

立法會

Legislative Council

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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 12 July 2006

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 12 May 2006 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2006; and
- (b) the Poisons List (Amendment) (No. 3) Regulation 2006.

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

RESOLUTION

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

RESOLVED that the following Regulations, made by the Pharmacy and Poisons Board on 26 June 2006, be approved –

- (a) the Pharmacy and Poisons (Amendment)(No. 3) Regulation 2006; and
- (b) the Poisons List (Amendment)(No. 3) Regulation 2006.

PHARMACY AND POISONS (AMENDMENT)(NO. 3) REGULATION 2006

(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, under the heading “A” –

- (a) by adding “Alemtuzumab”;
- (b) in the item relating to “Antisera, antitoxins, immunoglobulins and vaccines”, by adding “Rotavirus vaccines” after “Pneumococcal vaccines”;
- (c) by adding “Deferasirox; its salts; its esters; their 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, under the heading “A” –

- (a) by adding “Alemtuzumab”;
- (b) in the item relating to “Antisera, antitoxins, immunoglobulins and vaccines”, by adding “Rotavirus vaccines” after “Pneumococcal vaccines”;

- (c) by adding “Deferasirox; its salts; its esters; their salts”.

Chairman,
Pharmacy and Poisons Board

26 June 2006

Explanatory Note

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (“the principal Regulations”) to add 3 substances to the First and Third Schedules respectively so that the sale 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. 3)
REGULATION 2006**

(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

(1) The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, under the heading “A” –

- (a) by adding “Alemtuzumab”;
- (b) by repealing –
“para-Aminobenzoic acid, esters of; their salts”
and substituting –
“para-Aminobenzoic acid, esters of; their salts; except
benzocaine when contained in condoms”;
- (c) in the item relating to “Antisera, antitoxins,
immunoglobulins and vaccines”, by adding “Rotavirus
vaccines” after “Pneumococcal vaccines”;
- (d) by adding “Deferasirox; its salts; its esters; their salts”.

(2) The Schedule is amended, in Part II, under the heading “A”, by adding –

“Benzocaine when contained in condoms”.

Chairman,
Pharmacy and Poisons Board

26 June 2006

Explanatory Note

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (“principal Regulations”) –

- (a) to add 3 substances under the heading “A” in Part I of the Poisons List set out in the Schedule to the principal Regulations so that poisons containing those substances can only be sold on premises of authorized sellers of poisons by registered pharmacists or in his presence and under his supervision; and
- (b) to relax the control of benzocaine when it is contained in condoms such that the sale of condoms containing benzocaine is not required to be conducted on premises of authorized sellers of poisons by registered pharmacists or in his presence and under his supervision.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 12 JULY 2006

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2006
Poisons List (Amendment) (No. 3) Regulation 2006

Madam President,

I move that the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2006 and the Poisons List (Amendment) (No. 3) Regulation 2006 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 three new medicines and relaxing the control on one medicine.

5. Arising from the applications for registration of three pharmaceutical products, the Pharmacy and Poisons Board proposes to add three substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations. Pharmaceutical products containing any of these substances must be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. In addition, the Pharmacy and Poisons Board proposes to relax the control on Benzocaine when contained in condoms. At present, pharmaceutical products containing Benzocaine are classified in Part I of the Poisons List. That is to say, they must be sold in pharmacies in the presence and under the supervision of a registered pharmacist with sale records kept.

7. As the amount of Benzocaine contained in condoms is far below the toxic dose, the Board considers that the risk of over-dosage of Benzocaine from condoms is very low. Therefore the Board intends to reclassify Benzocaine when contained in condoms as Part II poison, so that they can be sold in both pharmacies and medicine companies.

8. We propose that these amendment regulations take immediate effect upon gazettal on 14 July 2006 to allow early control and sale of the relevant medicines.

9. 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.

10. With these remarks, Madam President, I move the motion.

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2006

Poisons List (Amendment) (No. 3) Regulation 2006

Supplementary Information to the Legislative Council

《2006年藥劑業及毒藥(修訂)(第3號)規例》

《2006年毒藥表(修訂)(第3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
Alemtuzumab (阿侖珠單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for treatment of patients with chronic lymphocytic leukaemia (CLL). It should only be used when the need is established by medical diagnosis. Close monitoring of patient is necessary. 此藥用於治療慢性淋巴細胞的白血病，用藥需經醫生診斷，而病人亦需於用藥時接受觀察。
Antisera, antitoxins, immunoglobulins and vaccines (a) the following- Rotavirus vaccines (抗血清、抗毒素、免疫球蛋白與疫苗如下— (a) 如下抗血清、抗毒素、免疫球蛋白與疫苗— 輪狀病毒疫苗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Used for immunization in infants against gastro-enteritis due to rotavirus infection. The use should be decided and monitored by a doctor. 用於因輪狀病毒感染腸胃炎的嬰兒免疫。用藥需經醫生確定及觀察。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Deferasirox; its salts; its esters; their salts (地拉羅司; 其鹽類; 其酯類; 它們的鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表 三毒藥	This drug is used for treatment of transfusion-induced haemosiderosis. It should only be used when the need is confirmed by a doctor. 此藥用於治療輸血引致的血鐵質沉 着。用藥需經醫生確定需要。