File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 7) REGULATION 2015

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. 7) Regulation 2015 ("the Amendment Regulation") at **Annex A** is to amend Schedules 1, 3 and 10 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. Having considered an application for re-classification of "Clotrimazole; its salts" when contained in pharmaceutical products labelled only for the treatment of tinea pedis or tinea cruris, or both, the Board recommends amending Division A of Part 1 and Division A of Part 2 of Schedule 10 to the Regulations. The proposed amendment aims to relax the control of "Clotrimazole; its salts" when contained in pharmaceutical products labelled only for the treatment of tinea pedis or tinea cruris, or both, by re-classifying them from Part 1 poisons to Part 2 poisons.

4. Moreover, arising from applications for registration of seven pharmaceutical products, the Board proposes to add the following substances to Division A of Schedule 1, Division A of Schedule 3 and Division A of Part 1 of the Poisons List set out in Schedule 10 to the Regulations.

(a) Ceritinib; its salts
(b) Dulaglutide
(c) Nivolumab
(d) Pembrolizumab
(e) Pirfenidone; its salts
(f) Pyriprole; its salts
(g) Secukinumab

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 re-classify the substance under the conditions listed in paragraph 3 above from Part 1 to Part 2 of Schedule 10 to the Regulations and to add the substances listed in paragraph 4 above to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	11 December 2015
Date of Commencement	11 December 2015

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 on the brief, please contact Mr Chow Tat-wing, Assistant Secretary for Food and Health, at 3509 8956.

Food and Health Bureau
December 2015

Pharmacy and Poisons (Amendment) (No. 7) Regulation 2015

(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 "Celiprolol; its salts"—

Add

"Ceritinib; its salts".

(2) Schedule 1, Division A, after item "Drotrecogin alfa"—

Add

"Dulaglutide".

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

Add

"Nivolumab".

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

Add

"Pembrolizumab".

(5) Schedule 1, Division A, after item "Pipobroman"—

Add

"Pirfenidone; its salts".

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

Add

"Pyriprole; its salts".

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

Add

"Secukinumab".

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 "Celiprolol; its salts"—

Add

"Ceritinib; its salts".

(2) Schedule 3, Division A, after item "Drotrecogin alfa"—

Add

"Dulaglutide".

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

Add

"Nivolumab".

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

Add

"Pembrolizumab".

(5) Schedule 3, Division A, after item "Pipobroman"—

Add

"Pirfenidone; its salts".

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

Add

"Pyriprole; its salts".

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

Add

"Secukinumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Ceritinib; its salts".

(2) Schedule 10, section 2, Table, Part 1, Division A—

Repeal item "Clotrimazole; its salts"

Substitute

"Clotrimazole; its salts; except when contained in pharmaceutical products labelled only for the treatment of tinea pedis or tinea cruris, or both".

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

Add

"Dulaglutide".

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

Add

"Nivolumab".

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

Add

"Pembrolizumab".

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

Add

"Pirfenidone; its salts".

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

Add

"Pyriprole; its salts".

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

Add

"Secukinumab".

(9) Schedule 10, section 2, Table, Part 1, Division A, item relating to "Terbinafine"—

Repeal

"labelled for the treatment of tinea pedis and/or tinea cruris only"

Substitute

"labelled only for the treatment of tinea pedis or tinea cruris, or both".

(10) Schedule 10, section 2, Table, Part 2, Division A, after item "alpha-Chloralose"—

Add

"Clotrimazole; its salts; when contained in pharmaceutical products labelled only for the treatment of tinea pedis or tinea cruris, or both".

(11) Schedule 10, section 2, Table, Part 2, Division A, item relating to "Terbinafine"—

Repeal

"labelled for the treatment of tinea pedis and/or tinea cruris only"

Substitute

"labelled only for the treatment of tinea pedis or tinea cruris, or both".

Chairman,
Pharmacy and Poisons Board

4 December 2015

Explanatory Note

This Regulation—

(a) adds 7 substances 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 those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations; and

(b) adds 7 substances to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations (***Poisons List***) so that, among other applicable requirements, poisons containing those substances 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.

2. This Regulation also amends the Poisons List—

(a) to relax the control over "Clotrimazole; its salts" when contained in pharmaceutical products labelled only for the treatment of tinea pedis or tinea cruris, or both; and

(b) to make certain textual amendments.

Pharmacy and Poisons (Amendment) (No. 7) Regulation 2015

Supplementary Information to the Legislative Council

《2015年藥劑業及毒藥(修訂)(第7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
Ceritinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer previously treated with crizotinib (ALK inhibitor). Side effects include anaemia, decreased appetite, diarrhoea, nausea, vomiting, abdominal pain, constipation, rash and fatigue. Its use should be decided by a doctor based on the patient's conditions.
塞瑞替尼；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於治療曾經接受克唑替尼(間變性淋巴瘤激酶(ALK)的抑製劑)療程，ALK呈陽性晚期非小細胞肺癌的成年患者。 副作用包括貧血、食慾下降、腹瀉、噁心、嘔吐、腹痛、便秘、皮疹和疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Dulaglutide	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adults with type 2 diabetes mellitus to improve glycaemic control as monotherapy, or add-on therapy in combination with other glucose-lowering medicinal products including insulin. Side effects include hypoglycaemia, nausea, diarrhoea, vomiting and abdominal pain. Its use should be decided by a doctor based on the patient's conditions.
Dulaglutide (註: 暫無中文名稱)	附表十第一部、 附表一及 附表三毒藥	此藥物可作為單獨療法，或綜合其他降糖藥物包括胰島素的附加療法，應用於糖尿病二型的成年患者，改善其血糖控制。 副作用包括低血糖、噁心、腹瀉、嘔吐和腹痛。 使用此藥物與否，須由醫生按病人情況決定。

Nivolumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor; and adult patients with metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy. Side effects include rash, fatigue, dyspnea, cough, musculoskeletal pain, decreased appetite, nausea and constipation. Its use should be decided by a doctor based on the patient's conditions.
尼伏人單抗	附表十第一部、 附表一及 附表三毒藥	此藥物用於治療不能切除或轉移性黑色素瘤，經伊匹木單抗治療後，及如BRAF V600突變呈陽性，經BRAF抑製劑治療後，病情仍惡化的成年患者；亦可用於治療轉移性鱗狀非小細胞肺癌，經鉑為基礎的化療後，病情仍惡化的成年患者。 副作用包括皮疹、疲勞、呼吸困難、咳嗽、肌肉骨骼疼痛、食慾下降、噁心和便秘。 使用此藥物與否，須由醫生按病人情況決定。

Pembrolizumab 匹博利組單抗	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十第一部、附表一及附表三毒藥	This drug is used for the treatment of adult patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. Side effects include fatigue, cough, nausea, rash, decreased appetite, constipation, arthralgia and diarrhoea. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療不能切除或轉移性黑色素瘤，經伊匹木單抗治療後，及如BRAF V600突變呈陽性，經BRAF抑製劑治療後，病情仍惡化的成年患者。 副作用包括疲勞、咳嗽、噁心、皮疹、食慾下降、便秘、關節痛和腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Pirfenidone; its salts 吡非尼酮；其鹽類	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十第一部、附表一及附表三毒藥	This drug is used in adults for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis. Side effects include anorexia, dyspepsia, nausea, diarrhoea, photosensitivity, rash and fatigue. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療輕至中度特發性肺部纖維化的成年患者。 副作用包括食慾不振、消化不良、噁心、腹瀉、光綫敏感、皮疹和疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Pyriprole; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment and prevention of flea and tick infestations in dogs. Side effects include pruritus, lethargy and emesis. Its use should be decided by a veterinary surgeon based on the animal's conditions.
Pyriprole；其鹽類 (註：Pyriprole 暫無中文名稱)	附表十第一部、 附表一及 附表三毒藥	此藥物用於治療和預防狗隻受到跳蚤和蜱的侵擾。 副作用包括瘙癢、嗜睡和嘔吐。 使用此藥物與否，須由獸醫按動物的情況決定。
Secukinumab	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 adults who are candidates for systemic therapy. Side effects include upper respiratory tract infection, oral herpes and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.
Secukinumab (註：暫無中文名稱)	附表十第一部、 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，中度至嚴重程度斑塊型銀屑病的成年患者。 副作用包括上呼吸道感染、口腔皰疹和腹瀉。 使用此藥物與否，須由醫生按病人情況決定。