立法會
Legislative Council

LC Paper No. LS8/05-06

Paper for the House Committee Meeting
on 11 November 2005

Legal Service Division Report on
Proposed Resolution under section 29 of the
Pharmacy and Poisons Ordinance (Cap. 138)

The Secretary for Health, Welfare and Food ("the Secretary") has given notice to move a motion at the Council meeting on 23 November 2005. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005 and the Poisons List (Amendment) (No. 3) Regulation 2005, both made by the Pharmacy and Poisons Board ("the Board") on 31 October 2005 pursuant to section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. According to the draft speech of the Secretary, the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005 and the Poisons List (Amendment) (No. 3) Regulation 2005 seek to:

(a) add 3 new drugs/medicines, i.e. Bemiparin and its salts, Duloxetine and its salts and Strontium ranelate to part A of the First and Third Schedules to the Pharmacy and Poisons Regulations and part A of Part I of the Poisons List;

(b) add 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 to part A of the First and Third Schedules to the Pharmacy and Poisons Regulations and part A of Part I of the Poisons List;

(c) add Codeine, except substances containing less than 0.2% of codeine to the item relating to "Alkaloids" in part A of the Third Schedule to the Pharmacy and Poisons Regulations;

(d) rectify certain minor errors appearing in various substances specified in part A of the First and Third Schedules to the Pharmacy and Poisons Regulations and the Poisons List; and

(e) repeal one of the items relating to "Chloral", which appears twice in part A of the Third Schedule to the Pharmacy and Poisons Regulations.

3. The Secretary has provided, in addition to his draft speech, supplementary information on the 3 new drugs/medicines, Vitamin A and Codeine, which is attached for Members' reference (Annex A). Their addition means that pharmaceutical products containing any of these 5 substances in the specified quantity, if any, must be sold in pharmacies by or under the supervision of a registered pharmacist and in his presence, with the support of prescriptions given by a registered medical practitioner, registered dentist or registered veterinary surgeon.

4. The Board considers that the proposed amendments necessary in view of the potency, toxicity and potential side-effects of the medicines concerned.

5. Except for the amendments relating to Vitamin A and Codeine, the two Amendment Regulations shall come into operation on the day when they are published in the Gazette after being approved by the Legislative Council i.e. 25 November 2005. To allow time for sellers, manufacturers and importers to adapt to the new requirements, the amendments relating to Vitamin A and Codeine shall come into operation 30 days after the day on which they are published in the Gazette.

6. In the light of the difference in the quantity of Codeine to be regulated in the First and Third Schedules to the Pharmacy and Poisons Regulations and the Poisons List, we have written to the Administration to clarify the differential control on Codeine. A copy of our letter (Annex C) and the Administration's reply (Annex B) is enclosed.

7. The new control in Codeine was requested by a member during the meeting of the Panel on Health Services ("the Panel") on 28 June 2005 when the Administration briefed the Panel on the current control of sale of cough preparations containing Codeine, and the current efforts on public education, treatment and rehabilitation in relation to substance abuse. Dr KWOK Ka-ki commented that the existing requirement that a record must be kept of every sale transaction of cough preparations containing Codeine at more than 0.1% was not an effective deterrent, as young people abusing the use of Codeine preparations had no difficulties in obtaining large quantities of the preparations by buying them from different pharmacies. He also pointed out that in the United States, the purchase of cough preparations containing Codeine at more than 0.2% required a doctor's prescription. He suggested the Administration to consider adopting such a requirement. The Administration undertook to convey the suggestion to the Pharmacy and Poisons Board for its consideration. Members may refer to the paper for the Panel on the Abuse of Cough Preparations Containing Codeine (Ref: LC Paper No. CB(2)2086/04-05(02)) and the minutes of the Panel meeting (Ref: LC Paper No.

CB(2)2595/04-05) for background information. The Panel has not been consulted on the other amendments.

8. The two Amendment Regulations are in order from the legal point of view.

Encl

Prepared by

Monna LAI
Assistant Legal Adviser
Legislative Council Secretariat
8 November 2005

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。

中華人民共和國香港特別行政區政府總部衞生福利及食物局
Health, Welfare and Food Bureau
Government Secretariat, Government of the Hong Kong Special Administrative Region
The People's Republic of China

Urgent by fax and thro' email

Your ref.: LS/R/1/05-06
Our ref.: HWF/H/23/4 Pt.21 96

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9 November 2005

Miss Monna LAI
Assistant Legal Adviser
Legislative Council Secretariat

Dear Miss Lai,

Proposed Resolution under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Resolution") - Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005 and Poisons List (Amendment) (No. 3) Regulation 2005

Thank you for your letter dated 7 November 2005.

The purpose of the proposed amendments is to enhance the regulatory measures in respect of cough preparations containing codeine to prevent possible abuse of such substances. It is noted that the higher the concentration of codeine in a particular cough preparation, the higher the chance of it being abused, hence it should be subject to tighter sale control.

At present, an incremental regulatory approach is adopted in respect of substances containing codeine. Depending on the level of codeine concentration, pharmaceutical products containing codeine are regulated as follows-

(i) "Codeine; its esters and ethers; [their quaternary compounds; any salt, simple or complex]" (regardless of the level of concentration) are regulated by the provisions applicable to **Part I** of the Poison List Regulations (Cap. 138 sub. leg. B, i.e., para 1(c) of your letter). They can only be sold by authorized sellers of poisons under the direct supervision of registered pharmacists (s21 of Cap. 138).

(ii) In addition to (i) above, "Codeine, **except** substances containing **not more than 0.1% of codeine**; [their quaternary compounds; any salts, simple or complex]" are regulated by the provisions applicable to the **First Schedule** of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A, i.e., para 1(a) of your letter). That is to say, in addition to being sold by authorized sellers, substances containing more that 0.1% of codeine must be kept in a locked receptacle to which customers are not permitted to have access (r19 of Cap. 138 sub. leg. A), and particulars of their sale, such as the names, addressees of the purchasers, the name and quantity of the medicines, and the purpose for which they are sold, must be recorded in a poisons book for two years (s22 of Cap. 138 and r3 of Cap. 138 sub. Leg. A).

In response to Members' concern on possible abuse of codeine-containing cough preparations expressed at the Health Services Panel Meeting dated 28 June 2005, we propose to tighten the control measures by making "Codeine, **except** substances containing **less than 0.2% of codeine**; [their quaternary compounds; any salts, simple or complex]" subject to the provisions applicable to the **Third Schedule** of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A, i.e. para 1(b) of your letter). Hence, in addition to the requirements under (i) and (ii) above, such substances will be required to be sold only with prescription from registered doctors, registered dentists or duly qualified veterinary surgeons. In addition, the prescription, which must specify the total amount of the medicine, the name and address of the person for whose treatment it is given, should be retained by pharmacies for two years (r9, Cap. 138 sub. leg. A).

To summarise, there will be three levels of control in respect of pharmaceutical products containing codeine-

Substances containing codeine at a concentration of	*Subject to control measures applicable to*
≤ 0.1%	Part I poisons
> 0.1% but < 0.2%	Part I and First Schedule poisons
≥ 0.2% codeine	Part I and First Schedule and Third Schedule poisons

I hope that the above clarification helps. Please let me know if I can assist further. Thank you.

Yours sincerely,

(Eric SF CHENG)
for Secretary for Health, Welfare and Food

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2877 5029

Secretary for Health, Welfare and Food
Health, Welfare and Food Bureau
Health Division
(Attn: Mr Eric CHENG, AS (H) 2)
19/F, Murray Building
Garden Road, Hong Kong

By Fax (2905 1326) and By Post

7 November 2005

Dear Mr CHENG

Proposed Resolution under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Resolution") - Pharmacy and Poisons (Amendment) (No. 3) Regulation 2005 and Poisons List (Amendment) (No. 3) Regulation 2005

I am scrutinizing the legal and drafting aspects of the Resolution. The proposed control of codeine pursuant to the amendments to the two Regulations appears to be:

(a) "codeine, except substances containing not more than 0.1% of codeine" will be regulated by provisions applicable to the First Schedule of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A);

(b) "codeine, except substances containing less than 0.2% of codeine" will be regulated by provisions applicable to the Third Schedule of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A); and

(c) "codeine; its esters and ethers" will be regulated by provisions applicable to the Part I of the Poison List Regulations (Cap. 138 sub. leg. B).

Please clarify the effect of the differential control.

It is appreciated that your reply in both Chinese and English could reach us by noon, 9 November 2005.

Yours sincerely

(Monna LAI)
Assistant Legal Adviser