立法會
Legislative Council

LC Paper No. CB(3) 180/06-07

Ref : CB(3)/M/OR

Tel : 2869 9205

Date : 29 November 2006

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 20 December 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 20 December 2006 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2006; and

(b) the Poisons List (Amendment) (No. 5) 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.

(Mrs Justina LAM)
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 27 November 2006, be approved –

(*a*) the Pharmacy and Poisons (Amendment)(No. 5) Regulation 2006; and

(*b*) the Poisons List (Amendment)(No. 5) Regulation 2006.

PHARMACY AND POISONS (AMENDMENT)(NO. 5) 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 "Entecavir; its salts; its esters; their salts";

(*b*) by adding "Micafungin; its salts; its esters".

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 "Entecavir; its salts; its esters; their salts";

(*b*) by adding "Micafungin; its salts; its esters".

Chairman,
Pharmacy and Poisons Board

27 November 2006

Explanatory Note

This Regulation adds 2 substances to the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("the principal Regulations") 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. 5) 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

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

(*a*) by adding "Entecavir; its salts; its esters; their salts";

(*b*) by adding "Micafungin; its salts; its esters".

Chairman,
Pharmacy and Poisons Board

27 November 2006

Explanatory Note

This Regulation adds 2 substances under the heading "A" in Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B), 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.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 20 DECEMBER 2006

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment)(No. 5) Regulation 2006
Poisons List (Amendment)(No. 5) Regulation 2006

Madam 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 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. Arising from two applications for registration pharmaceutical products, the Pharmacy and Poisons Board proposes to add two 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 then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

5. We propose that these amendment regulations take immediate effect upon gazettal on 22 December 2006 to allow early control and sale of the relevant medicines.

6. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under 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.

Poisons List (Amendment) (No. 5) Regulation 2006

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2006

Supplementary Information to the Legislative Council

《2006年毒藥表（修訂）(第 5 號) 規例》
《2006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
Entecavir; its salts; its esters; their salts (恩替卡韋; 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	For the treatment of chronic hepatitis B infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. It should only be used when the need is established by medical diagnosis. 用於治療有證據顯示體內乙型肝炎病毒複製情況活躍，及血清轉氨酶(丙氨酸轉氨酶或天冬氨酸轉氨酶)水平持續上升或組織學重症的慢性乙型肝炎成年人。此藥需經醫生確診及決定有需要時才可使用。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reason** 原因
Micafungin; its salts; its esters (米卡芬淨; 其鹽類; 其酯類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	For the treatment of patients with esophageal candidiasis. In the prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation. It should only be used when the need is established by medical diagnosis. 適用於治療患食道念珠菌病的病人。用於進行造血幹細胞移植的病人，以預防念珠菌感染。此藥需經醫生確診及決定有需要時才可使用。