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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 22 October 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 22 October 2008 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2008; and

(b) the Poisons List (Amendment) (No. 4) 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 29 September 2008, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2008; and

(*b*) the Poisons List (Amendment) (No. 4) Regulation 2008.

PHARMACY AND POISONS (AMENDMENT) (NO. 4) 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*) in the item relating to "Alkaloids", by repealing –

"Nicotine (except chewing gum and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece)"

and substituting –

"Nicotine (except when contained in (*a*) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (*b*) patches for external application, intended to be used in nicotine replacement therapy)";

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

(*c*) by adding "Etravirine";

(*d*) by adding "Fosaprepitant; its salts";

(*e*) by adding "Fulvestrant";

(*f*) by adding "Idursulfase";

(*g*) by adding "Palonosetron; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

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

(*b*) by adding "Etravirine";

(*c*) by adding "Fosaprepitant; its salts";

(*d*) by adding "Fulvestrant";

(*e*) by adding "Idursulfase";

(*f*) by adding "Palonosetron; its salts".

Chairman,
Pharmacy and Poisons Board

29 September 2008

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulations") –

(*a*) to relax the control of Nicotine under the First Schedule to the principal Regulations by providing for exceptions for the use of it in nicotine replacement therapy and –

(i) in the form of chewing gum or lozenges that contain not more than 4 mg of Nicotine per piece; or

(ii) in the form of patches for external application; and

(*b*) to add 6 substances to the First and Third Schedules to the principal Regulations 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. 4) 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

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

(*a*) in the item relating to "Alkaloids", by repealing –

"Nicotine (except chewing gum and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece)"

and substituting –

"Nicotine (except when contained in (*a*) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (*b*) patches for external application, intended to be used in nicotine replacement therapy)";

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

(*c*) by adding "Etravirine";

(*d*) by adding "Fosaprepitant; its salts";

(*e*) by adding "Fulvestrant";

(*f*) by adding "Idursulfase";

(*g*) by adding "Palonosetron; its salts".

(2) The Schedule is amended, in Part II, in Division A, by repealing –

"Nicotine: chewing gum and lozenges, intended to be used in nicotine replacement therapy and containing not more than 2 mg of Nicotine per piece"

and substituting –

"Nicotine when contained in (*a*) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (*b*) patches for external application, intended to be used in nicotine replacement therapy".

Chairman,
Pharmacy and Poisons Board

29 September 2008

Explanatory Note

This Regulation amends the Poisons List Regulations (Cap. 138 sub. leg. B) ("principal Regulations") –

(*a*) to relax the control of Nicotine under the Schedule to the principal Regulations by providing for exceptions for the use of it in nicotine replacement therapy and –

(i) in the form of chewing gum or lozenges that contain not more than 4 mg of Nicotine per piece; or

(ii) in the form of patches for external application; and

(*b*) to add 6 substances in Division A of Part I of the Poisons List set out in the Schedule to the principal Regulations so that, among other applicable requirements, poisons containing those substances can only be sold on registered

premises of an authorized seller of poisons by a registered pharmacist or in the pharmacist’s presence and under the pharmacist’s supervision.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 22 OCTOBER 2008

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2008
Poisons List (Amendment) (No. 4) Regulation 2008

[Mr / 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 six pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following six substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Anidulafungin; its salts; its esters; their salts;

(b) Etravirine ;

(c) Fosaprepitant; its salts;

(d) Fulvestrant;

(e) Idursulfase; and

(f) Palonosetron; its salts.

Pharmaceutical products containing these six 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 gum and lozenges intended to be used in nicotine replacement therapy which contain not more than 4mg of Nicotine per piece as well as patches (for external application) intended to be used in nicotine replacement therapy. At present, they are 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. These products have been studied in detail and have been found to be sufficiently safe to be available for self-selection by smokers who wish to quit smoking. As such, we propose reclassifying gum and lozenges intended to be used in nicotine replacement therapy which contain not more than 4mg of Nicotine per piece and patches (for external application) intended to be used in nicotine replacement therapy as Part II poisons, so that they can be sold by pharmacies as well as medicine companies, and their 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 24 October 2008 to allow early control and sale of the relevant medicine.

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, [Mr/Madam] President, I move the motion.

Poisons List (Amendment) (No.4) Regulation 2008
Pharmacy and Poisons (Amendment) (No.4) Regulation 2008

《2008年毒藥表（修訂）(第 4 號) 規例》
《2008年藥劑業及毒藥（修訂）(第 4 號) 規例》

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
5.1 Registration of six new pharmaceutical products		
(a) Anidulafungin; its salts; its esters; their salts 阿尼芬淨;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 to treat invasive candidiasis (a type of fungal infection caused by a yeast-like fungus called *Candida*). 'Invasive' means that the fungus has spread into the blood. This drug is only used in adults who are not neutropenic (i.e. who do not have low levels of neutrophils, a type of white blood cells). Its use should be decided by a doctor. 此藥用以治療侵襲性念珠菌感染(一種由稱爲*假絲酵母*的酵母狀真菌所引致的真菌感染)。'侵襲性'是指真菌擴散進入血液。此藥只是用於非中性白細胞減少的成人(即中性白細胞(一種白血球)的水平不是偏低的人)。 使用該藥與否，須由醫生決定。
(b) Etravirine 依曲韋林	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, in treatment-experienced adult AIDS patients. Its use should be decided by a doctor based on the patient's condition. 此藥與其他抗病毒藥混合，用於曾接受治療的成年愛滋病病人。 使用該藥與否，須由醫生按病人的病情決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
(c) Fosaprepitant; its salts 福沙匹坦; 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 with other drugs to prevent nausea and vomiting caused by cancer chemotherapy. Its use should be decided by a doctor. 此藥物與其他藥物共同使用，以預防由治療癌症的化學治療所引致的噁心和嘔吐。 使用該藥與否，須由醫生決定。
(d) Fulvestrant 氟維司群	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 locally advanced or metastatic breast cancer in women who have been through the menopause. It is used when the cancer is 'oestrogen receptor positive' (where the cancer cells have receptors for the hormone oestrogen on their surface). 'Metastatic' means that the cancer that has spread to other parts of the body. The drug is used when the disease has returned during or after treatment with an 'anti-oestrogen' (a type of medicine used to treat breast cancer), or when the disease has worsen during treatment with an anti-oestrogen. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療患有局部末期或轉移性乳癌並已停經的婦女。此藥物用於屬'雌激素受體陽性'(即癌細胞表面有賀爾蒙雌激素受體)的癌症。'轉移性'是指腫瘤已擴散至身體其他部分。如果使用一種'抗雌激素'(一種用以治療乳癌的藥物)進行治療期間或之後病情復發，或使用一種抗雌激素進行治療期間病情轉壞，便可使用此藥物。 使用該藥與否，須由醫生按病人的病情決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
(e) Idursulfase 艾度硫酸酯酶	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 patients with Hunter syndrome. Hunter syndrome, which is also known as mucopolysaccharidosis II, is a rare, inherited disease. Patients with Hunter syndrome do not produce an enzyme called iduronate-2-sulfatase. This enzyme is needed to break down substances in the body called glycosaminoglycans (GAGs). Since patients with Hunter syndrome cannot break these substances down, the GAGs gradually build up in most of the organs in the body and damage them. This causes a wide range of symptoms, particularly difficulty in breathing and difficulty in walking. Without treatment, these symptoms become more severe over time. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療亨特氏綜合症患者。 亨特氏綜合症亦稱爲黏多醣症第二型，是罕見的遺傳性疾病。亨特氏綜合症患者不會製造一種稱爲己醛醣酸鹽硫酸脂的酵素，這是身體分解稱爲糖胺多糖(GAGs)的物質所需的酵素。由於亨特氏綜合症患者無法分解這些物質，糖胺多糖在身體大部分器官逐漸積聚，並進行破壞，引致廣泛的症狀，尤其是呼吸困難和行動不便。如果不進行治療，這些症狀會隨時間變得越來越嚴重。 使用該藥與否，須由醫生按病人的病情決定。
(f) Palonosetron; its salts 帕洛諾司瓊; 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 prevent nausea and vomiting caused by cancer chemotherapy. Its use should be decided by a doctor based on the patient's condition. 此藥用於預防抗癌的化學治療所引致的噁心和嘔吐。 使用該藥與否，須由醫生按病人的病情決定。

5.2 Re-classification of medicines used in Nicotine replacement therapy		
Nicotine: chewing gum and lozenges intended to be used in nicotine replacement therapy and containing not more than 4mg of Nicotine per piece, and patches intended to be used in nicotine replacement therapy 煙鹼(尼古丁)：擬用於尼古丁替代療法而每片含有不多於4毫克尼古丁的口香糖及錠劑，及擬用於尼古丁替代療法的貼片	From Part I, First Schedule poison to Part II poison 由第一部附表一毒葯改爲第二部毒葯	These products have been studied in detail and have been found to be sufficiently safe to be available for self-selection by smokers who wish to quit smoking. 這些產品，經過詳細研究後，被証實其安全程度足以使其可以由願意戒煙的吸煙人士自我選購。