File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 5) 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. 5) 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 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) Alectinib; its salts
(b) Apremilast; its salts
(c) Carfilzomib; its salts
(d) Elotuzumab
(e) Osimertinib; its salts
(f) Palbociclib; its salts

4. Besides, the Board also proposes repealing the existing entry of "Pantoprazole; its salts" in Division A of First Schedule and Division A of Third Schedule to the Regulations, and replace it by "Pantoprazole; its salts; except when contained in oral preparations with 20mg or less per solid dosage unit, indicated with the maximum daily dose of 20mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days".

5. 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

6. The Amendment Regulation is to add the above drugs (in paragraphs 3 and 4) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

7. The legislative timetable will be –

Publication in the Gazette	25 November 2016
Date of Commencement	25 November 2016

IMPLICATIONS OF THE PROPOSAL

8. 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

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

Food and Health Bureau
November 2016

Pharmacy and Poisons (Amendment) (No. 5) 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 "Aldesleukin"—

Add

"Alectinib; its salts".

(2) Schedule 1, Division A, before item "Aprepitant; its salts"—

Add

"Apremilast; its salts".

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

Add

"Carfilzomib; its salts".

(4) Schedule 1, Division A, after item "Elosulfase alfa"—

Add

"Elotuzumab".

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

Add

"Osimertinib; its salts".

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

Add

"Palbociclib; its salts".

(7) Schedule 1, Division A—

Repeal item "Pantoprazole; its salts"

Substitute

"Pantoprazole; its salts; except when contained in oral preparations with 20 mg or less per solid dosage unit, indicated with the maximum daily dose of 20 mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days".

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 "Aldesleukin"—

Add

"Alectinib; its salts".

(2) Schedule 3, Division A, before item "Aprepitant; its salts"—

Add

"Apremilast; its salts".

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

Add

"Carfilzomib; its salts".

(4) Schedule 3, Division A, after item "Elosulfase alfa"—

Add

"Elotuzumab".

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

Add

"Osimertinib; its salts".

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

Add

"Palbociclib; its salts".

(7) Schedule 3, Division A—

Repeal item "Pantoprazole; its salts"

Substitute

"Pantoprazole; its salts; except when contained in oral preparations with 20 mg or less per solid dosage unit, indicated with the maximum daily dose of 20 mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days".

4. Schedule 10 amended (Poisons List)

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

Add

"Alectinib; its salts".

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

Add

"Apremilast; its salts".

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

Add

"Carfilzomib; its salts".

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

Add

"Elotuzumab".

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

Add

"Osimertinib; its salts".

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

Add

"Palbociclib; its salts".

Chairman,
Pharmacy and Poisons Board

18 November 2016

Explanatory Note

This Regulation—

(a) adds 6 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***); and

(b) replaces the item relating to "Pantoprazole" in those Divisions with another item.

The effect is that the sale, supply, labeling 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.

2. This Regulation also adds 6 items to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations. The effect is 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.

Annex B

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2016

Supplementary Information to the Legislative Council

《2016年藥劑業及毒藥（修訂）（第5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
Alectinib; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used for the treatment of adult patients with anaplastic lymphoma kinase-positive, metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib. Side effects include fatigue, constipation, edema, myalgia, cough, rash, nausea, headache, diarrhea and dyspnea. Its use should be decided by a doctor based on the patient's conditions.
阿來替尼；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物用於治療在接受克唑替尼後出現病情惡化或無法耐受，患有間變性淋巴瘤激酶呈陽性，轉移性非小細胞肺癌的成年患者。 副作用包括乏力、便秘、水腫、肌肉疼痛、咳嗽、皮疹、噁心、頭痛、腹瀉和呼吸困難。 使用此藥物與否，須由醫生按病人情況決定。

Apremilast; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used alone or in combination with Disease Modifying Anti-rheumatic Drugs (DMARDs) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy; and is also used for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light. Side effects include diarrhea, nausea, bronchitis, decreased appetite, insomnia, migraine, cough, vomiting, back pain and fatigue. Its use should be decided by a doctor based on the patient's conditions.
阿瑞司特；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物可單獨使用或與緩解病情抗風濕藥組合使用，用於治療對緩解病情抗風濕藥療效欠佳或無法耐受，患有活躍性牛皮癬關節炎的成年患者；亦可用於治療對其他全身療法包括環孢素、甲氨蝶呤或補骨酯素及紫外光線A型呈現無效，有使用禁忌或不能耐受，患有中度至嚴重程度慢性斑狀牛皮癬的成年患者。 副作用包括腹瀉、噁心、支氣管炎、食慾下降、失眠、偏頭痛、咳嗽、嘔吐、背痛和乏力。 使用此藥物與否，須由醫生按病人情況決定。

Carfilzomib; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Side effects include pneumonia, thrombocytopenia, neutropenia, hypokalemia, insomnia, dizziness, hypertension, dyspnea, vomiting, back pain, and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
卡非佐米；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物與來那度胺和地塞米松組合使用，用於治療患有多發性骨髓瘤，並曾接受過至少一次療程的成年患者。 副作用包括肺炎、血小板減少、中性粒細胞減少、低血鉀、失眠、頭暈、高血壓、呼吸困難、嘔吐、背痛和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Elotuzumab	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one to three prior therapies. Side effects include fatigue, diarrhea, pyrexia, constipation, cough, peripheral neuropathy, nasopharyngitis, upper respiratory tract infection, lymphopenia and hyperglycemia. Its use should be decided by a doctor based on the patient's conditions.
依洛珠單抗	附表一、附表三及附表十的第一部毒藥	此藥物與來那度胺和地塞米松組合使用，用於治療患有多發性骨髓瘤，並曾接受過一至三次療程的成年患者。 副作用包括乏力、腹瀉、發熱、便秘、咳嗽、周邊神經病變、鼻咽炎、上呼吸道感染、淋巴細胞減少和高血糖。 使用此藥物與否，須由醫生按病人情況決定。

Osimertinib; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor T790M mutation-positive non-small cell lung cancer. Side effects include diarrhea, stomatitis, rash, platelet count decreased and leukocytes decreased. Its use should be decided by a doctor based on the patient's conditions.
奧希替尼；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物用於治療患有局部晚期或轉移性表皮生長因子受體T790M突變呈陽性的非小細胞肺癌的成年患者。 副作用包括腹瀉、口腔炎、皮疹、血小板數量減少和白細胞減少。 使用此藥物與否，須由醫生按病人情況決定。

Palbociclib; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in combination with letrozole for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. Side effects include neutropenia, leukopenia, fatigue, anemia, upper respiratory tract infection, nausea, stomatitis, alopecia and diarrhea. Its use should be decided by a doctor based on the patient's conditions.
哌柏西利；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物與來曲唑組合使用，作為轉移性癌病的初期內分泌基礎療程，用於治療患有雌激素受體呈陽性，人類表皮生長因子受體2呈陰性的晚期乳腺癌的停經後婦女患者。 副作用包括中性粒細胞減少、白細胞減少、乏力、貧血、上呼吸道感染、噁心、口腔炎、脫髮和腹瀉。 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**
<u>From/由</u>		This drug is used for the relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above. Side effects include diarrhoea and headache. Its use should be decided by a pharmacist based on the patient's conditions.
Pantoprazole; its salts 泮托拉唑；其鹽類	Schedules 1 and 3 poison 附表1及附表3毒藥	
<u>To/轉成</u>		
Pantoprazole; its salts; except when contained in oral preparations with 20mg or less per solid dosage unit, indicated with the maximum daily dose of 20mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days 泮托拉唑；其鹽類；但每單一固體劑量包含20毫克或以下的口服製品，並標明每日最高劑量20毫克，供18歲或以上的病人，舒緩胃灼熱症狀相關的胃酸倒流，及包裝大小為含有最多7天的供應量除外。	Schedules 1 and 3 poison 附表1及附表3毒藥	此藥物舒緩因胃酸倒流引起的胃灼熱症狀，用於18歲或以上的患者。 副作用包括腹瀉和頭痛。 使用此藥物與否，須由藥劑師按病人的情況決定。