立法會
Legislative Council

LC Paper No. CB(3) 368/06-07

Ref : CB(3)/M/OR

Tel : 2869 9205

Date : 13 February 2007

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 7 March 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 7 March 2007 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) Regulation 2007; and

(b) the Poisons List (Amendment) 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 9 February 2007, be approved –

(*a*) the Pharmacy and Poisons (Amendment) Regulation 2007; and

(*b*) the Poisons List (Amendment) Regulation 2007.

PHARMACY AND POISONS (AMENDMENT) 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. Interpretation

Regulation 2(4) of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended –

(*a*) by repealing "under the headings "A"" and substituting "in Divisions A";

(*b*) by repealing "under the headings "B"" and substituting "in Divisions B".

2. First Schedule amended

(1) The heading of the First Schedule is repealed and the following substituted –

"SUBSTANCES TO WHICH CERTAIN RESTRICTIONS WITH RESPECT TO THE SALE, SUPPLY, LABELLING AND STORAGE APPLY UNDER REGULATIONS 3, 5, 6, 15, 19, 22, 23 AND 24".

(2) The First Schedule is amended, in the heading "**A**", by repealing "**A**" and substituting "DIVISION A".

(3) The First Schedule is amended, in Division A –

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

(*b*) by adding "Azacitidine; its salts";

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

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

(*e*) by adding "Rimonabant; its salts";

(*f*) by adding “Rotigotine; its salts”;

(*g*) by adding “Sorafenib; its salts”;

(*h*) by adding “Sunitinib; its salts; their salts”;

(*i*) by adding “Varenicline; its salts”.

(4) The First Schedule is amended, in the heading “**B**”, by repealing “**B**” and substituting “DIVISION B”.

3. Second Schedule amended

(1) The Second Schedule is amended, in Group II, in the heading “**A**”, by repealing “**A**” and substituting “DIVISION A”.

(2) The Second Schedule is amended, in Group II, in the heading “**B**”, by repealing “**B**” and substituting “DIVISION B”.

4. Third Schedule amended

(1) The Third Schedule is amended, in the heading “**A**”, by repealing “**A**” and substituting “DIVISION A”.

(2) The Third Schedule is amended, in Division A –

(*a*) in the item relating to “Antisera, antitoxins, immunoglobulins and vaccines”, by adding “Herpes zoster” after “Herpes simplex”;

(*b*) by adding “Azacitidine; its salts”;

(*c*) by adding “Darifenacin; its salts”;

(*d*) by adding “Ivabradine; its salts”;

(*e*) by adding “Rimonabant; its salts”;

(*f*) by adding “Rotigotine; its salts”;

(*g*) by adding “Sorafenib; its salts”;

(*h*) by adding “Sunitinib; its salts; their salts”;

(*i*) by adding “Varenicline; its salts”.

(3) The Third Schedule is amended, in the heading “**B**”, by repealing “**B**” and substituting “DIVISION B”.

5. Fourth Schedule amended

(1) The Fourth Schedule is amended, in the heading "**A**", by repealing "**A**" and substituting "DIVISION A".

(2) The Fourth Schedule is amended, in the heading "**B**", by repealing "**B**" and substituting "DIVISION B".

6. Sixth Schedule amended

(1) The Sixth Schedule is amended, in the heading "**A**", by repealing "**A**" and substituting "DIVISION A".

(2) The Sixth Schedule is amended, in the heading "**B**", by repealing "**B**" and substituting "DIVISION B".

7. Seventh Schedule amended

(1) The Seventh Schedule is amended, in the heading "**A**", by repealing "**A**" and substituting "DIVISION A".

(2) The Seventh Schedule is amended, in the heading "**B**", by repealing "**B**" and substituting "DIVISION B".

Chairman,
Pharmacy and Poisons Board

9 February 2007

Explanatory Note

This Regulation adds 9 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.

2. This Regulation also repeals and substitutes the heading of the First Schedule to the principal Regulations to specify in the heading that certain restrictions with respect to the sale, supply, labelling and storage apply to the substances referred to in that Schedule under regulations 3, 5, 6, 15, 19, 22, 23 and 24 of the principal Regulations.

3. This Regulation further makes alterations to regulation 2(4) of and the First, Second, Third, Fourth, Sixth and Seventh Schedules to the principal Regulations by adding "DIVISION" before "A" and "B" in the headings of certain Schedules so as to enhance the clarity of presentation.

POISONS LIST (AMENDMENT) 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. Interpretation

Regulation 2(*d*) of the Poisons List Regulations (Cap. 138 sub. leg. B) is amended –

(*a*) by repealing "under the headings "A"" and substituting "in Divisions A";

(*b*) by repealing "under the headings "B"" and substituting "in Divisions B".

2. The Poisons List

(1) The Schedule is amended, in Part I, in the heading "**A**", by repealing "**A**" and substituting "DIVISION A".

(2) The Schedule is amended, in Part I, in Division A –

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

(*b*) by adding "Azacitidine; its salts";

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

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

(*e*) by adding "Rimonabant; its salts";

(*f*) by adding "Rotigotine; its salts";

(*g*) by adding "Sorafenib; its salts";

(*h*) by adding "Sunitinib; its salts; their salts";

(*i*) by adding "Varenicline; its salts".

(3) The Schedule is amended, in Part I, in the heading "**B**", by repealing "**B**" and substituting "DIVISION B".

(4) The Schedule is amended, in Part II, in the heading "**A**", by repealing "**A**" and substituting "DIVISION A".

(5) The Schedule is amended, in Part II, in Division A, in the item beginning with "Pharmaceutical", by repealing "part A" and substituting "Division A".

(6) The Schedule is amended, in Part II, in the heading "**B**", by repealing "**B**" and substituting "DIVISION B".

(7) The Schedule is amended, in Part II, in Division B, in the item beginning with "Products", by repealing "Part IB" and substituting "Division B of Part I".

Chairman,
Pharmacy and Poisons Board

9 February 2007

Explanatory Note

This Regulation adds 9 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) ("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.

2. This Regulation also makes alterations to regulation 2(*d*) of and the Schedule to the principal Regulations by adding "DIVISION" before "A" and "B" in the headings of Parts I and II of the Schedule so as to enhance the clarity of presentation.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 7 MARCH 2007

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) Regulation 2007
Poisons List (Amendment) 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 nine applications for registration of pharmaceutical products, the Pharmacy and Poisons Board proposes to add nine 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 9 March 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 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.

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

Poisons List (Amendment) Regulation 2007

Pharmacy and Poisons (Amendment) Regulation 2007

Supplementary Information to the Legislative Council

《2007年毒藥表（修訂）規例》
《2007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**
In the item relating to "Antisera, antitoxins, immunoglobulins and vaccines" by adding "Herpes zoster" (在與"抗血清、抗毒素、免疫球蛋白與疫苗"有關的一項中加入"帶狀疱疹")	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Indicated for the prevention of herpes zoster (shingles), for prevention of postherpetic neuralgia (PHN) and for reduction of acute and chronic zoster-associated pain in individuals not less than 60 years old. The use should be decided by a doctor. 適用於60歲及以上人士，以預防帶狀疱疹、預防疱疹後神經痛，以及減輕與疱疹有關的劇烈和慢性痛楚。 使用該產品與否，須由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Azacitidine; its salts (阿紮胞苷; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Indicated for treatment of patients with the following myelodysplastic syndrome subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia. The use should be decided and monitored by a doctor. 適用於治療以下骨髓增生異常綜合症亞型的患者：難治性貧血或難治性貧血伴環狀鐵粒幼細胞(如伴有中性血細胞減少症或血小板減少症或需要輸血)、原始細胞增多型難治性貧血、轉化中的原始細胞增多型難治性貧血，以及慢性粒單細胞白血病。 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**
Darifenacin; its salts (達非那新; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Indicated for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. Its use should be decided by a doctor when the need is confirmed. 適用於治療膀胱過度活躍症患者可能出現的緊急失禁及／或泌尿頻率和緊急程度增加的症狀。 使用此產品與否，須在確定有這方面的需要時由醫生決定。
Ivabradine; its salts (伊伐雷定；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Symptomatic treatment of chronic stable angina pectoris in patients with normal sinus rhythm, who have a contra-indication or intolerance for beta-bockers. The use should be decided and monitored by a doctor. 用於治療竇性心律正常但忌用或不耐受β-受體阻斷劑的病人的慢性穩定心絞痛症狀。 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**
Rimonabant; its salts (利莫納班; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	As an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30 kg/m^2), or overweight patients (BMI > 27 kg/m^2) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia. Its use should be decided by a doctor when the need is confirmed. 用於輔助節食及運動，以治療有二型糖尿病或血脂異常症等疾病危險的肥胖病人(體重指數≥30 kg/m^2)或超重病人(體重指數>27 kg/m^2) 使用此產品與否，須在確定有這方面的需要時由醫生決定。
Rotigotine; its salts (羅替高汀; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa). The use should be decided by a doctor. 適用於作爲單一療法(即不使用左旋多巴)，以治療早期原發性柏金遜症的症狀。使用該產品與否，須由醫生決定。
Sorafenib; its salts (索拉非尼；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Indicated for the treatment of patients with advanced renal cell carcinoma. The use should be decided and monitored by a doctor. 適用於治療末期腎細胞癌症病人。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**
Sunitinib; its salts; their salts (舒尼替尼; 其鹽類; 它們的鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is indicated for the treatment of gastrointestinal stromal tumour (GIST) after disease progression on or intolerance to imatinib mesylate. It is also indicated for the treatment of advanced renal cell carcinoma (RCC). Approval for advanced renal cell carcinoma is based on partial response rates or duration of responses. There are no randomized trials of Sunitinib demonstrating clinical benefit such as increased survival or improvement in disease-related symptoms in renal carcinoma. The use should be decided and monitored by a doctor. 適用於在施用imatinib mesylate後病情惡化或不耐受imatinib mesylate的情況下，治療胃腸道間質腫瘤。 也適用於治療末期腎細胞癌症。根據部分反應率或反應持續時間而批准用於治療末期腎細胞癌症。並無顯示舒尼替尼有令存活率上升或腎癌相關病徵好轉等臨牀好處的隨機試驗。 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**
Varenicline; its salts (伐尼克蘭; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Indicated as aids to smoking cessation treatment. The use should be decided by a doctor. 適合用作戒煙治療的輔助藥物。使用該產品與否，須由醫生決定。