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Legislative Council

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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 2 July 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 2 July 2008 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2008; and

(b) the Poisons List (Amendment) (No. 3) 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.

(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 6 June 2008, be approved –

(*a*) the Pharmacy and Poisons (Amendment)(No. 3) Regulation 2008; and

(*b*) the Poisons List (Amendment)(No. 3) Regulation 2008.

PHARMACY AND POISONS (AMENDMENT) (NO. 3) 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 –

(*a*) by adding "Maraviroc; its salts";

(*b*) by adding "Nilotinib; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Maraviroc; its salts";

(*b*) by adding "Nilotinib; its salts".

Chairman,
Pharmacy and Poisons Board

6 June 2008

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, 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. 3) 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 –

(*a*) by adding "Maraviroc; its salts";

(*b*) by adding "Nilotinib; its salts".

Chairman,
Pharmacy and Poisons Board

6 June 2008

Explanatory Note

This Regulation adds 2 substances 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 those substances 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 2 JULY 2008

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2008
Poisons List (Amendment) (No. 3) 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 two pharmaceutical products, the Pharmacy and Poisons Board proposes to add maraviroc and its salts, as well as nilotinib 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 these two 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 4 July 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 medicines concerned.

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

Poisons List (Amendment) (No. 3) Regulation 2008

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2008

Supplementary Information to the Legislative Council

《2008年毒藥表（修訂）(第 3 號) 規例》
《2008年藥劑業及毒藥（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**
Maraviroc; its salts (馬拉韋羅；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 combination with other antiviral drugs, to treat adults with Acquired Immune Deficiency Syndrome (AIDS). AIDS virus can only reproduce itself within human blood cells. This drug blocks the entry of AIDS virus (the CCR5-tropic virus) into the cells. When used in combination with other antiviral drugs, this drug reduces the level of virus in the blood and keeps it at a low level. This drug does not cure AIDS but delays the damage to the immune system and the development of diseases associated with AIDS. Its use should be decided by a doctor. 此藥與其他抗病毒藥混合使用，用以治療成人愛滋病。愛滋病病毒只能在血細胞內繁殖。此藥能阻礙愛滋病病毒(CCR5-tropic病毒)進入人體血細胞。當此藥與其他抗病毒藥混合使用時，可減少病毒在血液裡的數量及可把病毒數量保持在低水平。此藥不能根治愛滋病，但能延遲愛滋病對免疫系統的破壞，及延遲其他與愛滋病相關疾病的發展。使用該藥與否，應由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Nilotinib; its salts (尼洛替尼; 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 to treat adults with chronic myelogenous leukaemia (CML), a type of cancer of the white blood cells where granulocytes (a type of white blood cell) start growing out of control. This drug is used when all of the following three criteria are fulfilled: (1) 'Philadelphia chromosome' test in patients is positive; (2) CML is in 'chronic' or 'accelerated' phase; and (3) Patients cannot tolerate other treatments such as imatinib (another anticancer medicine), or when their disease is not responding to treatment. The use of this drug should be decided by a doctor. 此藥用於治療成人慢性骨髓性白血病(簡稱CML)。CML是一種白血球癌病，白血球粒性細胞生長失控。當病人符合下列三種情況時方可用此藥: (1) 病人對費城染色體測試呈陽性; (2) CML處於「慢性期」或「加速期」; 及 (3) 當病人對其他抗癌治療如伊馬替尼(另一種抗癌藥) 出現不耐受，或癌病對治療沒反應。 使用該藥與否，應由醫生決定。