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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 16 December 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 16 December 2009 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2009; and

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

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 24 November 2009, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2009; and

(*b*) the Poisons List (Amendment) (No. 4) Regulation 2009.

PHARMACY AND POISONS (AMENDMENT) (NO. 4) 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 "Allergen extract of Dermatophagoides pteronyssinus";

(*b*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", in paragraph (*b*) –

(i) by adding ", viruses" after "diseases";

(ii) by adding –

"Bordetella species

Canine infectious disease";

(*c*) by adding "Mertiatide; its salts; its esters; their salts";

(*d*) by adding "Prasugrel; its salts";

(*e*) by adding "Racecadotril; its salts";

(*f*) by adding "Tafluprost";

(*g*) by adding "Trabectedin; its salts; its esters".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Allergen extract of Dermatophagoides pteronyssinus";

(*b*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", in paragraph (*b*) –

(i) by adding ", viruses" after "diseases";

(ii) by adding –

"Bordetella species

Canine infectious disease";

(*c*) by adding "Mertiatide; its salts; its esters; their salts";

(*d*) by adding "Prasugrel; its salts";

(*e*) by adding "Racecadotril; its salts";

(*f*) by adding "Tafluprost";

(*g*) by adding "Trabectedin; its salts; its esters".

Chairman,
Pharmacy and Poisons Board

24 November 2009

Explanatory Note

This Regulation adds 6 substances, as well as one organism and one disease under the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", to the Divisions A of 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, and of antisera, antitoxins, immunoglobulins or vaccines directed against that organism or disease, are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

2. The Regulation also adds a reference to "viruses" to paragraph (*b*) of the said item relating to "Antisera, antitoxins, immunoglobulins and vaccines" to make the description of that paragraph cover viruses as well.

POISONS LIST (AMENDMENT) (NO. 4) 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 "Allergen extract of Dermatophagoides pteronyssinus";

(*b*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", in paragraph (*b*) –

(i) by adding ", viruses" after "diseases";

(ii) by adding –

"Bordetella species

Canine infectious disease";

(*c*) by adding "Mertiatide; its salts; its esters; their salts";

(*d*) by adding "Prasugrel; its salts";

(*e*) by adding "Racecadotril; its salts";

(*f*) by adding "Tafluprost";

(*g*) by adding "Trabectedin; its salts; its esters".

Chairman,
Pharmacy and Poisons Board

24 November 2009

Explanatory Note

This Regulation adds 6 substances, as well as one organism and one disease under the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", 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, as well as poisons containing antisera, antitoxins, immunoglobulins or vaccines directed against that organism or disease, 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.

2. The Regulation also adds a reference to "viruses" to paragraph (*b*) of the said item relating to "Antisera, antitoxins, immunoglobulins and vaccines" to make the description of that paragraph cover viruses as well.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 16 December 2009

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2009
Poisons List (Amendment) (No. 4) 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 eight pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following eight substances to Part I of the Poisons List and

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

(a) Allergen extract of Dermatophagoides pteronyssinus

(b) Bordetella species

(c) Canine infectious diseases; [the above 2 items to be listed under item (b) of "Antisera, antitoxins, immunoglobulins and vaccines"]

(d) Mertiatide; its salts; its esters; their salts

(e) Prasugrel; its salts

(f) Racecadotril; its salts

(g) Tafluprost

(h) Trabectedin; 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 18 December 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.4) Regulation 2009

Pharmacy and Poisons (Amendment) (No.4) Regulation 2009

Supplementary Information to the Legislative Council

《2009年毒藥表（修訂）(第四號) 規例》
《2009年藥劑業及毒藥（修訂）(第四號) 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**
Allergen extract of Dermatophagoides pteronyssinus **(**Dermatophagoides pteronyssinus **的過敏原提取物)**	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 specific IgE-mediated allergy to the house dust mite *Dermatophagoides pteronyssinus*. In rare cases, severe allergic reaction may happen when the drug is used, and emergency treatment of this severe allergic reaction must be initiated promptly, therefore monitoring by doctor is required. 此藥適用於治療對家居塵蟎 *Dermatophagoides pteronyssinus*產生的特異性含藥免疫球蛋白E過敏。在罕見病例中，使用此藥時可能會出現嚴重過敏反應而必須立即爲這種嚴重過敏反應者進行緊急治療，因此需要醫生監察。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
- Bordetella species **(**博德氏菌屬**)** - Canine infectious diseases **(**犬科動物傳染性疾病**)** (In the item relating to "Antisera, antitoxin, immunoglobulins and vaccines" under (b)) (在"抗血清，抗毒素，免疫球蛋白與疫苗"一欄的(b)下）	Part I, First and Third Schedules poisons 第一部附表一及附表三毒藥	Vaccines directed against these organisms or diseases are for the vaccination of healthy dogs and puppies as an aid in the prevention of those diseases. Side effects of the vaccine include lethargy, anorexia sneezing, rhinitis, and cough. Its administration should be monitored by a veterinary surgeon. 針對這些生物或疾病的疫苗，是用於接種健康狗隻及幼犬，以協助預防這些疾病。疫苗的副作用包括嗜睡、厭食、打噴嚏、鼻炎及咳嗽。使用該疫苗時，須有獸醫監視。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
Mertiatide; its salts; its esters; their salts (巯替肽;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	Together with radioactive substance, this drug is used for imaging of the renal system. Side effects include skin rash, swelling of eyelids and coughing. Its use should be judged by a doctor. 此藥物與放射性物質並用，作腎臟系統造影。副作用包括皮疹、眼瞼腫脹及咳嗽。使用此藥物與否，應由醫生斷定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Prasugrel; its salts (普拉格雷；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 taken together with aspirin to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) in patients with acute coronary syndrome who are undergoing percutaneous coronary intervention. Acute coronary syndrome is a group of conditions that includes unstable angina (a severe type of chest pain caused by heart attack) and heart attack. Percutaneous coronary intervention is an operation used to unblock narrowed coronary arteries (blood vessels in the heart). Side effects include anaemia (low red blood cell counts), haematoma (a collection of blood under the skin or in a muscle), epistaxis (nosebleeds), gastrointestinal haemorrhage (bleeding in the stomach or gut), rash, haematuria (blood in the urine), bleeding from needle puncture sites, haematoma at puncture sites and bruising. It must not be used in patients who have a condition that causes excessive bleeding, who have had a stroke or transient ischaemic attack (a temporary reduction in the blood supply to part of the brain), or with severe liver problems. This drug should only be used upon medical judgment on appropriate usage. 此藥物與阿士匹靈共同使用，以預防患有急性冠脈綜合徵且正接受冠狀動脈介入治療術的病人出現粥狀動脈栓塞的情況(血凝塊及動脈硬化引致的問題)。急性冠脈綜合徵是一組情況，當中包括不穩定型心絞痛(一種由心臟病引起的嚴重胸痛)及心臟病發作。冠狀動脈介入治療術是一種用以疏通狹窄冠狀動脈(心臟血管)的手術。 副作用包括貧血、血腫(皮下或肌肉內血液積聚)、鼻出血、胃腸道出血、發疹、血尿、針刺部位出血、針刺部位血腫及瘀傷。此藥物不得用於病情會引致大量出血、曾中風或短暫性缺血發作(部分腦部的血液供應暫時減少)，或有嚴重肝臟問題的病人身上。需經醫生清楚診斷適用時，才能使用此藥物。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
Racecadotril; its salts (消旋卡多曲; 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 symptomatic treatment of acute diarrhea in adults, and as supplements to oral rehydration, symptomatic treatment of acute diarrhea in children above 1 month. Side effects include somnolence, skin rash and constipation. A medical decision is required for the use of this medicine. 此藥用於成人急性腹瀉的對症治療，及作爲口服補液，用於1個月大或以上兒童急性腹瀉的對症治療。副作用包括嗜睡、皮疹及便秘。選用此藥需經醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Tafluprost (他氟前列素)	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 reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension. (i) As monotherapy in patients: - insufficiently responsive to first line therapy - intolerant or contra-indicated to first line therapy (ii) As adjunctive therapy to beta-blockers. Side effects include conjunctival hyperaemia, abnormality in eye lashes, itching , eye irritation and iris pigmentation. Its use should be decided by a doctor based on the patient's condition. 此藥用於降低開角型青光眼及高眼壓症上升的眼壓。 (i)作爲病人的單一治療： - 對第一次治療的反應不足 - 對第一次治療不耐受或有禁忌徵候 (ii)作爲β-受體阻滯劑的輔助治療。 副作用包括結膜充血、睫毛狀態異常、發癢、眼睛刺激及虹膜色素沉著。使用該藥與否，須由醫生按病人的病情決定。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Trabectedin; its salts; its esters (曲貝替定; 其鹽類; 其酯類)	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 adults with advanced soft tissue sarcoma, a type of cancer that develops from the soft, supporting tissues of the body. It is used when treatment with anthracyclines and ifosfamide (other anticancer medicines) have stopped working, or in patients who cannot be given these medicines. Side effects include (seen in more than 1 patient in 10) are increased blood levels of creatine phosphokinase (a marker of muscle breakdown) and of creatinine (a marker of kidney problems), decreased blood levels of albumin (a marker of liver problems), neutropenia (low levels of neutrophils, a type of white blood cell), thrombocytopenia (low blood platelets counts), anaemia (low red blood cell counts), leucopenia (low levels of leucocytes, a type of white blood cell), headache, vomiting, nausea (feeling sick), constipation, loss of appetite, fatigue (tiredness), asthenia (weakness), hyperbilirubinaemia (high levels of bilirubin in the blood) and increased levels of liver enzymes in the blood (alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase and gamma-glutamyltransferase). This drug should only be used upon medical judgment on appropriate usage. 此藥物用以治療患有末期軟組織肉瘤(一種由體內柔軟、支持組織發展而成的腫瘤)的成人。蒽環類藥物及異環磷酰胺(其他抗癌藥物)失去療效、或病人無法服用這些藥物時，便使用此藥物。 副作用(見於10名病人中超過1人)包括：肌酸磷激酶的血液濃度上升(肌肉壞死的標記)及肌酸的血液濃度上升(腎臟問題的標記)、白蛋白的血液濃度下降(肝臟問題的標記)、中性白細胞減少(中性白細胞(一種白血球)的水平偏低)、血小板減少(低血小板計數)、貧血(低紅血球計數)、白血球減少(白細胞(一種白血球)的水平偏低)、頭痛、嘔吐、噁心(感到不適)、便秘、食慾不振、疲勞(倦怠)、虛弱(無力)、高膽紅素血症(血液中膽紅素的水平偏高)及血液中肝酵素(谷丙轉氨酶、谷草轉氨酶、鹼性磷酸酶及丙種谷氨酰轉移酶)的水平上升。需經醫生清楚診斷適用時，才能使用此藥物。