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 17 May 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 17 May 2006 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2006; and

(b) the Poisons List (Amendment) (No. 2) 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 April 2006, be approved –

(*a*) the Pharmacy and Poisons (Amendment)(No. 2) Regulation 2006; and

(*b*) the Poisons List (Amendment)(No. 2) Regulation 2006.

PHARMACY AND POISONS (AMENDMENT)(NO. 2) 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*) in the item relating to "Alkaloids", by repealing –

"Nicotine, except chewing gum intended to be used in nicotine replacement therapy which contains not more than 2 mg of Nicotine per piece"

and substituting –

"Nicotine (except chewing gums and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece)";

(*b*) by adding "Everolimus; its salts; its esters; their salts";

(*c*) by adding "Omalizumab";

(*d*) by adding "Pegvisomant; its salts";

(*e*) by adding "Solifenacin; 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 "Everolimus; its salts; its esters; their salts";

(*b*) by adding "Omalizumab";

(*c*) by adding "Pegvisomant; its salts";

(*d*) by adding "Solifenacin; its salts; its esters; their salts".

Chairman,
Pharmacy and Poisons Board

26 April 2006

Explanatory Note

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulation") –

(*a*) to relax the control of Nicotine where it is intended to be used in nicotine replacement therapy and in the form of lozenges containing not more than 2 mg of Nicotine per piece; and

(*b*) to add 4 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 Regulation.

POISONS LIST (AMENDMENT)(NO. 2) 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*) in the item relating to "Alkaloids", by repealing –

"Nicotine, except chewing gum intended to be used in nicotine replacement therapy which contains not more than 2 mg of Nicotine per piece"

and substituting –

"Nicotine (except chewing gums and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece)";

(*b*) by adding "Everolimus; its salts; its esters; their salts";

(*c*) by adding "Omalizumab";

(*d*) by adding "Pegvisomant; its salts";

(*e*) by adding "Solifenacin; its salts; its esters; their salts".

(2) The Schedule is amended, in Part II, under the heading "A", by repealing –

"Nicotine: chewing gum intended to be used in nicotine replacement therapy which contains not more than 2 mg of Nicotine per piece"

and substituting –

"Nicotine: chewing gums and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece".

Chairman,
Pharmacy and Poisons Board

26 April 2006

Explanatory Note

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

(*a*) to relax the control of Nicotine where it is intended to be used in nicotine replacement therapy and in the form of lozenges containing not more than 2 mg of Nicotine per piece; and

(*b*) to add 4 substances under the heading "A" in Part I of the Poisons List set out in the Schedule to the principal Regulation. (Poisons listed under the heading "A" are essentially for medicinal use. Under the Pharmacy and Poisons Ordinance (Cap. 138) 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 17 MAY 2006

Pharmacy and Poisons Ordinance (Cap 138)

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2006
Poisons List (Amendment) (No. 2) Regulation 2006

Madam President,

I move that the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2006 and the Poisons List (Amendment) (No. 2) 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 four new medicines and relaxing the control of one medicine.

5. Arising from the applications for registration of four pharmaceutical products, the Pharmacy and Poisons Board proposes to add four 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 certain lozenges (i.e. medicinal tablets) used as nicotine replacement therapies. At present, lozenges containing not more than 2mg of Nicotine per piece are classified in Part I of the Poisons List and in the First Schedule to the Pharmacy and Poisons Regulations. That is to say, among other controls, they must be kept in a locked receptacle and sold in pharmacies in the presence and under the supervision of a registered pharmacist with sale records kept.

7. On the other hand, chewing gums containing not more than 2 mg of Nicotine per piece are currently classified as Part II poisons. That is to say, they can be sold in pharmacies and in other medicines retail outlets, and no pharmacist supervision or record-keeping of sale is required. While the level of control differs, there is sufficient medical evidence showing that there is no material difference between the lozenges and the chewing gums in terms of potency, toxicity and potential side effects. Therefore we intend to reclassify the above lozenges as Part II poisons.

8. We propose that these amendment regulations take immediate effect upon gazettal on 19 May 2006 to allow early control and sale of medicines 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.

Poisons List (Amendment) (No. 2) Regulation 2006

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2006

Supplementary Information to the Legislative Council

《2006年毒藥表（修訂）(第 2 號) 規例》
《2006年藥劑業及毒藥（修訂）(第 2 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**
Everolimus; its salts; its esters; their salts 依維莫司; 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 the prophylaxis of organ transplant rejection. Its use should be decided by a doctor when the need is confirmed, and monitoring of the patient is required during its administration. 此藥用於預防器官移植排斥。用藥需經醫生確定需要, 而病人亦需於用藥時接受觀察。
Omalizumab 奧馬珠單抗	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for patients with moderate to severe persistent asthma who have had a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. It should only be used when the need is established by medical diagnosis. 此藥用於中度至嚴重性持續哮喘的病人，對非季節性的過敏原的皮膚測試或體外測試必須呈陽性反應。吸入性皮質類固醇亦不足以控制其症狀。此藥需經醫生確診及決定有需要時才可用。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Pegvisomant; its salts 培維索孟; 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 in the treatment of patients with acromegaly. It should only be used when the need is established by medical diagnosis. 此藥用治療有肢端肥大症的病人。此藥需經醫生確診及決定有需要時才可用藥
Solifenacin; its salts; its esters; their salts 索利那新;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 the symptomatic treatment of urge incontinence and increased urinary frequency and urgency. Its use should be decided by a doctor when the need is confirmed. 此藥用治療緊急失禁及泌尿頻率和緊急加增的症狀。用藥需經醫生確定需要。