立法會
Legislative Council

LC Paper No. CB(3) 838/09-10

Ref. : CB(3)/M/OR

Tel : 2869 9205

Date : 25 June 2010

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 14 July 2010

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 14 July 2010 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2010; and

(b) the Poisons List (Amendment) (No. 3) Regulation 2010.

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 21 June 2010, be approved –

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2010; and

(b) the Poisons List (Amendment) (No. 3) Regulation 2010.

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2010

(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 "Agomelatine; its salts";

(b) by adding "Galsulfase";

(c) by adding "Golimumab";

(d) by adding "Nebivolol; its salts";

(e) by adding "Saxagliptin; its salts";

(f) by adding "Tolvaptan".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(a) by adding "Agomelatine; its salts";

(b) by adding "Galsulfase";

(c) by adding "Golimumab";

(d) by adding "Nebivolol; its salts";

(e) by adding "Saxagliptin; its salts";

(f) by adding "Tolvaptan".

Chairman,
Pharmacy and Poisons Board

21 June 2010

Explanatory Note

This Regulation adds 6 substances to Divisions A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("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) (NO. 3) REGULATION 2010

(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 adding "Agomelatine; its salts";

(b) by adding "Galsulfase";

(c) by adding "Golimumab";

(d) by adding "Nebivolol; its salts";

(e) by adding "Saxagliptin; its salts";

(f) by adding "Tolvaptan".

Chairman,
Pharmacy and Poisons Board

21 June 2010

Explanatory Note

This Regulation adds 6 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.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 14 JULY 2010

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2010
Poisons List (Amendment) (No. 3) Regulation 2010

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 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) Agomelatine; its salts
(b) Galsulfase
(c) Golimumab
(d) Nebivolol; its salts
(e) Saxagliptin; its salts
(f) Tolvaptan

5. 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.

6. We propose that these amendment regulations take immediate effect upon gazettal on 16 July 2010 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. 3) Regulation 2010

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2010

Supplementary Information to the Legislative Council

《2010年毒藥表（修訂）(第三號) 規例》
《2010年藥劑業及毒藥（修訂）(第三號) 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
Agomelatine; its salts (阿戈美拉汀; 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 major depression in adults. Major depression is a condition in which patients have mood disturbances that interfere with their everyday life. Side effects include headache, dizziness, somnolence (sleepiness), insomnia, migraine, nausea, diarrhoea, constipation, upper abdominal pain (tummy ache), hyperhidrosis (excessive sweating), back pain, tiredness, increases in liver enzymes and anxiety. Most side effects are mild or moderate in intensity and happen within the first two weeks of treatment. This drug should only be used upon medical judgment.

		此藥用以治療成人重症抑鬱症。患有重症抑鬱症的病人會出現情緒波動，妨礙他們的日常生活。 此藥物的副作用包括頭痛、暈眩、嗜睡、失眠症、偏頭痛、噁心、腹瀉、便秘、上腹痛(肚痛)、多汗症、背部疼痛、疲勞、肝酶上升及焦慮。大部分副作用均屬輕度或中度，並在治療的首2個星期內出現。需經醫生清楚診斷適用時，才能使用此藥物。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
Galsulfase (戈硫酯酶)	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 who have mucopolysaccharidosis VI (MPS VI or Maroteaux-Lamy syndrome). This disease is caused by the lack of an enzyme called arylsulfatase B, which is needed to break down substances in the body called glycosaminoglycans (GAGs). If the enzyme is not present, GAGs cannot be broken down and will build up in the cells. This causes the signs of the disease, the most noticeable being a short body stature, a large head and difficulty in moving about. Side effects includes ear pain, dyspnoea (difficulty in breathing), abdominal (tummy) pain, general pain, fever, chills, rash and hives. A medical decision is required for the use of this drug. 此藥物用以治療患有黏多醣症第六型(MPS VI或馬洛托-拉米氏症)的病人。此疾病是因缺乏一種稱爲芳基硫酸酯酶B的酵素而引致的，這是身體分解稱爲糖胺多糖(GAGs)的物質所需的酵素。如果缺乏這種酵素，糖胺多糖便不能被分解，並在細胞內積聚。這會引致此疾病的徵候，其中最顯著的是身裁短小、大頭及活動困難。 副作用包括耳痛、呼吸困難、腹痛、全身疼痛、發燒、發冷、紅疹及蕁麻疹。選用此藥需經醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
Golimumab (戈利木單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This is an anti-inflammatory medicine, used in adults to treat the following diseases: - moderate to severe active rheumatoid arthritis (a disease causing inflammation of the joints). This drug is used in combination with methotrexate in patients who have not responded adequately to other treatments including methotrexate - active and progressive psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints). This drug is used in patients who have not responded adequately to other treatments. It can be used alone or in combination with methotrexate; - severe active ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine). This drug is used in patients who have not responded adequately to other treatments. Side effects include upper respiratory tract infections such as nasopharyngitis (infection of the nose and throat), pharyngitis (infection of the throat), laryngitis (infection of the voice box) and rhinitis (runny nose). Its use should be judged by a doctor.

		這是消炎藥，用以治療患有以下疾病的成人： - 中度至嚴重活動性風濕性關節炎(一種令關節發炎的疾病)。此藥物與甲氨蝶呤混合使用，用於對其他治療(包括甲氨蝶呤)沒有足夠反應的病人。 - 活動性及進行性牛皮癬關節炎(一種令皮膚出現紅色鱗狀斑塊及令關節發炎的疾病)。此藥物用於對其他治療沒有足夠反應的病人。此藥物可單獨使用或與甲氨蝶呤混合使用。 - 嚴重活動性強直性脊椎炎(一種令脊椎關節發炎及疼痛的疾病)。此藥物用於對其他治療沒有足夠反應的病人。 副作用包括上呼吸道感染，例如鼻咽炎、咽炎、喉炎及鼻炎。選用此藥需經醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Nebivolol; its salts (奈必洛爾；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 for hypertension and chronic heart failure. Side effects include headache, dizziness, paraesthesia, dyspnoea (difficulty in breathing), constipation, nausea, diarrhea, tiredness and oedema. Its use should be decided by a doctor based on the patient's condition. 此藥物用於高血壓及慢性心臟衰竭。副作用包括頭痛、暈眩、感覺異常、呼吸困難、便秘、噁心、腹瀉、疲倦及水腫。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**
Saxagliptin; its salts (沙格列汀；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 add-on combination therapy in adults with type 2 diabetes mellitus to improve glycaemic control : - In combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control; - In combination with sulphonylurea, when sulphonylurea alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate. - In combination with thiazolidinedione, when thiazolidinedione alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of thiazolindinedione is considered appropriate. The most common side effects are upper respiratory tract infection, urinary tract infection, gastroenteritis, sinusitis, headache, vomiting and mild to moderate peripheral oedema (swelling, especially of the ankles and feet). A medical decision is required for the use of this drug.

		此藥物用作爲輔助性混合療法，用於患有二型糖尿病的成年病人，以改善血糖控制： - 與甲福明混合使用，在單獨使用甲福明再配合節食及運動，仍無法提供足夠血糖控制的情況下適用； - 與磺酰脲混合使用，在單獨使用磺酰脲再配合節食及運動，仍無法爲不適合使用甲福明的病人提供足夠血糖控制的情況下適用； - 與格列酮類藥物混合使用，在單獨使用格列酮類藥物再配合節食及運動，仍無法爲適合使用格列酮類藥物的病人提供足夠血糖控制的情況下適用。 最常見的副作用是上呼吸道感染、尿道感染、腸胃炎、鼻竇炎、頭痛和嘔吐，輕微至中度周邊水腫(尤其是足踝及足部)。選用此藥需經醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Tolvaptan (托伐坦)	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 hyponatraemia (abnormally low levels of sodium in the blood). Side effects include thirst and nausea. It must not be used in patients with anuria (an inability to pass urine), very low blood volume, low blood sodium levels with low blood volume, hypernatremia (abnormally high levels of sodium in the blood) or in patients who cannot perceive thirst. It must also not be used in women who are pregnant or breast-feeding. A medical decision is required for the use of this drug. 此藥物用以治療患有低鈉血症(血液中的鈉水平異常低)的病人。副作用包括口渴及噁心。此藥物不得用於出現無尿症、血容量極低、血鈉水平及血容量偏低、高鈉血症(血液中的鈉水平異常高)情況的病人，或不能察覺口渴的病人。此藥物亦不得用於懷孕或哺乳的婦女。選用此藥需經醫生決定。