File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 5) REGULATION 2019

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.5) Regulation 2019 ("the Amendment Regulation") at **Annex A** is to amend Schedule 1, Schedule 3 and Schedule 10 to the Regulations.

JUSTIFICATIONS

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 pharmaceutical products and an ongoing review of sales control of pharmaceutical products, the Board proposes adding the following drugs 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 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) Abemaciclib; its salts;
(b) Cannabidiol; its salts; when contained in pharmaceutical products;
(c) Epoprostenol
(d) Gemtuzumab ozogamicin;
(e) Indigo carmine;
(f) Larotrectinib; its salts
(g) Nicardipine; its salts
(h) Risankizumab;
(i) Semaglutide; and
(j) Sodium zirconium cyclosilicate.

4. In addition, the Board proposes –

(a) amending the existing entry of "Etidronic acid; its salts" to "Etidronic acid; its salts; when contained in pharmaceutical products" in Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10 of the Regulations; and
(b) repealing the existing entry of "Pentoxifylline" under "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin —", and replacing it by "Pentoxifylline; its salts" in Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10 of the Regulations.

5. Details of the above drugs (in paragraphs 3 and 4) 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

6. The Amendment Regulation proposes amending the relevant Schedules to the Regulations in accordance to paragraphs 3 and 4.

LEGISLATIVE TIMETABLE

7. The legislative timetable shall be –

Publication in the Gazette	13 December 2019
Date of Commencement	13 December 2019[1] or 13 December 2020[2]

IMPLICATIONS OF THE PROPOSAL

8. The proposal shall impose appropriate control on pharmaceutical products which consist of the above drugs (in paragraphs 3 and 4). The proposal allows the pharmaceutical products to be sold in the market upon fulfillment of relevant regulations.

ENQUIRY

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

Food and Health Bureau
December 2019

[1] For the drugs in paragraphs 3 and 4(a).

[2] For the drugs in paragraph 4(b), the Board recommends that the proposed amendment be implemented 12 months after the date of publication in the Gazette. This is to give affected registration certification holders sufficient time to (a) recall the affected products from the market and (b) re-label the affected products to comply with the labelling requirements due to changes in sales control.

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2019

(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. Commencement

(1) Subject to subsection (2), this Regulation comes into operation on the day on which it is published in the Gazette.

(2) Sections 3(7) and (9), 4(7) and (9) and 5(7) and (9) come into operation on 13 December 2020.

2. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 3, 4 and 5.

3. 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 "Abciximab"—

Add

"Abemaciclib; its salts".

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

Add

"Cannabidiol; its salts; when contained in pharmaceutical products".

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

Add

"; when contained in pharmaceutical products".

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

Add

"Gemtuzumab ozogamicin".

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

Add

"Larotrectinib; its salts".

(6) Schedule 1, Division A, after item "Nevirapine; its salts"—

Add

"Nicardipine; its salts".

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

Add

"Pentoxifylline; its salts".

(8) Schedule 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Icodextrin"—

Add

"Indigo carmine".

(9) Schedule 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"—

Repeal sub-item "Pentoxifylline".

(10) Schedule 1, Division A, item "Prostaglandins, the following and their derivatives", after sub-item "Dinoprostone"—

Add

"Epoprostenol".

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

Add

"Risankizumab".

(12) Schedule 1, Division A, after item "Selexipag; its salts"—

Add

"Semaglutide".

(13) Schedule 1, Division A, after item "Sodium nitroprusside"—

Add

"Sodium zirconium cyclosilicate".

(14) Schedule 1, Chinese text, Division A, item "供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但與胰島素的混合物除外"—

Repeal

"與胰島素的混合物"

Substitute

"在與胰島素的混合物內者".

4. 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 "Abciximab"—

Add

"Abemaciclib; its salts".

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

Add

"Cannabidiol; its salts; when contained in pharmaceutical products".

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

Add

"; when contained in pharmaceutical products".

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

Add

"Gemtuzumab ozogamicin".

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

Add

"Larotrectinib; its salts".

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

Add

"Nicardipine; its salts".

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

Add

"Pentoxifylline; its salts".

(8) Schedule 3, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Icodextrin"—

Add

"Indigo carmine".

(9) Schedule 3, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"—

Repeal sub-item "Pentoxifylline".

(10) Schedule 3, Division A, item "Prostaglandins, the following and their derivatives", after sub-item "Dinoprostone"—

Add

"Epoprostenol".

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

Add

"Risankizumab".

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

Add

"Semaglutide".

(13) Schedule 3, Division A, after item "Sodium nitroprusside"—

Add

"Sodium zirconium cyclosilicate".

(14) Schedule 3, Chinese text, Division A, item "供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但與胰島素的混合物除外"—

Repeal

"與胰島素的混合物"

Substitute

"在與胰島素的混合物內者".

5. Schedule 10 amended (Poisons List)

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

Add

"Abemaciclib; its salts".

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

Add

"Cannabidiol; its salts; when contained in pharmaceutical products".

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

Add

"; when contained in pharmaceutical products".

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

Add

"Gemtuzumab ozogamicin".

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

Add

"Larotrectinib; its salts".

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

Add

"Nicardipine; its salts".

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

Add

"Pentoxifylline; its salts".

(8) Schedule 10, section 2, Table, Part 1, Division A, item "Pharmaceutical products for human parenteral administration

containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Icodextrin"—

Add

"Indigo carmine".

(9) Schedule 10, section 2, Table, Part 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"—

Repeal sub-item "Pentoxifylline".

(10) Schedule 10, section 2, Table, Part 1, Division A, item "Prostaglandins, the following and their derivatives", after sub-item "Dinoprostone"—

Add

"Epoprostenol".

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

Add

"Risankizumab".

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

Add

"Semaglutide".

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

Add

"Sodium zirconium cyclosilicate".

(14) Schedule 10, Chinese text, section 2, Table, Part 1, Division A, item "供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但與胰島素的混合物除外"—

Repeal

"與胰島素的混合物"

Substitute

"在與胰島素的混合物內者".

Chairman,
Pharmacy and Poisons Board

5 December 2019

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) to add new items and sub-items to, and remove certain sub-items from, the following schedules to the principal Regulations—

(a) Division A of Schedule 1 (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply);

(b) Division A of Schedule 3 (substances required to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon); and

(c) Division A of Part 1 of the Poisons List set out in Schedule 10.

Annex B
附件B

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2019
Supplementary Information to the Legislative Council

《2019 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	**Remarks** 備註
Abemaciclib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of women with hormone receptor positive, human epidermal growth factor receptor 2 negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone agonist. Side effects include diarrhoea, neutropenia, infections, nausea and fatigue. Its use should be decided by a doctor based on the patient's conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
阿貝西利；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於治療患有激素受體呈陽性、第二型人類表皮生長因子受體呈陰性的晚期或轉移性乳癌的婦女，並且需與芳香酶抑製劑或氟維司群結合使用，作為初期內分泌基礎療程或用於曾接受內分泌療程的婦女。 對於停經前或停經中期的婦女，內分泌療程應與黃體生成素釋放激素激動劑一拼使用。 副作用包括腹瀉、中性白細胞減少症、感染、噁心及疲勞。 使用此藥物與否，須由醫生按病人情況決定。
Cannabidiol; its salts; when contained in pharmaceutical product	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. Side effects include somnolence, decreased appetite, diarrhoea, fatigue and rash. Its use should be decided by a doctor based on the patient’s conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
大麻二酚；其鹽類；但限於包含在藥劑製品內者	附表10的第1部，附表1及附表3毒藥	此藥物用於治療與Lennox-Gastaut綜合症或Dravet綜合症相關的癲癇的兩歲或以上的患者。 副作用包括嗜眠、食慾下降、腹瀉、疲勞及皮疹。 使用此藥物與否，須由醫生按病人情況決定。
Epoprostenol	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison (under the entry of "Prostaglandins, the following and their derivatives—")	This drug is used for the treatment of pulmonary arterial hypertension (PAH) (idiopathic or heritable PAH and PAH associated with connective tissue diseases) in adult patients with WHO Functional Class III–IV symptoms to improve exercise capacity. It is also used in haemodialysis in adult in emergency situations when use of heparin carries a high risk of causing or exacerbating bleeding or when heparin is otherwise contraindicated. Side effects include headache, facial flushing, nausea, vomiting and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
依前列醇	附表10的第1部，附表1及附表3毒藥 (納入下列的條文內： “前列腺素類如下及它們的衍生物—”)	此藥物用於治療屬世界衞生組織功能級別第Ⅲ及Ⅳ型症狀的肺動脈高血壓症(PAH) (自發性或遺傳性PAH及與結締組織疾病相關的PAH)的成年患者，以改善其運動能力。 此藥物亦用於成人在緊急情況下的血液透析，當使用肝素會有高風險引致或加劇出血，或不宜使用肝素時。 副作用包括頭痛、面部潮紅、噁心、嘔吐及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Gemtuzumab ozogamicin	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for combination therapy with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia, except acute promyelocytic leukaemia. Side effects include infection, haemorrhage, haemoglobin decreased, platelets decreased and white blood cells decreased.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
奧加米星吉妥組單抗	附表10的第1部，附表1及附表3毒藥	Its use should be decided by a doctor based on the patient's conditions. 此藥物與柔紅霉素及阿糖胞苷結合使用，用作治療15歲及以上患有原發性CD33型呈陽性的急性粒細胞性白血病 (急性早幼粒細胞白血病除外) ，而之前未曾接受治療的患者。 副作用包括感染、出血、血紅蛋白減少、血小板減少及白血球減少。 使用此藥物與否，須由醫生按病人情況決定。
Indigo carmine	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison (to be put under the entry of "Pharmaceutical products for human parenteral administration containing the following or	This drug is used for localising ureteral orifices as well as ureteral fistulas during cystoscopy and ureteral catherization. Side effects include hypersensitivity reactions, hypertension, bradycardia, nausea and vomiting. Its use should be decided by a doctor based on the patient's conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
	their salts, as active ingredients, except in mixture with insulin –")	
現時沒有中文名稱	附表10的第1部，附表1及附表3毒藥 (列於以下條文內："供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但與胰島素的混合物除外 - "	此藥物用於膀胱鏡檢查和輸尿管導管插入術時作輸尿管口和輸尿管癆的定位。 副作用包括過敏反應、高血壓、心搏過緩、噁心及嘔吐。 使用此藥物與否，須由醫生按病人情況決定。
Larotrectinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult and paediatric patients with solid tumours that: - have a neurotrophic tyrosine receptor kinase gene fusion without a known acquired resistance mutation, - are metastatic or where surgical resection is likely to result in severe morbidity, and - have no satisfactory treatment options.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
拉羅替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	Side effects include fatigue, nausea, dizziness, vomiting and anaemia. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有實體腫瘤出現以下情況的成人及兒童： - 在沒有已知的後天抗藥性突變下，出現神經營養受體酪氨酸激酶基因融合； - 腫瘤屬於轉移性，或接受外科手術切除很可能導致重症 ;及 - 沒有合適的治療選項。 副作用包括疲勞、噁心、眩暈、嘔吐及貧血。 使用此藥物與否，須由醫生按病人情況決定。
Nicardipine; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of acute life-threatening hypertension, particularly in the event of: - Malignant arterial hypertension/Hypertensive encephalopathy; - Aortic dissection, when short acting beta-blocker therapy is not

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
尼卡地平；其鹽類	附表10的第1部，附表1及附表3毒藥	suitable, or in combination with a beta-blocker when beta-blockade alone is not effective; - Severe pre-eclampsia, when other intravenous antihypertensive agents are not recommended or are contraindicated. The drug is also used for the treatment of post-operative hypertension. Side effects include headache, dizziness, peripheral oedema, palpitations and flushing. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療急性致命的高血壓，尤其是在以下的情況： - 惡性動脈高血壓/高血壓性腦病； - 當短效β受體阻滯劑療法不適合，或當β受體阻滯劑單一療法無效時需要與β受體阻滯劑一併使用，作主動脈剝離的治療； - 當其他靜脈注射的抗高血壓藥物不建議使用或是禁忌時，作嚴重子癇前期的治療。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		此藥物亦可用於手術後的高血壓。 副作用包括頭痛、眩暈、周邊水腫、心悸及潮紅。 使用此藥物與否，須由醫生按病人情況決定。
Pentoxifylline; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for prolongation of walking distance in adult patients with chronic peripheral arterial occlusive disease at Fontaine stage IIb (intermittent claudication) if other measures such as walking training, angioplasty and/or reconstructive procedures cannot be performed or are not indicated. It is also used in inner ear dysfunction caused by circulatory disorders (including hardness of hearing, sudden hearing loss). Side effects include flushing, nausea, vomiting, bloatedness and diarrhoea. Its use should be decided by a doctor based on the patient’s conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
己酮可可鹼；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於患有慢性周邊動脈閉塞性疾病Fontaine IIb級（間歇性跛行）的成年病人，並且當其他措施例如步行訓練，血管成形術及/或重建手術不可行或不被使用時，用作延長步行距離。 此藥物亦用於因循環障礙而導致的內耳功能失調（包括聆聽困難、突然失聰）。 副作用包括潮紅、噁心、嘔吐、氣脹及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Risankizumab	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 infections, headache, pruritus, fatigue and injection site reactions. Its use should be decided by a doctor based on the patient’s conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
利生奇組單抗	附表10的第1部，附表1及附表3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斑塊型銀屑病的成年人士。 副作用包括上呼吸道感染、頭痛、瘙癢、疲勞及注射部位反應。 使用此藥物與否，須由醫生按病人情況決定。
Semaglutide	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise - as monotherapy when metformin is considered inappropriate due to intolerance or contraindications. - in addition to other medicinal products for the treatment of diabetes. Side effects include hypoglycaemia, nausea, diarrhoea, dizziness and decreased appetite. Its use should be decided by a doctor based on the patient’s conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
司美魯肽	附表10的第1部，附表1及附表3毒藥	此藥物用於治療二型糖尿病控制不足的成年患者，作為飲食及運動的輔助: - 因不耐受或禁忌症以致不適合使用甲福明時作為單一治療。 - 與其他治療糖尿病的藥物一併使用。 副作用包括低血糖症、噁心、腹瀉、頭暈及食慾下降。 使用此藥物與否，須由醫生按病人情況決定。
Sodium zirconium cyclosilicate 現時沒有中文名稱	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表10的第1部，附表1及附表3毒藥	This drug is indicated for the treatment of hyperkalaemia in adult patients. Side effects include hypokalaemia and oedema related events. Its use should be decided by a doctor based on the patient’s conditions. 此藥物用於治療患有高鉀血症的成年人士。 副作用包括低鉀血症及水腫相關情況。 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**	**Remarks** **備註**
Etidronic acid; its salts; when contained in pharmaceutical product	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of symptomatic Paget's disease of bone and in the prevention and treatment and heterotopic ossification following total hip replacement or due to spinal cord injury. Side effects include diarrhea and nausea. Its use should be decided by a doctor based on patient's conditions
羥乙磷酸；其鹽類；但限於包含在藥劑製品內者	附表10的第1部，附表1及附表3毒藥	此藥物用於治療有症狀的佩吉特氏骨病，並用於預防及治療髖關節全關節置換術後或因脊髓損傷後所導致的異位性骨化。 副作用包括腹瀉及噁心。 使用此藥物與否，須由醫生按病人情況決定。