File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 2) REGULATION 2018

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. 2) Regulation 2018 ("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 six 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) Baricitinib; its salts
(b) Cabozantinib; its salts
(c) Deoxycholic acid;
(under the entry of "Pharmaceutical products for human

parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin —")

(d) Etelcalcetide; its salts
(e) Glecaprevir; its salts
(f) Pibrentasvir; 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	16 March 2018
Date of Commencement	16 March 2018

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
March 2018

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2018

(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, before item "Basiliximab; its salts"—

Add

"Baricitinib; its salts".

(2) Schedule 1, Division A, after item "Cabergoline; its salts"—

Add

"Cabozantinib; its salts".

(3) Schedule 1, Division A, after item "Etanercept"—

Add

"Etelcalcetide; its salts".

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

Add

"Glecaprevir; its salts".

(5) Schedule 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Cimetidine"—

Add

"Deoxycholic acid".

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

Add

"Pibrentasvir; 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, before item "Basiliximab; its salts"—

Add

"Baricitinib; its salts".

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

Add

"Cabozantinib; its salts".

(3) Schedule 3, Division A, after item "Etanercept"—

Add

"Etelcalcetide; its salts".

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

Add

"Glecaprevir; its salts".

(5) Schedule 3, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Cimetidine"—

Add

"Deoxycholic acid".

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

Add

"Pibrentasvir; its salts".

4. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, before item "Basiliximab; its salts"—

Add

"Baricitinib; its salts".

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

Add

"Cabozantinib; its salts".

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

Add

"Etelcalcetide; its salts".

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

Add

"Glecaprevir; its salts".

(5) Schedule 10, section 2, Table, Part 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Cimetidine"—

Add

"Deoxycholic acid".

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

Add

"Pibrentasvir; its salts".

Chairman,
Pharmacy and Poisons Board

7 March 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 5 items and 1 sub-item to—

(a) Division A of Schedule 1;

(b) Division A of Schedule 3; and

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

2. The amendments relate to requirements concerning sale, supply, labelling and storage. Main effects of the amendments include—

(a) that the sale, by retail, of substances newly specified—

(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. 2) Regulation 2018

Supplementary Information to the Legislative Council

《2018年藥劑業及毒藥（修訂）（第2號）規例》

提交立法會的補充資料

Baricitinib; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. This drug may be used as monotherapy or in combination with methotrexate. Side effects include hypercholesterolaemia, upper respiratory tract infections and nausea. Its use should be decided by a doctor based on the patient's conditions.
巴瑞替尼；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療中度至嚴重活性類風濕關節炎的成年患者，已對一種或多種緩解病情抗風濕病藥物反應不佳或無法耐受。此藥物可單獨使用或與甲氨蝶呤合併使用。 副作用包括高膽固醇血症、上呼吸道感染和噁心。 使用此藥物與否，須由醫生按病人情況決定。

Cabozantinib; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of advanced renal cell carcinoma in adults following prior vascular endothelial growth factor (VEGF) -targeted therapy. Side effects include diarrhoea, fatigue, nausea, decreased appetite, palmar-plantar erythrodysaesthesia syndrome, hypertension, vomiting, weight decreased and constipation. Its use should be decided by a doctor based on the patient's conditions.
卡波替尼；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療曾接受VEGF標靶治療後的晚期腎細胞癌的成年患者。 副作用包括腹瀉、疲勞、噁心、食慾下降、手足症候群、高血壓、嘔吐、體重減輕和便秘。 使用此藥物與否，須由醫生按病人情況決定。

Deoxycholic acid	Part 1 of the Tenth Schedule, First and Third Schedules poison (under the entry of "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin-")	This drug is used for the treatment of moderate to severe convexity or fullness associated with submental fat in adults when the presence of submental fat has a psychological impact for the patient. Side effects include injection site reactions, e.g. pain, oedema, swelling, anaesthesia, nodule, haematoma, paraesthesia, induration, erythema and pruritus. Its use should be decided by a doctor based on the patient's conditions.
去氧膽酸	附表十的第一部，附表一及附表三毒藥 (納入下列的條文內："供注射入人體的藥劑製品，並包括(作為有效成分)以下物質或它們的鹽類，但與胰島素的混合物除外-")	此藥物用於治療頦下脂肪相關的中度至嚴重程度凸起或飽滿，並因頦下脂肪產生心理影響之成年患者。 副作用包括注射部位反應，例如疼痛、水腫、腫脹、感覺缺失、結節、瘀血、感覺異常、硬結、紅斑和瘙癢。 使用此藥物與否，須由醫生按病人情況決定。

Etelcalcetide; its salts 維拉卡肽；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 secondary hyperparathyroidism in adult patients with chronic kidney disease on haemodialysis therapy. Side effects include blood calcium decreased, muscle spasms, diarrhoea, nausea and vomiting. Its use should be decided by a doctor based on the patient's conditions. 此藥物治療繼發性甲狀旁腺功能亢進，用於接受血液透析治療的成年慢性腎病患者。 副作用包括血鈣下降、肌肉痙攣、腹瀉、噁心和嘔吐。 使用此藥物與否，須由醫生按病人情況決定。
Glecaprevir; its salts 格卡瑞韋；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 a combination product with pibrentasvir for the treatment of chronic hepatitis C virus infection (genotype 1, 2, 3, 4, 5 or 6) in adults. Side effects include headache, fatigue, diarrhoea, nausea and asthenia. Its use should be decided by a doctor based on the patient's conditions. 此藥物與哌侖他韋同用於一款混合型產品，治療慢性丙型肝炎(屬1，2，3，4，5或6基因型)的成年患者。 副作用包括頭痛、疲勞、腹瀉、噁心和乏力。 使用此藥物與否，須由醫生按病人情況決定。

Pibrentasvir; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used in a combination product with glecaprevir for the treatment of chronic hepatitis C virus infection (genotype 1, 2, 3, 4, 5 or 6) in adults. Side effects include headache, fatigue, diarrhoea, nausea and asthenia. Its use should be decided by a doctor based on the patient's conditions.
哌侖他韋；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物與格卡瑞韋同用於一款混合型產品，治療慢性丙型肝炎(屬1，2，3，4，5或6基因型)的成年患者。 副作用包括頭痛、疲勞、腹瀉、噁心和乏力。 使用此藥物與否，須由醫生按病人情況決定。