File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) 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. 1) 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 nine 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) Atezolizumab
(b) Elbasvir; its salts
(c) Grazoprevir; its salts
(d) Ioflupane Iodine-123; its salts; when contained in pharmaceutical products

(e) Ixazomib; its salts
(f) Ribociclib; its salts
(g) Selexipag; its salts
(h) Silodosin; its salts
(i) Tipiracil; its salts; when contained in pharmaceutical products

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	26 January 2018
Date of Commencement	26 January 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
January 2018

Pharmacy and Poisons (Amendment) 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, after item "Atenolol; its salts"—

Add

"Atezolizumab".

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

Add

"Elbasvir; its salts".

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

Add

"Grazoprevir; its salts".

(4) Schedule 1, Division A, after item "Iodine-131; its salts; when contained in pharmaceutical products"—

Add

"Ioflupane Iodine-123; its salts; when contained in pharmaceutical products".

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

Add

"Ixazomib; its salts".

(6) Schedule 1, Division A, after item "Ribavirin; its salts"—

Add

"Ribociclib; its salts".

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

Add

"Selexipag; its salts".

(8) Schedule 1, Division A, before item "Siltuximab"—

Add

"Silodosin; its salts".

(9) Schedule 1, Division A, after item "Tiotropium; its salts"—

Add

"Tipiracil; its salts; when contained in pharmaceutical products".

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 "Atenolol; its salts"—

Add

"Atezolizumab".

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

Add

"Elbasvir; its salts".

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

Add

"Grazoprevir; its salts".

(4) Schedule 3, Division A, after item "Iodine-131; its salts; when contained in pharmaceutical products"—

Add

"Ioflupane Iodine-123; its salts; when contained in pharmaceutical products".

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

Add

"Ixazomib; its salts".

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

Add

"Ribociclib; its salts".

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

Add

"Selexipag; its salts".

(8) Schedule 3, Division A, before item "Siltuximab"—

Add

"Silodosin; its salts".

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

Add

"Tipiracil; its salts; when contained in pharmaceutical products".

4. Schedule 10 amended (Poisons List)

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

Add

"Atezolizumab".

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

Add

"Elbasvir; its salts".

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

Add

"Grazoprevir; its salts".

(4) Schedule 10, section 2, Table, Part 1, Division A, after item "Iodine-131; its salts; when contained in pharmaceutical products"—

Add

"Ioflupane Iodine-123; its salts; when contained in pharmaceutical products".

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

Add

"Ixazomib; its salts".

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

Add

"Ribociclib; its salts".

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

Add

"Selexipag; its salts".

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

Add

"Silodosin; its salts".

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

Add

"Tipiracil; its salts; when contained in pharmaceutical products".

Chairman,
Pharmacy and Poisons Board

23 January 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 9 items 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 specified in the 9 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. 1) Regulation 2018

Supplementary Information to the Legislative Council

《2018年藥劑業及毒藥(修訂)(第1號)規例》

提交立法會的補充資料

Atezolizumab	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. Side effects include fatigue, decreased appetite, dyspnea, cough, nausea and musculoskeletal pain. Its use should be decided by a doctor based on the patient's conditions.
阿替利組單抗	附表十的第一部，附表一及附表三毒藥	此藥物用於治療接受含鉑化療期間或之後仍呈現病情惡化的轉移性非小細胞肺癌的成年患者。 副作用包括疲勞、食慾下降、呼吸困難、咳嗽、噁心和肌肉骨骼疼痛。 使用此藥物與否，須由醫生按病人情況決定。

Elbasvir; its salts 艾爾巴韋；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 grazoprevir for the treatment of chronic hepatitis C genotype 1a, 1b and 4 in adults. Side effects include fatigue, headache, decreased appetite, insomnia, dizziness, nausea, pruritus and arthralgia. Its use should be decided by a doctor based on the patient's conditions. 此藥物與格拉瑞韋同用於一款混合型產品，治療慢性丙型肝炎屬1a，1b及4基因型的成年患者。 副作用包括疲勞、頭痛、食慾下降、失眠、頭暈、噁心、瘙癢和關節痛。 使用此藥物與否，須由醫生按病人情況決定。
Grazoprevir; its salts 格拉瑞韋；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 elbasvir for the treatment of chronic hepatitis C genotype 1a, 1b and 4 in adults. Side effects include fatigue, headache, decreased appetite, insomnia, dizziness, nausea, pruritus and arthralgia. Its use should be decided by a doctor based on the patient's conditions. 此藥物與艾爾巴韋同用於一款混合型產品，治療慢性丙型肝炎屬1a，1b及4基因型的成年患者。 副作用包括疲勞、頭痛、食慾下降、失眠頭暈、噁心、瘙癢和關節痛。 使用此藥物與否，須由醫生按病人情況決定。

Ioflupane Iodine-123; its salts; when contained in pharmaceutical products	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for detecting loss of functional dopaminergic neuron terminals in the striatum in adult patients with clinically uncertain Parkinsonian Syndromes. Side effects include headache, increased appetite, nausea and vertigo. Its use should be decided by a doctor based on the patient's conditions.
碘-123氟潘；其鹽類；限於包含在藥劑製品者	附表十的第一部，附表一及附表三毒藥	此藥物針對屬於臨牀不能確認的柏金遜綜合症的成年患者，用於檢測其紋狀體中喪失機能的多巴胺神經元終端。 副作用包括頭痛、增加食慾、噁心和頭暈。 使用此藥物與否，須由醫生按病人情況決定。
Ixazomib; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug in combination with lenalidomide and dexamethasone is used for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Side effects include diarrhoea, constipation, thrombocytopenia, peripheral neuropathy and nausea. Its use should be decided by a doctor based on the patient's conditions.
伊沙佐米；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物與來那度胺和地塞米松組合使用，用於治療曾接受最少一次先前療程的多發性骨髓瘤的成年患者。 副作用包括腹瀉、便秘、血小板減少、周邊性神經病變和噁心。 使用此藥物與否，須由醫生按病人情況決定。

Ribociclib; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer. Side effects include neutropenia, nausea, fatigue, diarrhoea, alopecia and leukopenia. Its use should be decided by a doctor based on the patient's conditions.
瑞波西利；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物與芳香酶抑製劑組合使用，作為初期內分泌基礎療程，用於治療激素受體呈陽性、人類表皮生長因子受體2型呈陰性的晚期或轉移性乳腺癌的停經婦女患者。 副作用包括中性粒細胞減少、噁心、疲勞、腹瀉、脫髮和白細胞減少。 使用此藥物與否，須由醫生按病人情況決定。

Selexipag; its salts (現時沒有中文名稱)	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 long-term treatment of pulmonary arterial hypertension in adult patients with WHO functional class II–III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist and/or a phosphodiesterase type 5 inhibitor, or as monotherapy in patients who are not candidates for these therapies. Side effects include headache, flushing, nasopharyngitis, diarrhoea and jaw pain. Its use should be decided by a doctor based on the patient's conditions. 此藥物用作長期治療屬世界衞生組織功能級別II及III型的肺動脈高血壓症的成年患者，對使用內皮素受體拮抗劑和/或磷酸二酯酶5型抑製劑仍不足夠控制病情的患者作為組合使用，或對不適合上述療法的患者作為單獨使用。 副作用包括頭痛、潮紅、鼻咽炎、腹瀉和下顎疼痛。 使用此藥物與否，須由醫生按病人情況決定。
Silodosin; its salts 西洛多新；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 adults for the treatment of bladder outlet obstruction associated with benign prostatic hyperplasia. Side effects include abnormal ejaculation, thirst, diarrhoea, dizziness and nasal congestion. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療良性前列腺增生相關的膀胱通道阻塞的成年患者。 副作用包括射精異常、口渴、腹瀉、頭暈和鼻塞。 使用此藥物與否，須由醫生按病人情況決定。

Tipiracil; its salts; when contained in pharmaceutical products	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used in a combination product with trifluridine for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. Side effects include anaemia, neutropenia, fatigue, nausea, thrombocytopenia, decreased appetite, diarrhoea and vomiting. Its use should be decided by a doctor based on the patient's conditions.
替匹嘧啶；其鹽類；限於包含在藥劑製品者	附表十的第一部，附表一及附表三毒藥	此藥物與曲氟尿苷同用於一款混合型產品，治療曾接受氟嘧啶、奧沙利鉑和伊立替康類化療，抗VEGF生物療法，及抗EGFR療法當屬RAS不受控型的轉移性大腸癌的成年患者。 副作用包括貧血、中性粒細胞減少、疲勞、噁心、血小板減少、食慾下降、腹瀉和嘔吐。 使用此藥物與否，須由醫生按病人情況決定。