File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 4) REGULATION 2016

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 2016 ("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 eight 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) Alirocumab
(b) Bedaquiline; its salts
(c) Cobimetinib; its salts
(d) Idarucizumab
(e) Lurasidone; its salts

(f) Panobinostat; its salts
(g) Sacubitril; its salts
(h) Simeprevir; 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	7 October 2016
Date of Commencement	7 October 2016

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
October 2016

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2016

(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 "Alglucosidase alfa"—

Add

"Alirocumab".

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

Add

"Bedaquiline; its salts".

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

Add

"Cobimetinib; its salts".

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

Add

"Idarucizumab".

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

Add

"Lurasidone; its salts".

(6) Schedule 1, Division A, after item "Panitumumab"—

Add

"Panobinostat; its salts".

(7) Schedule 1, Division A, after item "Ruxolitinib; its salts"—

Add

"Sacubitril; its salts".

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

Add

"Simeprevir; 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 "Alglucosidase alfa"—

Add

"Alirocumab".

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

Add

"Bedaquiline; its salts".

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

Add

"Cobimetinib; its salts".

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

Add

"Idarucizumab".

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

Add

"Lurasidone; its salts".

(6) Schedule 3, Division A, after item "Panitumumab"—

Add

"Panobinostat; its salts".

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

Add

"Sacubitril; its salts".

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

Add

"Simeprevir; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Alirocumab".

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

Add

"Bedaquiline; its salts".

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

Add

"Cobimetinib; its salts".

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

Add

"Idarucizumab".

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

Add

"Lurasidone; its salts".

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

Add

"Panobinostat; its salts".

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

Add

"Sacubitril; its salts".

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

Add

"Simeprevir; its salts".

Chairman,
Pharmacy and Poisons Board

3 October 2016

Explanatory Note

This Regulation—

(a) adds 8 items to Division A of Schedule 1, and Division A of Schedule 3, to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) so that the sale, supply, labelling and storage of substances in those items are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations; and

(b) adds 8 items to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations so that, among other applicable requirements, substances in those items 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. 4) Regulation 2016

Supplementary Information to the Legislative Council

《2016年藥劑業及毒藥（修訂）（第4號）規例》

提交立法會的補充資料

Alirocumab	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol. Side effects include nasopharyngitis, influenza, urinary tract infection and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.
阿利人單抗	附表一、附表三及附表十的第一部毒藥	此藥物為輔助飲食及接受最高耐受劑量他汀類藥物，用作治療患有雜合家族性高膽固醇血症或臨牀動脈粥樣硬化心血管病，並需額外降低低密度脂蛋白膽固醇的成年患者。 副作用包括鼻咽炎、感冒、尿道感染和腹瀉。 使用此藥物與否，須由醫生按病人情況決定。

Bedaquiline; its salts (現時沒有中文名稱)	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison 附表一、附表三及附表十的第一部毒藥	This drug is used as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. Side effects include headache, dizziness, nausea, vomiting and arthralgia. Its use should be decided by a doctor based on the patient's conditions. 此藥物作為對耐多藥肺結核病的合適組合治療方案的其中一部分，用於治療因耐藥性或耐受性而不能使用其他有效治療方案的成年患者。 副作用包括頭痛、頭暈、噁心、嘔吐和關節痛。 使用此藥物與否，須由醫生按病人情況決定。
Cobimetinib; its salts 可美替尼；其鹽類	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison 附表一、附表三及附表十的第一部毒藥	This drug is used in combination with vemurafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Side effects include anaemia, serous retinopathy, hypertension, haemorrhage, diarrhoea, nausea, vomiting, rash and pyrexia. Its use should be decided by a doctor based on the patient's conditions. 此藥物與維莫非尼組合使用，用於治療BRAF V600突變而不能切除或轉移性黑色素瘤的成年患者。 副作用包括貧血、漿液性視網膜病變、高血壓、出血、腹瀉、噁心、嘔吐、皮疹和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Idarucizumab 依達組單抗	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison 附表一、附表三及附表十的第一部毒藥	This drug is used as a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures, and in life-threatening or uncontrolled bleeding. Side effects include hypokalemia, delirium, constipation, pyrexia and pneumonia. Its use should be decided by a doctor based on the patient's conditions. 此藥物作為對達比加群的特定逆轉劑，在成年患者使用達比加群治療後，用於因接受緊急手術或急切程序，及於危及生命或流血不止的情況下，而需要快速逆轉其抗凝結作用。 副作用包括低血鉀、譫妄、便秘、發熱及肺炎。 使用此藥物與否，須由醫生按病人情況決定。
Lurasidone; its salts 魯拉西酮；其鹽類	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison 附表一、附表三及附表十的第一部毒藥	This drug is used for the treatment of adult patients with schizophrenia. Side effects include somnolence, extrapyramidal disorder, akathisia, nausea and insomnia. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有精神分裂症的成年患者。 副作用包括嗜睡、錐體外失常、不能靜坐、噁心和失眠。 使用此藥物與否，須由醫生按病人情況決定。

Panobinostat; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent. Side effects include upper respiratory tract infection, pancytopenia, insomnia, dizziness, hypotension, cough, diarrhoea, fatigue and weight loss. Its use should be decided by a doctor based on the patient's conditions.
帕比司他；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物與硼替佐米和地塞米松組合使用，用於治療患有復發及/或難治多發性骨髓瘤，而曾經接受最少兩款治療方案，其中包括硼替佐米和免疫調節劑的成年患者。 副作用包括上呼吸道感染、全血細胞減少、失眠、頭暈、低血壓、咳嗽、腹瀉、乏力和體重下降。 使用此藥物與否，須由醫生按病人情況決定。

Sacubitril; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug and valsartan, as sacubitril valsartan sodium salt complex, is used in adult patients for the treatment of symptomatic chronic heart failure (NYHA class II-IV) with reduced ejection fraction to reduce the risk of cardiovascular death and hospitalization due to heart failure. Side effects include hyperkalaemia, hypotension, renal impairment, anaemia, dizziness, cough, diarrhoea and fatigue. Its use should be decided by a doctor based on the patient's conditions.
沙庫巴曲；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物與纈沙坦，成為沙庫巴曲纈沙坦鈉鹽複合物，用於治療患有減少排血分數的有症狀慢性心臟衰竭（紐約心臟協會II-IV級別）的成年患者，達致降低心血管疾病而死亡和因心臟衰竭導致入院的風險。 副作用包括高鉀血症、低血壓、腎功能受損、貧血、頭暈、咳嗽、腹瀉和乏力。 使用此藥物與否，須由醫生按病人情況決定。
Simeprevir; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in combination with other medicinal products for the treatment of chronic hepatitis C in adult patients. Side effects include dyspnoea, nausea, rash, pruritus and constipation. Its use should be decided by a doctor based on the patient's conditions.
西美瑞韋；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物與其他藥物組合使用，用於治療患有慢性丙型肝炎的成年患者。 副作用包括呼吸困難、噁心、皮疹、瘙癢和便秘。 使用此藥物與否，須由醫生按病人情況決定。