立法會
Legislative Council

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Tel : 2869 9205

Date : 8 June 2007

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 27 June 2007

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 27 May 2007 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2007; and

(b) the Poisons List (Amendment) (No. 3) Regulation 2007.

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 5 June 2007, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2007; and

(*b*) the Poisons List (Amendment) (No. 3) Regulation 2007.

PHARMACY AND POISONS (AMENDMENT)(NO. 3) REGULATION 2007

(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 "Agalsidase beta";

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

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Agalsidase beta";

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

Chairman,
Pharmacy and Poisons Board

5 June 2007

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 2007

(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 "Agalsidase beta";

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

Chairman,
Pharmacy and Poisons Board

5 June 2007

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 premises of authorized sellers of poisons 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 27 JUNE 2007

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment)(No. 3) Regulation 2007
Poisons List (Amendment)(No. 3) Regulation 2007

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, dentist or a veterinary surgeon.

4. Arising from two applications for registration of 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 29 June 2007 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 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 2007
Pharmacy and Poisons (Amendment)(No. 3) Regulation 2007

Supplementary Information to the Legislative Council

《2007年毒藥表（修訂）（第 3 號）規例》
《2007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**
Agalsidase beta 阿加糖酶β	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	The drug is used on patients with Fabry disease, caused by a deficiency of an enzyme. Its use should be decided and monitored by a doctor. 此藥適用於治療缺乏一種酵素的法布里病患者。使用該產品與否，須由醫生決定及監察。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Dasatinib; its salts 達沙替尼; 其鹽類	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	The drug is used for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy including imatinib. It is also used for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy. Its use should be decided and monitored by a doctor. 適用於治療慢性期、加速期或骨髓或淋巴急變期的慢性骨髓性白血病的成年患者，而患者對先前的治療包括imatinib(伊馬替尼)呈現耐藥性或不耐性。 此藥亦適用於治療伴有費城染色體的急性淋巴細胞白血病的成年患者，而患者對先前的治療呈現耐藥性或不耐性。使用該產品與否，須由醫生決定及監察。