

立法會
Legislative Council

LC Paper No. LS81/04-05

**Paper for the House Committee Meeting
on 17 June 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 29 June 2005. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2005 and the Poisons List (Amendment) (No. 2) Regulation 2005, both made by the Pharmacy and Poisons Board ("the Board") on 4 June 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. 2) Regulation 2005 and the Poisons List (Amendment) (No. 2) Regulation 2005 seek to add 4 new drugs/medicines, i.e. Bevacizumab, Enfuvirtide, Melagatran, its salts, its derivatives and their salts and Milnacipran and its salts 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. The Secretary has provided, in addition to his draft speech, supplementary information on these 4 new drugs/medicines, which is attached for Members' reference (see Annex). Their addition means that pharmaceutical products containing any of these 4 substances 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.

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

4. 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.

5. The Panel on Health Services has not been consulted on the two Amendment Regulations.

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

Encl

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10 June 2005

Poisons List (Amendment) (No. 2) Regulation 2005

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2005

Supplementary Information to the Legislative Council

〈 2005年毒藥表 (修訂) (第 2 號) 規例 〉
 〈 2005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
Bevacizumab (貝伐珠單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used in the treatment of metastatic cancer of the colon or rectum. Monitoring of patients is required during its administration and its use should be decided by a doctor when the need is confirmed.</p> <p>此藥用於治療擴散性結腸及直腸癌。須經醫生決定有需要時才可用藥，而病人亦須於用藥時接受觀察。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Enfuvirtide (恩夫韋肽)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used in the treatment of HIV-1 infections. It should only be used after established diagnosis. Pneumonia has been seen in patients treated with Enfuvirtide. Patients should be closely monitored for signs and symptoms of pneumonia.</p> <p>此藥用於治療人免疫缺陷病毒-1感染。此藥須經醫生確診後才使用。有發現服用恩夫韋肽的病人有肺炎。病人須於用藥時接受肺炎之觀察。</p>
Melagatran; its salts; its derivatives; their salts (美拉加群; 其鹽類; 其衍生物; 它們的鹽類)	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 prevent thromboembolic events after elective hip or knee replacement surgery. A doctor's decision is required as to whether or not this medicine should be used. Medical monitoring is also required during and after surgery and during treatment period.</p> <p>此藥用於自選補換髖部或膝蓋手術。此藥須由醫生決定有需要時才使用。此外，醫生亦須於手術進行時、進行後及用藥期間觀察病人。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Milnacipran; its salts (米那普侖; 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. 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。須經醫生確診及決定有需要時才可用藥。