File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 2) REGULATION 2017

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. 2) Regulation 2017 ("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 five 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) Avanafil; its salts
(b) Blinatumomab
(c) Daratumumab
(d) Mepolizumab
(e) Iodine-131; 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	17 March 2017
Date of Commencement	17 March 2017

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
March 2017

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2017

(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 "Auranofin"—

Add

"Avanafil; its salts".

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

Add

"Blinatumomab".

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

Add

"Daratumumab".

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

Add

"Iodine-131; its salts; when contained in pharmaceutical products".

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

Add

"Mepolizumab".

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 "Auranofin"—

Add

"Avanafil; its salts".

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

Add

"Blinatumomab".

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

Add

"Daratumumab".

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

Add

"Iodine-131; its salts; when contained in pharmaceutical products".

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

Add

"Mepolizumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Avanafil; its salts".

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

Add

"Blinatumomab".

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

Add

"Daratumumab".

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

Add

"Iodine-131; its salts; when contained in pharmaceutical products".

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

Add

"Mepolizumab".

Chairman,
Pharmacy and Poisons Board

8 March 2017

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 5 items to—

(a) Division A of its Schedule 1;

(b) Division A of its Schedule 3; and

(c) Division A of Part 1 of the Poisons List set out in its 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 5 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. 2) Regulation 2017

Supplementary Information to the Legislative Council

《2017年藥劑業及毒藥（修訂）（第2號）規例》

提交立法會的補充資料

Avanafil; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of erectile dysfunction in adult men. Side effects include headache, flushing and nasal congestion. Its use should be decided by a doctor based on the patient's conditions.
阿伐那非；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療勃起功能障礙的成年男性患者。 副作用包括頭痛、臉紅和鼻塞。 使用此藥物與否，須由醫生按病人情況決定。

Blinatumomab	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia Side effects include pyrexia, headache, peripheral edema, febrile neutropenia, nausea, hypokalemia and constipation. Its use should be decided by a doctor based on the patient's conditions.
蘭妥莫單抗	附表十的第一部，附表一及附表三毒藥	此藥物用於治療患有費城染色體呈陰性的復發或難治性B細胞前體急性淋巴細胞白血病的成年患者。 副作用包括發熱、頭痛、周邊水腫、發熱性中性粒細胞減少、噁心、低鉀血症和便秘。 使用此藥物與否，須由醫生按病人情況決定。

Daratumumab	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy. Side effects include pneumonia, upper respiratory tract infection, nasopharyngitis, anaemia, neutropenia, thrombocytopenia, headache, hypertension, cough, nasal congestion, dyspnea, nausea, diarrhoea, constipation, vomiting, back pain, arthralgia, pyrexia and chills. Its use should be decided by a doctor based on the patient's conditions.
達雷木單抗	附表十的第一部，附表一及附表三毒藥	此藥物作為單獨療法，用於治療患有復發和難治性多發性骨髓瘤的成年病人，而其先前有用療程包括蛋白酶體抑製劑和免疫調節劑，及在最近療程後仍呈現病情惡化。 副作用包括肺炎、上呼吸道感染、鼻咽炎、貧血、中性粒細胞減少、血小板減少、頭痛、高血壓、咳嗽、鼻塞、呼吸困難、噁心、腹瀉、便秘、嘔吐、背痛、關節痛、發熱和發冷。 使用此藥物與否，須由醫生按病人情況決定。

Mepolizumab 美泊珠單抗	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 as an add-on treatment for severe refractory eosinophilic asthma in adult patients. Side effects include headache, lower respiratory tract infection, hypersensitivity reactions, nasal congestion, upper abdominal pain, eczema, back pain and pyrexia. Its use should be decided by a doctor based on the patient's conditions. 此藥物作為附加治療製劑，用於治療嚴重難治性嗜酸性哮喘的成年患者。 副作用包括頭痛、下呼吸道感染、過敏反應、鼻塞、上腹痛、濕疹、背痛和發熱。 使用此藥物與否，須由醫生按病人情況決定。
Iodine-131; its salts; when contained in pharmaceutical products 碘-131；其鹽類；限於包含在藥劑製品者	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 children and adults for the treatment of Graves' disease, toxic multinodular goitre or autonomous nodules, and papillary and follicular thyroid carcinoma including metastatic disease. Side effects include dry mouth, nausea, vomiting, hypothyroidism, radiation thyroiditis, radiation associated pain and tracheal obstruction. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有格雷夫斯病，毒性多結節甲狀腺腫症或自主性結節，並包括轉移性病情的乳頭狀和濾泡性甲狀腺腫瘤的兒童和成年患者。 副作用包括口乾、噁心、嘔吐、甲狀腺功能減退、輻射性甲狀腺炎、輻射性相關疼痛和氣管阻塞。 使用此藥物與否，須由醫生按病人情況決定。