File Ref.: FHB/H/23/5

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 4) 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. 4) 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 12 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 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) "Acalabrutinib; its salts"
(ii) "Agalsidase alfa";
(iii) "Alpelisib; its salts";
(iv) "Carglumic acid; its salts; its esters; their salts";
(v) "Darolutamide; its salts";
(vi) "Dinutuximab beta";
(vii) "Human cytomegalovirus immunoglobulin";
(viii) "Lutetium-177; its salts; when contained in pharmaceutical products";
(ix) "Pegaspargase";
(x) "Remdesivir; its salts";
(xi) "Siponimod; its salts; its esters; their salts"; and
(xii) "Upadacitinib; 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	30 October 2020
Date of Commencement	30 October 2020

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
October 2020

Pharmacy and Poisons (Amendment) (No. 4) 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. 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 "Abiraterone; its salts"—

Add

"Acalabrutinib; its salts".

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

Add

"Agalsidase alfa".

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

Add

"Alpelisib; its salts".

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

Add

"Carglumic acid; its salts; its esters; their salts".

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

Add

"Darolutamide; its salts".

(6) Schedule 1, Division A, after item "Dimethyl fumarate when contained in pharmaceutical products"—

Add

"Dinutuximab beta".

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

Add

"Human cytomegalovirus immunoglobulin".

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

Add

"Lutetium-177; its salts; when contained in pharmaceutical products".

(9) Schedule 1, Division A, after item "Pegaptanib; its salts"—

Add

"Pegaspargase".

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

Add

"Remdesivir; its salts".

(11) Schedule 1, Division A, after item "Simvastatin"—

Add

"Siponimod; its salts; its esters; their salts".

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

Add

"Upadacitinib; its salts".

(13) Schedule 1, Chinese text, Division A—

(a) **Repeal item "Secukinumab";**

(b) after item "司美魯肽"—

Add

"司庫奇尤單抗".

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 "Abiraterone; its salts"—

Add

"Acalabrutinib; its salts".

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

Add

"Agalsidase alfa".

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

Add

"Alpelisib; its salts".

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

Add

"Carglumic acid; its salts; its esters; their salts".

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

Add

"Darolutamide; its salts".

(6) Schedule 3, Division A, after item "Dimethyl fumarate when contained in pharmaceutical products"—

Add

"Dinutuximab beta".

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

Add

"Human cytomegalovirus immunoglobulin".

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

Add

"Lutetium-177; its salts; when contained in pharmaceutical products".

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

Add

"Pegaspargase".

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

Add

"Remdesivir; its salts".

(11) Schedule 3, Division A, after item "Simvastatin"—

Add

"Siponimod; its salts; its esters; their salts".

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

Add

"Upadacitinib; its salts".

(13) Schedule 3, Chinese text, Division A—

(a) **Repeal item "Secukinumab";**

(b) after item "司美魯肽"—

Add

"司庫奇尤單抗".

4. Schedule 10 amended (Poisons List)

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

Add

"Acalabrutinib; its salts".

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

Add

"Agalsidase alfa".

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

Add

"Alpelisib; its salts".

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

Add

"Carglumic acid; its salts; its esters; their salts".

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

Add

"Darolutamide; its salts".

(6) Schedule 10, section 2, Table, Part 1, Division A, after item "Dimethyl fumarate when contained in pharmaceutical products"—

Add

"Dinutuximab beta".

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

Add

"Human cytomegalovirus immunoglobulin".

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

Add

"Lutetium-177; its salts; when contained in pharmaceutical products".

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

Add

"Pegaspargase".

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

Add

"Remdesivir; its salts".

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

Add

"Siponimod; its salts; its esters; their salts".

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

Add

"Upadacitinib; its salts".

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

(a) **Repeal item "Secukinumab";**

(b) after item "司美魯肽"—

Add

"司庫奇尤單抗".

Chairman,
Pharmacy and Poisons Board

23 October 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 specified provisions relate to requirements concerning sale, supply, labelling and storage. The Regulation adds 12 items to the specified provisions. Main effects of the amendments include—

(a) that the sale, by retail, of substances specified in those 12 new 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.

3. The Regulation also amends the Chinese text of the specified provisions to refer to an existing item by its Chinese name instead of its English name.

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2020

Supplementary Information to the Legislative Council

《2020 年藥劑業及毒藥(修訂)(第 4 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**
Acalabrutinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy. It is also used for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma. Side effects include anemia, thrombocytopenia, headache, neutropenia and diarrhea. Its use should be decided by a doctor based on the patient's conditions.
阿可替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於曾接受至少一次療程的被套細胞淋巴瘤的成年患者。 此藥物亦用於治療患有慢性淋巴細胞白血病或小淋巴細胞淋巴瘤的成年患者。 副作用包括貧血、血小板減少症、頭痛、中性白細胞減少症及腹瀉。 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**
Agalsidase alfa 阿加糖酶 α	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 long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry Disease (α-galactosidase A deficiency). Side effects include headache, flushing, nausea, pyrexia and fatigue. Its use should be decided by a doctor based on the patient's conditions. 此藥物在確診為法柏氏症（α-半乳糖苷酶A缺乏症）的成年患者用作長期酵素酶替代療法。 副作用包括頭痛、潮紅、噁心、發熱及疲勞。 使用此藥物與否，須由醫生按病人情況決定。
Alpelisib; its salts 阿吡利塞；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 in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor positive, human epidermal growth factor receptor 2 negative, PIK3CA- mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen. Side effects include glucose increased, creatinine increased, diarrhoea, rash and lymphocyte count decreased. Its use should be decided by a doctor based on the patient's conditions. 此藥物與氟維司群結合使用作為治療具激素受體呈陽性、第二型人類表皮生長因子受體呈陰性、PIK3CA突變，及在接受內分泌基礎方案後仍出現病情惡化的晚期或轉移性乳癌的絕經後婦女及男性患者。

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		副作用包括葡萄糖升高、肌酸酐升高、腹瀉、皮疹及淋巴細胞數量減少。 使用此藥物與否，須由醫生按病人情況決定。
Carglumic acid; its salts; its esters; their salts 卡谷氨酸；其鹽類；其酯類；它們的鹽類	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 in paediatric patients for the treatment of: • hyperammonaemia due to N-acetylglutamate synthase primary deficiency. • hyperammonaemia due to isovaleric acidaemia. • hyperammonaemia due to methymalonic acidaemia. • hyperammonaemia due to propionic acidaemia. Side effects include increased sweating. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於兒童患者以治療： • 因原發性缺乏N-乙醯谷氨酸合酶而引起的高氨血症； • 因異戊酸血症而引起的高氨血症； • 因甲基丙二酸血症而引起的高氨血症； • 因丙酸血症而引起的高氨血症。 副作用包括出汗增加。 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**
Darolutamide; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with non-metastatic castration-resistant prostate cancer. Side effects include fatigue, pain in extremity and rash. Its use should be decided by a doctor based on the patient's conditions.
達羅他胺；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非轉移性不可切除前列腺癌的成年病人。 副作用包括疲勞、四肢疼痛及皮疹。 使用此藥物與否，須由醫生按病人情況決定。
Dinutuximab beta	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures. In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, this drug should be combined with interleukin-2. Side effects include pyrexia, pain, hypersensitivity, vomiting and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.
達妥昔單抗β	附表10的第1部，附表1及附表3毒藥	此藥物用於治療年齡12個月及以上，先前曾接受誘導化學療法及至少達到部分緩

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		解，隨後進行了清髓治療及幹細胞移植的高危神經母細胞瘤患者。此藥物亦可用於有復發或難治性神經母細胞瘤病史，不論有否殘存疾病的患者。在治療復發性神經母細胞瘤之前，應透過其他合適的措施穩定任何正在惡化的疾病。 對於有復發或難治性病史的患者以及在一線療法並未達到完全緩解的患者，此藥物應與介白素2結合使用。 副作用包括發熱、疼痛、過敏、嘔吐及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Human cytomegalovirus immunoglobulin 人類巨細胞病毒免疫球蛋白	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 prophylaxis of clinical manifestations of cytomegalovirus (CMV) infection in patients subjected to immunosuppressive therapy, particularly in transplant recipients. The concomitant use of adequate virostatic agents should be considered for CMV-prophylaxis. Side effects include haemolytic anaemia, anaphylactic shock, headache, vomiting and rash. Its use should be decided by a doctor based on the patient's conditions. 此藥物是當病人正在接受免疫抑制治療時用於預防巨細胞病毒感染臨床表現，特別是用於移植接受者。 在預防巨細胞病毒感染時，應考慮同時使用適當的抑制病毒藥物。 副作用包括溶血性貧血、過敏性休克、頭痛、嘔吐及皮疹。

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。
Lutetium-177; its salts; when contained in pharmaceutical products 鐿-177；其鹽類；但限於包含在藥劑製品內者	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 a radiopharmaceutical precursor, and it is not intended for direct use in patients. It is to be used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride. Side effects include anaemia, thrombocytopenia, nausea, vomiting, and alopecia Its use should be decided by a doctor based on the patient's conditions. 此藥物是一種放射性藥物前體，並不擬直接使用於病人。它僅用於放射性標記該些專門研發並批准以氯化鐿[177Lu]作放射性標記的載體分子。 副作用包括貧血、血小板減少症、噁心、嘔吐及脫髮。 使用此藥物與否，須由醫生按病人情況決定。
Pegaspargase 培門冬酶	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 as a component of antineoplastic combination therapy in acute lymphoblastic leukaemia in paediatric patients from birth to 18 years, and adult patients. Side effects include febrile neutropenia, anaemia, pancreatitis, diarrhoea and abdominal pain. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於出生至十八歲的兒童及成年患者作為急性淋巴母細胞性白血病的抗腫瘤聯合治療的一個組成部分。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括發熱性中性白細胞減少症、貧血、胰腺炎、腹瀉及腹痛。 使用此藥物與否，須由醫生按病人情況決定。
Remdesivir; its salts 瑞德西韋；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 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection in adult and paediatric patients. Side effects include headache, nausea, transaminases increased and rash. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於感染嚴重急性呼吸系統綜合症冠狀病毒2型的成年及兒童患者。 副作用包括頭痛、噁心、轉氨酶升高及皮疹。 使用此藥物與否，須由醫生按病人情況決定。
Siponimod; its salts; its esters; their salts 西尼莫德；其鹽類；其酯類；它們的鹽類	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 secondary progressive multiple sclerosis with active disease evidenced by relapses or imaging features of inflammatory activity. Side effects include headache, hypertension, dizziness, nausea and diarrhoea. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療已證實有復發或造影特徵的發炎活動、並處於活躍疾病期的繼發漸進型多發性硬化症的成年患者。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括頭痛、高血壓、眩暈、噁心及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Upadacitinib; its salts 烏帕替尼；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 moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. It may be used as monotherapy or in combination with methotrexate. Side effects include upper respiratory tract infections, nausea, blood creatine phosphokinase increased and cough. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療已對一種或多種緩解病情抗風濕病藥物反應不佳或無法耐受的中度至嚴重活性類風濕關節炎的成年患者。此藥物可作為單一療法或與甲氨蝶呤合併使用。 副作用包括上呼吸道感染、噁心、肌酸磷激酶的血液濃度上升及咳嗽。 使用此藥物與否，須由醫生按病人情況決定。