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Legislative Council

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Date : 18 April 2008

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 7 May 2008

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 7 May 2008 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2008; and

(b) the Poisons List (Amendment) (No. 2) Regulation 2008.

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.

(Ms Miranda HON)
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 15 April 2008, be approved–

(*a*) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2008; and

(*b*) the Poisons List (Amendment) (No. 2) Regulation 2008.

PHARMACY AND POISONS (AMENDMENT) (NO. 2) REGULATION 2008

(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, by adding "Raltegravir; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A, by adding "Raltegravir; its salts".

Chairman,
Pharmacy and Poisons Board

15 April 2008

Explanatory Note

This Regulation adds a new item 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, supply, labelling and storage of raltegravir or its salts are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

POISONS LIST (AMENDMENT) (NO. 2) REGULATION 2008

(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, by adding "Raltegravir; its salts".

Chairman,
Pharmacy and Poisons Board

15 April 2008

Explanatory Note

This Regulation adds a new item in 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 poisons containing raltegravir or its salts can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in his presence and under his supervision.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 7 MAY 2008

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2008
Poisons List (Amendment) (No. 2) Regulation 2008

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 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 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, dentist or veterinary surgeon.

4. Arising from an application for registration of a pharmaceutical product, the Pharmacy and Poisons Board proposes to add raltegravir and its salts to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations. Pharmaceutical products containing this substance 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 9 May 2008 to allow early control and sale of the relevant medicine.

6. 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.

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

Poisons List (Amendment) (No. 2) Regulation 2008

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2008

Supplementary Information to the Legislative Council

《2008年毒藥表（修訂）(第 2 號) 規例》
《2008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**
Raltegravir; its salts (拉替拉韋; 其鹽類)	Part I, First and Third Schedules poisons 第一部附表一及附表三毒藥	This drug is used in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who evidently have viral replication and HIV-1 strains resistant to multiple antiretroviral agents. The use of the drug should be decided by a doctor. 此藥與其他抗逆轉錄病毒藥物混合使用，適用於治療曾接受治療的成年病人的愛滋病病毒一型(HIV-1)感染，而該等病人明顯有病毒複製的情況及對多重抗逆轉錄病毒藥物有抗藥性的HIV-1型病毒毒株。使用該藥與否，應由醫生決定。