

立法會
Legislative Council

LC Paper No. LS19/03-04

**Paper for the House Committee Meeting
on 5 December 2003**

**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 two motions at the Legislative Council meeting on 17 December 2003. The motions are for seeking the Legislative Council's approval of -

- (a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2003;
- (b) the Poisons List (Amendment) (No. 4) Regulation 2003,
- (c) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2003; and
- (d) the Poisons List (Amendment) (No. 5) Regulation 2003.

2. According to the draft speech of the Secretary, for the purpose of imposing control on 13 newly-registered pharmaceutical products, the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2003 and the Poisons List (Amendment) (No. 4) Regulation 2003 seek to -

- (a) add one new substance, i.e. Levodropropizine and its salts, which is a drug used to treat persistent cough, to Part I of the Poisons List such that pharmaceutical products containing this substance must be sold in pharmacies under the supervision of registered pharmacists and in their presence; and
- (b) add 12 new substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations so that 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.

3. The above two Amendment Regulations shall come into operation on the day when they are published in the Gazette if they are approved by the Legislative Council, i.e. on 19 December 2003 to allow early control and sale of medicines containing these substances.

4. Further, for the purpose of tightening control on 20 existing medicines, the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2003 and the Poisons List (Amendment) (No. 5) Regulation 2003 seek to add 20 substances, now classified as non-poisons, to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations so that 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. These two Amendment Regulations shall come into operation on 19 January 2004 to allow time for the manufacturers and importers to recall pharmaceutical products containing these substances from medicines outlets other than pharmacies.

5. The Secretary has provided, in addition to his draft speech, supplementary information on these substances, which is attached for Members' reference (see Annex).

6. These Regulations are all made by the Pharmacy and Poisons Board ("the Board") pursuant to section 29 of the Pharmacy and Poisons Ordinance (Cap. 138). The Board considers that the proposed amendments necessary in view of the potency, toxicity and potential side-effects of the medicines concerned.

7. The four Amendment Regulations are in order from the legal point of view.

Encl

Prepared by

HO Ying-chu, Anita
Assistant Legal Adviser
Legislative Council Secretariat
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**Poisons List (Amendment) (No. 4) Regulation 2003
Pharmacy and Poisons (Amendment) (No. 4) Regulation 2003**

Supplementary Information to the Legislative Council

《 2003年毒藥表 (修訂) (第四號) 規例 》
《 2003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
Adalimumab (阿達木單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used for relief of rheumatoid arthritis when other medicines have failed to work. Use of this drug requires medical decision and monitoring.</p> <p>經使用其它藥物無效之後, 此藥用作舒緩類風濕性關節炎的症狀。選用此藥需經醫生決定及觀察。</p>
Anagrelide; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used for thrombocythaemia, a disease in which there is an increased number of platelets in the blood. It should be used after confirmed medical diagnosis and under careful monitoring.</p> <p>此藥用作治療血小板增多症。需經醫生確定診症後才用藥而病人需被小心觀察。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Bosentan; its salts (波生坦;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 raised blood pressure within the blood vessels supplying the lungs. It should be used after confirmed medical diagnosis and under careful monitoring by a doctor.</p> <p>此藥用作治療肺動脈高壓。需經醫生確定診症後才用藥而病人需被小心觀察。</p>
Darbepoetin alfa	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 anaemia associated with kidney failure. Use of this drug requires medical decision and monitoring.</p> <p>此藥用作治療腎衰竭引致之貧血。選用此藥需經醫生決定及觀察。</p>
Dutasteride (度他雄胺)	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 moderate to severe symptoms of benign prostate enlargement and reduce the risk of acute urinary retention and surgery for these patients. A doctor's decision is required on whether or not to use this medicine.</p> <p>此藥用於治療中度至嚴重良性前列腺肥大症狀及減少此類病人急性閉尿症和需做手術之風險。選用此藥需經醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Gadobutrol; its salts (釷布醇;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 as a contrast medium in magnetic resonance imaging of the head and spine. Medical decision is required for the use of this drug.</p> <p>此藥用作頭和脊骨磁力共振掃描的造影劑。選用此藥需經醫生決定。</p>
Gefitinib; its salts (吉非替尼;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 advanced or metastatic Non Small Cell Lung Cancer after other drugs failed. It should be used after confirmed medical diagnosis and under careful monitoring.</p> <p>此藥用於治療已經使用其它藥物而無效的末期或已擴散之非小細胞肺癌。需經醫生確定診症後才用藥而病人需被小心觀察。</p>
Ferucarbotran; its salts (鐵羧葡胺;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 as a contrast medium in magnetic resonance imaging. Medical decision is required for the use of this drug.</p> <p>此藥用作磁力共振掃描的造影劑。選用此藥需經醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Levodropropizine; its salts (左旋羥丙哌 ； 其鹽類)	Part I poison 第一部毒藥	<p>This drug is used to treat persistent cough but should not be used when there is excessive discharge of mucus. Patients may become drowsy after taking this medicine. Professional advice is required from a pharmacist for proper usage of this drug.</p> <p>此藥用於治療久咳，但不應用於過多黏痰之咳嗽。病人亦可能會感到昏昏欲睡。需由藥劑師提供專業指示才服用此藥。</p>
Memantine; its salts (美金鋼；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 for the treatment of moderately severe to severe Alzheimer's disease (progressive form of mental disorder, marked by memory loss, occurring in middle age). Medical decision is required for the use of this drug.</p> <p>此藥用於治療中度至嚴重的早老性痴呆症。需經醫生決定後才用藥。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Rosuvastatin; its salts (瑞舒伐他汀; 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 lower high blood cholesterol level after non-drug measures failed. This drug should not be used in patients with active liver disease and may cause increase in liver enzymes levels in patients. Liver function tests are required prior to, and 3 months following initiating treatment. Use of this drug requires medical decision and monitoring.</p> <p>此藥用於經非藥物治療失敗後以降低血內的過高膽固醇含量。有活躍肝病的病人不應服用此藥，而此藥亦可能令病人肝酵素上升。用藥前及用藥三個月內，需檢查肝臟功能。選用此藥需經醫生決定及觀察。</p>
Sulphur Hexafluoride (六氟化硫)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used as a diagnostic aid in ultrasound imaging. Use of this drug requires medical decision.</p> <p>此藥用作超聲波掃描的造影劑。選用此藥需經醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Vardenafil; its salts (伐地那非;其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p data-bbox="903 277 1479 696"> This drug is used to treat erectile dysfunction. This drug should not be used in patients taking certain cardiac drugs and those who have severe liver impairments and end stage kidney disease, hypotension, recent history of stroke or heart attacks. Medical decision is required for the use of this drug. </p> <p data-bbox="903 801 1479 1032"> 此藥用於治療勃起障礙。此藥不應用於正在服用某些心臟藥的病人或有嚴重肝損害、末期腎病、血壓低和近期有中風或心臟病發記錄的病人。選用此藥需經醫生決定。 </p>