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Date : 31 December 2004

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 19 January 2005

Proposed resolution under the Pharmacy and Poisons Ordinance

I forward for Members' consideration a proposed resolution which the Secretary for Health, Welfare and Food will move at the Council meeting of 19 January 2005 under the Pharmacy and Poisons Ordinance. The President has directed that "it be printed in the terms in which it was handed in" on the Agenda of the Council.

2. The speech, in both English and Chinese versions, which the Secretary will deliver when moving the proposed resolution, and the supplementary information provided by the Secretary, are also attached.

(Ray CHAN)
for Clerk to the Legislative Council

Encl.

PHARMACY AND POISONS ORDINANCE

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RESOLUTION

(Under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138))

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RESOLVED that the following Regulations, made by the Pharmacy and Poisons Board on 28 December 2004, be approved –

(a) the Pharmacy and Poisons (Amendment)(No. 4) Regulation 2004; and

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

PHARMACY AND POISONS (AMENDMENT)(NO. 4) REGULATION 2004

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. Substances falling within the Poisons List to which special restrictions apply under regulations 3 and 5

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended, in part A –

(a) in the item "Tromantadine; its salts", by adding "; except when contained in pharmaceutical products labelled for the treatment of cold sores only" after "salts";

(b) by adding –

"Eplerenone
Olmesartan; its salts; its esters; their salts
Pregabalin; its salts".

2. Substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon

The Third Schedule is amended, in part A –

(a) in the item "Tromantadine; its salts", by adding "; except when contained in pharmaceutical products labelled for the treatment of cold sores only" after "salts";

(b) by adding –

"Eplerenone
Olmesartan; its salts; its esters; their salts
Pregabalin; its salts".

Chairman,
Pharmacy and Poisons Board

28 December 2004

Explanatory Note

This Regulation adds 3 substances to each of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) so that the sale and storage of the 3 substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the Regulations.

2. The Regulation also provides that Tromantadine or its salts, if contained in pharmaceutical products labelled for the treatment of cold sores only, would be excepted from the application of the First and Third Schedules, and thus will no longer be subject to the above restrictions.

POISONS LIST (AMENDMENT)(NO. 4) REGULATION 2004

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. The Poisons List

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in part A, by adding –

"Eplerenone
Olmesartan; its salts; its esters; their salts
Pregabalin; its salts".

Chairman,
Pharmacy and Poisons Board

28 December 2004

Explanatory Note

This Regulation adds 3 substances to part A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B). Poisons listed in that part are essentially for medicinal use. The Pharmacy and Poisons Ordinance (Cap. 138) and its subsidiary legislation provide, among others, that such poisons may only be sold on the premises registered under the Ordinance by a registered pharmacist or in his presence and under his supervision.

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	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. 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。

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	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. 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。
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	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. 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。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Tromantadine; its salts (when contained in pharmaceutical products labelled 'for the treatment of cold sores only') 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)	Part I poison 第一部毒藥	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. 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。

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 19 JANUARY 2005

Pharmacy and Poisons Ordinance (Cap 138)
Pharmacy and Poisons (Amendment) Regulation (No. 4) 2004
Poisons List (Amendment) Regulation (No. 4) 2004

Madam President,

I move that the Poisons List (Amendment) (No. 4) Regulation 2004 and the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2004 as set out under my name in the paper circulated to Members be approved.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and inspection system set up in accordance with the Pharmacy and Poisons Ordinance. The Ordinance maintains a Poisons List under the Poisons List Regulations and several Schedules under the Pharmacy and Poisons Regulations. Pharmaceutical products put on different parts of the Poisons List and different Schedules are subject to different levels of control in regard to the conditions of sale and keeping of records.

3. For the protection of public health, some pharmaceutical products can only be sold in pharmacies under the supervision of registered pharmacists and in their presence. For certain pharmaceutical products, proper records of the particulars of the sale must be kept, including the date of sale, the name and address of the purchaser, the name and

quantity of the medicine and the purpose for which it is required. The sale of some pharmaceutical products must be authorized by prescription from a registered medical practitioner, a registered dentist or a registered veterinary surgeon.

4. The Amendment Regulations now before Members seek to amend the Poisons List in the Poisons List Regulations and the Schedules to the Pharmacy and Poisons Regulations for the purpose of imposing control on three new pharmaceutical products, as well as to relax control on one pharmaceutical product.

5. The Pharmacy and Poisons Board proposes to add three 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 such substances must be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. Besides, the Pharmacy and Poisons Board proposes to partially relax the control on "Tromantadine; its salts". Pharmaceutical products containing this substance and labeled "for the treatment of cold sores only" will be re-classified 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 this substance are still Part I, First and Third Schedules poisons (i.e. prescription medicines).

7. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under section 3 of the Ordinance to regulate the registration and control of pharmaceutical products. The Board comprises members engaged in the pharmacy, medical and academic professions. The Board considers the proposed amendments necessary in view of the potency, toxicity and potential side effects of the medicines concerned.

8. With these remarks, Madam President, I move the motion.