

**立法會**  
**Legislative Council**

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Date : 9 June 2005

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

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**Council meeting of 29 June 2005**

**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 29 June 2005 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2005; and
- (b) the Poisons List (Amendment) (No. 2) Regulation 2005.

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

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**RESOLUTION**

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

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RESOLVED that the following Regulations, made by the Pharmacy  
and Poisons Board on 4 June 2005, be approved -

- (a) the Pharmacy and Poisons (Amendment)(No. 2)  
Regulation 2005; and
- (b) the Poisons List (Amendment)(No. 2) Regulation 2005.

**PHARMACY AND POISONS (AMENDMENT)(NO. 2) REGULATION 2005**

(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, in part A, by adding -

- (a) "Bevacizumab";
- (b) "Enfuvirtide";
- (c) "Melagatran; its salts; its derivatives; their salts";
- (d) "Milnacipran; 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, in part A, by adding -

- (a) "Bevacizumab";
- (b) "Enfuvirtide";
- (c) "Melagatran; its salts; its derivatives; their salts";
- (d) "Milnacipran; its salts".

Chairman,  
Pharmacy and Poisons Board

4 June 2005

**Explanatory Note**

This Regulation adds 4 substances each to the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) so that the sale and storage of the 4 substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the Regulations.

**POISONS LIST (AMENDMENT)(NO. 2) REGULATION 2005**

(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 part A, by adding -

- (a) "Bevacizumab";
- (b) "Enfuvirtide";
- (c) "Melagatran; its salts; its derivatives; their salts";
- (d) "Milnacipran; its salts".

Chairman,  
Pharmacy and Poisons Board

4 June 2005

**Explanatory Note**

This Regulation adds 4 substances to part A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B). Poisons listed in that part 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 29 JUNE 2005**

**Pharmacy and Poisons Ordinance (Cap 138)  
Pharmacy and Poisons (Amendment) Regulation (No. 2) 2005  
Poisons List (Amendment) Regulation (No. 2) 2005**

Madam President,

I move that the Poisons List (Amendment) (No. 2) Regulation 2005 and the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2005 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 four new pharmaceutical products.

5. The Pharmacy and Poisons Board proposes to add four new substances to Part I of the Poisons List, and the First and Third Schedules to the Pharmacy and Poisons Regulations so that pharmaceutical products containing such substances must be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

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) (No. 2 ) Regulation 2005**

**Pharmacy and Poisons (Amendment) (No. 2 ) Regulation 2005**

**Supplementary Information to the Legislative Council**

《 2005年毒藥表 ( 修訂 ) (第 2 號) 規例 》  
《 2005年藥劑業及毒藥 ( 修訂 ) (第 2 號) 規例 》  
提交立法會的補充資料

<b>Drug Name 藥名</b>	<b>Proposed Classification 建議類別</b>	<b>Reason 原因</b>
Bevacizumab (貝伐珠單抗)	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 the treatment of metastatic cancer of the colon or rectum. Monitoring of patients is required during its administration and its use should be decided by a doctor when the need is confirmed.</p> <p>此藥用於治療擴散性結腸及直腸癌。須經醫生決定有需要時才可用藥，而病人亦須於用藥時接受觀察。</p>



<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Enfuvirtide (恩夫韋肽)	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 the treatment of HIV-1 infections. It should only be used after established diagnosis. Pneumonia has been seen in patients treated with Enfuvirtide. Patients should be closely monitored for signs and symptoms of pneumonia.</p> <p>此藥用於治療人免疫缺陷病毒-1感染。此藥須經醫生確診後才使用。有發現服用恩夫韋肽的病人有肺炎。病人須於用藥時接受肺炎之觀察。</p>
Melagatran; its salts; its derivatives; their salts (美拉加群; 其鹽類; 其衍生物; 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 to prevent thromboembolic events after elective hip or knee replacement surgery. A doctor's decision is required as to whether or not this medicine should be used. Medical monitoring is also required during and after surgery and during treatment period.</p> <p>此藥用於自選補換髖部或膝蓋手術。此藥須由醫生決定有需要時才使用。此外，醫生亦須於手術進行時、進行後及用藥期間觀察病人。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Milnacipran; its salts (米那普侖; 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 to treat major depression in adults. It should only be used when the need is established by medical diagnosis.</p> <p>此藥用於治療成人的嚴重憂鬱症。須經醫生確診及決定有需要時才可用藥。</p>