File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 6) REGULATION 2018

INTRODUCTION

The Pharmacy and Poisons Regulations ("the Regulations") (Cap. 138A) was made under section 29 of the Pharmacy and Poisons Ordinance ("the Ordinance") (Cap. 138). The Pharmacy and Poisons (Amendment) (No. 6) Regulation 2018 ("the Amendment Regulation") at **Annex A** is to amend Schedule 1, Schedule 3 and Schedule 10 to the Regulations.

JUSTIFICATIONS

General Background

2. The Pharmacy and Poisons Board ("the Board") is established under section 3 of the Ordinance. Under section 29(1B) of the Ordinance, the Board is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Regulations, subject to the approval of the Secretary for Food and Health and of the Poisons Committee, established under section 31 of the Ordinance.

Proposal of the Pharmacy and Poisons Board

3. Arising from applications for registration of 12 pharmaceutical products, the Board proposes adding the following 12 new drug substances to Division A of Schedule 1 (relating to the requirement to keep sales records), Division A of Schedule 3 (relating to the requirements to supply in accordance with a prescription and to keep dispensing records) and Division A of Part I of the Poisons List set out in Schedule 10 (relating to the requirements for sales to be conducted in a pharmacy by a registered pharmacist or in his presence and under his supervision, and for the drug to be kept in a locked receptacle) to the Regulations:

(a) Aceclofenac; its salts;

(b) Allergen extract of Dermatophagoides farinae;

(c) Avelumab;

(d) Benralizumab;

(e) Bictegravir; its salts;

(f) Brodalumab;

(g) Dupilumab;

(h) Lipegfilgrastim;

(i) Olaratumab;

(j) Pimobendan; its salts;

(k) Ponatinib; its salts; and

(l) Porfimer; its salts.

4. Details of the above drugs (in paragraph 3) 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 drugs.

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 shall be –

Publication in the Gazette	26 October 2018
Date of Commencement	26 October 2018

IMPLICATIONS OF THE PROPOSAL

7. The proposal shall impose appropriate control on pharmaceutical products which consist of the above drugs (in paragraph 3). It allows the pharmaceutical products to be sold in the market upon fulfillment of relevant regulations.

ENQUIRY

8. For any enquiries, please contact Mr. Dan Chan, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
October 2018

Pharmacy and Poisons (Amendment) (No. 6) 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 "Acebutolol; its salts"—

Add

"Aceclofenac; its salts".

(2) Schedule 1, Division A, before item "Allergen extract of Dermatophagoides pteronyssinus"—

Add

"Allergen extract of Dermatophagoides farinae".

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

Add

"Avelumab".

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

Add

"Benralizumab".

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

Add

"Bictegravir; its salts".

(6) Schedule 1, Division A, before item "Bromocriptine; its salts"—

Add

"Brodalumab".

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

Add

"Dupilumab".

(8) Schedule 1, Division A, after item "Linezolid; its salts"—

Add

"Lipegfilgrastim".

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

Add

"Olaratumab".

(10) Schedule 1, Division A, after item "Piminodine; its salts"—

Add

"Pimobendan; its salts".

(11) Schedule 1, Division A, after item "Pomalidomide; its salts"—

Add

"Ponatinib; its salts".

(12) Schedule 1, Division A, after item "Poractant alfa"—

Add

"Porfimer; 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 "Acebutolol; its salts"—

Add

"Aceclofenac; its salts".

(2) Schedule 3, Division A, before item "Allergen extract of Dermatophagoides pteronyssinus"—

Add

"Allergen extract of Dermatophagoides farinae".

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

Add

"Avelumab".

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

Add

"Benralizumab".

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

Add

"Bictegravir; its salts".

(6) Schedule 3, Division A, before item "Bromocriptine; its salts"—

Add

"Brodalumab".

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

Add

"Dupilumab".

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

Add

"Lipegfilgrastim".

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

Add

"Olaratumab".

(10) Schedule 3, Division A, after item "Pimecrolimus"—

Add

"Pimobendan; its salts".

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

Add

"Ponatinib; its salts".

(12) Schedule 3, Division A, after item "Poractant alfa"—

Add

"Porfimer; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Aceclofenac; its salts".

(2) Schedule 10, section 2, Table, Part 1, Division A, before item "Allergen extract of Dermatophagoides pteronyssinus"—

Add

"Allergen extract of Dermatophagoides farinae".

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

Add

"Avelumab".

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

Add

"Benralizumab".

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

Add

"Bictegravir; its salts".

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

Add

"Brodalumab".

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

Add

"Dupilumab".

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

Add

"Lipegfilgrastim".

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

Add

"Olaratumab".

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

Add

"Pimobendan; its salts".

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

Add

"Ponatinib; its salts".

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

Add

"Porfimer; its salts".

Chairman,
Pharmacy and Poisons Board

22 October 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 12 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 12 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 pharmacists; 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.

Pharmacy and Poisons (Amendment) (No. 6) Regulation 2018

Supplementary Information to the Legislative Council

《2018年藥劑業及毒藥（修訂）（第6號）規例》

提交立法會的補充資料

Drug Name 藥名	**Proposed Classification** 建議類別	**Remarks** 備註
Aceclofenac; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for symptomatic treatment of pain and inflammation in osteoarthritis, rheumatoid arthritis (chronic polyarthritis) and ankylosing spondylitis in adult patients. Side effects include dizziness, dyspepsia, abdominal pain, nausea, diarrhoea and hepatic enzyme increased. Its use should be decided by a doctor based on the patient's conditions.
醋氯芬酸；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於患有骨關節炎，類風濕性關節炎（慢性多發性關節炎）及強直性脊椎炎的成年患者的疼痛和炎症的對症治療。 副作用包括眩暈、消化不良、腹痛、噁心、腹瀉及肝酶增加。 使用此藥物與否，須由醫生按病人情況決定。

Allergen extract of Dermatophagoides farinae	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adult patients diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom relieving medication. Side effects include nasopharyngitis, ear pruritus, throat irritation, lip oedema and oedema mouth. Its use should be decided by a doctor based on the patient's conditions.
Dermatophagoides farinae的過敏原提取物[1]	附表十的第一部，附表一及附表三毒藥	此藥物用於經臨床病史診斷和屋塵蟎敏感測試（皮膚點刺測試及/或特異型免疫球蛋白E）呈陽性反應，並在使用症狀緩解藥物的情況下持續出現由屋塵蟎誘發的中度至嚴重程度的過敏性鼻炎的成年患者。 副作用包括鼻咽炎、耳瘙癢、咽喉刺激、嘴唇水腫及口腔水腫。 使用此藥物與否，須由醫生按病人情況決定。

[1] 根據世界衞生組織「國際非專利藥品名稱」（International Nonproprietary Name for Pharmaceutical Substances），「Dermatophagoides farinae」現時沒有正式的中文名稱。

Avelumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the treatment of adult patients with metastatic merkel cell carcinoma. Side effects include anaemia, decreased appetite, cough, dyspnoea and nausea. Its use should be decided by a doctor based on the patient's conditions.
阿維蘆人單抗	附表十的第一部，附表一及附表三毒藥	此藥物用作單一療法治療轉移性默克細胞癌的成年患者。 副作用包括貧血、食慾下降、咳嗽、呼吸困難及噁心。 使用此藥物與否，須由醫生按病人情況決定。

Benralizumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β-agonists. Side effects include pharyngitis, hypersensitivity reactions, headache, pyrexia and injection site reaction. Its use should be decided by a doctor based on the patient's conditions.
Benralizumab[2]	附表十的第一部，附表一及附表三毒藥	此藥物用於患有嚴重嗜酸性哮喘的成年人士，在使用高劑量吸入性皮質類固醇及長效乙類促效劑後，仍不能控制病情時作為其附加維持的治療。 副作用包括咽炎、過敏反應、頭痛、發熱及注射部位反應。 使用此藥物與否，須由醫生按病人情況決定。

[2] 根據世界衞生組織「國際非專利藥品名稱」（International Nonproprietary Name for Pharmaceutical Substances），「Benralizumab」現時沒有正式的中文名稱。

Bictegravir; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is indicated in combination with emtricitabine and tenofovir alafenamide for the treatment of adults infected with human immunodeficiency virus-1 without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir. Side effects include depression, headache, dizziness, diarrhea and nausea. Its use should be decided by a doctor based on the patient's conditions.
比克替拉韋；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物與恩曲他濱及磷丙替諾福韋結合使用，治療感染人類免疫力缺乏病毒一型，並且沒有證據顯示現在或過去對整合酶抑制劑類、恩曲他濱或替諾福韋產生病毒抗藥性的成年患者。 副作用包括抑鬱症、頭痛、眩暈、腹瀉及噁心。 使用此藥物與否，須由醫生按病人情況決定。

Brodalumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. Side effects include arthralgia, headache, fatigue, diarrhoea and oropharyngeal pain. Its use should be decided by a doctor based on the patient's conditions.
布羅蘆單抗	附表十的第一部，附表一及附表三毒藥	此藥用於治療適合接受全身系統性療程，患有中度至嚴重程度斑塊型銀屑病的成年人士。 副作用包括關節痛、頭痛、疲勞、腹瀉、口咽部疼痛。 使用此藥物與否，須由醫生按病人情況決定。

Dupilumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy. Side effects include injection site reactions, conjunctivitis, blepharitis, headache and oral herpes. Its use should be decided by a doctor based on the patient's conditions.
度匹蘆人單抗	附表十的第一部，附表一及附表三毒藥	此藥物用於治療適合接受全身系統性療程，患有中度至嚴重程度特應性皮炎的成年人士。 副作用包括注射部位反應、結膜炎、瞼炎、頭痛及口腔疱疹。 使用此藥物與否，須由醫生按病人情況決定。

Lipegfilgrastim	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) Side effects include musculoskeletal pain, thrombocytopenia, hypokalaemia, headache and skin reactions. Its use should be decided by a doctor based on the patient's conditions.
利培非格司亭	附表十的第一部，附表一及附表三毒藥	此藥物用於經接受細胞毒性化療的惡性腫瘤（慢性粒細胞性白血病及骨髓發育不良綜合徵除外）的成年患者，用作縮短中性白細胞減少症的持續時間及減低發熱性中性白細胞減少症的發病率。 副作用包括肌骨骼疼痛、血小板減少症、低鉀血症、頭痛及皮膚反應。 使用此藥物與否，須由醫生按病人情況決定。

Olaratumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin. Side effects include neutropenia, lymphopenia, headache, diarrhoea and mucositis. Its use should be decided by a doctor based on the patient's conditions.
Olaratumab[3]	附表十的第一部，附表一及附表三毒藥	此藥物與多柔比星結合使用，治療患有晚期軟組織肉瘤的成年人士，而這些患者並不適合接受根治性手術或放射治療，及在以前未曾接受過多柔比星的治療。 副作用包括中性白細胞減少症、淋巴球減少症、頭痛、腹瀉及粘膜炎。 使用此藥物與否，須由醫生按病人情況決定。

[3] 根據世界衞生組織「國際非專利藥品名稱」（International Nonproprietary Name for Pharmaceutical Substances），「Olaratumab」現時沒有正式的中文名稱。

Pimobendan; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of : canine with congestive heart failure originating from dilated cardiomyopathy or valvular insufficiency (mitral and/or tricuspid valve regurgitation); dilated cardiomyopathy in the preclinical stage (asymptomatic with an increase in left ventricular end-systolic and end-diastolic diameter) in Doberman Pinschers following echocardiographic diagnosis of cardiac disease. Side effects include rise in heart rate, vomiting, transient diarrhoea, anorexia and lethargy. Its use should be decided by a veterinary surgeon based on the animal's conditions.
匹莫苯旦；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： 因擴張型心肌病或瓣膜功能不全（二尖瓣及/或三尖瓣反流）引致的充血性心臟衰竭的犬隻； 經心臟超聲波掃描診斷心臟疾病後的臨床前階段擴張型心肌病（無症狀，伴隨左心室收縮末期和舒張末期內徑增加）的杜賓犬。 副作用包括心率上升、嘔吐、短暫性腹瀉、食慾缺乏及昏睡。 使用此藥物與否，須由獸醫按動物情況決定。

Ponatinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adults patients with: chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation; Philadelphia chromosome positive acute lymphoblastic leukaemia who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. Side effects include upper respiratory tract infection, anaemia, decreased appetite, insomnia and headache. Its use should be decided by a doctor based on the patient's conditions.
泊那替尼；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於成年患者作： 治療患有慢性期、加速期或急性期慢性粒細胞性白血病，且對達沙替尼或尼洛替尼具抗藥性；或無法耐受達沙替尼或尼洛替尼，並於臨床上不適合以伊馬替尼作後續治療；或出現T315I突變； 治療患有陽性費城染色體的急性淋巴母細胞性白血病，且對達沙替尼具抗藥性；或無法耐受達沙替尼，並於臨床上不適合以伊馬替尼作後續治療；或出現T315I突變。 副作用包括上呼吸道感染、貧血、食慾下降、失眠症及頭痛。 使用此藥物與否，須由醫生按病人情況決定。

Porfimer; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used with photodynamic therapy in adult patients for: - palliative treatment of obstructing endobronchial non-small cell lung cancer; - palliative treatment of obstructing oesophageal cancer. Side effects include photosensitivity reaction, pneumonia, dyspnoea, pyrexia and anaemia. Its use should be decided by a doctor based on the patient's conditions.
卟吩姆；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物與光動力療法一併使用於成年患者作： - 阻塞性支氣管內非小細胞肺癌的姑息治療; - 阻塞性食管癌的姑息治療。 副作用包括光敏反應、肺炎、呼吸困難、發熱及貧血。 使用此藥物與否，須由醫生按病人情況決定。