File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2017

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 2017 ("the Amendment Regulation") at **Annex A** is to amend 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 applications for registration of seven pharmaceutical products, the Board proposes adding the following substances to Division A of First Schedule, Division A of Third Schedule and Division A of Part I of the Poisons List set out in Tenth Schedule to the Regulations:

(a) Afoxolaner; its salts
(b) Firocoxib; its salts
(c) Fluralaner; its salts
(d) Ixekizumab
(e) Necitumumab

(f) Tafamidis; its salts
(g) Velpatasvir; its salts

4. Details of the above substances 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 above drugs (in paragraph 3) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	9 June 2017
Date of Commencement	9 June 2017

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, please contact Mr Lam Fong-tat James, Assistant Secretary for Food and Health at 3509 8956.

Food and Health Bureau
June 2017

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2017

(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. Schedule 1 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) Schedule 1, Division A, after item "Aflibercept"—

Add

"Afoxolaner; its salts".

(2) Schedule 1, Division A, after item "Fingolimod; its salts; its esters; their salts"—

Add

"Firocoxib; its salts".

(3) Schedule 1, Division A, after item "Flupenthixol; its salts"—

Add

"Fluralaner; its salts".

(4) Schedule 1, Division A, after item "Ivabradine; its salts"—

Add

"Ixekizumab".

(5) Schedule 1, Division A, after item "Nebivolol; its salts"—

Add

"Necitumumab".

(6) Schedule 1, Division A, before item "Tafluprost"—

Add

"Tafamidis; its salts".

(7) Schedule 1, Division A, after item "Vedolizumab"—

Add

"Velpatasvir; its salts".

3. Schedule 3 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) Schedule 3, Division A, after item "Aflibercept"—

Add

"Afoxolaner; its salts".

(2) Schedule 3, Division A, after item "Fingolimod; its salts; its esters; their salts"—

Add

"Firocoxib; its salts".

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

Add

"Fluralaner; its salts".

(4) Schedule 3, Division A, after item "Ivabradine; its salts"—

Add

"Ixekizumab".

(5) Schedule 3, Division A, after item "Nebivolol; its salts"—

Add

"Necitumumab".

(6) Schedule 3, Division A, before item "Tafluprost"—

Add

"Tafamidis; its salts".

(7) Schedule 3, Division A, after item "Vedolizumab"—

Add

"Velpatasvir; its salts".

4. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, after item "Aflibercept"—

Add

"Afoxolaner; its salts".

(2) Schedule 10, section 2, Table, Part 1, Division A, after item "Fingolimod; its salts; its esters; their salts"—

Add

"Firocoxib; its salts".

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

Add

"Fluralaner; its salts".

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

Add

"Ixekizumab".

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

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2017

Add

"Necitumumab".

(6) Schedule 10, section 2, Table, Part 1, Division A, before item "Tafluprost"—

Add

"Tafamidis; its salts".

(7) Schedule 10, section 2, Table, Part 1, Division A, after item "Vedolizumab"—

Add

"Velpatasvir; its salts".

Chairman,
Pharmacy and Poisons Board

2 June 2017

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 7 items to—

(a) Division A of its Schedule 1;

(b) Division A of its Schedule 3; and

(c) Division A of Part 1 of the Poisons List set out in its Schedule 10.

2. The amendments relate to requirements concerning sale, supply, labelling and storage, including—

(a) that the sale, by retail, of substances specified in the 7 items—

(i) may only be effected 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; and

(ii) may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon; and

(b) that the substances, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.

Annex B

附件B

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2017

Supplementary Information to the Legislative Council

《2017年藥劑業及毒藥（修訂）（第3號）規例》

提交立法會的補充資料

Afoxolaner; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of flea and tick infestations in dogs. Side effects include vomiting, diarrhoea, pruritus, lethargy and anorexia. Its use should be decided by a veterinary surgeon based on the animal's conditions.
阿福拉納；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療受到跳蚤和蜱侵擾的狗隻。 副作用包括嘔吐、腹瀉、瘙癢、嗜睡和食慾不振。 使用此藥物與否，須由獸醫按動物的情況決定。

Firocoxib; its salts 非羅考昔；其鹽類	Part 1 of the Tenth Schedule, First and Third Schedules poison 附表十的第一部，附表一及附表三毒藥	This drug is used in dogs for the relief of pain and inflammation associated with osteoarthritis, and post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery. Side effects include vomiting and diarrhoea. Its use should be decided by a veterinary surgeon based on the animal's conditions. 此藥物用於狗隻，舒緩與骨關節炎相關的疼痛和炎症，及與軟組織、外科矯形和牙科手術相關的手術後疼痛和炎症。 副作用包括嘔吐和腹瀉。 使用此藥物與否，須由獸醫按動物的情況決定。
Fluralaner; its salts 氟雷拉納；其鹽類	Part 1 of the Tenth Schedule, First and Third Schedules poison 附表十的第一部，附表一及附表三毒藥	This drug is used for the treatment of flea and tick infestations in dogs. Side effects include diarrhoea, vomiting, anorexia and drooling. Its use should be decided by a veterinary surgeon based on the animal's conditions. 此藥物用於治療受到跳蚤和蜱侵擾的狗隻。 副作用包括腹瀉、嘔吐、食慾不振和流口水。 使用此藥物與否，須由獸醫按動物的情況決定。

Ixekizumab 伊凱珠單抗	Part 1 of the Tenth Schedule, First and Third Schedules poison 附表十的第一部，附表一及附表三毒藥	This drug is used for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Side effects include upper respiratory tract infection, injection site reactions, tinea infection, oropharyngeal pain and nausea. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於患有中度至嚴重程度的斑塊狀銀屑病，屬適合接受全身治療的成年患者。 副作用包括上呼吸道感染、注射部位反應、癬菌感染、口咽疼痛和噁心。 使用此藥物與否，須由醫生按病人情況決定。

Necitumumab 奈昔木單抗	Part 1 of the Tenth Schedule, First and Third Schedules poison 附表十的第一部，附表一及附表三毒藥	This drug is used in combination with gemcitabine and cisplatin, for first-line treatment of adult patients with metastatic squamous non-small cell lung cancer. Side effects include rash, vomiting, diarrhoea and dermatitis acneiform. Its use should be decided by a doctor based on the patient's conditions. 此藥物與吉西他濱及順鉑聯合使用，用作一線治療患有轉移性鱗狀非小細胞肺癌的成年患者。 副作用包括皮疹、嘔吐、腹瀉和皮炎痤瘡。 使用此藥物與否，須由醫生按病人情況決定。

Tafamidis; its salts 氯苯唑酸；其鹽類	Part 1 of the Tenth Schedule, First and Third Schedules poison 附表十的第一部，附表一及附表三毒藥	This drug is used for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment. Side effects include urinary tract infection, vaginal infection, diarrhoea and upper abdominal pain. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有轉甲狀腺素澱粉樣蛋白疾病屬第一期帶症狀多發性神經病變的成年患者，用作延遲周邊神經障礙的產生。 副作用包括尿道炎、陰道炎、腹瀉和上腹疼痛。 使用此藥物與否，須由醫生按病人情況決定。
Velpatasvir; its salts 維帕他韋；其鹽類	Part 1 of the Tenth Schedule, First and Third Schedules poison 附表十的第一部，附表一及附表三毒藥	This drug is used in combination with sofosbuvir for the treatment of chronic hepatitis C virus infection in adults. Side effects include headache, fatigue and nausea. Its use should be decided by a doctor based on the patient's conditions. 此藥物與索磷布韋聯合使用，用於治療慢性丙型肝炎病毒感染的成年患者。 副作用包括頭痛、疲勞和噁心。 使用此藥物與否，須由醫生按病人情況決定。