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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 12 March 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 12 March 2008 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) Regulation 2008; and

(b) the Poisons List (Amendment) 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 15 February 2008, be approved –

(*a*) the Pharmacy and Poisons (Amendment) Regulation 2008; and

(*b*) the Poisons List (Amendment) Regulation 2008.

PHARMACY AND POISONS (AMENDMENT) 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 "Alglucosidase alfa";

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

(*c*) by adding "Laronidase";

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

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Alglucosidase alfa";

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

(*c*) by adding "Laronidase";

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

Chairman,
Pharmacy and Poisons Board

15 February 2008

Explanatory Note

This Regulation adds a number of 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) 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 repealing "Cetirizine" under "Antihistamine substances, the following; their salts; any compound with any substance falling within this item –";

(*b*) by adding "Alglucosidase alfa";

(*c*) by adding "Aliskiren; its salts; its esters; their salts";

(*d*) by adding "Laronidase";

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

Chairman,
Pharmacy and Poisons Board

15 February 2008

Explanatory Note

This Regulation amends the list of 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 –

(*a*) poisons containing the substance removed from the list can be sold by authorized sellers of poisons on registered

premises without involving a registered pharmacist, or by listed sellers of poisons; and

(*b*) poisons containing those substances added to the list 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 12 MARCH 2008

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) Regulation 2008
Poisons List (Amendment) 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 four applications for registration of

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 then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

5. In addition, the Pharmacy and Poisons Board proposes to relax the control of cetirizine. At present, cetirizine is classified in Part I of the Poisons List, and can only be sold in pharmacies in the presence and under the supervision of a registered pharmacist. Cetirizine is an antihistamine drug used for the relief of nasal and skin allergies. As nasal and skin allergies are transient and can be self-diagnosed by patients, we propose reclassifying cetirizine as Part II poisons, so that it can be sold by pharmacies as well as medicine companies, and its sale would not be required to be conducted in the presence and under the supervision of registered pharmacists.

6. We propose that these amendment regulations take immediate effect upon gazettal on 14 March 2008 to allow early control and sale of the relevant medicines.

7. 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.

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

Poisons List (Amendment) Regulation 2008

Pharmacy and Poisons (Amendment) Regulation 2008

Supplementary Information to the Legislative Council

《2008年毒藥表（修訂）規例》
《2008年藥劑業及毒藥（修訂）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**
Alglucosidase alfa (阿糖苷酶α)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used in patients with Pompe disease (α-glucosidase deficiency). This drug has been shown to improve ventilator-free survival in patients with infantile-onset Pompe disease as compared to an untreated historical control, whereas use in patients with other forms of Pompe disease has not been adequately studied to assure safety and efficacy. The use of this drug should be decided by a doctor. 此藥適用於治療龐貝氏症(葡萄糖甘酵母缺乏症)患者。與無接受治療的歷史性對照組比較，此產品可以提高嬰兒期發病的龐貝氏症患者在無須使用呼吸器下的存活率。不過，此藥在用以治療其他類型的龐貝氏症患者方面未有充分研究，不能確保其安全性和療效。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**
Aliskiren; its salts; its esters; their salts (阿利吉侖; 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 treatment of essential hypertension. Its use should be decided by a doctor. 此藥適用於用以治療自發性高血壓。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**
Laronidase (拉羅尼酶)	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 Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of using this drug for treating mildly affected patients with the Scheie form have not been established. It has been shown to improve pulmonary function and walking capacity. The use of this drug should be decided by a doctor. 此藥適用於治療Hurler氏病及Hurler-Scheie亞型的黏多醣症第一型(MPS1)患者，以及症狀屬中度至嚴重的Scheie亞型患者。用以治療病情輕微的Scheie亞型患者的風險及好處仍未確立。此藥可以改善患者的肺功能及步行能力。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**
Posaconazole; its salts; its esters; their salts (泊沙康唑；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 treatment of the following fungal infections in adults : - Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; - Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; - Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; - Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products; - Oropharyngeal candidiasis: as first-line therapy in patients who have severe disease or are immunocompromised, in whom response to topical therapy is expected to be poor. prophylaxis of invasive fungal infections in the following patients: - Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; - Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections. The use of this drug should be decided by a doctor.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
		此藥用以治療受下列真菌感染的成年患者： - 侵襲性曲菌病：患有兩性霉素B或伊曲康唑均難以治療的疾病的病人，或對這些藥用產品不耐受的病人； - 鐮孢菌病：患有兩性霉素B難以治療的疾病的病人，或對兩性霉素B不耐受的病人； - 著色真菌病及足分支菌病：患有伊曲康唑難以治療的疾病的病人，或對伊曲康唑不耐受的病人； - 球孢子菌病：患有兩性霉素B、伊曲康唑或氟康唑均難以治療的疾病的病人，或對這些藥用產品不耐受的病人； - 口咽念珠菌病：適用於患有嚴重疾病或免疫力缺陷疾病並預期對局部治療反應欠佳的病人，作爲第一線治療。 作爲下列病人受侵襲性真菌感染的預防性治療： - 接受緩解誘導化療的急性髓細胞性白血病或骨髓增生異常綜合症病人，並預期治療會導致他們患上長期中性血細胞減少症，以及容易引發侵襲性真菌感染； - 造血幹細胞移植受贈人，他們因移植體抗宿主反應而接受高劑量免疫抑制治療，以及容易引發侵襲性真菌感染。 使用此藥與否，應由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Cetirizine 西替利嗪	From Part I poison to Part II poison 由第一部毒藥轉爲第二部毒藥	Cetirizine is an antihistamine drug used for the relief of nasal and skin allergies. As nasal and skin allergies are transient and can be self-diagnosed by the patient, pharmaceutical products containing this drug should be classified as Part II poisons, so that they can be sold from medicine companies in addition to pharmacies. 西替利嗪是一種抗組織胺藥物，適用於減輕鼻及皮膚過敏的病徵。因鼻及皮膚過敏爲短暫性，病人亦可自行診斷症狀，含西替利嗪的藥物可被列爲第二部毒藥，使其除藥房外也可在藥行發售。