

立法會
Legislative Council

LC Paper No. LS133/02-03

**Paper for the House Committee Meeting
on 20 June 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 a motion at the Council meeting on 2 July 2003. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No.2) Regulation 2003, the Poisons List (Amendment) (No.2) Regulation 2003, the Pharmacy and Poisons (Amendment) (No.3) Regulation 2003 and the Poisons List (Amendment) (No.3) Regulation 2003; all made by the Pharmacy and Poisons Board ("the Board") 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 2003 and the Poisons List (Amendment) (No.2) Regulation 2003 seek to add 10 new drugs/medicines, i.e. Bimatoprost, Adefovir and its salts, Etoricoxib and its salts, Ezetimibe, Pimecrolimus, Sevelamer and its salts, Tadalafil and its salts, Tianeptine; its salts; its esters and their salts, Valganciclovir and its salts and Voriconazole and its salts to the First and Third Schedules to the Pharmacy and Poisons Regulations and Part A of Part I of the Poisons List. Their addition means that pharmaceutical products containing any of these 10 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. 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. 4 July 2003 to allow early control and sale of medicines containing these substances.

3. According to the draft speech of the Secretary, the Pharmacy and Poisons (Amendment) (No.3) Regulation 2003 and the Poisons List (Amendment) (No.3) Regulation 2003 seek to add 19 substances, now classified as non-poisons, i.e. Acetazolamide and its salts, Antilymphocyte Immunoglobulins, Chorionic Gonadotrophin, Clofazimine and its salts, Desferrioxamine and its salts, Dimeflin and its salts, Etamivan and its salts, Ethosuximide and its salts, Etilefrine and its salts, Flavoxate and its salts, Folinic acid and its salts, Glucagon and its salts, Gonadorelin and

its salts, Inosine pranobex, Metyrapone and its salts, Midodrine and its salts, Moroxydine and its salts, Ribavirin and its salts and Vidarabine and its salts to the First and Third Schedules to the Pharmacy and Poisons Regulations and Part A of Part I of the Poisons List. Their addition means that pharmaceutical products containing any of these 19 substances, which are sold in all kinds of medicines outlets now, must then 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. The two Amendment Regulations shall come into operation on 4 August 2003 to allow time for the manufacturers and importers to recall pharmaceutical products containing these substances from medicines outlets other than pharmacies.

4. The Secretary has provided, in addition to his draft speech, supplementary information on these 29 new drugs/medicines, which is attached for Members' reference (see Annex).

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

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

Encl

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17 June 2003

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	This drug is used to treat serious fungal infections. Use of this drug requires medical decision and monitoring. 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。

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	<p>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.</p> <p>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。</p>
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	<p>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.</p> <p>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。</p>
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	<p>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.</p> <p>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。</p>

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	<p>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.</p> <p>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。</p>
Inosine pranobex	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 various viral infections. A doctor's diagnosis is required before drug use. Close medical supervision during use.</p> <p>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。</p>
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	<p>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.</p> <p>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。</p>

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 嗎口林瓜; 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>