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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 4 May 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 4 May 2005 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) Regulation 2005; and
- (b) the Poisons List (Amendment) Regulation 2005.

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

RESOLUTION

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

RESOLVED that the following Regulations, made by the Pharmacy and Poisons Board on _____ 2005, be approved -

- (a) the Pharmacy and Poisons (Amendment) Regulation 2005;
- and
- (b) the Poisons List (Amendment) Regulation 2005.

PHARMACY AND POISONS (AMENDMENT) REGULATION 2005

(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, by adding -

"Aripiprazole

Atomoxetine; its salts

Bortezomib

Cetuximab

Nicotinic acid; its salts; only when contained in

pharmaceutical products the recommended daily dose of which

contains more than 200 mg of nicotinic acid

Pemetrexed; its salts; its esters; their 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, by adding -

"Aripiprazole

Atomoxetine; its salts

Bortezomib

Cetuximab

Nicotinic acid; its salts; only when contained in
pharmaceutical products the recommended daily dose of which
contains more than 200 mg of nicotinic acid
Pemetrexed; its salts; its esters; their salts".

Chairman,
Pharmacy and Poisons Board

2005

Explanatory Note

This Regulation adds 6 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 6 substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the Regulations. (Of the 6 substances, Nicotinic acid and its salts are subject to the restrictions only when they are contained in pharmaceutical products and the recommended daily dose of the products contains more than 200 mg of nicotinic acid.)

POISONS LIST (AMENDMENT) REGULATION 2005

(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 -

"Aripiprazole

Atomoxetine; its salts

Bortezomib

Cetuximab

Nicotinic acid; its salts; only when contained in

pharmaceutical products the recommended daily dose of

which contains more than 200 mg of nicotinic acid

Pemetrexed; its salts; its esters; their salts".

Chairman,
Pharmacy and Poisons Board

2005

Explanatory Note

This Regulation adds 6 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. Under the Pharmacy and Poisons Ordinance (Cap. 138) 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.

**SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 4 MAY 2005**

**Pharmacy and Poisons Ordinance (Cap 138)
Pharmacy and Poisons (Amendment) Regulation 2005
Poisons List (Amendment) Regulation 2005**

Madam President,

I move that the Poisons List (Amendment) Regulation 2005 and the Pharmacy and Poisons (Amendment) Regulation 2005 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 six new pharmaceutical products.

5. The Pharmacy and Poisons Board proposes to add six 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. 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.

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

Poisons List (Amendment) Regulation 2005

Pharmacy and Poisons (Amendment) Regulation 2005

Supplementary Information to the Legislative Council

《 2005年毒藥表（修訂）規例 》
《 2005年藥劑業及毒藥（修訂）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
Aripiprazole (阿立哌唑)	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 schizophrenia. It should only be used after the need is established by a medical diagnosis. Patients with established diabetes or risk for diabetes should be monitored.</p> <p>此藥用於治療精神分裂症。此藥需經醫生確診後，決定有需要時才使用。有糖尿病或有糖尿病風險的病人，用此藥時需要醫生觀察病人。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Atomoxetine; its salts (托莫西汀; 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 for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children 6 years of age and older. Monitoring is required during its administration and its use should be decided by a doctor when the need is confirmed.</p> <p>此藥用於治療六歲以上兒童之過度活躍症。服用此藥需由醫生觀察病人而選用此藥應由醫生決定有需要時才使用。</p>
Bortezomib (硼替左米)	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 treatment of myeloma (malignancy of bone marrow). A doctor's decision is required as to whether or not this medicine should be used after proper diagnosis. Medical monitoring is also required during administration.</p> <p>此藥用於治療骨髓瘤。此藥需經醫生確診後,決定有需要時才使用。用此藥時亦需要醫生小心觀察病人。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Cetuximab (西妥昔单抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used as a second line treatment for metastatic colorectal cancer. A doctor's decision is required for whether or not to use this medicine. 此藥用於擴散性結腸/直腸癌的第二線治療。此藥需由醫生決定有需要時才使用。
Nicotinic acid; its salts; when contained in pharmaceutical products and with a recommended daily dose exceeding 200mg of nicotinic acid. (煙酸;其鹽類; 當載於藥劑製品及其每日建議用量超過200毫克煙酸時)	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 cholesterol and lipid levels. The need to use this drug should be established by medical diagnosis and monitoring of patients is required during administration. 此藥用於治療高膽固醇及高血脂症。此藥應經醫生診斷有需要時，才能使用。而病人亦需於用藥時接受觀察。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Pemetrexed; its salts; its esters; their salts (培美曲塞; 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 tumour of the pleura and metastatic lung cancer. The need to use this drug should be established by medical diagnosis. Monitoring of blood count is required before and during treatment.</p> <p>此藥用於治療胸膜間皮瘤和擴散性肺癌。此藥需經醫生確診後，決定有需要時才用。病人服用此藥前或服藥期間需接受血细胞計數的監察。</p>