File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2015

INTRODUCTION

The Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations") was made under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"). The Pharmacy and Poisons (Amendment) (No. 3) Regulation 2015 ("the Amendment Regulation") at **Annex A** is to amend the First, Third and Tenth Schedules to the Regulations.

JUSTIFICATIONS

General Background

2. Under section 29(1B) of the Ordinance, the Pharmacy and Poisons Board ("the Board") set up under section 3 of the Ordinance is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Regulations, subject to section 31 of the Ordinance and to the approval of the Secretary for Food and Health.

Proposal of the Pharmacy and Poisons Board

3. Arising from an application for registration of five pharmaceutical products, the Board proposes to add the following substances to Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in the Tenth Schedule to the Regulations:

(a) Ambrisentan; its salts; its esters; their salts
(b) Ranolazine; its salts
(c) Tapentadol; its salts
(d) Umeclidinium; its salts
(e) Vortioxetine; its salts

4. Details of the above medicines are set out at **Annex B**. The Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the substances.

THE AMENDMENT REGULATION

5. The Amendment Regulation is to add the five substances listed in paragraph 3 above to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	27 March 2015
Date of Commencement	27 March 2015

IMPLICATIONS OF THE PROPOSAL

7. The proposal will impose appropriate control on pharmaceutical products consisting of the above substances so that they can be sold in the market upon fulfillment of the relevant regulations.

ENQUIRY

8. For any enquiries on the brief, please contact Mr Chow Tat-wing, Assistant Secretary for Food and Health at 3509 8956.

Food and Health Bureau
March 2015

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2015

(Made by the Pharmacy and Poisons Board under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Secretary for Food and Health)

1. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2, 3 and 4.

2. First Schedule amended (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply under regulations 3, 5, 6, 22 and 24)

(1) First Schedule, Division A, after item "Amantadine; its salts"—

Add

"Ambrisentan; its salts; its esters; their salts".

(2) First Schedule, Division A, after item "Ranibizumab"—

Add

"Ranolazine; its salts".

(3) First Schedule, Division A, after item "Tamoxifen; its salts"—

Add

"Tapentadol; its salts".

(4) First Schedule, Division A, after item "Tybamate"—

Add

"Umeclidinium; its salts".

(5) First Schedule, Division A, after item "Voriconazole; its salts"—

Add

"Vortioxetine; its salts".

3. Third Schedule amended (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)

(1) Third Schedule, Division A, after item "Amantadine; its salts"—

Add

"Ambrisentan; its salts; its esters; their salts".

(2) Third Schedule, Division A, after item "Ranibizumab"—

Add

"Ranolazine; its salts".

(3) Third Schedule, Division A, after item "Tamoxifen; its salts"—

Add

"Tapentadol; its salts".

(4) Third Schedule, Division A, after item "Tybamate"—

Add

"Umeclidinium; its salts".

(5) Third Schedule, Division A, after item "Voriconazole; its salts"—

Add

"Vortioxetine; its salts".

4. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part I, Division A, after item "Amantadine; its salts"—

Add

"Ambrisentan; its salts; its esters; their salts".

(2) Schedule 10, section 2, Table, Part I, Division A, after item "Ranibizumab"—

Add

"Ranolazine; its salts".

(3) Schedule 10, section 2, Table, Part I, Division A, after item "Tamoxifen; its salts"—

Add

"Tapentadol; its salts".

(4) Schedule 10, section 2, Table, Part I, Division A, after item "Tybamate"—

Add

"Umeclidinium; its salts".

(5) Schedule 10, section 2, Table, Part I, Division A, after item "Voriconazole; its salts"—

Add

"Vortioxetine; its salts".

Chairman,
Pharmacy and Poisons Board

16 March 2015

Explanatory Note

This Regulation—

(a) adds 5 substances to Division A of the First Schedule and Division A of the Third Schedule 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; and

(b) adds 5 substances to Division A of Part I of the Poisons List set out in Schedule 10 to the principal Regulations 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 presence and under the supervision of a registered pharmacist.

Pharmacy and Poisons (Amendment) (No.3) Regulation 2015

Supplementary Information to the Legislative Council

《2015年藥劑業及毒藥(修訂)(第3號)規例》

提交立法會的補充資料

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Ambrisentan; its salts; its esters; their salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Side effects include headache, fluid retention, anaemia, dizziness, cardiac failure, palpitation, hypotension, epistaxis, dyspnoea, abdominal pain, constipation, hepatic transaminases increased and chest pain/discomfort. Its use should be decided by a doctor based on the patient's conditions.
安立生坦；其鹽類；其酯類；它們的鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於治療屬世界衞生組織II及III功能級別的肺動脈高血壓症的成年患者，以提高運動能力。 副作用包括頭痛、體液瀦留、貧血、頭暈、心臟衰竭、心悸、低血壓、流鼻血、呼吸困難、腹痛、便秘、肝轉氨酶提升和胸部疼痛/不適。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Ranolazine; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies. Side effects include dizziness, headache, constipation, vomiting, nausea and asthenia. Its use should be decided by a doctor based on the patient's conditions.
雷諾嗪；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於對症治療患有穩定型心絞痛而病情未能充分受控或對一線抗心絞痛藥物不耐受的成人患者作附加治療。 副作用包括頭暈、頭痛、便秘、嘔吐、噁心、和虛弱感覺。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Tapentadol; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in adults for the management of moderate to severe acute pain; and pain severe enough to require daily, around-the-clock, long term opioid treatment and for which alternative treatment options are inadequate, including neuropathic pain associated with diabetic peripheral neuropathy. Side effects include nausea, vomiting, constipation, dizziness, somnolence, and headache. Its use should be decided by a doctor based on the patient's conditions.
他噴他多；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於成人患者，治療中度至嚴重程度的急性疼痛；及治療嚴重疼痛，並需要每天、不間斷、長期使用鴉片類藥物，而其他替代治療方案並不足夠應付，亦包括糖尿病周邊神經病變相關的神經性疼痛。 副作用包括噁心、嘔吐、便秘、頭暈、嗜睡和頭痛。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Umeclidinium; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used as maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. Side effects include urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, constipation and dry mouth. Its use should be decided by a doctor based on the patient's conditions.
烏美溴銨；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於成人患者作維持支氣管擴張治療，紓緩慢性阻塞性肺病的症狀。 副作用包括尿道感染、鼻竇炎、鼻咽炎、咽喉炎、上呼吸道感染、頭痛、咳嗽、便秘和口乾。 使用此藥物與否，須由醫生按病人情況決定。
Vortioxetine; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of major depressive episodes in adults. Side effects include nausea, decreased appetite, dizziness, diarrhoea, constipation and vomiting. Its use should be decided by a doctor based on the patient's conditions.
伏硫西汀；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於治療嚴重抑鬱症的成人患者。 副作用包括噁心、食慾下降、頭暈、腹瀉、便秘和嘔吐。 使用此藥物與否，須由醫生按病人情況決定。