File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 4) 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. 4) 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, including the First Schedule and Third Schedule to 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 applications for registration of five pharmaceutical products, the Board proposes to:

(a) 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:

- Elosulfase alfa
- Nalmefene; its salts
- Olodaterol; its salts
- Vismodegib; its salts

(b) add the following mixtures of two Part I poisons to Division A of the First Schedule and Division A of the Third Schedule to the Regulations:

- Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine
- Tetracaine; its salts in mixture with lignocaine or in mixture with the salts of lignocaine

(Tetracaine is an amino alcohol esterified with a derivative of benzoic acid and hence a Part I poison)

4. Details of the above substances/mixtures 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/mixtures.

THE AMENDMENT REGULATION

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

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	29 May 2015
Date of Commencement	29 May 2015

IMPLICATIONS OF THE PROPOSAL

7. The proposal will impose appropriate control on pharmaceutical products consisting of the above substances/mixtures 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
26 May 2015

Pharmacy and Poisons (Amendment) (No. 4) 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 "Eletriptan; its salts"—

Add

"Elosulfase alfa".

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

Add

"Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine".

(3) First Schedule, Division A, after item "Nalidixic acid"—

Add

"Nalmefene; its salts".

(4) First Schedule, Division A, after item "Olmesartan; its salts; its esters; their salts"—

Add

"Olodaterol; its salts".

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

Add

"Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine".

(6) First Schedule, Division A, after item "Vinorelbine; its salts"—

Add

"Vismodegib; 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 "Eletriptan; its salts"—

Add

"Elosulfase alfa".

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

Add

"Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine".

(3) Third Schedule, Division A, after item "Nalidixic acid"—

Add

"Nalmefene; its salts".

(4) Third Schedule, Division A, after item "Olmesartan; its salts; its esters; their salts"—

Add

"Olodaterol; its salts".

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

Add

"Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine".

(6) Third Schedule, Division A, after item "Vinorelbine; its salts"—

Add

"Vismodegib; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Elosulfase alfa".

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

Add

"Nalmefene; its salts".

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

Add

"Olodaterol; its salts".

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

Add

"Vismodegib; its salts".

Chairman,
Pharmacy and Poisons Board

22 May 2015

Explanatory Note

This Regulation—

(a) adds 6 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 4 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.

Annex B
附件 B

Pharmacy and Poisons (Amendment) (No.4) Regulation 2015

Supplementary Information to the Legislative Council

《2015年藥劑業及毒藥（修訂）（第4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
Elosulfase alfa	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in patients of all ages for the treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA). Side effects include headache, dizziness, dyspnoea, diarrhoea, vomiting, abdominal pain, nausea, hypersensitivity and myalgia. Its use should be decided by a doctor based on the patient's conditions.
依洛硫酸酯酶α	附表十第一部、附表一及附表三毒藥	此藥物用於治療IVA型黏多糖貯積病（Morquio A 綜合症，MPS IVA）的所有年齡患者。 副作用包括頭痛、頭暈、呼吸困難、腹瀉、嘔吐、腹痛、噁心、過敏和肌肉疼痛。 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
Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine and vice versa 利多卡因；其鹽類與丁卡因的混合物，或與丁卡因的鹽類的混合物 及反之亦然	First and Third Schedules poison 附表一及附表三毒藥	This drug is used in adults to produce local dermal anaesthesia on intact skin prior to dermatological procedures. Side effects include erythema, skin discoloration and skin oedema. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於成人的皮膚科手術前，在完好的皮膚進行局部麻醉。 副作用包括紅斑、皮膚褪色和皮膚水腫。 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
Nalmefene; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification. Side effects include insomnia, dizziness, headache, nausea, decreased appetite, somnolence, palpitations, vomiting, muscle spasm, fatigue and weight decreased. Its use should be decided by a doctor based on the patient's conditions.
納美芬；其鹽類	附表十第一部、 附表一及 附表三毒藥	此藥物用於對酒精依賴及飲酒屬高風險水平，而沒有身體脱癮症狀和不需緊急解毒的成年患者，使其減少飲用酒精。 副作用包括失眠、頭暈、頭痛、噁心、食慾下降、嗜睡、心悸、嘔吐、肌肉痙攣、疲勞和體重下降。 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
Olodaterol; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used as a maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease. Side effects include nasopharyngitis, dizziness, rash, hypertension, and arthralgia. Its use should be decided by a doctor based on the patient's conditions.
奧達特羅；其鹽類	附表十第一部、附表一及 附表三毒藥	此藥物用於慢性阻塞性肺病患者，作為維持支氣管擴張治療。 副作用包括鼻咽炎、頭暈、皮疹、高血壓和關節痛。 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
Vismodegib; its salts (Note: Chinese name currently not available)	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with symptomatic metastatic basal cell carcinoma or locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy. Side effects include decreased appetite, nausea, diarrhea, constipation, vomiting, alopecia, pruritus, muscle spasms, amenorrhea, weight decreased and fatigue. Its use should be decided by a doctor based on the patient's conditions.
Vismodegib；其鹽類 (註：Vismodegib暫無中文名稱)	附表十第一部、附表一及 附表三毒藥	此藥物用於治療帶有症狀的轉移性基底細胞癌，或不適合接受手術或放射治療的局部晚期基底細胞癌的成年患者。 副作用包括食慾下降、噁心、腹瀉、便秘、嘔吐、脫髮、瘙癢、肌肉痙攣、閉經、體重下降和疲勞。 使用此藥物與否，須由醫生按病人情況決定。