立法會
Legislative Council

LC Paper No. CB(3) 104/05-06

Ref : CB(3)/M/OR

Tel : 2869 9205

Date : 3 November 2005

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 23 November 2005

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 23 November 2005 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005; and

(b) the Poisons List (Amendment) (No. 3) Regulation 2005.

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.

(Ray CHAN)
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 31 October 2005, be approved –

(*a*) the Pharmacy and Poisons (Amendment)(No. 3) Regulation 2005; and

(*b*) the Poisons List (Amendment)(No. 3) Regulation 2005.

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2005

(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. Commencement

Sections 2(d) and 3(d) and (e) shall come into operation 30 days after the day on which this Regulation is published in the Gazette.

2. Substances falling within the Poisons List to which special restrictions apply under regulations 3 and 5

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended, in part A –

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

(b) by adding "Duloxetine; its salts";

(c) by adding "Strontium ranelate";

(d) by adding "Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10,000 international units of vitamin A";

(e) in the item "加替沙星；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(f) in the item "麥考酚酸；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(g) in the item "氯屈膦酸；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(h) in the item "噻加賓；其鹽類；其脂類；它們的鹽類", by repealing "脂" and substituting "酯";

(i) by repealing the item "Adefovir" and substituting –

"Adefovir; its salts; its esters; their salts";

(j) by repealing the item "Nicotinic acid" and substituting –

"Nicotinic acid and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 200 mg of nicotinic acid".

3. Substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon

The Third Schedule is amended, in part A –

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

(b) by adding "Duloxetine; its salts";

(c) by adding "Strontium ranelate";

(d) by adding "Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10,000 international units of vitamin A";

(e) in the item relating to "Alkaloids", by adding –

"Codeine, except substances containing less than 0.2% of codeine"

after –

"Calabar bean, alkaloids of";

(f) by repealing "Chloral; its addition and its condensation products other than alphachloralose; any compound with any substance falling within this item; except when contained, in the form of chloral hydrate, in preparations intended for external application only" where it secondly appears;

(g) in the item "加替沙星；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(h) in the item "格帕沙星；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(i) in the item "麥考酚酸；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(j) in the item "噻加賓；其鹽類；其脂類；它們的鹽類", by repealing "脂" and substituting "酯";

(k) by repealing the item "Adefovir" and substituting –

"Adefovir; its salts; its esters; their salts";

(l) by repealing the item "Nicotinic acid" and substituting –

"Nicotinic acid and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 200 mg of nicotinic acid".

Chairman,
Pharmacy and Poisons Board

31 October 2005

Explanatory Note

This Regulation adds 4 substances to the First Schedule and 5 substances to the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulation") so that the sale and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulation.

2. The Regulation rectifies certain minor errors appearing in various substances specified in the First and Third Schedules.

3. The Regulation repeals one of the item relating to "chloral" which appears twice in the Third Schedule.

POISONS LIST (AMENDMENT)(NO. 3) REGULATION 2005

(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. Commencement

Section 2(1)(d) shall come into operation 30 days after the day on which this Regulation is published in the Gazette.

2. The Poisons List

(1) The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in part A –

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

(b) by adding "Duloxetine; its salts";

(c) by adding "Strontium ranelate";

(d) by adding "Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10,000 international units of vitamin A";

(e) in the item "六水膦甲酸納", by repealing "納" and substituting "鈉";

(f) in the item "加替沙星；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(g) in the item "色甘酸納", by repealing "納" and substituting "鈉";

(h) in the item "麥考酚酸；其鹽類；其脂類", by repealing "脂" and substituting "酯";

(i) in the item "硝普納", by repealing "納" and substituting "鈉";

(j) in the item "酮洛芬（苯酮笨丙酸）；其鹽類", by repealing "笨" and substituting "苯";

(k) in the item "噻加賓；其鹽類；其脂類；它們的鹽類", by repealing "脂" and substituting "酯";

(l) by repealing the item "Adefovir" and substituting –

"Adefovir; its salts; its esters; their salts";

(m) by repealing the item "Nicotinic acid" and substituting –

"Nicotinic acid and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 200 mg of nicotinic acid".

(2) The Schedule is amended, in Part II, in part B, in the item "亞硝酸納", by repealing "納" and substituting "鈉".

Chairman,
Pharmacy and Poisons Board

31 October 2005

Explanatory Note

This Regulation adds 4 substances to part A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B). Poisons listed in that part are essentially for medicinal use. Under the Pharmacy and Poisons Ordinance (Cap. 138) such poisons may only be sold on the premises registered under the Ordinance by a registered pharmacist or in his presence and under his supervision.

2. The Regulation rectifies certain minor errors appearing in various substances specified in that Schedule.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 23 NOVEMBER 2005

Pharmacy and Poisons Ordinance (Cap 138)

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005
Poisons List (Amendment) (No. 3) Regulation 2005

Madam President,

I move that the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005 and the Poisons List (Amendment) (No. 3) Regulation 2005 as set out under my name in the paper circulated to Members be approved.

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, a registered dentist or a registered veterinary surgeon.

4. The Amendment Regulations now before members seek to amend the Poisons List in the Poisons List Regulations and the Schedules to the Pharmacy and Poisons Regulations for the purpose of imposing control on three new medicines and tightening the control on two existing medicines.

5. Arising from the applications for registration of three pharmaceutical products, the Pharmacy and Poisons Board proposes to add three 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 be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions. We propose that these amendment regulations take immediate effect upon gazettal on 25 November 2003 to allow early control and sale of medicines containing these substances.

6. In addition, the Pharmacy and Poisons Board proposes to tighten the control on two existing medicines. At present, substances containing not less than 0.2% of Codeine, now classified as Part I and First Schedule poisons, can be sold in pharmacies without the support of prescriptions. Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10,000 international units of vitamin A, now classified as non-poisons, are sold in all kinds of medicines outlets. By classifying these two substances as Part I, First and Third Schedules poisons, pharmaceutical products containing any of them must be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions. To allow time for sellers, manufacturers and importers to adapt to the new requirements, we propose that these amendments take effect 30 days after the day of their gazettal.

7. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under section 3 of 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.

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

Poisons List (Amendment) (No. 3) Regulation 2005

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005

Supplementary Information to the Legislative Council

《2005年毒藥表（修訂）(第 3 號) 規例》
《2005年藥劑業及毒藥（修訂）(第 3 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**
Bemiparin; its salts 貝納肝素; 其鹽類	Part I, First and Third Schedules poisons (i.e. prescription-only medicines) 第一部附表一及附表三毒藥 (即處方藥)	This drug is used in the prevention of blood clotting events after surgery and treatment of deep vein thrombosis . Medical monitoring is required during treatment period. 此藥用於預防手術後的血栓塞和治療深部靜脈血栓形成。用藥期間須由醫生觀察病人。
Duloxetine; its salts 度洛西汀; 其鹽類	Part I, First and Third Schedules poisons (i.e. prescription-only medicines) 第一部附表一及附表三毒藥 (即處方藥)	This drug is used to treat major depression in adults and stress urinary incontinence for women . It should only be used when the need is established by medical diagnosis. 此藥用於治療成人的嚴重憂鬱症及女性壓抑性小便失禁。需經醫生確診及決定有需要時才可用藥。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Strontium ranelate (無中文名)	Part I, First and Third Schedules poison (i.e. prescription-only medicine) 第一部附表一及附表三毒藥(即處方藥)	This drug is used for treatment of postmenopausal osteoporosis. It should only be used when the need is established by medical diagnosis. 此藥用於治療閉經後骨質疏鬆。此藥需經醫生確診及決定有需要時才可用藥。
Vitamin A; its esters; when contained in pharmaceutical products the recommended daily dosage of which contains 10,000 international units or above of vitamin A 維生素 A;其酯類;在包含於藥劑製品內並且該等製品的建議每日劑量含10,000國際單位或以上維生素A時	Part I, First and Third Schedules poisons (i.e. prescription-only medicines) 第一部附表一及附表三毒藥(即處方藥)	High doses of vitamin A could result in side effects such as liver toxicity, gastrointestinal disturbances, foetal abnormalities, and reduced bone growth in children. 高劑量的維生素A可能引致如肝中毒， 腸胃不適，胎兒不正常， 和小孩骨骼增長受到阻礙等副作用。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Codeine, except substances containing less than 0.2% of codeine 可待因，但含有少於0.2%可待因的物質除外	Third Schedule poisons (i.e. prescription-only medicines) (such preparations are already Part I First Schedule poisons) 附表三毒藥(即處方藥)(此類製劑已經屬於第一部附表一毒藥)	This tightening of the control on the sale of preparations containing codeine at 0.2% or above is made in view of the rise in the number of abusers of cough preparations in recent years, as shown by data in the Central Registry of Drug Abuse of the Narcotics Division of the Security Bureau. 這一收緊銷售含有可待因0.2%或以上的製劑的管制，源於保安局禁毒處的藥物濫用資料中央檔案室的數據顯示，近年濫用止咳藥的人士的數字正在上升。