File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 5) REGULATION 2018

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. 5) 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 the applications for registration of ten pharmaceutical products, the Board proposes:

(a) adding the following nine 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 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 drugs to be kept in a locked receptacle) to the Regulations:

(i) Brivaracetam; its salts;

(ii) Citicoline; its salts / Citicoline;

- Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both; and

- Citicoline
  (under the entry of "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin")

(iii) Durvalumab;

(iv) Emicizumab;

(v) Guselkumab;

(vi) Inotuzumab ozogamicin;

(vii) Methoxyflurane;

(viii) Niraparib; its salts; and

(ix) Voxilaprevir; its salts.

(b) adding the following combination drug to Division A of Schedule 1 and Division A of Schedule 3 to the Regulations:

(i) "Lignocaine; its salts; when in mixture with prilocaine or in mixture with the salts of prilocaine, and intended to be used for the treatment of premature ejaculation".[1]

4. In addition, arising from the legal advices obtained from the Department of Justice on the proper presentation of a combination drug, the Board proposes updating Division A of Schedule 1 and Division A of Schedule 3 to the Regulations by repealing the existing entries of "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine" and "Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine", and replacing them by "Lignocaine; its salts; when in mixture with tetracaine (being an amino alcohol esterified with a derivative of benzoic acid) or in mixture with the salts of tetracaine".

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 is to add the above drugs (in paragraphs 3 and 4) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

7. The legislative timetable shall be –

[1] "Lignocaine; its salts" has already been listed as a poison in Part 1 of the Poisons List in Schedule 10. The legislative control on "Lignocaine; its salts" on its own shall remain the same.

Publication in the Gazette	19 October 2018
Date of Commencement	19 October 2018

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). It 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
October 2018

Pharmacy and Poisons (Amendment) (No. 5) 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 "Brinzolamide; its salts"—

Add

"Brivaracetam; its salts".

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

Add

"Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both".

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

Add

"Durvalumab".

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

Add

"Emicizumab".

(5) Schedule 1, Division A, after item relating to "Guanidines"—

Add

"Guselkumab".

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

Add

"Inotuzumab ozogamicin".

(7) Schedule 1, Division A, after item "Lidoflazine"—

Add

"Lignocaine; its salts; when in mixture with prilocaine or in mixture with the salts of prilocaine, and intended to be used for the treatment of premature ejaculation".

(8) Schedule 1, Division A—

Repeal item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"

Substitute

"Lignocaine; its salts; when in mixture with tetracaine (being an amino alcohol esterified with a derivative of benzoic acid) or in mixture with the salts of tetracaine".

(9) Schedule 1, Division A, after item "Methoxsalen"—

Add

"Methoxyflurane".

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

Add

"Niraparib; its salts".

(11) 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 "Cimetidine"—

Add

"Citicoline".

(12) Schedule 1, Division A—

Repeal item "Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine".

(13) Schedule 1, Division A, after item "Vortioxetine; its salts"—

Add

"Voxilaprevir; 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 "Brinzolamide; its salts"—

Add

"Brivaracetam; its salts".

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

Add

"Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both".

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

Add

"Durvalumab".

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

Add

"Emicizumab".

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

Add

"Guselkumab".

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

Add

"Inotuzumab ozogamicin".

(7) Schedule 3, Division A, after item "Lidoflazine"—

Add

"Lignocaine; its salts; when in mixture with prilocaine or in mixture with the salts of prilocaine, and intended to be used for the treatment of premature ejaculation".

(8) Schedule 3, Division A—

Repeal item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"

Substitute

"Lignocaine; its salts; when in mixture with tetracaine (being an amino alcohol esterified with a derivative of benzoic acid) or in mixture with the salts of tetracaine".

(9) Schedule 3, Division A, after item "Methoxsalen"—

Add

"Methoxyflurane".

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

Add

"Niraparib; its salts".

(11) 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 "Cimetidine"—

Add

"Citicoline".

(12) Schedule 3, Division A—

Repeal item "Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine".

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

Add

"Voxilaprevir; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Brivaracetam; its salts".

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

Add

"Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both".

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

Add

"Durvalumab".

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

Add

"Emicizumab".

(5) Schedule 10, section 2, Table, Part 1, Division A, after item relating to "Guanidines"—

Add

"Guselkumab".

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

Add

"Inotuzumab ozogamicin".

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

Add

"Methoxyflurane".

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

Add

"Niraparib; its salts".

(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", after sub-item "Cimetidine"—

Add

"Citicoline".

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

Add

"Voxilaprevir; its salts".

Chairman,
Pharmacy and Poisons Board

11 october 2018

Explanatory Note

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

(a) add 10 items and 1 sub-item to Division A of Schedule 1 and Division A of Schedule 3;

(b) replace 2 existing items with a single one in Division A of Schedule 1 and Division A of Schedule 3; and

(c) add 9 items and 1 sub-item to Division A of Part 1 of the Poisons List set out in Schedule 10.

2. A substance specified in an item or sub-item in those Schedules is subject to requirements concerning sale, supply, labelling and storage. Among other applicable requirements—

(a) for a substance specified in an item or sub-item included in both Schedules 1 and 3—the sale, by retail, of the substance may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon; and

(b) for a substance specified in an item or sub-item in Part 1 of the Poisons List set out in Schedule 10—

(i) the sale, by retail, of the substance 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) the substance, 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. 5) Regulation 2018

Supplementary Information to the Legislative Council

《2018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**
Brivaracetam; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent patients from 16 years of age with epilepsy. Side effects include dizziness, somnolence, nausea, fatigue and decreased appetite. Its use should be decided by a doctor based on the patient's conditions.
布立西坦；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於輔助治療患有局部性發作，伴有或不伴有繼發全身性發作的成人及16歲或以上青少年的癲癇患者。 副作用包括眩暈、嗜眠、噁心、疲勞及食慾下降。 使用此藥物與否，須由醫生按病人情況決定。

Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison (including under the entry of "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin-")	This drug is used for the treatment of cognitive and neurological disorders associated with acute and sub-acute stroke as well as traumatic brain injuries in adults. Side effects include nausea, dyspnoea, vertigo, oedema and hallucinations. Its use should be decided by a doctor based on the patient's conditions.
胞磷膽鹼；其鹽類；但限於包含在擬用於治療腦血管病或腦損傷（或腦血管病兼腦損傷）相關的認知及神經失調的藥劑製品內者	附表十的第一部，附表一及附表三毒藥（包括納入下列的條文內："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-"）	此藥物用於治療與急性和亞急性中風及創傷性腦損傷相關的認知與神經失調的成年患者。 副作用包括噁心、呼吸困難、眩暈、水腫及幻覺。 使用此藥物與否，須由醫生按病人情況決定。

Durvalumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy; or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Side effects include fatigue, musculoskeletal pain, constipation, decreased appetite and nausea. Its use should be decided by a doctor based on the patient's conditions.
度伐人單抗	附表十的第一部，附表一及附表三毒藥	此藥物用於治療在接受鉑類化療期間或之後出現病情惡化；或在接受有新輔助性或輔助性治療的鉑類化療後十二個月內出現病情惡化的局部晚期或轉移性泌尿道上皮癌的成年患者。 副作用包括疲勞、肌骨骼疼痛、便秘、食慾下降及噁心。 使用此藥物與否，須由醫生按病人情況決定。

Emicizumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for routine prophylaxis of bleeding episodes in patients with haemophilia A with factor VIII inhibitors in all age groups. Side effects include injection site reactions, headache, arthralgia, diarrhoea and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
艾米希組單抗	附表十的第一部，附表一及附表三毒藥	此藥物用於所有年齡層病者患有凝血因子VIII抑制劑的甲型血友病，用作常規預防出血事件。 副作用包括注射部位反應、頭痛、關節痛、腹瀉及發熱。 使用此藥物與否，須由醫生按病人情況決定。

Guselkumab	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 infection, headache, diarrhoea, urticaria and arthralgia. Its use should be decided by a doctor based on the patient's conditions.
古塞庫人單抗	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，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、頭痛、腹瀉、蕁麻疹及關節痛。 使用此藥物與否，須由醫生按病人情況決定。

Inotuzumab ozogamicin	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor. Side effects include thrombocytopenia, neutropenia, infection, anaemia and fatigue. Its use should be decided by a doctor based on the patient's conditions.
伊珠單抗奧加米星	附表十的第一部，附表一及附表三毒藥	此藥物用作單一治療患有復發或頑固性CD22陽性前體B細胞急性淋巴母細胞性白血病（ALL）的成年病人。而成年病人患有陽性費城染色體的復發或頑固性前體B細胞急性淋巴母細胞性白血病，則應至少曾使用一種酪胺酸激酶抑制劑治療但失敗。 副作用包括血小板減少症、中性白細胞減少症、感染、貧血及疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Methoxyflurane	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used: - For emergency relief of pain in conscious haemodynamically stable patients with trauma and associated pain - For the relief of pain in monitored conscious patients who require analgesia for surgical procedures. Side effects include dizziness, headache, somnolence, euphoria and nausea. Its use should be decided by a doctor based on the patient's conditions.
甲氧氟烷	附表十的第一部，附表一及附表三毒藥	此藥物用作： - 緊急緩解因創傷引致的相關疼痛，該病人為清醒及血液動力穩定。 - 緩解疼痛，該病人是在外科手術過程中需要鎮痛，且在監察下為清醒的病人。 副作用包括眩暈、頭痛、嗜眠、欣快及噁心。 使用此藥物與否，須由醫生按病人情況決定。

Lignocaine; its salts; when in mixture with prilocaine or in mixture with the salts of prilocaine, and intended to be used for the treatment of premature ejaculation	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of primary premature ejaculation in adult men. Side effects include hypoaesthesia of male genital, erectile dysfunction and genital burning sensation. Its use should be decided by a doctor based on the patient's conditions.
利多卡因；其鹽類；但限於與丙胺卡因混合或與丙胺卡因的鹽類混合，並擬用於治療早泄者	附表十的第一部，附表一及附表三毒藥	此藥物用於治療成年男性的原發性早洩。 副作用包括男性生殖器感覺減退、勃起功能障礙及生殖器灼熱感。 使用此藥物與否，須由醫生按病人情況決定。

Niraparib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Side effects include nausea, thrombocytopenia, fatigue, anaemia and neutropenia. Its use should be decided by a doctor based on the patient's conditions.
尼拉帕利；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於單一維持治療患有鉑敏感性復發的高級別漿液性上皮卵巢癌、輸卵管癌或原發性腹膜癌，並對含鉑化療有反應（完全或部分）的成年患者。 副作用包括噁心、血小板減少症、疲勞、貧血及中性白細胞減少症。 使用此藥物與否，須由醫生按病人情況決定。

Voxilaprevir ; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of chronic hepatitis C virus infection (all genotypes) in adults. Side effects include headache, diarrhoea, nausea, abdominal pain and decreased appetite. Its use should be decided by a doctor based on the patient's conditions.
伏西瑞韋；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療慢性丙型肝炎(所有基因型)的成年患者。 副作用包括頭痛、腹瀉、噁心、腹痛及食慾下降。 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**
From/由		
"Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine" and "Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine" 「利多卡因；其鹽類與丁卡因的混合物，或與丁卡因的鹽類的混合物」及「丁卡因（屬經苯甲酸的衍生物酯化的氨基醇）；其鹽類與利多卡因的混合物，或與利多卡因的鹽類的混合物」	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	This drug is used in adults to produce local dermal anaesthesia on intact skin prior to dermatological procedures. Side effects include erythema, skin discoloration and skin oedema. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於成人的皮膚科手術前，在完好的皮膚進行局部麻醉。 副作用包括紅斑、皮膚褪色和皮膚水腫。 使用此藥物與否，須由醫生按病人情況決定。
To/轉為		
Lignocaine; its salts; when in mixture with tetracaine (being an amino alcohol esterified with a derivative of benzoic acid) or in mixture with the salts of tetracaine 利多卡因；其鹽類；但限於與丁卡因（屬經苯甲酸的衍生物酯化的氨基醇）混合或與丁卡因的鹽類混合者	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	