File Ref.: FHB/H/23/6

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 5) REGULATION 2020

INTRODUCTION

The Pharmacy and Poisons Regulations ("the Regulations") (Cap. 138A) were made under section 29 of the Pharmacy and Poisons Ordinance ("the Ordinance") (Cap. 138). The Pharmacy and Poisons (Amendment) (No. 5) Regulation 2020 ("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 an ongoing review of sales control of pharmaceutical products and applications for registration of pharmaceutical products, the Board proposes –

(a) adding the following 8 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 1 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 Regulation:

(i) "Antisera, antitoxins, immunoglobulins and vaccines against Severe Acute Respiratory Syndrome Coronavirus 2" *(by adding "Severe Acute Respiratory Syndrome Coronavirus 2" under the entry of sub-item (b) "directed against the following diseases, viruses or organisms -" under "Antisera, antitoxins, immunoglobulins and vaccines -")*;
(ii) "Brolucizumab";
(iii) "Capmatinib; its salts";
(iv) "Icatibant; its salts; its esters; their salts";
(v) "Lemborexant; its salts";
(vi) "Ripretinib; its salts";
(vii) "Satralizumab"; and
(viii) "Trospium chloride";

(b) adding the following 2 drug substances to Division A of Part 1 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 Regulation:

(i) Azelaic acid; and
(ii) Diprophylline; its salts.

4. Details of the above drugs (in paragraph 3) 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

5. The Amendment Regulation proposes amending the relevant Schedules to the Regulations in accordance to paragraph 3.

LEGISLATIVE TIMETABLE

6. The legislative timetable shall be –

Publication in the Gazette	11 December 2020
Date of Commencement	11 December 2020[1] or 11 December 2021[2]

IMPLICATIONS OF THE PROPOSAL

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

ENQUIRY

8. For any enquiries, please contact Miss Wendy WONG, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
December 2020

[1] For the drugs in paragraphs 3(a) (i)-(vii).

[2] For the drugs in paragraphs 3(a) (viii) and 3(b), the Board recommends that the proposed amendments to take effect one year after the date of publication in the Gazette.

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2020

(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(8), 4(8) and 5(2), (5), (8) and (11) come into operation on 11 December 2021.

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, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b), after sub-item "Rubella"—

Add

"Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)".

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

Add

"Brolucizumab".

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

Add

"Capmatinib; its salts".

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

Add

"Icatibant; its salts; its esters; their salts".

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

Add

"Lemborexant; its salts".

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

Add

"Ripretinib; its salts".

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

Add

"Satralizumab".

(8) Schedule 1, Division A, after item "Tropisetron; its salts"—

Add

"Trospium chloride".

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, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b), after sub-item "Rubella"—

Add

"Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)".

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

Add

"Brolucizumab".

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

Add

"Capmatinib; its salts".

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

Add

"Icatibant; its salts; its esters; their salts".

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

Add

"Lemborexant; its salts".

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

Add

"Ripretinib; its salts".

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

Add

"Satralizumab".

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

Add

"Trospium chloride".

5. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b), after sub-item "Rubella"—

Add

"Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)".

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

Add

"Azelaic acid".

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

Add

"Brolucizumab".

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

Add

"Capmatinib; its salts".

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

Add

"Diprophylline; its salts".

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

Add

"Icatibant; its salts; its esters; their salts".

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

Add

"Lemborexant; 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"—

Repeal sub-item "Diprophylline".

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

Add

"Ripretinib; its salts".

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

Add

"Satralizumab".

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

Add

"Trospium chloride".

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

(a) item "氰氟蟲腙；其鹽類";

(b) item "氰苯哌酸；其鹽類";

(c) item "4-氰基-1-甲基-4-苯基哌啶；其鹽類";

(d) item "4-氰基-2-二甲胺基-4，4-二苯基丁烷；其鹽類"—

Repeal the items.

(13) Schedule 10, Chinese text, section 2, Table, Part 1, Division A, after item "氮芥及二氯乙胺於 N 位被取代的任何其他衍生物；它們的鹽類"—

Add

"氰氟蟲腙；其鹽類

氰苯哌酸；其鹽類

4-氰基-1-甲基-4-苯基哌啶；其鹽類

4-氰基-2-二甲胺基-4，4-二苯基丁烷；其鹽類".

Chairman,
Pharmacy and Poisons Board

8 December 2020

Explanatory Note

This Regulation amends the following provisions of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***specified provisions***)—

(a) Division A of Schedule 1;

(b) Division A of Schedule 3; and

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

2. The substances listed in the specified provisions are subject to specific requirements concerning sale, supply, labelling and storage. The Regulation adds certain substances to the specified provisions. Main effects of the amendments include—

(a) that the sale, by retail, of the newly added substances—

(i) may only be effected on the 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 (except for Azelaic acid and Diprophylline and its salts); and

(b) that the newly added substances, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.

3. The Regulation also updates the arrangement order of certain substances in the Chinese text of Division A of Part 1 of the Poisons List set out in Schedule 10.

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2020
Supplementary Information to the Legislative Council

《2020 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
Antisera, antitoxins, immunoglobulins and vaccines against Severe Acute Respiratory Syndrome Coronavirus 2	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison *(by adding "Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)" under the entry of sub-item "(b) directed against the following diseases, viruses or organisms-"under*	These drugs are used against Severe Acute Respiratory Syndrome Coronavirus 2. Their 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**
	"Antisera, antitoxins, immunoglobulins and vaccines-")	
用於對付嚴重急性呼吸系統綜合症冠狀病毒2型的抗血清、抗毒素、免疫球蛋白與疫苗	附表10的第1部，附表1及附表3毒藥 *（於"抗血清、抗毒素、免疫球蛋白與疫苗如下—" 的"(b) 用於對付以下疾病、病毒或生物的抗血清、抗毒素、免疫球蛋白與疫苗—"條文內加入"嚴重急性呼吸系統綜合症冠狀病毒2"）*	此等藥物用於對付嚴重急性呼吸系統綜合症冠狀病毒2。 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**
Azelaic acid 壬二酸	Part 1 of Schedule 10 poison 附表10的第1部毒藥	This drug is used in the topical treatment of mild to moderate inflammatory acne and for the inflammatory papules and pustules of mild to moderate rosacea in adults and adolescents. Side effects include burning, stinging, pruritus, dryness and scaling. Its sales should be supervised by a pharmacist. 此藥物用於局部治療有輕度至中度炎性痤瘡，以及輕度至中度酒渣鼻的炎性丘疹及膿疱的成年及青少年患者。 副作用包括灼傷、刺痛、瘙癢、乾燥及鱗屑。 此藥物必須在藥劑師監督下售賣。
Brolucizumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adults for the treatment of neovascular (wet) age-related macular degeneration. Side effects include hypersensitivity, reduced visual acuity, retinal

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		haemorrhage, uveitis and iritis. Its use should be decided by a doctor based on the patient's conditions.
布西組單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於治療新生血管（濕性）的老年黃斑退化的成年患者。 副作用包括過敏反應、視敏度下降、視網膜出血、眼色素層炎及虹膜炎。 使用此藥物與否，須由醫生按病人情況決定。
Capmatinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping. Side effects include peripheral oedema, nausea, fatigue, vomiting and dyspnoea. 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**
卡馬替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於治療有間質上皮轉化外顯子14跳躍突變的轉移性非小細胞肺癌的成年患者。 副作用包括周邊水腫、噁心、疲勞、嘔吐及呼吸困難。 使用此藥物與否，須由醫生按病人情況決定。
Diprophylline; its salts	Part 1 of Schedule 10 poison	This drug is used as a bronchodilator in reversible airways obstruction. Side effects include nausea, vomiting, abdominal pain, diarrhoea and headache. Its sales should be supervised by a pharmacist.
二羥丙茶鹼；其鹽類	附表10的第1部毒藥	此藥物為支氣管擴張劑，用於可逆性的氣道阻塞。

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		副作用包括噁心、嘔吐、腹痛、腹瀉及頭痛。 此藥物必須在藥劑師監督下售賣。
Icatibant; its salts; its esters; their salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the symptomatic treatment of acute attacks of hereditary angioedema in adults, adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency. Side effects include injection site reactions, dizziness, headache, nausea and rash. Its use should be decided by a doctor based on the patient's conditions.
艾替班特；其鹽類；其酯類；它們的鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於對症治療遺傳性血管性水腫的急性發作並患有C1酯酶抑製劑缺乏的成人，青少年及兩歲或以上兒童。 副作用包括注射部位反應、眩暈、頭痛、噁心及皮疹。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		使用此藥物與否，須由醫生按病人情況決定。
Lemborexant; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Side effects include somnolence or fatigue, headache, and nightmare or abnormal dreams. Its use should be decided by a doctor based on the patient's conditions.
萊博雷生；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於治療特別有難以入睡及/或維持睡眠特徵的失眠症的成年患者。 副作用包括嗜眠或疲勞、頭痛、惡夢或異常的夢。 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**
Ripretinib; its salts 瑞派替尼；其鹽類	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 used for the treatment of adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with 3 or more kinase inhibitors, including imatinib. Side effects include alopecia, fatigue, nausea, abdominal pain and constipation. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療已接受過包括伊馬替尼在內的三種或更多種激酶抑製劑療程的晚期胃腸道間質腫瘤的成年患者。 副作用包括脫髮、疲勞、噁心、腹痛及便秘。 使用此藥物與否，須由醫生按病人情況決定。
Satralizumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as a monotherapy or in combination with immunosuppressive therapy for the treatment of neuromyelitis optica spectrum disorders in adult and adolescents in whom aquaporin-4 lgG

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
薩特利珠單抗	附表10的第1部，附表1及附表3毒藥	antibodies are detected (i. e. who are AQP4 lgG seropositive). Side effects include headache, arthralgia, leucopenia and injection related reactions. Its use should be decided by a doctor based on the patient's conditions. 此藥物作為單一療法或與免疫抑制療法聯合使用, 用於治療患有視神經脊髓炎譜系障礙並驗出有aquaporin-4免疫球蛋白G抗體(即AQP4免疫球蛋白G血清反應陽性)的成年及青少年患者。 副作用包括頭痛、關節痛、白細胞減少及注射相關反應。 使用此藥物與否，須由醫生按病人情況決定。
Trospium chloride	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of symptoms associated with involuntary loss of urine (wetting) and/or increased frequency of urination and imperative urge of urination in adult patients with

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
曲司氯銨	附表10的第1部，附表1及附表3毒藥	hyperactive urinary bladder (involuntary urge of urination and voiding problems of unknown origin or due to nervous system disorders). Side effects include dryness of the mouth, constipation, nausea, abdominal pain and dyspepsia. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於患有膀胱過度活躍（原因不明或神經系統異常引起的非自主尿急及排尿問題）的成年患者，以治療尿失禁和/或尿頻及迫切的尿急的相關症狀。 副作用包括口乾、便秘、噁心、腹痛及消化不良。 使用此藥物與否，須由醫生按病人情況決定。