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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 29 April 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 29 April 2009 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) Regulation 2009; and

(b) the Poisons List (Amendment) 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 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 6 April 2009, be approved –

(*a*) the Pharmacy and Poisons (Amendment) Regulation 2009; and

(*b*) the Poisons List (Amendment) Regulation 2009.

PHARMACY AND POISONS (AMENDMENT) 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*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", in paragraph (*b*), by adding "Feline immunodeficiency virus";

(*b*) by adding "Metaflumizone; its salts";

(*c*) by adding "Methylnaltrexone; its salts";

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

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

(*f*) by adding "Rivaroxaban; its salts".

2. Second Schedule amended

The Second Schedule is amended, in Group II, in Division A, in the item relating to "Androgenic, oestrogenic and progestational substances", by repealing –

"Preparations intended for external application only; except preparations containing more than 4 milligrammes of oestrogenic substance per 100 grammes of inert substance"

and substituting –

"Preparations intended for external application only; except preparations containing more than 4 milligrammes of oestrogenic substance per 100 grammes of inert substance and preparations containing testosterone or its esters".

3. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", in paragraph (*b*), by adding "Feline immunodeficiency virus";

(*b*) by adding "Metaflumizone; its salts";

(*c*) by adding "Methylnaltrexone; its salts";

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

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

(*f*) by adding "Rivaroxaban; its salts".

Chairman,
Pharmacy and Poisons Board

6 April 2009

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulations") –

(*a*) to add 6 substances to the First and Third Schedules to the 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; and

(*b*) to alter the Second Schedule to the principal Regulations so that preparations intended for external application only

containing testosterone or its esters are no longer exempt from the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

POISONS LIST (AMENDMENT) 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*) in the item relating to "Antisera, antitoxins, immunoglobulins and vaccines", in paragraph (*b*), by adding "Feline immunodeficiency virus";

(*b*) by adding "Metaflumizone; its salts";

(*c*) by adding "Methylnaltrexone; its salts";

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

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

(*f*) by adding "Rivaroxaban; its salts".

Chairman,
Pharmacy and Poisons Board

6 April 2009

Explanatory Note

This Regulation adds 6 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 29 APRIL 2009

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 1) Regulation 2009
Poisons List (Amendment) (No. 1) 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 six pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following six substances to Part I of the Poisons List and

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

(a) Feline immunodeficiency virus vaccine;
(b) Metaflumizone; its salts;
(c) Methylnaltrexone; its salts;
(d) Nepafenac; its salts;
(e) Ractopamine; its salts; and
(f) Rivaroxaban; its salts

In addition, the Pharmacy and Poisons Board proposes, by amending the Second Schedule to the Pharmacy and Poisons Regulations, to include the preparations containing testosterone or its esters intended for external application only into the First and Third Schedules to the Pharmacy and Poisons Regulations.

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 30 April 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. 1) Regulation 2009

Pharmacy and Poisons (Amendment) (No. 1) Regulation 2009

Supplementary Information to the Legislative Council

《2009年毒藥表（修訂）(第一號) 規例》
《2009年藥劑業及毒藥（修訂）(第一號) 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**
Feline Immunodeficiency Virus (In the item relating to "Antisera, antitoxin, immunoglobulins and vaccines" under (b)) 貓科免疫缺陷病毒（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 poison 第一部附表一及附表三毒藥	The vaccine containing this virus is administered to cats for the prevention of infections caused by the virus. The side effects of the vaccine include pain on injection site, lethargy, fever, vomiting, diarrhea, and anorexia. Its administration should be monitored by a veterinary surgeon. 含此病毒的疫苗用於預防貓隻因貓科免疫缺陷病毒所引致的感染。此疫苗的副作用包括注射部位疼痛，嗜睡，發熱，嘔吐，腹瀉及厭食。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**
Metaflumizone; its salts （無中文名）	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is an ectoparasiticide i.e. it kills parasites that live on the skin or in the fur of animals, such as fleas and ticks. It is used alone to treat or prevent flea infestations in cats. It is also used together with another drug amitraz to treat or prevent tick and flea infestations in dogs. It can also be used as part of a treatment strategy for the control of flea allergy dermatitis (an allergic reaction of cats or dogs to flea bites). Animals being treated with this drug might salivate considerably for a short period after licking the application site. The side effects of the drug in dogs also include lethargy and sedation as well as slow and shallow breathing. Because of the side effects of the drug, its use should be decided by a veterinary surgeon. 這是一種殺外寄生蟲藥，能殺滅在動物皮膚上或毛皮裏生存的寄生蟲，例如跳蚤及蜱。此藥單獨使用時，用以治療和預防貓隻身上的跳蚤侵擾。與另一種藥阿米曲士(amitraz)並用時，用以治療和預防狗隻身上的蜱及跳蚤侵擾。此藥亦可用作控制跳蚤過敏性皮膚炎計劃的一部份(貓隻或狗隻被跳蚤咬後所引致的一種過敏反應)。動物舔吃塗用部位後，可能會在短期內分泌相當多的唾液。在狗的副作用中，還包括嗜睡和鎮靜及呼吸緩慢和淺呼吸。由於藥物的副作用，使用該藥與否，須由獸醫決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Methylnaltrexone; its salts (甲納曲酮; 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 to treat the constipation caused by the administration of morphine or morphine-like painkillers. The side effects of this drug include abdominal pain, nausea, flatulence and diarrhoea. It should also not be used in patients whose bowel is blocked or who have a condition that needs immediate bowel surgery. Its use should be decided by a doctor based on the patient's condition. 此藥用以治療因服用嗎啡或嗎啡類止痛藥所引致的便秘。此藥物的副作用包括腹痛，噁心，腸胃氣脹和腹瀉。患腸阻塞或需要立即做腸道手術的病人不應用此藥物。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**
Nepafenac; its salts (奈帕芬胺; 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 to treat the pain and inflammation associated with cataract surgery. The side effects of this drug include keratitis. In some susceptible patients, sight-threatening side effects may occur which includes corneal erosion, corneal ulceration or corneal perforation. Its use should be decided by a doctor based on the patient's condition. 此藥用以治療眼睛白內障手術後可能出現的痛楚和炎症。此藥物的副作用包括角膜炎。在一些敏感病人，影響視力的副作用可能會出現，包括角膜侵蝕，角膜潰瘍或角膜穿孔。 使用此藥與否，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**
Ractopamine; its salts (雷托巴胺；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 to mix into feedstuff for feeding grown swine (i.e. swine from 68kg to 109kg body weight) to increase the rate of weight gain, improve feed efficiency and increase carcass leanness. Improper use may cause harm in persons with cardiovascular diseases who handle the drug. 此葯用以混入喂飼成長豬(即體重68至109公斤的豬)，以增加其體重增加速度，改善飼料功效及增加瘦肉。不正當地使用會對有心臟病而需要處理該葯的人士帶來傷害。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Rivaroxaban; its salts (利伐沙班; 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 to prevent the formation of clots in the veins (venous thromboembolism, VTE) in adults who are undergoing surgery to replace a hip or knee. The side effects of this drug include bleeding following an operation, nausea, anaemia and increased levels of some liver enzymes in the blood. Its use should be decided by a doctor based on the patient's condition. 此藥用以預防正接受置換髖部或膝部手術的成人在靜脈內形成血塊 (靜脈血栓栓塞症，VTE)。此藥的副作用包括手術後出血，噁心，貧血(低紅細球數量)和提高一些在血液中的肝酶水平。使用此藥與否，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
Preparations for external application only containing Testosterone or its esters (擬只作外用的含有睾酮或其酯類的製劑)	Part I, First and Third Schedules poison (by amending the Second Schedule) 第一部附表一及附表三毒藥(以修訂附表二來達成)	These preparations are used for the treatment of testosterone deficiency in men. They may increase the risk of benign prostatic hypertrophy (enlarged prostate gland) and prostate cancer. Regular examination of the prostate gland of the user by a doctor is required. The use of these preparations should be decided by a doctor based on the patient's condition. 這些製劑用於治療缺乏睾酮的男性。這些製劑可能會增加良性前列腺增生症及患前列腺癌的風險。用者應由醫生定期檢查前列腺。使用這些製劑與否，須由醫生按病人的病情決定。

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