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Legislative Council

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Date : 4 October 2010

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 20 October 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 20 October 2010 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2010; and
- (b) the Poisons List (Amendment) (No. 4) 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 13 September 2010, be approved—

- (a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2010; and
- (b) the Poisons List (Amendment) (No. 4) Regulation 2010.

Pharmacy and Poisons (Amendment) (No. 4) 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. Pharmacy and Poisons Regulations amended

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

2. First Schedule amended

First Schedule, Division A—

- (a) **Add**
“Dapoxetine; its salts”;
- (b) **Add**
“Indacaterol; its salts; its esters; their salts”;
- (c) **Add**
“Plerixafor; its salts”.

3. Third Schedule amended

Third Schedule, Division A—

- (a) **Add**
“Dapoxetine; its salts”;
- (b) **Add**
“Indacaterol; its salts; its esters; their salts”;

- (c) **Add**
“Plerixafor; its salts”.

Chairman,
Pharmacy and Poisons Board

13 September 2010

Explanatory Note

This Regulation adds 3 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) (No. 4) 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. Poisons List Regulations amended

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

2. Schedule amended

The Schedule, Part I, Division A—

- (a) **Add**
“Dapoxetine; its salts”;
- (b) **Add**
“Indacaterol; its salts; its esters; their salts”;
- (c) **Add**
“Plerixafor; its salts”.

Chairman,
Pharmacy and Poisons Board

13 September 2010

Explanatory Note

This Regulation adds 3 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 20 OCTOBER 2010**

Pharmacy and Poisons Ordinance (Cap. 138)

**Pharmacy and Poisons (Amendment) (No. 4) Regulation 2010
Poisons List (Amendment) (No. 4) 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 three pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following three substances to Part I of the Poisons List and

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

- (a) Dapoxetine; its salts
- (b) Indacaterol; its salts; its esters; their salts
- (c) Plerixafor; its salts

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 22 October 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.4) Regulation 2010

Pharmacy and Poisons (Amendment) (No.4) Regulation 2010

Supplementary Information to the Legislative Council

《 2010年毒藥表（修訂）(第四號) 規例 》
《 2010年藥劑業及毒藥（修訂）(第四號) 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
Dapoxetine; its salts (達泊西汀; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及 附表三毒藥	<p>This drug is used to treat premature ejaculation, in men between 18 and 64 years old. Premature ejaculation is a common sexual problem. It is when a man ejaculates with little sexual stimulation and before the man wants to. This can cause problems for the man and may cause problems in sexual relationships.</p> <p>Side effects include feeling dizzy, headache, feeling sick, feeling irritable, anxious, agitated or restless, feeling numb or having “pins and needles”, difficulty getting or keeping an erection, sweating more than normal or flushing, diarrhoea, constipation or having wind, stomach pain, bloating or being sick, problems sleeping or strange dreams, feeling tired or sleepy, yawning, blocked nose (nasal congestion), a rise in blood pressure, difficulty concentrating, shaking or trembling, lower interest in sex, ringing in the ears, blurred vision, indigestion and dry mouth. This drug should only be used upon medical judgment.</p> <p>此藥用以治療18至64歲男性早洩。早洩是常見的性問題。這是指男性在很少性刺激的情況下，以及在想射精前射精。這會對該名男性帶來問題，並可能在性關係上造成問題。</p> <p>副作用包括感到暈眩、頭痛、感到不適、感到易怒、焦慮、激動或煩躁、感到麻木或手腳發麻、勃起或維持勃起有困難、出汗比平常多或臉部發熱、腹瀉、便秘或腸氣、胃痛、肚脹或不適、睡眠問題或怪夢、感到疲倦或想睡、打呵欠、鼻塞(鼻腔堵塞)、血壓上升、無法集中精神、發抖或震顫、性慾下降、耳鳴、視力模糊、消化不良及口乾。需經醫生清楚診斷，才能使用此藥物。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
<p>Indacaterol; its salts; its esters; their salts</p> <p>(茚達特羅;其鹽類; 其酯類; 它們的鹽類)</p>	<p>Part I, First and Third Schedules poison</p> <p>第一部附表一及附表三毒藥</p>	<p>This drug is used to keep the airways open in adults with chronic obstructive pulmonary disease (COPD). COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing air in and out of the lungs.</p> <p>Side effects include nasopharyngitis (inflammation of the nose and throat), upper respiratory tract infection (colds), sinusitis (inflammation of the sinuses), diabetes mellitus and hyperglycaemia (high blood sugar levels), headache, ischaemic heart disease (disease of the heart caused by failure in the blood supply), cough, pharyngolaryngeal (throat) pain, rhinorrhoea (runny nose), respiratory tract congestion (blocked airways), muscle spasm (cramps) and peripheral oedema (swelling, especially of the ankles and feet). A medical decision is required for the use of this medicine.</p> <p>此藥用以使患有慢性阻塞性呼吸道疾病的成人的氣道保持張開。慢性阻塞性呼吸道疾病是一種長期疾病，患者肺內的氣道和氣囊會被破壞或阻塞，導致肺部吸入和呼出空氣困難。</p> <p>副作用包括鼻咽炎(鼻子及喉嚨發炎)、上呼吸道感染、鼻竇炎、糖尿病和血糖過多症(血糖水平偏高)、頭痛、缺血性心臟病(血液供應不足所引致的心臟疾病)、咳嗽、咽喉痛、鼻漏(流鼻涕)、呼吸道阻塞(氣道受阻)、肌肉痙攣以及周邊水腫(尤其是足踝及足部)。選用此藥需經醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Plerixafor; its salts (普樂沙福; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used to help to collect haematopoietic stem cells (cells in the bone marrow that can develop into different types of blood cells) for transplantation. It is used in patients with non-hodgkin's lymphoma or multiple myeloma (types of blood cell cancer) for autologous transplantation (when the patient's own cells are used in the transplant).</p> <p>Side effects include diarrhoea, nausea (feeling sick) and reactions at the site of injection. Its use should be judged by a doctor.</p> <p>此藥用以幫助收集造血幹細胞(骨髓內的細胞，可以發展成爲不同種類的血細胞)作移植之用。它用於患有非霍奇金氏淋巴瘤或多發性骨髓瘤(各種血細胞癌症)的病人，以進行自體移植(移植的細胞是病人自己的細胞)。</p> <p>副作用包括腹瀉、噁心(感到不適)和在注射位置出現反應。選用此藥需經醫生決定。</p>