# 立法會
# *Legislative Council*

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Tel : 2869 9205

Date : 24 May 2010

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

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**Council meeting of 9 June 2010**

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

I forward for Members' consideration a proposed resolution which the Secretary for Food and Health will move at the Council meeting of 9 June 2010 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2010; and

(b) the Poisons List (Amendment) (No. 2) Regulation 2010.

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.

( Mrs Justina LAM )
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 19 May 2010, be approved –

(a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2010; and

(b) the Poisons List (Amendment) (No. 2) Regulation 2010.

# PHARMACY AND POISONS (AMENDMENT) (NO. 2) REGULATION 2010

(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. First Schedule amended**

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended, in Division A –

(a) by adding "Arsenic trioxide when contained in pharmaceutical products";

(b) by adding "Canakinumab".

**2. Third Schedule amended**

The Third Schedule is amended, in Division A –

(a) by adding "Arsenic trioxide when contained in pharmaceutical products";

(b) by adding "Canakinumab".

Chairman,
Pharmacy and Poisons Board

19 May 2010

**Explanatory Note**

This Regulation adds 2 substances to Divisions A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulations") respectively so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

# POISONS LIST (AMENDMENT) (NO. 2) REGULATION 2010

(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 Division A –

(a) by adding "Arsenic trioxide when contained in pharmaceutical products";

(b) by adding "Canakinumab".

Chairman,
Pharmacy and Poisons Board

19 May 2010

**Explanatory Note**

This Regulation adds 2 substances to Division A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) so that, among other applicable requirements, poisons containing those substances can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the pharmacist's presence and under the pharmacist's supervision.

**SPEECH BY**
**THE SECRETARY FOR FOOD AND HEALTH**
**AT THE LEGISLATIVE COUNCIL**
**ON 9 JUNE 2010**

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

**Pharmacy and Poisons (Amendment) (No. 2) Regulation 2010**
**Poisons List (Amendment) (No. 2) Regulation 2010**

Mr President,

I move that the motion under my name, as printed on the Agenda, be passed.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and monitoring 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 under 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, dentist or veterinary surgeon.

4. Arising from an application for registration of two pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following two substances to Part I of the Poisons List and

the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Arsenic trioxide when contained in pharmaceutical products

(b) Canakinumab.

5. Pharmaceutical products containing the above substances must then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. We propose that these amendment regulations take immediate effect upon gazettal on 11 June 2010 to allow early control and sale of the relevant medicine.

7. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under the Ordinance to regulate 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 medicine concerned.

8. With these remarks, Mr President, I move the motion.

**Poisons List (Amendment) (No. 2) Regulation 2010**

**Pharmacy and Poisons (Amendment) (No. 2) Regulation 2010**

**Supplementary Information to the Legislative Council**

**《2010年毒藥表（修訂）(第二號) 規例》**
**《2010年藥劑業及毒藥（修訂）(第二號) 規例》**
**提交立法會的補充資料**

| **Drug Name**<br>**藥名** | **Proposed Classification**<br>**建議類別** | **Reason**<br>**原因** |
|---|---|---|
| Arsenic trioxide when contained in pharmaceutical products<br><br>(三氧化二砷，限於包含在藥劑製品內者) | Part I, First and Third Schedules poison<br>第一部附表一及附表三毒藥 | This drug is used in the treatment of patients with acute promyelocytic leukemia (APL). Side effects include rashes and gastrointestinal upset. This drug may also cause prolonged QT interval on an electrocardiogram (irregular heart beat), increased levels of liver enzymes. This drug should only be used upon medical judgment.<br><br>此藥物用於治療急性早幼粒細胞白血病(APL)的病人。副作用包括出疹及腸胃道不適。此藥物亦可能引致心電圖的QT間期延長（心跳不規則）、肝酶水平升高。需經醫生清楚診斷適用時，才能使用此藥物。 |

| **Drug Name**<br>**藥名** | **Proposed Classification**<br>**建議類別** | **Reason**<br>**原因** |
|---|---|---|
| Canakinumab<br><br>(卡那奴單抗) | Part I, First and Third Schedules poison<br><br>第一部附表一及附表三毒藥 | This drug is used to treat cryopyrin-associated periodic syndromes (CAPS). CAPS are a group of diseases where patients have a defect in the gene that produces a protein called cryopirin. This leads to inflammation in many parts of the body, with symptoms such as fever, rash, joint pain and tiredness. Severe disabilities such as deafness and loss of vision may also occur. Side effects include vertigo (a spinning sensation), nasopharyngitis (inflammation of the nose and throat), and reactions at the injection site. A medical decision is required for the use of this medicine.<br><br>此藥物用以治療cryopyrin相關周期性綜合症(CAPS)(下稱綜合症)。該綜合症是一組疾病，患者身上製造名爲cryopirin蛋白質的基因出現缺損，引致身體多處發炎，徵狀包括發燒、出疹、關節痛及疲倦。嚴重的身體殘障(如耳聾及失明)亦可能會出現。副作包括眩暈(旋轉的感覺) 、鼻咽炎(鼻子及喉嚨發炎)及注射部位的反應。選用此藥與否需經醫生決定。 |