File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) REGULATION 2022

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) Regulation 2022 ("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 adding the following six 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 Regulations:

(i) Dostarlimab;
(ii) Luspatercept;
(iii) Pemigatinib; its salts;
(iv) Ponesimod; its salts;
(v) Selumetinib; its salts; and
(vi) Tepotinib; 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	14 January 2022
Date of Commencement	14 January 2022

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 Mr. Simon CHEUNG, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
January 2022

Pharmacy and Poisons (Amendment) Regulation 2022

(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 "Dorzolamide; its salts"—

Add

"Dostarlimab".

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

Add

"Luspatercept".

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

Add

"Pemigatinib; its salts".

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

Add

"Ponesimod; its salts".

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

Add

"Selumetinib; its salts".

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

Add

"Tepotinib; 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 "Dorzolamide; its salts"—

Add

"Dostarlimab".

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

Add

"Luspatercept".

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

Add

"Pemigatinib; its salts".

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

Add

"Ponesimod; its salts".

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

Add

"Selumetinib; its salts".

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

Add

"Tepotinib; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Dostarlimab".

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

Add

"Luspatercept".

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

Add

"Pemigatinib; its salts".

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

Add

"Ponesimod; its salts".

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

Add

"Selumetinib; its salts".

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

Add

"Tepotinib; its salts".

Chairman,
Pharmacy and Poisons Board

5 January 2022

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; 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.

Pharmacy and Poisons (Amendment) Regulation 2022
Supplementary Information to the Legislative Council

《2022 年藥劑業及毒藥(修訂)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**
Dostarlimab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the treatment of adult patients with mismatch repair deficient/microsatellite instability-high recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen. Side effects include anaemia, nausea, diarrhoea, vomiting and infusion-related reaction. Its use should be decided by a doctor based on the patient's conditions.
多塔利單抗	附表10的第1部，附表1及附表3毒藥	此藥物用作單一治療在接受含鉑療法期間或治療後出現病情惡化之復發性或晚期錯配修復缺陷或微衛星體不穩定性高的子宮內膜癌的成年患者。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括貧血、噁心、腹瀉、嘔吐及輸注相關反應。 使用此藥物與否，須由醫生按病人情況決定。
Luspatercept 羅特西普	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 transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes with ring sideroblasts, who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy. It is also indicated for the treatment of adult patients with transfusion-dependent anaemia associated with beta-thalassaemia. Side effects include dizziness, headache, diarrhea, back pain and fatigue. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療對紅細胞生成素的療程反應不佳或不適合，因非常低、低及中風險骨髓增生異常綜合症候群伴環狀鐵粒幼細胞而

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		導致輸血依賴性貧血的成年患者。 此藥物亦可用於治療患有與乙型地中海貧血相關的輸血依賴性貧血的成年患者。 副作用包括眩暈、頭痛、腹瀉、背痛及疲勞。 使用此藥物與否，須由醫生按病人情況決定。
Pemigatinib; its salts 佩米替尼；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's monotherapy is used for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or rearrangement that have progressed after at least one prior line of systemic therapy. Side effects include dry eye, nausea, stomatitis, alopecia and fatigue. Its use should be decided by a doctor based on the patient's conditions. 此藥物的單一療法用於治療先前已接受過至少一種全身系統性療程後出現病情惡化，具有成纖維細胞生長因子受體二型融合或重

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		排的局部晚期或轉移性膽管癌的成年患者。 副作用包括眼乾、噁心、口腔炎、脫髮及疲勞。 使用此藥物與否，須由醫生按病人情況決定。
Ponesimod; its salts	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 nasopharyngitis, upper respiratory tract infection, alanine aminotransferase increased, dyspnoea and fatigue. Its use should be decided by a doctor based on the patient's conditions.
泊沙莫德；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於治療以臨床或造影特徵定義為處於活躍疾病期的復發性多發性硬化症的成年患者。 副作用包括鼻咽炎、上呼吸道感染、丙氨酸氨基轉移酶上升、呼吸

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		困難及疲勞。 使用此藥物與否，須由醫生按病人情況決定。
Selumetinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of paediatric patients 2 years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas. Side effects include vomiting, abdominal pain, diarrhoea, nausea and rash. Its use should be decided by a doctor based on the patient's conditions.
司美替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於治療患有神經纖維瘤病一型，並且出現有症狀、手術無法清除的叢狀神經纖維瘤的兩歲及以上的兒童患者。 副作用包括嘔吐、腹痛、腹瀉、噁心及皮疹。 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**
Tepotinib; 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 harboring mesenchymal-epithelial transition exon 14 skipping alterations. Side effects include oedema, fatigue, nausea, diarrhoea and musculoskeletal pain. Its use should be decided by a doctor based on the patient's conditions.
特泊替尼；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跳躍改變的轉移性非小細胞肺癌的成年患者。 副作用包括水腫、疲勞、噁心、腹瀉及肌骨骼疼痛。 使用此藥物與否，須由醫生按病人情況決定。