

**立法會**  
**Legislative Council**

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Date : 8 June 2009

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

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**Council meeting of 24 June 2009**

**Proposed resolution under  
the Pharmacy and Poisons Ordinance**

I forward for Members' consideration a proposed resolution which the Secretary for Food and Health will move at the Council meeting of 24 June 2009 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2009; and
- (b) the Poisons List (Amendment) (No. 2) Regulation 2009.

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.

( Mrs Justina LAM )  
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 3 June 2009, be approved –

- (a) the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2009; and
- (b) the Poisons List (Amendment) (No. 2) Regulation 2009.

## **PHARMACY AND POISONS (AMENDMENT) (NO. 2) REGULATION 2009**

(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. First Schedule amended**

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

- (a) by adding “Abatacept”;
- (b) in the item relating to “Antisera, antitoxins, immunoglobulins and vaccines”, in paragraph (b), by adding –  
“Feline calicivirus  
Feline Chlamydia psittaci  
Feline leukemia virus  
Feline panleukopenia virus  
Feline rhinotracheitis virus”;
- (c) by adding “Cinacalcet; its salts”;
- (d) by adding “Fesoterodine; its salts; its esters; their salts”;
- (e) by adding “Temsirolimus; its salts; its esters”.

### **2. Third Schedule amended**

The Third Schedule is amended, in Division A –

- (a) by adding “Abatacept”;
- (b) in the item relating to “Antisera, antitoxins, immunoglobulins and vaccines”, in paragraph (b), by adding –  
“Feline calicivirus  
Feline Chlamydia psittaci  
Feline leukemia virus

Feline panleukopenia virus

Feline rhinotracheitis virus”;

- (c) by adding “Cinacalcet; its salts”;
- (d) by adding “Fesoterodine; its salts; its esters; their salts”;
- (e) by adding “Temsirolimus; its salts; its esters”.

Chairman,  
Pharmacy and Poisons Board

3 June 2009

### **Explanatory Note**

This Regulation adds 9 substances to the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (“principal Regulations”) respectively so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

## **POISONS LIST (AMENDMENT) (NO. 2) REGULATION 2009**

(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 Division A –

- (a) by adding “Abatacept”;
- (b) in the item relating to “Antisera, antitoxins, immunoglobulins and vaccines”, in paragraph (b), by adding –  
“Feline calicivirus  
Feline Chlamydia psittaci  
Feline leukemia virus  
Feline panleukopenia virus  
Feline rhinotracheitis virus”;
- (c) by adding “Cinacalcet; its salts”;
- (d) by adding “Fesoterodine; its salts; its esters; their salts”;
- (e) by adding “Temsirolimus; its salts; its esters”.

Chairman,  
Pharmacy and Poisons Board

3 June 2009

### **Explanatory Note**

This Regulation adds 9 substances to Division A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) so that, among other applicable requirements, poisons containing those substances can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the pharmacist's presence and under the pharmacist's supervision.

**SPEECH BY  
THE SECRETARY FOR FOOD AND HEALTH  
AT THE LEGISLATIVE COUNCIL  
ON 24 June 2009**

**Pharmacy and Poisons Ordinance (Cap. 138)**

**Pharmacy and Poisons (Amendment) (No. 2) Regulation 2009  
Poisons List (Amendment) (No. 2) Regulation 2009**

Mr President,

I move that the motion under my name, as printed on the Agenda, be passed.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and monitoring 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, dentist or veterinary surgeon.

4. Arising from an application for registration of nine pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following nine substances to Part I of the Poisons List and

the First and Third Schedules to the Pharmacy and Poisons Regulations:

- (a) Abatacept;
- (b) Feline calicivirus;
- (c) Feline Chlamydia psittaci;
- (d) Feline leukemia virus;
- (e) Feline panleukopenia virus;
- (f) Feline rhinotracheitis virus;
- (g) Cinacalcet; its salts;
- (h) Fesoterodine; its salts; its esters; their salts;
- (i) Temsirolimus; its salts; its esters.

5. Pharmaceutical products containing the above substances must then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. We propose that these amendment regulations take immediate effect upon gazettal on 26 June 2009 to allow early control and sale of the relevant medicine.

7. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under the Ordinance to regulate 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 medicine concerned.

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



## Poisons List (Amendment) (No. 2) Regulation 2009

### Pharmacy and Poisons (Amendment) (No. 2) Regulation 2009

#### Supplementary Information to the Legislative Council

《2009年毒藥表(修訂)(第二號)規例》  
《2009年藥劑業及毒藥(修訂)(第二號)規例》  
提交立法會的補充資料

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
Abatacept (阿巴西普)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This is an anti-inflammatory drug for treating adults with moderate to severe active rheumatoid arthritis (an immune system disease causing damage and inflammation in the joints). It is used in patients who have not had a sufficient response to other medicines for rheumatoid arthritis including at least one ‘tumour necrosis factor (TNF) blocker’, or who cannot be given these medicines. It should not be used in patients with severe and uncontrolled infections, such as sepsis (serious blood infection) or ‘opportunistic’ infections (infections seen in patients with damaged immune systems). Its use should be decided by a doctor based on the patient’s condition.</p> <p>這是消炎藥，用以治療患有中度至嚴重風濕性關節炎(一種令關節受到破壞及發炎的免疫系統疾病)的成人。此藥物用於對其他治療風濕性關節炎藥物(包括至少一種‘腫瘤壞死因子(TNF)阻斷劑’)沒有足夠反應的病人，或不能服用這些藥物的病人。此藥物不應用於受到嚴重及未經控制感染(例如屬嚴重血液感染的敗血病)或‘機會性’感染(見於免疫系統受破壞病人的感染)的病人。使用該藥與否，須由醫生按病人的病情決定。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
<ul style="list-style-type: none"> <li>- Feline calicivirus</li> <li>- Feline Chlamydia psittaci</li> <li>- Feline leukemia virus</li> <li>- Feline panleukopenia virus</li> <li>- Feline rhinotracheitis virus</li> </ul> <p>(In the item relating to “Antisera, antitoxin, immunoglobulins and vaccines” under (b))</p> <p>(在“抗血清，抗毒素，免疫球蛋白與疫苗”一欄的(b)下)</p>	<p>Part I, First and Third Schedules            poison            第一部附表一及附表三毒藥</p>	<p>This vaccine is used for aid in the prevention of disease caused by Feline leukemia, rhinotracheitis, calici, panleukopenia viruses and feline Chlamydia psittaci in healthy cats 8-10 weeks of age or older. The side effects of the vaccine include shock, pain on injection site, lethargy, fever, vomiting, and diarrhea. Its administration should be monitored by a veterinary surgeon.</p> <p>這種疫苗用以預防在8至10個星期大或以上健康貓隻中由貓鼻氣管炎、卡里西、白細胞減少病病毒及貓披衣菌所引致的疾病。此疫苗的副作用包括休克，注射部位疼痛，嗜睡，發熱，嘔吐，及腹瀉。使用該疫苗時，須有獸醫監視。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
Cinacalcet; its salts (西那卡塞；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 secondary hyperparathyroidism. This is a condition in which the parathyroid glands in the neck produce too much parathyroid hormone (PTH). ‘Secondary’ means that the hyperparathyroidism is caused by another condition. It is used in patients with serious kidney disease who need dialysis to clear their blood of waste products. It can be used as part of treatment including phosphate binders or vitamin D sterols. Its use should be decided by a doctor based on the patient’s condition.</p> <p>此藥物用以治療繼發性副甲狀腺機能亢進，其情況是頸部的副甲狀腺製造過多的副甲狀腺激素 (PTH)。「繼發性」是指副甲狀腺機能亢進是由另一種情況所引致的。此藥物用於需用透析法清除血液中廢物的嚴重腎病患者。此藥物可用作包括磷酸鹽結合劑或維生素D固醇等治療的一部分。使用該藥與否，須由醫生按病人的病情決定。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
<p>Fesoterodine; its salts; its esters; their salts</p> <p>(非索羅定；其鹽類；其酯類；它們的鹽類)</p>	<p>Part I, First and Third Schedules poison</p> <p>第一部附表一及附表三毒藥</p>	<p>This drug is used in patients with overactive bladder syndrome to treat the symptoms of the disease: increased urinary frequency (need to urinate frequently), urgency (sudden urge to pass urine), and urgency incontinence (sudden lack of control over urination). This drug should not be used in patients with urinary retention (difficulty in passing urine), gastric retention (when the stomach does not empty properly), uncontrolled narrow-angle glaucoma (increased eye pressure even with treatment), myasthenia gravis (a disease of the nerves causing muscle weakness), severe hepatic impairment (severe liver disease), severe ulcerative colitis (severe inflammation of the large intestine causing ulceration and bleeding), and toxic megacolon (a very serious complication of colitis). This drug should only be used upon medical judgment on appropriate usage.</p> <p>此藥物用於膀胱過度活躍症患者，以治療這種疾病的症狀：尿頻次數增加(經常需要小便)、尿急(突然想小便)，以及急迫性尿失禁(突然不能控制小便)。此藥物不應用於患有以下疾病的病人：尿滯留(小便困難)、胃滯留(腸胃不能正常排便)、未經控制的窄角型青光眼(經治療後眼壓仍持續上升)、重症肌無力症(一種引致肌肉無力的神經疾病)、嚴重肝損傷(嚴重肝病)、嚴重潰瘍性結腸炎(大腸嚴重發炎，引致潰瘍及出血)，以及中毒性巨結腸(一種非常嚴重的巨結腸併發症)。需經醫生清楚診斷適用時，才能使用此藥物。</p>

<b>Drug Name</b> <b>藥名</b>	<b>Proposed Classification</b> <b>建議類別</b>	<b>Reason</b> <b>原因</b>
<p>Temsirolimus; its salts: its esters (坦羅莫司；其鹽類；其酯類)</p>	<p>Part I, First and Third Schedules poison 第一部附表一及附表三毒藥</p>	<p>This drug is used to treat patients with advanced renal cell carcinoma (kidney cancer). The most common side effects include anaemia (low red blood cell counts), nausea (feeling sick), rash, anorexia (loss of appetite), oedema (swelling) and asthenia (weakness). A medical decision is required for the use of this medicine.</p> <p>此藥物用以治療晚期腎細胞瘤(腎癌)患者。最常見的副作用包括貧血(低紅血球計數)、噁心(感到不適)、發疹、厭食(食慾不振)、水腫(腫脹)及虛弱(無力)。選用此藥需經醫生決定。</p>