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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 16 May 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 16 May 2007 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2007; and

(b) the Poisons List (Amendment) (No. 2) 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 24 April 2007, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2007; and

(*b*) the Poisons List (Amendment) (No. 2) Regulation 2007.

PHARMACY AND POISONS (AMENDMENT)(NO. 2) 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. 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 "Lanthanum carbonate";

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

(*c*) by adding "Ranibizumab";

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

(*e*) by adding "Telbivudine; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Lanthanum carbonate";

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

(*c*) by adding "Ranibizumab";

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

(*e*) by adding "Telbivudine; its salts".

Chairman,
Pharmacy and Poisons Board

24 April 2007

Explanatory Note

This Regulation adds 5 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.

POISONS LIST (AMENDMENT)(NO. 2) 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. 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 "Lanthanum carbonate";

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

(*c*) by adding "Ranibizumab";

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

(*e*) by adding "Telbivudine; its salts".

Chairman,
Pharmacy and Poisons Board

24 April 2007

Explanatory Note

This Regulation adds 5 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) 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.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 16 MAY 2007

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment)(No. 2) Regulation 2007
Poisons List (Amendment)(No. 2) 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 five applications for registration of pharmaceutical products, the Pharmacy and Poisons Board proposes to add five 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 18 May 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)(No. 2) Regulation 2007

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2007

Supplementary Information to the Legislative Council

《2007年毒藥表（修訂）(第2號) 規例》
《2007年藥劑業及毒藥（修訂）(第2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**
Lanthanum carbonate (碳酸鑭)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	A phosphate binding agent for use in the control of hyperphosphataemia in patients with chronic renal failure who are on haemodialysis or continuous ambulatory peritoneal dialysis. Its use should be decided by a doctor. 磷酸鹽結合劑，用於正在使用血液透析法或連續可攜帶腹膜透析法的慢性腎衰竭患者，以控制高磷酸血症。 藥物的使用應由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Propiverine; its salts (丙呱維林；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Treatment of urinary incontinence, as well as urgency and frequency of urination in patients who have either idiopathic detrusor overactivity (overactive bladder) or neurogenic detrusor overactivity (detrusor hyperreflexia) from spinal cord injuries e.g. transverse lesion paraplegia. The use should be decided by a doctor. 治療小便失禁，以及因脊髓受傷(如橫貫性損傷截癱)而患有特發性逼尿肌過度活動(膀胱過動症)或神經性逼尿肌過度活動(逼尿肌反射亢進)的病人的尿急及尿頻症狀。 藥物的使用應由醫生決定。
Ranibizumab (雷珠單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Treatment of wet age-related macular degeneration (AMD). The use should be decided and monitored by a doctor. 治療濕性老年黃斑病變。 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**
Sertindole; its salts (舍吲哚；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Treatment of schizophrenia. Due to cardiovascular safety concerns, sertindole should only be used for patients intolerant to other antipsychotic drugs. Sertindole should not be used in emergency situations for urgent relief of symptoms in acutely disturbed patients. The use should be decided and monitored by a doctor. 治療精神分裂症。 基於心血管安全問題，舍吲哚(sertindole)只能用於不耐受其他抗精神病劑的病人。此產品不能在緊急情況下用於非常不穩定的病人以急切減輕其症狀。 藥物的使用，應由醫生決定和監察。
Telbivudine; its salts (替比夫定；其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Treatment of chronic hepatitis B in patients with evidence of viral replication and active liver inflammation. Its use should be decided by a doctor when the need is confirmed. 適用於有證據顯示體內出現病毒複製及肝炎活躍的病人，以治療其慢性乙型肝炎。 使用此產品與否，須在確定有這方面的需要時由醫生決定。