

立法會 *Legislative Council*

立法會LS19/03-04號文件

2003年12月5日內務委員會會議文件

根據《藥劑業及毒藥條例》(第138章)第29條 提出的決議案

法律事務部報告

衛生福利及食物局局長(下稱“局長”)已發出預告，表示將於2003年12月17日的立法會會議席上動議兩項議案。該兩項議案旨在請立法會通過 ——

- (a) 《2003年藥劑業及毒藥(修訂)(第4號)規例》；
- (b) 《2003年毒藥表(修訂)(第4號)規例》；
- (c) 《2003年藥劑業及毒藥(修訂)(第5號)規例》；及
- (d) 《2003年毒藥表(修訂)(第5號)規例》。

2. 根據局長的發言擬稿，為對13種新註冊的藥劑製品施加管制，《2003年藥劑業及毒藥(修訂)(第4號)規例》及《2003年毒藥表(修訂)(第4號)規例》旨在 ——

- (a) 把一種新物質，即用於治療久咳的左旋羥丙哌嗪及其鹽類，加入毒藥表的第I部內。任何含有這種物質的藥劑製品，必須由註冊藥劑師在場監督下在藥房內出售；及
- (b) 把12種新物質加入毒藥表的第I部及《藥劑業及毒藥規例》的附表1和附表3內。任何含有這些物質其中任何一種的藥劑製品，均必須根據處方，由註冊藥劑師在場監督下在藥房內出售。

3. 上述兩項修訂規例若獲立法會通過，將於刊登憲報當日(即2003年12月19日)起生效，以便盡早對含有這些物質的藥劑製品加以管制，以及讓這類藥劑製品早日在市場銷售。

4. 另外，為加強對20種現有藥物的管制，《2003年藥劑業及毒藥(修訂)(第5號)規例》及《2003年毒藥表(修訂)(第5號)規例》旨在把20種現時被界定為非毒藥的物質，加入毒藥表的第I部及《藥劑業及毒藥規例》的附表1和附表3內。任何含有這些物質其中任何一種的藥劑製品，均必須根據處方，由註冊藥劑師在場監督下在藥房內出售。該兩項修訂規例將於2004年1月19日起生效，讓製造商及進口商有足夠的時間從藥房以外的藥物銷售點回收含有這些物質的藥劑製品。

5. 局長除在發言擬稿提供資料外，亦就這些物質提供一些補充資料，現隨文附上有關的資料，供議員參考(見附件)。

6. 該等規例均由藥劑業及毒藥管理局(下稱“管理局”)根據《藥劑業及毒藥條例》(第138章)第29條訂立。管理局認為，鑒於有關藥物的效用、毒性及潛在副作用，必須作出擬議的修訂。

7. 從法律觀點而言，該4項修訂規例均無問題。

連附件

立法會秘書處
助理法律顧問
何瑩珠
2003年12月1日

**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>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
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>
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>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
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>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>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>