# 立法會

# Legislative Council

LC Paper No. CB(3) 425/02-03

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Tel: 2869 9205

Date: 27 February 2003

From: Clerk to the Legislative Council

To : All Members of the Legislative Council

#### **Council meeting of 19 March 2003**

#### 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 19 March 2003 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) Regulation 2003; and
- (b) the Poisons List (Amendment) Regulation 2003.

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 -

- (a) the Pharmacy and Poisons (Amendment) Regulation 2003; and
- (b) the Poisons List (Amendment) Regulation 2003, made by the Pharmacy and Poisons Board on 25 February 2003, be approved.

#### PHARMACY AND POISONS (AMENDMENT) REGULATION 2003

(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 -

"Drotrecogin alfa

Tegaserod; its salts

Thymosin alpha 1".

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 -

"Drotrecogin alfa

Tegaserod; its salts

Thymosin alpha 1".

# (Dr Margaret CHAN) Chairman, Pharmacy and Poisons Board

25 February, 2003

#### 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) REGULATION 2003

(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)

#### 3. The Poisons List

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) is amended, in Part I, in part A, by adding -

"Drotrecogin alfa

Tegaserod; its salts

Thymosin alpha 1".

(Dr Margaret CHAN)
Chairman,
Pharmacy and Poisons Board

25 February, 2003

#### Explanatory Note

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) by adding 3 substances to part A of Part I of the Poisons List.

# Poisons List (Amendment) Regulation 2003

# Pharmacy and Poisons (Amendment) Regulation 2003

# **Supplementary Information to the Legislative Council**

# 《2003年毒藥表(修訂)規例》

# 《2003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
Drotrecogin alfa	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used for the treatment of adult patients with severe sepsis who have a high risk of death. A medical decision is required for the use of this medicine.
		此藥用於治療有高度死亡風險之成 年敗血病病人。選用此藥需經醫生 決定。

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Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Tegaserod 替加色羅	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used for the treatment of constipation-predominant irritable bowel syndrome in female patients. This drug should only be used when the need is established by a medical diagnosis.
		此藥用於治療女性以便秘爲主徵之 應激性腸綜合徵。此藥應經醫生診 斷有需要時才用。
Thymosin alpha 1 胸腺月太 α 1	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This medicine is used to augment the effect of influenza and hepatitis B vaccination given to patients with impaired immunity. This drug should only be used when the need is established by a medical diagnosis.
		此藥用於免疫系統功能不全的病人 注射感冒及肝炎預防疫苗時之佐 劑,以加強其效力。需經醫生淸楚 診斷有需要時,才應使用此藥物。

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# SPEECH BY THE SECRETARY FOR HEALTH, WELFARE AND FOOD AT THE LEGISLATIVE COUNCIL ON 19 MARCH 2003

Pharmacy and Poisons Ordinance (Cap 138)

Poisons List (Amendment) Regulation 2003 Pharmacy and Poisons (Amendment) Regulation 2003

Madam President,

I move that the Poisons List (Amendment) Regulation 2003 and the Pharmacy and Poisons (Amendment) Regulation 2003 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.

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- 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 three new medicines.
- 5. The Pharmacy and Poisons 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.

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