File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO.2) 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. 2) Regulation 2016 ("the Amendment Regulation") at **Annex A** is to amend the 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 to add the following substances to Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in the Tenth Schedule to the Regulations:

(a) Aclidinium; its salts
(b) Asunaprevir; its salts
(c) Daclatasvir; its salts
(d) Evolocumab
(e) Lenvatinib; its salts

(f) Siltuximab

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	29 April 2016
Date of Commencement	29 April 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
April 2016

Pharmacy and Poisons (Amendment) (No. 2) 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 "Acitretin; its salts; its esters"—

Add

"Aclidinium; its salts".

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

Add

"Asunaprevir; its salts".

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

Add

"Daclatasvir; its salts".

(4) Schedule 1, Division A, after item "Everolimus; its salts; its esters; their salts"—

Add

"Evolocumab".

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

Add

"Lenvatinib; its salts".

(6) Schedule 1, Division A, after item "Sildenafil; its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts"—

Add

"Siltuximab".

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 "Acitretin; its salts; its esters"—

Add

"Aclidinium; its salts".

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

Add

"Asunaprevir; its salts".

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

Add

"Daclatasvir; its salts".

(4) Schedule 3, Division A, after item "Everolimus; its salts; its esters; their salts"—

Add

"Evolocumab".

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

Add

"Lenvatinib; its salts".

(6) Schedule 3, Division A, after item "Sildenafil; its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts"—

Add

"Siltuximab".

4. Schedule 10 amended (Poisons List)

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

Add

"Aclidinium; its salts".

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

Add

"Asunaprevir; its salts".

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

Add

"Daclatasvir; its salts".

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

Add

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2016

"Evolocumab".

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

Add

"Lenvatinib; its salts".

(6) Schedule 10, section 2, Table, Part 1, Division A, after item "Sildenafil; its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts"—

Add

"Siltuximab".

Chairman,
Pharmacy and Poisons Board

25 April 2016

Explanatory Note

This Regulation—

(a) adds 6 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 6 substances 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, 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.

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2016

Supplementary Information to the Legislative Council

《2016年藥劑業及毒藥（修訂）（第2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
Aclidinium; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. Side effects include sinusitis, nasopharyngitis, headache, cough, diarrhoea and nausea. Its use should be decided by a doctor based on the patient's conditions.
阿地溴銨；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用作維持支氣管擴張的療法，減輕慢性阻塞性肺病的成年患者的症狀。 副作用包括鼻竇炎、鼻咽炎、頭痛、咳嗽、腹瀉和噁心。 使用此藥物與否，須由醫生按病人情況決定。

Asunaprevir; its salts 阿舒瑞韋；其鹽類	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 combination with other medicinal products for the treatment of chronic hepatitis C virus infection in adults with compensated liver disease, including cirrhosis. Side effects include fatigue, headache, diarrhoea, pruritus, insomnia, nausea and cough. Its use should be decided by a doctor based on the patient's conditions. 此藥物聯同其他藥物用於治療慢性丙型肝炎病毒感染的成年病者並患有代償性肝病，包括肝硬化。 副作用包括疲勞、頭痛、腹瀉、瘙癢、失眠、噁心和咳嗽。 使用此藥物與否，須由醫生按病人情況決定。
Daclatasvir; its salts 達拉他韋；其鹽類	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 combination with other medicinal products for the treatment of chronic hepatitis C virus infection in adults with compensated liver disease, including cirrhosis. Side effects include fatigue, headache, nausea, diarrhoea, insomnia, pyrexia and dizziness. Its use should be decided by a doctor based on the patient's conditions. 此藥物聯同其他藥物用於治療慢性丙型肝炎病毒感染的成年病者並患有代償性肝病，包括肝硬化。 副作用包括疲勞、頭痛、噁心、腹瀉、失眠、發熱和頭暈。 使用此藥物與否，須由醫生按病人情況決定。

Evolocumab 依伏庫人單抗	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 in patients of the target age as an adjunct to diet and (i) maximally tolerated statin therapy with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease; or (ii) other low density lipoprotein-lowering therapies with homozygous familial hypercholesterolemia, who require additional lowering of low density lipoprotein cholesterol. Side effects include nasopharyngitis, upper respiratory tract infection, back pain and cough. Its use should be decided by a doctor based on the patient's conditions. 此藥物用作輔助飲食及接受〈i〉他汀類藥物最高耐受劑量治療雜合家族性高膽固醇血症，或臨牀動脈粥樣硬化心血管病；或〈ii〉其他降低低密度脂蛋白藥物治療純合家族性高膽固醇血症，另需額外降低低密度脂蛋白膽固醇的合適年齡患者。 副作用包括鼻咽炎、上呼吸道感染、背痛和咳嗽。 使用此藥物與否，須由醫生按病人情況決定。

Lenvatinib; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma, refractory to radioactive iodine. Side effects include hypertension, diarrhoea, decreased appetite, weight decreased, nausea, proteinuria, stomatitis and vomiting. Its use should be decided by a doctor based on the patient's conditions.
侖伐替尼；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療患有使用放射性碘仍難以治愈的逐步蔓延、局部晚期或轉移性、分化型甲狀腺腫瘤的成年患者。 副作用包括高血壓、腹瀉、食慾下降、體重下降、噁心、蛋白尿、口腔炎和嘔吐。 使用此藥物與否，須由醫生按病人情況決定。

Siltuximab 司妥昔單抗	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 for the treatment of adult patients with multicentric Castleman's disease who are human immunodeficiency virus negative and human herpesvirus-8 negative. Side effects include upper respiratory tract infection, nasopharyngitis, neutropenia, thrombocytopenia, hypertension, abdominal pain, pruritus, renal impairment and weight increased. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療對人類免疫力缺乏病毒和人類疱疹病毒8型呈陰性反應的多發型Castleman病症的成年患者。 副作用包括上呼吸道感染，鼻咽炎，中性粒細胞減少，血小板減少，高血壓，腹痛，瘙癢，腎功能受損和體重增加。 使用此藥物與否，須由醫生按病人情況決定。