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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 19 January 2011

**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 19 January 2011 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2010; and
- (b) the Poisons List (Amendment) (No. 5) Regulation 2010.

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 Chinese and English, 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 28 December 2010, be approved—

- (a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2010; and
- (b) the Poisons List (Amendment) (No. 5) Regulation 2010.

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2010

(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. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2 and 3.

2. First Schedule amended

(1) First Schedule, Chinese text, Division A—

Repeal

“苯丙胺；其鹽類”。

(2) First Schedule, Division A—

(a) After item “Benzylmorphine; its salts”

Add

“Besifloxacin; its salts; its esters; their salts”;

(b) After item “Eletriptan; its salts”

Add

“Eltrombopag; its salts; its esters; their salts”;

(c) After item “Enoximone”

Add

“Enrofloxacin; its salts; its esters”;

(d) After item “Paroxetine; its salts”

Add

“Pazopanib; its salts”;

- (e) Chinese text, after item “安定及具有雙氫-1，4-苯二氮草的化學結構在任何程度上被取代的其他化合物；它們的鹽類”

Add

“安非他酮；其鹽類”.

3. Third Schedule amended

- (1) Third Schedule, Chinese text, Division A—

Repeal

“苯丙胺；其鹽類”.

- (2) Third Schedule, Division A—

- (a) After item “Benztropine and its homologues; their salts”

Add

“Besifloxacin; its salts; its esters; their salts”;

- (b) After item “Eletriptan; its salts”

Add

“Eltrombopag; its salts; its esters; their salts”;

- (c) After item “Enoximone”

Add

“Enrofloxacin; its salts; its esters”;

- (d) After item “Paroxetine; its salts”

Add

“Pazopanib; its salts”;

- (e) Chinese text, after item “安定及具有雙氫-1，4-苯二氮草的化學結構在任何程度上被取代的其他化合物；它們的鹽類”

Add

“安非他酮；其鹽類”.

Chairman,
Pharmacy and Poisons Board

28 December 2010

Explanatory Note

This Regulation adds 4 substances to Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (*principal Regulations*) 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.

2. This Regulation also amends the Chinese expression of the term “Bupropion”.

Poisons List (Amendment) (No. 5) Regulation 2010

(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. Poisons List Regulations amended

The Poisons List Regulations (Cap. 138 sub. leg. B) are amended as set out in section 2.

2. Schedule amended

(1) The Schedule, Chinese text, Part I, Division A—

Repeal

“苯丙胺；其鹽類”；

(2) The Schedule, Part I, Division A—

(a) After item “Benzylmorphine; its salts”

Add

“Besifloxacin; its salts; its esters; their salts”;

(b) After item “Eletriptan; its salts”

Add

“Eltrombopag; its salts; its esters; their salts”;

(c) After item “Enoximone”

Add

“Enrofloxacin; its salts; its esters”;

(d) After item “Paroxetine; its salts”

Add

“Pazopanib; its salts”;

- (e) Chinese text, after item “安定及雙氫-1，4-苯二氮草的化學結構在任何程度上被取代的其他化合物；它們的鹽類”—

Add

“安非他酮；其鹽類”.

Chairman,
Pharmacy and Poisons Board

28 December 2010

Explanatory Note

This Regulation adds 4 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.

2. This Regulation also amends the Chinese expression of the term "Bupropion".

**SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 19 JANUARY 2011**

Pharmacy and Poisons Ordinance (Cap. 138)

**Pharmacy and Poisons (Amendment) (No. 5) Regulation 2010
Poisons List (Amendment) (No. 5) Regulation 2010**

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 under 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 four pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following four substances to Part I of the Poisons List and

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

- (a) Besifloxacin; its salts; its esters; their salts
- (b) Eltrombopag; its salts; its esters; their salts
- (c) Enrofloxacin; its salts; its esters
- (d) Pazopanib; its salts

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.

5. In addition, the Pharmacy and Poisons Board proposes to amend the Chinese translation of an existing substance under Part I of the Poisons List of the Poisons List Regulation (“PLR”) and the First and Third Schedules to the Pharmacy and Poisons Regulation (“PPR”) “Bupropion; its salts” from “苯丙胺；其鹽類” to its correct translation “安非他酮；其鹽類”.

6. We propose that these amendment regulations take immediate effect upon gazettal on 21 January 2010 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. 5) Regulation 2010

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2010

Supplementary Information to the Legislative Council

《 2010年毒藥表（修訂）（第五號）規例 》
《 2010年藥劑業及毒藥（修訂）（第五號）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
<p>Besifloxacin; its salts; its esters; their salts</p> <p>(貝西沙星; 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 for treatment of eye infections.</p> <p>Side effects include conjunctival redness, blurred vision, eye pain, eye irritation, eye pruritus and headache. This drug should only be used upon medical judgment.</p> <p>此藥用以治療眼部感染。</p> <p>副作用包括結膜紅腫、視力模糊、眼痛、眼部不適、眼部瘙癢及頭痛。需經醫生清楚診斷，才能使用此藥物。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
<p>Eltrombopag; its salts; its esters; their salts</p> <p>(艾曲泊帕; 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 adults with long-term immune thrombocytopenic purpura (ITP) in patients who have had their spleen removed and who do not respond to treatment with medicines such as corticosteroids or immunoglobulins. ITP is a disease in which the patient's immune system destroys the platelets (components in the blood that help it to clot). Patients with ITP have low platelet counts and are at risk of bleeding. The spleen is an organ that is involved in the destruction of platelets.</p> <p>This drug can also be considered for use in patients who have previously been treated for ITP and who cannot have surgery to remove their spleen.</p> <p>Side effects include headache. There is also a risk of liver problems and thromboembolic complications (problems with clots in blood vessels). Bleeding can also come back after the medicine is stopped. This drug should only be used upon medical judgment and medical monitoring is also required during administration.</p> <p>此藥用於已切除脾臟及對皮質類固醇或免疫球蛋白等藥物治療沒有反應的患有長期免疫性血小板減少性紫癜的成人病人。此病患者的免疫系統會破壞血小板(血液中幫助血液凝結的成分)。患免疫性血小板減少性紫癜的病人血小板數量偏低，有出血的風險。脾臟是涉及破壞血小板的器官。</p> <p>此藥亦可用於先前曾因免疫性血小板減少性紫癜接受治療，但無法動手術切除脾臟的病人。</p> <p>副作用包括頭痛，亦有出現肝臟毛病和血栓塞併發症(血管中出現血凝塊的問題)的風險。停藥後也可能再有出血的情況。需經醫生清楚診斷適用時，才能使用此藥物，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
<p>Enrofloxacin; its salts; its esters</p> <p>(恩氟沙星;其鹽類; 其酯類)</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 for treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa in dogs and cats.</p> <p>In cats, side effects include retinotoxic effect (eye damage) including blindness. Its use should be judged by a veterinary surgeon.</p> <p>此藥用以治療貓狗消化道、呼吸道和泌尿生殖道細菌感染、皮膚感染、繼發傷口感染及外耳炎。</p> <p>如用於貓隻，副作用包括毒視網膜作用(視力受損)包括失明。選用此藥需經獸醫決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Pazopanib; its salts (帕唑帕尼; 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 advanced renal cell carcinoma (a type of kidney cancer). It is used in patients who have not received any previous treatment or in patients who have already been treated for their advanced disease with anticancer medicines called ‘cytokines’. ‘Advanced’ means that the cancer has started to spread.</p> <p>Side effects include reduced appetite, dysgeusia (taste disturbances), hypertension (high blood pressure), diarrhoea, nausea (feeling sick), vomiting, abdominal pain (stomach ache), hair colour change, fatigue (tiredness) and increased blood levels of the liver enzymes alanine aminotransferase and aspartate aminotransferase. A doctor’s decision is required as to whether or not this medicine should be used, medical monitoring is also required during administration.</p> <p>此藥用以治療末期腎細胞癌症(腎癌的一種)。它用於先前沒有接受過任何治療的病人，或因末期癌症已接受稱為‘細胞活素’的抗癌藥物治療的病人。‘末期’指癌症已開始擴散。</p> <p>副作用包括食慾下降、味覺障礙(味覺失調)、高血壓(血壓高)、腹瀉、噁心(感到不適)、嘔吐、腹痛(胃痛)、頭髮顏色轉變、疲勞(倦怠)及肝酵素丙氨酸氨基轉換酶，和天冬氨酸轉氨酶 的血液濃度上升。</p> <p>此藥需經醫生確診後才使用，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
<p>Bupropion; its salts</p> <p>(安非他酮; 其鹽類)</p>	<p>Already classified as Part I, First and Third Schedules poison</p> <p>已經分類為第一部附表一及附表三毒藥</p>	<p>This drug is already registered, it is used for smoking cessation or for treatment of major depressive disorder. Side effects include insomnia, nervousness, shakiness, concentration disturbance, headache, dizziness, taste disorder, dry mouth, constipation, nausea, vomiting, urticaria, rash, pruritis, sweating and fever.</p> <p>This drug is currently classified as Prescription-only-medicine (i.e. Part I, First and Third Schedules poison). It is listed in Poisons List under the entry “Bupropion; its salts 苯丙胺；其鹽類”.</p> <p>The correct Chinese name is “安非他酮; 其鹽類”, the original Chinese name 苯丙胺；其鹽類 will be repealed and amended to 安非他酮; 其鹽類.</p> <p>此藥已經註冊，用於戒煙，或治療抑鬱症。副作用包括失眠，神經緊張，顫抖，不能集中精神，頭痛，頭暈，味覺失調，口乾，便秘，噁心，嘔吐，風疹，皮疹，瘙癢，出汗，及發熱。</p> <p>此藥是醫生處方藥（即第一部附表一及附表三毒藥），它已列在毒藥表中，在 “Bupropion; its salts 苯丙胺；其鹽類” 的項目下。</p> <p>正確的中文名稱是 “安非他酮；其鹽類”，原中文名稱 “苯丙胺；其鹽類” 將被廢除，而修改為 “安非他酮；其鹽類”。</p>