative Council

《 2007年毒藥表 (修訂)(第五號)規例 》
《 2007年藥劑業及毒藥 (修訂)(第五號)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
Diacerein; its salts; its esters (雙醋瑞因; 其鹽類; 其酯類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to alleviate the pain of patients with osteoarthritis and improve their conditions. The use of the drug should be decided by a doctor based on the patient's condition. 此藥用於舒緩骨關節炎病人的痛楚及改善病人的情況。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
Exenatide (艾塞那肽)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used, in combination with metformin and/or sulphonylurea drugs, for the treatment of type 2 diabetes mellitus in patients who have not achieved adequate blood sugar control despite being treated with the highest tolerated doses of the latter two drugs. Its use should be decided by a doctor.</p> <p>此藥與甲福明及／或磺酰尿類藥物混合使用，適用於治療服用後兩種藥物的最高劑量但仍未能控制血糖的二型糖尿病病人。使用該藥與否，須由醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Lapatinib; its salts (拉帕替尼; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used, in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Its use should be decided by a doctor.</p> <p>此藥與卡培他濱混合使用，適用於治療腫瘤過度表達HER2，及曾接受包括蒽環類抗生素、紫杉醇及曲妥珠單抗治療的晚期或轉移性乳癌的病人。使用該藥與否，須由醫生決定。</p>
Paliperidone; its salts (帕利哌酮;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>The drug is used for the treatment of schizophrenia. Its use should be decided by a doctor.</p> <p>此藥用於治療精神分裂症。使用該藥與否，須由醫生決定。</p>