

立法會

Legislative Council

LC Paper No. LS27/04-05

Paper for the House Committee Meeting on 7 January 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 19 January 2005. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2004 and the Poisons List (Amendment) (No. 4) Regulation 2004, both made by the Pharmacy and Poisons Board ("the Board") on 28 December 2004 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. 4) Regulation 2004 and the Poisons List (Amendment) (No. 4) Regulation 2004 seek to:

- (a) add 3 new drugs/medicines, i.e. Eplerenone, Olmesartan; its salts; its esters and their salts and Pregabalin 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 3 new drugs/medicines, which is attached for Members' reference (see Annex). Their addition means that pharmaceutical products containing any of these 3 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; and

- (b) amend the item “Tromantadine; its salts” in part A of the First and Third Schedules to the Pharmacy and Poisons Regulations by adding “; except when contained in pharmaceutical products labelled for the treatment of cold sores only” after “salts”. The effect of such amendment is to relax the control on pharmaceutical products containing “Tromantadine; its salts” and labelled “for the treatment of cold sores only” by re-classifying them from Part I, First and Third Schedules poisons into Part I poisons (i.e. to be sold under the direct supervision of registered pharmacists without the requirement of a prescription). Other pharmaceutical products containing “Tromantadine; its salts” are still Part I, First and Third Schedules poisons (i.e. pharmaceutical products containing such 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 Secretary has provided, in addition to his draft speech, supplementary information on “Tromantadine; its salts (when contained in pharmaceutical products labelled ‘for the treatment of cold sores only’)”, which is attached for Members’ reference (see Annex).

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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5 January 2005

Poisons List (Amendment) (No.4) Regulation 2004

Pharmacy and Poisons (Amendment) (No.4) Regulation 2004

Supplementary Information to the Legislative Council

《 2004年毒藥表（修訂）(第4號) 規例 》
《 2004年藥劑業及毒藥（修訂）(第4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
Eplerenone (依普利酮)	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 risk of death in patients with heart failure after a recent heart attack. A doctor's decision is required for whether or not to use this medicine after establishing diagnosis. Medical monitoring is required during its administration.</p> <p>此藥用於降低近期心臟病發之心臟衰竭病人的死亡風險。此藥需經醫生確診後, 決定有需要時才使用。用此藥時需要醫生小心觀察病人。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Olmesartan; its salts; its esters; their salts (奧美沙坦; 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	<p>This drug is used for the treatment of high blood pressure. A doctor's decision is required for whether or not to use this medicine after establishing diagnosis. Medical monitoring is required particularly in patients with impaired kidney function.</p> <p>此藥用於治療高血壓。此藥需經醫生確診後,決定有需要時才使用。腎臟功能障礙病人用此藥時,特別需要醫生小心觀察病人。</p>
Pregabalin; its salts (普瑞巴林; 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 for the treatment of peripheral nerve pain and as a supportive treatment for localized epileptic seizures. It should only be used when the need and suitability is established by a medical practitioner.</p> <p>此藥用於治療外周神經痛及作為治療限界性癲癇之佐藥。應經醫生診斷有需要及適用時,才能使用。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
<p>Tromantadine; its salts (when contained in pharmaceutical products labelled ‘for the treatment of cold sores only’)</p> <p>曲金剛胺; 其鹽類 (當存在於標明只作治療唇皰疹之用的藥物內時)</p>	<p>Part I poison 第一部毒藥</p>	<p>This drug is used for the treatment of various viral infections of the skin and mucous membranes, including cold sores. As cold sores are self-limiting and are comparatively non-serious, treatment of cold sores with this drug does not require a doctor’s supervision. Other viral infections are more serious and a doctor’s diagnosis and advice are required for treatment. Products containing this drug and labelled “for the treatment of cold sores only” should be sold, without prescription, by a pharmacist who ensures that the product is only used for cold sores. Other products containing the drug will continue to be Part I, First and Third Schedules poisons, i.e. prescription-only medicines.</p> <p>此藥用於治療各種皮膚及黏膜的病毒感染，包括唇皰疹。由於唇皰疹是會自行痊癒而嚴重性亦比較低，所以用此藥治療唇皰疹時並不需要醫生的監督。其它的病毒感染比較嚴重，所以需要醫生的診斷和專業意見才可用此藥。含有此藥而又標明「只作治療唇皰疹之用」的產品，可在未有醫生處方的情況下由藥劑師在確實此藥只用作治療唇皰疹時售賣。而其它含有此藥的藥品則仍然是第一部附表一及附表三毒藥，即醫生處方藥品。</p>