File Ref.: FHB/H/23/8

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 2) REGULATION 2021

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. 2) Regulation 2021 ("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 <u>five</u> 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) Belantamab mafodotin;
(ii) Cabotegravir; its salts;
(iii) Isatuximab;
(iv) Ofatumumab; and
(v) Risdiplam; its salts;

(b) adding the following one drug substance to Division A of Schedule 1 and Division A of Schedule 3 to the Regulation:

(vi) Allopurinol; and

(c) adding the following one drug substance to Division A of Part 1 of the Poisons List in Schedule 10 to the Regulation:

(vii) Phenazopyridine; 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	3 September 2021
Date of Commencement	3 September 2021[1] or 3 September 2022[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
August 2021

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

[2] For the drugs in paragraphs 3(b)(vi) and 3(c)(vii), the Board recommends that the proposed amendments be implemented 12 months after the date of publication in the Gazette. This is to give affected registration certification holders of pharmaceutical products 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. 2) Regulation 2021

(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(1), 4(1) and 5(5) come into operation on 3 September 2022.

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 "Allergen extract of Dermatophagoides pteronyssinus"—

Add

"Allopurinol".

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

Add

"Belantamab mafodotin".

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

Add

"Cabotegravir; its salts".

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

Add

"Isatuximab".

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

Add

"Ofatumumab".

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

Add

"Risdiplam; its salts".

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 "Allergen extract of Dermatophagoides pteronyssinus"—

Add

"Allopurinol".

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

Add

"Belantamab mafodotin".

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

Add

"Cabotegravir; its salts".

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

Add

"Isatuximab".

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

Add

"Ofatumumab".

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

Add

"Risdiplam; its salts".

5. Schedule 10 amended (Poisons List)

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

Add

"Belantamab mafodotin".

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

Add

"Cabotegravir; its salts".

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

Add

"Isatuximab".

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

Add

"Ofatumumab".

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

Add

"Phenazopyridine; its salts".

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

Add

"Risdiplam; its salts".

Chairman,
Pharmacy and Poisons Board

30 August 2021

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 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;

(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; and

(c) that the sale, by retail, of the newly added substances (except for phenazopyridine and its salts) may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon.

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2021
Supplementary Information to the Legislative Council

《2021 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**	**Remarks** **備註**
Allopurinol 別嘌醇	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表10的第1部，附	This drug is used for treatment or prevention of chronic primary or secondary gout, uric acid nephropathy, uric acid stone formation, and problems associated with hyperuricemia (i.e. tissue urate deposition, renal calculi, or acute urate nephropathy) secondary to cancer chemotherapy or radiation therapy. Side effects include hypersensitivity reactions (skin rash), nausea, vomiting, abdominal pain, diarrhoea and drowsiness. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療或預防慢性原發性或繼發性痛風、尿酸性腎病、尿

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
	表1及附表3毒藥	酸結石形成，以及與癌症化療或放射治療繼發的高尿酸血症（即組織尿酸鹽沉積、腎結石或急性尿酸鹽腎病）相關的問題.。 副作用包括過敏反應（皮疹）、噁心、嘔吐、腹痛、腹瀉及昏昏欲睡。 使用此藥物與否，須由醫生按病人情況決定。
Belantamab mafodotin	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy. Side effects include pneumonia, thrombocytopenia, keratopathy, nausea and pyrexia. 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**
瑪貝妥單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於單一治療患有多發性骨髓瘤的成年患者，而這些患者先前已接受過至少四種療法，而其疾病至少對一種蛋白酶體抑製劑、一種免疫調節劑和一種抗CD38單克隆抗體是難治的，以及在最後療程出現病情惡化。 副作用包括肺炎、血小板減少症、角膜病變、噁心及發熱。 使用此藥物與否，須由醫生按病人情況決定。
Cabotegravir; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class. Side effects include headache, injection site reactions, pyrexia, depression and dizziness.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
卡替拉韋；其鹽類	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. 此藥物與利匹韋林注射液聯合使用，作為治療人類免疫力缺乏病毒一型感染的成年患者，當其服用穩定的抗逆轉錄病毒療法病毒受抑制(人類免疫力缺乏病毒一型RNA <50copies/mL)，並且沒有證據顯示現在或過去對非核苷逆轉錄酶抑製劑和整合酶抑制劑類藥物產生抗藥性及沒有過往病毒治療失敗。 副作用包括頭痛、注射部位反應、發熱、抑鬱症及眩暈。 使用此藥物與否，須由醫生按病人情況決定。
Isatuximab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used - in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		- in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Side effects include neutropenia, infusion reaction, pneumonia, upper respiratory tract infection and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.
艾沙妥昔單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於 -與泊馬度胺和地塞米松聯合使用，作為治療患有復發性或難治性的多發性骨髓瘤的成年患者，而這些患者先前已接受過包括來那度胺及蛋白酶體抑製劑的至少兩種療法，並在最後療程出現病情惡化。 -與卡非佐米和地塞米松聯合使用，作為治療患有多發性骨髓瘤的成年患者，而這些患者先前已接受過至少一種療法。 副作用包括中性白細胞減少症、輸注反應、肺炎、上呼吸道感染

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Ofatumumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features. Side effects include upper respiratory tract infections, urinary tract infections, oral herpes, injection-site reactions (local) and injection-related reactions (systemic). Its use should be decided by a doctor based on the patient's conditions.
奧法木單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於治療以臨床或造影特徵定義、是處於活躍疾病期的復發性多發性硬化症的成年患者。 副作用包括上呼吸道感染、尿道感染、口腔疱疹、注射部位反應（局部）及注射相關反應（全身）。

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。
Phenazopyridine; its salts	Part 1 of Schedule 10 poison	This drug is used for the symptomatic relief of pain, burning, urgency, frequency, and other discomforts resulting from irritation of the lower urinary tract mucosa caused by infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters. Side effects include headache, vertigo, rash, pruritus and mild gastrointestinal disturbances. Its use should be decided by a doctor based on the patient's conditions.
非那吡啶；其鹽類	附表10的第1部毒藥	此藥物用於舒緩由感染、外傷、手術、內窺鏡程序或聲音或導管通過引起的下泌尿道黏膜刺激所引致的疼痛、灼熱、尿急、尿頻及其他不適症狀。 副作用包括頭痛、眩暈、皮疹、瘙癢及輕度胃腸道紊亂。 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
Risdiplam; its salts 利司撲蘭；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 spinal muscular atrophy in patients 2 months of age and older. Side effects include fever, diarrhoea, rash, mouth and aphthous ulcers, and arthralgia. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療脊髓性肌肉萎縮症的年齡在兩個月及以上的患者。 副作用包括發燒、腹瀉、皮疹、口瘡及關節痛。 使用此藥物與否，須由醫生按病人情況決定。