

**立法會**  
**Legislative Council**

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Tel : 2869 9205

Date : 6 October 2004

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

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**Council meeting of 20 October 2004**

**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 20 October 2004 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004; and
- (b) the Poisons List (Amendment) (No. 3) Regulation 2004.

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

24 September 2004, be approved –

- (a) the Pharmacy and Poisons (Amendment)(No. 3) Regulation 2004; and
- (b) the Poisons List (Amendment)(No. 3) Regulation 2004.

## **PHARMACY AND POISONS (AMENDMENT)(NO. 3) REGULATION 2004**

(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 –

"Articaine; its salts

Atazanavir; its salts

Efalizumab

Pemirolast; 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 –

"Articaine; its salts

Atazanavir; its salts

Efalizumab

Pemirolast; its salts".

Chairman,  
Pharmacy and Poisons Board

24 September 2004

**Explanatory Note**

This Regulation adds 4 substances to each of 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. 3) REGULATION 2004**

(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 –

"Articaine; its salts

Atazanavir; its salts

Efalizumab

Pemirolast; its salts".

Chairman,  
Pharmacy and Poisons Board

24 September 2004

### **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. The Pharmacy and Poisons Ordinance (Cap. 138) and its subsidiary legislation provide, among others, that 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 20 OCTOBER 2004**

**Pharmacy and Poisons Ordinance (Cap 138)  
Pharmacy and Poisons (Amendment) Regulation (No. 3) 2004  
Poisons List (Amendment) Regulation (No. 3) 2004**

Madam President,

I move that the Poisons List (Amendment) (No. 3) Regulation 2004 and the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004 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. 3) Regulation 2004

### Pharmacy and Poisons (Amendment) (No. 3) Regulation 2004

#### Supplementary Information to the Legislative Council

《 2004年毒藥表 ( 修訂 ) (第3號) 規例 》  
《 2004年藥劑業及毒藥 ( 修訂 ) (第3號) 規例 》  
提交立法會的補充資料

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Articaine; its salts (阿替卡因; 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 as a local (infiltration and nerve block) anaesthetic for dental procedures. It should only be used for this purpose and when the need is established by a dental practitioner.  此藥用作牙科手術局部 (浸潤及神經傳導阻滯) 麻醉劑。此藥應該只用於此用途及經牙醫診斷有需要時才使用。



<b>Drug Name 藥名</b>	<b>Proposed Classification 建議類別</b>	<b>Reason 原因</b>
Atazanavir; its salts (阿扎那韋; 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 HIV-1/AIDS infection in combination with other anti-HIV medications. A doctor's decision is required as to whether or not this medicine should be used after proper diagnosis. Medical monitoring is also required during administration.</p> <p>此藥用於與其它藥物一起治療 HIV-1/愛滋病感染。此藥需經醫生確診後,決定有需要時才使用。用此藥時亦需要醫生小心觀察病人。</p>
Efalizumab (依法珠單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to treat moderate to severe plaque psoriasis in adults. Use of this drug requires proper medical diagnosis and careful monitoring of its side effects.</p> <p>此藥用於治療成人之中度至嚴重性版狀牛皮癬。用此藥時需要經醫生確診及小心觀察病人有否產生副作用。</p>

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Pemirolast; its salts (吡嘑司特; 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 allergic conjunctivitis and spring catarrh. Its use requires careful monitoring of its side effects by a doctor.</p> <p>此藥用於治療敏感性結膜炎及春季結膜炎。用此藥時需由醫生小心觀察病人有否產生副作用。</p>