

# 立法會

## *Legislative Council*

LC Paper No. CB(3) 179/02-03

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Tel : 2869 9205  
Date : 28 November 2002  
From : Clerk to the Legislative Council  
To : All Members of the Legislative Council

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### **Council meeting of 18 December 2002**

#### **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 18 December 2002 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2002; and
- (b) the Poisons List (Amendment) (No. 5) Regulation 2002.

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 draft speech, in both English and Chinese versions, which the Secretary for Health, Welfare and Food 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 -

- (a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2002; and
- (b) the Poisons List (Amendment) (No. 5) Regulation 2002, made by the Pharmacy and Poisons Board on 25 November 2002, be approved.

**PHARMACY AND POISONS (AMENDMENT) (NO. 5) REGULATION 2002**

(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.) is amended in part A by adding -

"Infliximab

Tiotropium; its salts

Trastuzumab".

**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 -

"Infliximab

Tiotropium; its salts

Trastuzumab".

(Dr Margaret CHAN)  
Chairman,  
Pharmacy and Poisons Board

25 November 2002

### **Explanatory Note**

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) by adding to them 3 substances respectively.

## **POISONS LIST (AMENDMENT) (NO. 5) REGULATION 2002**

(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.) is amended, in Part I, in part A, by adding -

"Infliximab

Sertaconazole; its salts

Tiotropium; its salts

Trastuzumab".

(Dr Margaret CHAN)  
Chairman,  
Pharmacy and Poisons  
Board

25 November 2002

### **Explanatory Note**

This Regulation amends the Schedule to the Poisons List  
Regulations (Cap. 138 sub. leg.) by adding 4 substances to part  
A of Part I of the Poisons List.

## Poisons List (Amendment) (No. 5) Regulation 2002

## Pharmacy and Poisons (Amendment) (No. 5) Regulation 2002

### Supplementary Information to the Legislative Council

《 2002 年毒藥表 ( 修訂 ) ( 第 5 號 ) 規例 》

《 2002 年藥劑業及毒藥 ( 修訂 ) ( 第 5 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
Sertaconazole 舍他康唑	Part I poison 第一部毒藥	<p>This drug is used for the treatment of superficial fungal infection of the skin. Professional advice from a pharmacist to ascertain the fungal infection and for proper usage of this medicine is required.</p> <p>此藥用於治療皮膚表層之真菌感染症。需經藥劑師確認受真菌感染並指導正確的用藥方法，才可使用此藥。</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>
<b>Infliximab</b> <b>因福利美</b>	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 the treatment of rheumatoid arthritis and Crohn's disease when conventional treatment is not sufficient. This drug should only be used when the need is established by a medical diagnosis. Use of this medicine requires careful medical monitoring.</p> <p>此藥用於治療當其它常用藥物未能有足夠療效之風濕性關節炎及克隆氏病。需經醫生清楚診斷有需要時，才能使用此藥物。用此藥時，醫護人員需要小心觀察病人。</p>
<b>Tiotropium</b> <b>噻托</b>	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 the maintenance of conditions such as asthma, chronic bronchitis and emphysema. A doctor's decision and supervision is required on the use of this medicine.</p> <p>此藥用於控制哮喘,慢性支氣管炎,及肺氣腫等症。選用此藥需經醫生決定，並由醫生在使用過程中小心觀察。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Trastuzumab 曲妥珠單抗	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This drug is used for the treatment of breast cancer when conventional therapy fails. This drug should only be used when the need is established by a medical diagnosis. Use of this medicine requires careful medical monitoring.</p> <p>此藥用於當其它常用藥物未能有足夠療效時作治療乳癌用。需經醫生清楚診斷有需要時，才能使用此藥物。用此藥時，醫護人員需要小心觀察病人。</p>



**SPEECH BY**  
**THE SECRETARY FOR HEALTH, WELFARE AND FOOD**  
**AT THE LEGISLATIVE COUNCIL**  
**ON 18 DECEMBER 2002**

**Pharmacy and Poisons Ordinance (Cap 138)**

**Poisons List (Amendment) (No. 5) Regulation 2002**

**Pharmacy and Poisons (Amendment) (No. 5) Regulation 2002**

Madam President,

I move that the Poisons List (Amendment) (No. 5) Regulation 2002 and the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2002 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 medicines.

5. The Pharmacy and Poisons Board proposes to add one new substance to Part I of the Poisons List so that pharmaceutical products containing this substance must be sold in pharmacies under the supervision of registered pharmacists. In addition, the Board proposes to add three 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 any of them 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.