

立法會
Legislative Council

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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 15 February 2006

**Proposed resolution under
the Pharmacy and Poisons Ordinance**

I forward for Members' consideration a proposed resolution which the Secretary for Health, Welfare and Food will move at the Council meeting of 15 February 2006 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) Regulation 2006; and
- (b) the Poisons List (Amendment) Regulation 2006.

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.

(Ray CHAN)
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 19 January 2006, be approved –

- (a) the Pharmacy and Poisons (Amendment) Regulation 2006; and
- (b) the Poisons List (Amendment) Regulation 2006.

**PHARMACY AND POISONS (AMENDMENT)
REGULATION 2006**

(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. Substances falling within the Poisons List to
which special restrictions apply under
regulations 3 and 5**

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub.
leg. A) is amended, under the heading “A” –

- (a) by adding “Erlotinib; its salts”;
- (b) by adding “Gadoxetic acid; its salts”;
- (c) by adding “Nesiritide”;
- (d) by adding “Paricalcitol; its salts; its esters; their salts”;
- (e) by adding “Pegaptanib; its salts”.

**2. Substances required by regulation 9 to be
sold by retail only upon a prescription given
by a registered medical practitioner,
registered dentist or registered
veterinary surgeon**

The Third Schedule is amended, under the heading “A” –

- (a) by adding “Erlotinib; its salts”;
- (b) by adding “Gadoxetic acid; its salts”;
- (c) by adding “Nesiritide”;
- (d) by adding “Paricalcitol; its salts; its esters; their salts”;
- (e) by adding “Pegaptanib; its salts”.

Chairman,
Pharmacy and Poisons Board

19 January 2006

Explanatory Note

This Regulation adds 5 substances respectively to the First Schedule and the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (“principal Regulation”) so that the sale and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulation.

POISONS LIST (AMENDMENT) REGULATION 2006

(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, under the heading “A” –

- (a) by adding “Erlotinib; its salts”;
- (b) by adding “Gadoxetic acid; its salts”;
- (c) by adding “Nesiritide”;
- (d) by adding “Paricalcitol; its salts; its esters; their salts”;
- (e) by adding “Pegaptanib; its salts”.

Chairman,
Pharmacy and Poisons Board

19 January 2006

Explanatory Note

This Regulation adds 5 substances under the heading “A” in Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B). Poisons listed under that heading are essentially for medicinal use. Under the Pharmacy and Poisons Ordinance (Cap. 138) such poisons may only be sold on the premises registered under the Ordinance by a registered pharmacist or in his presence and under his supervision.

**SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 15 FEBRUARY 2006**

Pharmacy and Poisons Ordinance (Cap 138)

**Pharmacy and Poisons (Amendment) Regulation 2006
Poisons List (Amendment) Regulation 2006**

Madam President,

I move that the Pharmacy and Poisons (Amendment) Regulation 2006 and the Poisons List (Amendment) Regulation 2006 as set out under my name in the paper circulated to Members be approved.

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, a registered dentist or a registered veterinary surgeon.

4. The Amendment Regulations now before members seek to amend the Poisons List in the Poisons List Regulations and the Schedules to the Pharmacy and Poisons Regulations for the purpose of imposing control on five new medicines.

5. Arising from the applications for registration of five pharmaceutical products, the Pharmacy and Poisons Board proposes to add five 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 be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions. We propose that these amendment regulations take immediate effect upon gazettal on 17 February 2006 to allow early control and sale of medicines containing these substances.

6. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under section 3 of the Ordinance to regulate the registration and control of 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) Regulation 2006

Pharmacy and Poisons (Amendment) Regulation 2006

Supplementary Information to the Legislative Council

《2006年毒藥表（修訂）規例》
《2006年藥劑業及毒藥（修訂）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
Nesiritide 奈西立肽	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat patients with acutely decompensated congestive heart failure. It should only be used when the need is established by medical diagnosis.</p> <p>此藥用於治療急性充血性心臟衰竭。此藥需經醫生確診及決定有需要時才可用藥。</p>
Pegaptanib; its salts 培加尼布; 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 neovascular (wet) age-related macular degeneration. It should only be used when the need is established by medical diagnosis.</p> <p>此藥用於與年齡有關的新血管（濕）班退化。此藥需經醫生確診及決定有需要時才可用藥。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Gadoxetic acid; its salts 釷塞酸; 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 for magnetic resonance imaging of the liver. Monitoring of patients is required during its administration and its use should be decided by a doctor when the need is confirmed.</p> <p>此藥用於肝臟的磁共振。用藥需經醫生確定需要，而病人亦需於用藥時接受觀察。</p>
Erlotinib; its salts 厄洛替尼; 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 for treatment of non-small cell lung cancer. It should only be used when the need is established by medical diagnosis</p> <p>此藥用於非小細胞肺癌。此藥需經醫生確診及決定有需要時才可用藥。</p>
Paricalcitol; its salts; its esters; their salts 帕立骨化醇;其鹽類; 其酯類; 它們的鹽類	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used for prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure. It should only be used when the need is established by medical diagnosis.</p> <p>此藥用於預防和治療次要性甲狀腺機能亢進。此藥需經醫生確診及決定有需要時才可用藥。</p>