立法會
Legislative Council

LC Paper No. CB(3) 906/10-11

Ref. : CB(3)/M/OR

Tel : 2869 9205

Date : 16 June 2011

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 6 July 2011

Proposed resolution under the Pharmacy and Poisons Ordinance

I forward for Members' consideration a proposed resolution **(Appendix I)** the Secretary for Food and Health will move at the Council meeting of 6 July 2011 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) Regulation 2011; and

(b) the Poisons List (Amendment) Regulation 2011.

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 Chinese and English **(Appendix II)** which the Secretary will deliver when moving the proposed resolution, and the supplementary information provided by the Secretary **(Appendix III)** 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 13 June 2011, be approved—

(a) the Pharmacy and Poisons (Amendment) Regulation 2011; and

(b) the Poisons List (Amendment) Regulation 2011.

Appendix I

Pharmacy and Poisons (Amendment) Regulation 2011

(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. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2 and 3.

2. First Schedule amended

First Schedule, Division A—

(a) Before item "Colaspase"—

Add

"Clozapine; its salts";

(b) Before item "Corticorelin; its salts"—

Add

"Corifollitropin alfa";

(c) After item "Demecarium bromide"—

Add

"Denosumab";

(d) After item "Fentiazac; its salts"—

Add

"Fenticonazole; its salts";

(e) After item "Protriptyline; its salts; its derivatives; their salts"—

Add

"Prulifloxacin; its salts; its esters; their salts";

(f) After item "Ranibizumab"—

Add

"Rasagiline; its salts";

(g) After item "Rofecoxib; its salts"—

Add

"Roflumilast; its salts";

(h) Before item "Ropinirole; its salts"—

Add

"Romiplostim".

3. Third Schedule amended

Third Schedule, Division A—

(a) Before item "Colaspase"—

Add

"Clozapine; its salts";

(b) Before item "Corticorelin; its salts"—

Add

"Corifollitropin alfa";

(c) After item "Demecarium bromide"—

Add

"Denosumab";

(d) After item "Fentiazac; its salts"—

Add

"Fenticonazole; its salts";

(e) After item "Protriptyline; its salts; its derivatives; their salts"—

Add

"Prulifloxacin; its salts; its esters; their salts";

(f) After item "Ranibizumab"—

Add

"Rasagiline; its salts";

(g) After item "Rofecoxib; its salts"—

Add

"Roflumilast; its salts";

(h) Before item "Ropinirole; its salts"—

Add

"Romiplostim".

Chairman,
Pharmacy and Poisons Board

13 June 2011

Explanatory Note

This Regulation adds 8 substances to Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***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) Regulation 2011

(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. Poisons List Regulations amended

The Poisons List Regulations (Cap. 138 sub. leg. B) are amended as set out in section 2.

2. Schedule amended

(1) The Schedule, Part I, Division A—

(a) Before item "Colaspase"—

Add

"Clozapine; its salts";

(b) Before item "Corticorelin; its salts"—

Add

"Corifollitropin alfa";

(c) After item "Demecarium bromide"—

Add

"Denosumab";

(d) After item "Fentiazac; its salts"—

Add

"Fenticonazole; its salts";

(e) After item "Protriptyline; its salts; its derivatives; their salts"—

Add

"Prulifloxacin; its salts; its esters; their salts";

(f) After item "Ranibizumab"—

Add

"Rasagiline; its salts";

(g) After item "Rofecoxib; its salts"—

Add

"Roflumilast; its salts";

(h) Before item "Ropinirole; its salts"—

Add

"Romiplostim";

(i) **Repeal the item "Terbinafine; its salts"**

Substitute

"Terbinafine; its salts; except when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as a single application and when labelled for the treatment of tinea pedis and/or tinea cruris only".

(2) The Schedule, Part II, Division A, after item relating to "Phenols as defined in Part I of this List in substances containing less than 60%, weight in weight, of phenols"—

Add

"Terbinafine; its salts; when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as a single application and when labelled for the treatment of tinea pedis and/or tinea cruris only".

Chairman,
Pharmacy and Poisons Board

13 June 2011

Explanatory Note

This Regulation adds 8 substances to 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, 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.

2. This Regulation also relaxes the control of "Terbinafine".

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 6 JULY 2011

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) Regulation 2011
Poisons List (Amendment) Regulation 2011

Mr 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 under 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 eight pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following eight substances to Part I of the Poisons List and

the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Clozapine; its salts
(b) Corifollitropin alfa
(c) Denosumab
(d) Fenticonazole; its salts
(e) Prulifloxacin; its salts; its esters; their salts
(f) Rasagiline; its salts
(g) Roflumilast; its salts
(h) Romiplostim

Pharmaceutical products containing the above 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 Terbinafine; its salts when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as single application and when labelled for the treatment of tinea pedis and/or tinea cruris only; by re-classifying them from Part I of the Poisons List to Part II of the Poisons List only.

6. We propose that these amendment regulations take immediate effect upon gazettal on 8 July 2011 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 medicine concerned.

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

Poisons List (Amendment) (No. 1) Regulation 2011

Pharmacy and Poisons (Amendment) (No. 1) Regulation 2011

Supplementary Information to the Legislative Council

《2011年毒藥表（修訂）(第 1 號) 規例》
《2011年藥劑業及毒藥（修訂）(第 1 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
Clozapine; its salts	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 schizophrenia in patients who fail to respond to other antipsychotics or who cannot tolerate side effects of these drugs. This drug can cause neutropenia which, if the drug is not withdrawn immediately, may progress to a potentially fatal agranulocytosis. Blood monitoring is essential. Sedation and weight gain may be prominent. There is an increased risk of developing inflammation of heart muscles associated with the use of this drug. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療對其它精神科藥物無效或不能忍受其它精神科藥物副作用的精神分裂症病人。 此藥物可導致嗜中性白血球減少症，而若不即時停用此藥，可引致致命的粒性白血球缺乏症。血液監控是必需的。鎮靜和增加體重也是可顯著的。使用此藥可增加患心肌炎的風險。使用此藥與否，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
Corifollitropin alfa (絨促卵泡素α)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is for controlled ovarian stimulation in women participating in assisted reproductive technology program. Side effects include over stimulation of the ovaries, pelvic pain and discomfort, headache, nausea, fatigue and breast discomforts. Its use should be decided by a doctor based on the patient's condition. 此藥物用於對參與協助人類生殖科技計劃的女性進行控制性刺激卵巢。 副作用包括過度刺激卵巢、盆骨痛楚和不適、頭痛、噁心、疲勞及胸部不適。使用此藥與否，須由醫生按病人的病情決定。
Denosumab 地舒單抗	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 postmenopausal women with osteoporosis. Side effects include hypocalcaemia, serious skin infection, back pain, pain in extremity, dermatitis, eczema, musculoskeletal pain, hypercholesterolemia, cystitis, and osteonecrosis of the jaw. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療絕經後婦女的骨質疏鬆症。 副作用包括低血鈣症、嚴重皮膚感染、背部疼痛、四肢疼痛、皮膚炎、濕疹、肌骨骼疼痛、高血脂症、膀胱炎及顎骨壞死。使用此藥與否，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
Fenticonazole; its salts (芬替康唑; 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 fungal infections in the female genital tract. When used topically, side effect mainly involve burning sensation. Prolonged topical application may cause sensitization reactions. In the event of a hypersensitivity reaction or development of resistant organisms, treatment should be discontinued. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療女性生殖道的真菌感染。 如局部使用，副作用主要涉及灼熱的感覺。使用過久，可引致敏感。如產生過敏反應或抗藥性，應停止使用此藥。使用此藥與否，須由醫生按病人的病情決定。
Prulifloxacin; its salts; its esters; their salts 普芦沙星; 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 cystitis, lower urinary tract infections and acute exacerbation of chronic bronchitis. Side effects include rhabdomyolysis, tendonitis, epigastralgia, gastritis, nausea, headache, dizziness and anorexia. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療膀胱炎、下尿道感染及慢性支氣管炎急性惡化。 副作用包括橫紋肌溶解、腱炎、上腹部痛、胃炎、噁心、頭痛、暈眩及厭食。使用此藥與否，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
Rasagiline; its salts (雷沙吉蘭; 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 for treatment of Parkinson's disease. Side effects include influenza, depression, leucopenia, skin carcinoma, dermatitis, headache, conjunctivitis, rhinitis and musculoskeletal pain. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療帕金遜病。 副作用包括感冒、抑鬱、白血球減少症、皮膚癌、皮膚炎、頭痛、結膜炎、鼻炎及肌骨骼疼痛。使用此藥與否，須由醫生按病人的病情決定。
Roflumilast; its salts 羅氟司特；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 as maintenance treatment of severe chronic obstructive pulmonary disease associated with chronic bronchitis. Side effects include weight decrease, decreased appetite, sleeplessness, headache, diarrhea, nausea, stomach, hypersensitivity, sensation of irregular heartbeat, muscle pain or cramps and suicidal thinking/behavior. Its use should be decided by a doctor based on the patient's condition. 此藥物用以持續治療慢性支氣管炎引起的嚴重慢性阻塞性呼吸道疾病。 副作用包括體重下降、食慾不振、失眠、頭痛、腹瀉、噁心、胃痛、過敏、心跳不規則感覺、肌肉疼痛或抽搐，以及有自殺意念／行爲。使用此藥與否，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
Romiplostim 羅米司亭	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 Adult chronic immune (idiopathic) thromobocytopenic purpura. Side effects include increased bone marrow reticulin, thrombocytopenia, pulmonary embolism, muscle pain and back pain. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療成人原發性慢性免疫性血小板減少引致的紫癜。 副作用包括骨髓網硬蛋白增加、血小板減少症、肺栓塞、肌肉疼痛及背部疼痛。使用此藥與否，須由醫生按病人的病情決定。