立法會
Legislative Council

LC Paper No. CB(3) 9/06-07

Ref : CB(3)/M/OR

Tel : 2869 9205

Date : 29 September 2006

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 18 October 2006

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 18 October 2006 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2006; and

(b) the Poisons List (Amendment) (No. 4) Regulation 2006.

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 25 September 2006, be approved –

(*a*) the Pharmacy and Poisons (Amendment)(No. 4) Regulation 2006; and

(*b*) the Poisons List (Amendment)(No. 4) Regulation 2006.

PHARMACY AND POISONS (AMENDMENT)(NO. 4) REGULATION 2006

(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. Substances falling within the Poisons List to which special restrictions apply under regulations 3 and 5

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended, under the heading "A" –

(*a*) by adding "Alefacept";

(*b*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", by adding "Human papillomavirus" after "Herpes simplex";

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

(*d*) by adding "Ibritumomab tiuxetan";

(*e*) by adding "Pegfilgrastim";

(*f*) by adding "Poractant alfa";

(*g*) by adding "Thyrotropin alfa".

2. Substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon

The Third Schedule is amended, under the heading "A" –

(*a*) by adding "Alefacept";

(*b*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", by adding "Human papillomavirus" after "Herpes simplex";

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

(*d*) by adding "Ibritumomab tiuxetan";

(*e*) by adding “Pegfilgrastim”;

(*f*) by adding “Poractant alfa”;

(*g*) by adding “Thyrotropin alfa”.

Chairman,
Pharmacy and Poisons Board

25 September 2006

Explanatory Note

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (“the principal Regulations”) to add 7 substances to the First and Third Schedules respectively so that the sale 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 2006

(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, under the heading "A" –

(*a*) by adding "Alefacept";

(*b*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", by adding "Human papillomavirus" after "Herpes simplex";

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

(*d*) by adding "Ibritumomab tiuxetan";

(*e*) by adding "Pegfilgrastim";

(*f*) by adding "Poractant alfa";

(*g*) by adding "Thyrotropin alfa";

(*h*) in the item "吩諾嗎汛；其鹽類；其酯類及醚類；它門的鹽類", in the Chinese text, by repealing "門" and substituting "們".

Chairman,
Pharmacy and Poisons Board

25 September 2006

Explanatory Note

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

(*a*) to add 7 substances under the heading "A" in Part I of the Poisons List set out in the Schedule to the principal Regulations so that poisons containing those substances can only be sold on premises of authorized sellers of poisons by registered pharmacists or in his presence and under his supervision; and

(*b*) to rectify a clerical error appearing in a substance specified in that Schedule.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 18 OCTOBER 2006

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2006
Poisons List (Amendment) (No. 4) Regulation 2006

Madam President,

I move that the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2006 and the Poisons List (Amendment) (No. 4) Regulation 2006 as set out under my name in the paper circulated to Members be approved.

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, a registered dentist or a registered veterinary surgeon.

4. The Amendment Regulations now before members seek to amend the Poisons List in the Poisons List Regulations and the Schedules to the Pharmacy and Poisons Regulations for the purpose of imposing control on seven new medicines.

5. Arising from seven applications for registration pharmaceutical products, the Pharmacy and Poisons Board proposes to add seven 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 be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

7. We propose that these amendment regulations take immediate effect upon gazettal on 20 October 2006 to allow early control and sale of the relevant medicines.

8. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under section 3 of the Ordinance to regulate the registration and control of 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.

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

Poisons List (Amendment)(No. 4) Regulation 2006

Pharmacy and Poisons (Amendment)(No. 4) Regulation 2006

Supplementary Information to the Legislative Council

《2006年毒藥表（修訂）(第 4 號) 規例》
《2006年藥劑業及毒藥（修訂）(第 4 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**
Alefacept (阿來法塞)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Treatment of adult patients with moderate to severe chronic plaque psoriasis who are suitable for systemic therapy or phototherapy. It should only be used when the need is established by medical diagnosis. Close monitoring of patient is necessary. 用以治療患有中度至嚴重慢性斑狀牛皮癬並適宜接受全身療法或光線療法的成年病人。使用此產品前須經醫生診斷爲確有這方面的需要，並須密切監察病人的情況。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
In the item relating to "Antisera, antitoxins, immunoglobulins and vaccines" by adding "Human papillomavirus vaccines" (在與"抗血清、抗毒素、免疫球蛋白與疫苗"有關的一項中加入"人類乳頭瘤病毒疫苗")	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This vaccine is used in girls and women aged 9 to 26 for prevention of the following diseases caused by Human Papilloma Viruses types 6,11, 16 and 18: - cervical cancer - genital warts (condyloma acuminata) and the following precancerous or dysplastic lesions: - cervical adenocarcinoma *in situ* (AIS) - cervical intraepithelial neoplasia (CIN) grade 2 and grade 3 - vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3 - vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3 - cervical intraepithelial neoplasia (CIN) grade 1 The use should be decided by a doctor. 此疫苗適用於年齡介乎9至26歲的女童及婦女，用作預防人類乳頭瘤病毒第6、11、16及18型所引致的下列病症： - 宮頸癌 - 生殖器疣(尖銳濕疣) 以及下列癌前或異常病變： - 宮頸原位腺癌 - 宮頸上皮內瘤形成第 2 級和第 3 級 - 外陰上皮內瘤形成第 2 級和第 3 級 - 陰道上皮內瘤形成第 2 級和第 3 級 - 宮頸上皮內瘤形成第 1 級 疫苗的使用，應由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Dexrazoxane; its salts (右雷佐生；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is used for the prevention of cardiotoxicity resulting from cytotoxic chemotherapy with anthracycline-containing chemotherapy regimens. The use should be decided and monitored by a doctor. 此藥用作以預防因用含蒽環類抗生素的細胞毒素化學療程時所引起的心臟中毒。藥物的使用，應由醫生決定和監察。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Ibritumomab tiuxetan (替伊莫單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	The drug, when labelled with the radioactive yttrium-90 [^{90}Y], is used for treatment of adult patients with rituximab relapsed or refractory CD20+ follicular B-cell non-Hodgkin's lymphoma (NHL). It should only be used when the need is established by medical diagnosis. Administration should be done by personnel with appropriate training for the use and manipulation of radionuclides with designated clinical setting. 此藥以放射性釔-90[^{90}Y]示蹤，用以治療患有CD20抗原陽性和濾泡性B細胞的非何杰金氏淋巴瘤。此藥只可用於曾接受"利妥昔單抗"療法但其後復發或療效欠佳的的成年病人。 使用此產品前須經醫生診斷爲確有這方面的需要，並應由獲適當訓練使用和操控放射性核素的人員在指定的臨牀環境下施用。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Pegfilgrastim (培非司亭)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Used for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy against cancers (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). The use should be decided by a doctor. 用於曾經接受細胞毒素化學治療來對抗惡性腫瘤(慢性骨髓細胞白血病及骨髓增生異常綜合症除外)的病人，以縮短中性粒細胞減少症發病期，及減低發熱性中性粒細胞減少症發病率。使用該產品與否，須由醫生決定。
Poractant alfa	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	For treatment of respiratory distress syndrome (RDS) in pre-term babies. Prophylactic use in premature infants at risk for RDS. Its use should be decided by a doctor when the need is confirmed. 用以治療患有呼吸窘迫綜合症的早產嬰兒，亦可用於易患此症的早產嬰兒以作預防用途。使用此產品與否，須在確定有這方面的需要時由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Thyrotropin alfa (促甲狀腺素α)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is used as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well differentiated thyroid cancer. Its use should be decided by a doctor when the need is confirmed. 用於跟進患有高度分化甲狀腺癌的病人，可連同或不連同放射性碘造影用作血清甲狀腺球蛋白測試的輔助診斷工具。使用此產品與否，須在確定有這方面的需要時由醫生決定。