

立法會 *Legislative Council*

立法會 LS133/02-03號文件

2003年6月20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7月2日的立法會會議席上動議一項議案。該議案旨在請立法會通過《2003年藥劑業及毒藥(修訂)(第2號)規例》、《2003年毒藥表(修訂)(第2號)規例》、《2003年藥劑業及毒藥(修訂)(第3號)規例》及《2003年毒藥表(修訂)(第3號)規例》。該4條修訂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。

2. 根據局長的發言擬稿，《2003年藥劑業及毒藥(修訂)(第2號)規例》及《2003年毒藥表(修訂)(第2號)規例》旨在把10種新藥物加入《藥劑業及毒藥規例》附表1及附表3，以及毒藥表第I部的A部內。該等新藥物為Bimatoprost、阿德福韋及其鹽類、依托考昔及其鹽類、依折麥布、Pimecrolimus、Sevelamer及其鹽類、Tadalafil及其鹽類、噻萘普汀；其鹽類；其酯類及它們的鹽類、Valganciclovir及其鹽類，以及Voriconazole及其鹽類。把這些藥物加入上述兩條規例的規管範圍後，任何含有這10種物質其中任何一種的藥劑製品，均必須根據註冊醫生、註冊牙醫或註冊獸醫開出的處方，在藥房內由註冊藥劑師親自或在場監督下出售。該兩項修訂規例獲立法會通過後，將於刊登憲報當日(即2003年7月4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。

3. 根據局長的發言擬稿，《2003年藥劑業及毒藥(修訂)(第3號)規例》及《2003年毒藥表(修訂)(第3號)規例》旨在把19種現時被界定為非毒藥的物質，加入《藥劑業及毒藥規例》附表1及附表3，以及毒藥表第I部的A部內。該等物質為乙酰唑胺及其鹽類、Antilymphocyte Immunoglobulins、絨促性素、氯法齊明及其鹽類、去鐵胺及其鹽類、二甲弗林及其鹽類、香草二乙胺及其鹽類、乙琥胺及其鹽類、依替福林及其鹽類、黃酮哌酯及其鹽類、亞葉酸及其鹽類、高血糖素及其鹽類、戈那瑞林及其鹽類、Inosine pranobex、美替拉酮及其鹽類、米多君及其鹽類、嗎啉胍及其鹽類、利巴韋林及其鹽類，以及阿糖腺苷及其鹽類。現時，含有這19種物質的藥劑製品可在任何類型的藥物銷售點出售。把這些物質加入上述兩條規例的規管範圍後，任何含有這19種物質其中任何一種的藥劑製品，均必須根據註冊醫生、註冊牙醫或註冊獸醫

開出的處方，在藥房內由註冊藥劑師親自或在場監督下出售。該兩項修訂規例將於2003年8月4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。

4. 局長除在發言擬稿提供資料外，亦就這29種新藥物提供一些補充資料，現隨文附上供議員參考(見附件)。

5. 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。

6. 從法律觀點而言，該4條修訂規例均無問題。

連附件

立法會秘書處
助理法律顧問
黎順和
2003年6月17日

Pharmacy and Poisons (Amendment)(No. 2) Regulation 2003

Poisons List (Amendment) (No. 2) Regulation 2003

Supplementary Information to the Legislative Council

《2003年藥劑業及毒藥（修訂）（第2號）規例》

《2003年毒藥表（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
Adefovir; its salts (阿德福韋；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 for the treatment of chronic hepatitis B. This drug should only be used when the need is established by a medical diagnosis and under careful monitoring. 此藥用於治療慢性乙型肝炎。此藥 應經醫生清楚診斷時，才能使用。 而使用時亦需小心觀察。
Bimatoprost, under the entry beginning with “Prostaglandins, the following and their derivatives-”	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	This drug is used to reduce intraocular pressure in patients with glaucoma or ocular hypertension. A doctor’s decision is required for whether or not to use this medicine. 此藥用於降低青光眼或高眼壓病人 的眼壓。選用此藥需經醫生決定。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Etoricoxib; its salts (依托考昔; 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 for the relief of arthritis and acute pain. Use of this medicine requires medical monitoring. 此藥用於舒緩關節炎及急性痛症。用此藥時，醫護人員需要小心觀察病人。
Ezetimibe (依折麥布)	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 patients with high blood cholesterol and homozygous sitosterolemia. A medical decision is required for the use of this medicine. 此藥用於治療高膽固醇及純合高麥胚脂醇之病人。選用此藥需經醫生決定。
Pimecrolimus	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 mild to moderate atopic dermatitis as a second line therapy. It should only be used when the need is established by a medical diagnosis. 此藥用於治療其他藥物不適用之輕微至中度特應性皮膚炎。此藥應經醫生診斷有需要時才用。
Sevelamer; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to reduce blood phosphorus level in patients with end-stage renal disease. Use of this drug requires careful monitoring. 此藥用於降低末期腎病病人之血含磷量。用此藥時需小心觀察病人。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Tadalafil; its salts	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 erectile dysfunction. Use of this drug requires careful monitoring. 此藥用於治療勃起障礙。用此藥時需小心觀察病人。
Tianeptine; its salts; its esters; their salts (噻萘普汀；其鹽類；其酯類；它們的鹽類)	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. This drug should only be used when a positive diagnosis of depression has been established by a doctor. 此藥用於治療嚴重抑鬱症。需經醫生清楚診斷病人有需要時才可選用。
Valganciclovir; its salts	Part I, First and Third Schedules poison	This drug is used to treat inflammation of the retina caused by cytomegalovirus in patients with AIDS. It should be used after confirmed medical diagnosis and under careful monitoring. 此藥用於治療愛滋病人由巨細胞病毒引致之視網膜炎。需經醫生確定診症後才用藥而病人需被小心觀察。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Voriconazole; 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 to treat serious fungal infections. Use of this drug requires medical decision and monitoring.</p> <p>此藥用於治療嚴重真菌感染。選用此藥需經醫生決定及觀察。</p>

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2003

Poisons List (Amendment) (No. 3) Regulation 2003

Supplementary Information to the Legislative Council

《2003年藥劑業及毒藥（修訂）（第3號）規例》

《2003年毒藥表（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
Acetazolamide; its salts 乙酰唑胺；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 for glaucoma, oedema and some forms of epilepsy. A medical decision is required to diagnose the disease and to establish the need for this drug. Proper medical supervision is also required during administration.</p> <p>此藥用於青光眼，水腫，和某些癲癇症。選用此藥需經醫生斷症及確定有需要才用。用藥時需要適當的醫護監督。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Antilymphocyte Immunoglobulins	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to suppress the immune system in an acute rejection episode or as preventive treatment during organ/tissue transplants. It is also used in aplastic anaemia. Medical decision is required on the use of this drug and medical supervision is required during administration. 此藥用於在器官/組織移植過程中出現急性排斥現象時抑制免疫系統，以及作預防性治療。此藥亦可用於治療成形不全性貧血。需經醫生決定才使用此藥而用藥時需由醫生監督。
Chorionic Gonadotrophin 絨促性素	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to induce ovulation in infertile women and treat prepubertal males with cryptorchidism (testes failing to descend). A medical decision is required on whether or not this drug should be used. 此藥用作不育婦女引導排卵用及治療青春期前少男之隱睪病。需經醫生決定才可使用此藥。
Clofazimine; its salts 氯法齊明；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 multibacillary leprosy and severe mycobacterial infections. This drug should only be used when a proper medical diagnosis has been made. 此藥用於治療多種細菌感染之麻瘋及嚴重分支桿菌感染。此藥應經適當的診斷後才用。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Desferrioxamine; its salts 去鐵胺; 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 chronic iron overload and acute iron poisoning. The need to use this drug should be established by a medical diagnosis. Medical monitoring of the side effects is also required. 此藥用於治療慢性鐵質過高及急性鐵質中毒。選用此藥需經醫生斷症及確定有需要才用。用此藥時，醫護人員需要小心觀察病人副作用反應。
Dimeflin; its salts 二甲弗林; 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 acute respiratory failure and postoperative respiratory depression. Medical decision is required on the use of this drug and medical supervision is required during administration. 此藥用於治療急性呼吸衰歇及手術後呼吸抑制。選用此藥需經醫生決定而用藥時醫護人員需要小心觀察病人。
Etamivan; its salts 香草二乙胺; 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 in treatment of acute respiratory failure. The need to use this drug should be established by a medical diagnosis. 此藥用於治療急性呼吸衰歇。選用此藥需經醫生斷症適用。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Ethosuximide; its salts 乙琥胺; 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 seizures. The need to use this drug should be established by a medical diagnosis. Close medical supervision is also required during use. 此藥用於治療癲癇發作。選用此藥需經醫生斷症及確定有需要才用。用藥時醫護人員需要緊密觀察病人。
Etilefrine; its salts 依替福林; 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 hypotensive states. Medical decision and monitoring are required for the use of this drug. 此藥用於治療血壓過低狀態。用此藥時需經醫生決定及觀察。
Flavoxate; its salts 黃酮哌酯; 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 relieve pain, urinary frequency and incontinence associated with inflammatory disorders of the urinary tract. A medical decision is required on whether or not to use this drug. 此藥用於舒緩因尿道發炎引致之痛楚, 尿頻及失禁。需經醫生決定才用此藥。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Folinic acid; its salts 亞葉酸；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 reduce the toxicity of methotrexate, a chemotherapy agent. It is also used to enhance the effect of another chemotherapeutic agent, fluouracil. Folinic acid is also used to treat folate-deficient megaloblastic anaemia. A medical decision and close supervision are required for the administration of this drug.</p> <p>此藥用於減低抗癌藥「甲氨蝶呤」之毒性及增進另一抗癌藥「氟尿嘧啶」之藥效。亞葉酸亦用於治療因缺乏葉酸而致的幼巨紅細胞式貧血病。選用此藥需經醫生決定才用而用藥時醫護人員需要緊密觀察病人。</p>
Glucagon; its salts 高血糖素；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 severe hypoglycaemic reactions and as a diagnostic aid in gastrointestinal examinations. A medical decision and close monitoring are required on using this drug.</p> <p>此藥用於治療嚴重低血糖反應症及胃腸道檢查之症工具。選用此藥需經醫生決定才用而用藥時醫護人員需要緊密觀察病人。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Gonadorelin; its salts 戈那瑞林; 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 in the diagnosis of hypothalamic-pituitary-gonadal dysfunction. It is also used in the treatment of amenorrhoea and infertility. The drug should be used only when the need is established by a medical diagnosis. 此藥用作診斷丘腦下部-垂體-性腺功效失調, 也用於治療閉經及不育。選用此藥需經醫生斷症適用。
Inosine pranobex	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 various viral infections. A doctor's diagnosis is required before drug use. Close medical supervision during use. 此藥用於治療各種病毒感染。選用此藥需經醫生決定才用而用藥時醫護人員需要緊密觀察病人。
Metyrapone; its salts 美替拉酮; 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 in the diagnosis and management of Cushing's syndrome. It has also been used to treat some resistant oedema. Medical diagnosis is required before use of this drug. 此藥用作診斷及控制庫興氏綜合症, 亦曾用作治療某些抗藥水腫。選用此藥需經醫生斷症適用。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Midodrine; its salts 米多君; 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 hypotensive states such as orthostatic hypotension. It is also used as an adjunct in the management of urinary incontinence. The need to use this drug should be established by a medical diagnosis.</p> <p>此藥用於治療血壓過低狀態，例如直立性低血壓。也用作控制失禁之佐藥。選用此藥需經醫生斷症適用。</p>
Moroxydine; its salts 嗎口林 胍; 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 in the treatment of herpes simplex and varicella-zoster infections. It is also used as an ingredient in medicines for the treatment of cold and flu symptoms. A medical diagnosis and supervision is needed for the use of the drug.</p> <p>此藥用於治療單純疱疹及水痘-帶狀疱疹感染。它亦是某些傷風感冒藥品的成份。選用此藥需經醫生斷症適用而用藥時需要觀察病人。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Ribavirin; its salts 利巴韋林; 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 respiratory syncytial virus infections and treatment of chronic hepatitis C. It has also been tried in haemorrhagic fevers and recently, in the management of Severe Acute Respiratory Syndrome. This drug should only be used when the need is established by a medical diagnosis. Proper medical supervision is required during administration.</p> <p>此藥用於治療呼吸道融合細胞病毒感染及慢性丙形肝炎,亦試用於出血性發熱和近來的嚴重急性呼吸系統綜合症。選用此藥需經醫生斷症適用而用藥時需要觀察病人。</p>
Vidarabine; its salts 阿糖腺苷; 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 in treatment of severe and disseminated herpes simplex infections and herpes zoster. Topically, it is used in treatment of herpes simplex keratitis and keratoconjunctivitis. This drug should only be used when the need is established by a medical diagnosis.</p> <p>此藥用於治療嚴重及播散性單純疱疹及帶狀疱疹感染。外用時用於單純疱疹引致之角膜炎和角膜結膜炎。選用此藥需經醫生斷症適用。</p>