File Ref.: FHB/H/23/7

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) 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) 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 nine 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) Avapritinib; its salts;
(ii) Fremanezumab;
(iii) Gilteritinib; its salts;
(iv) Inclisiran; its salts;
(v) Lanadelumab;
(vi) Ozanimod; its salts;
(vii) Ravulizumab;
(viii) Tildrakizumab; and
(ix) Trifarotene; its salts; its esters; their 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	25 June 2021
Date of Commencement	25 June 2021

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
June 2021

Pharmacy and Poisons (Amendment) 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. 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 "Avanafil; its salts"—

Add

"Avapritinib; its salts".

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

Add

"Fremanezumab".

(3) Schedule 1, Division A, after item "Gemtuzumab ozogamicin"—

Add

"Gilteritinib; its salts".

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

Add

"Inclisiran; its salts".

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

Add

"Lanadelumab".

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

Add

"Ozanimod; its salts".

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

Add

"Ravulizumab".

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

Add

"Tildrakizumab".

(9) Schedule 1, Division A, after item "2,2,2-Trichloroethyl alcohol, esters of; their salts"—

Add

"Trifarotene; its salts; its esters; their 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 "Avanafil; its salts"—

Add

"Avapritinib; its salts".

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

Add

"Fremanezumab".

(3) Schedule 3, Division A, after item "Gemtuzumab ozogamicin"—

Add

"Gilteritinib; its salts".

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

Add

"Inclisiran; its salts".

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

Add

"Lanadelumab".

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

Add

"Ozanimod; its salts".

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

Add

"Ravulizumab".

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

Add

"Tildrakizumab".

(9) Schedule 3, Division A, after item "2,2,2-Trichloroethyl alcohol, esters of; their salts"—

Add

"Trifarotene; its salts; its esters; their salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Avapritinib; its salts".

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

Add

"Fremanezumab".

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

Add

"Gilteritinib; its salts".

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

Add

"Inclisiran; its salts".

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

Add

"Lanadelumab".

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

Add

"Ozanimod; its salts".

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

Add

"Ravulizumab".

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

Add

"Tildrakizumab".

(9) Schedule 10, section 2, Table, Part 1, Division A, after item "2,2,2-Trichloroethyl alcohol, esters of; their salts"—

Add

"Trifarotene; its salts; its esters; their salts".

Chairman,
Pharmacy and Poisons Board

18 June 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—

(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 2021
Supplementary Information to the Legislative Council

《2021 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**
Avapritinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours harbouring the platelet-derived growth factor receptor alpha D842V mutation. Side effects include nausea, vomiting, diarrhoea, decreased appetite and anaemia. Its use should be decided by a doctor based on the patient's conditions.
阿伐替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用作單一療法治療患有攜帶血小板源性生長因子受體 α D842V突變的不可切除或轉移性胃腸道間質瘤的成年患者。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括噁心、嘔吐、腹瀉、食慾下降及貧血。 使用此藥物與否，須由醫生按病人情況決定。
Fremanezumab 夫瑞奈組單抗	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 preventive treatment of migraine in adults. Side effects include injection site reactions. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於成人作為偏頭痛的預防性治療。 副作用包括注射部位反應。 使用此藥物與否，須由醫生按病人情況決定。
Gilteritinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia with a FLT3 mutation.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
吉瑞替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	Side effects include diarrhoea, fatigue, nausea, constipation and cough. Its use should be decided by a doctor based on the patient's conditions. 此藥物用作單一療法於治療患有FLT3突變的復發性或難治性的急性粒細胞性白血病的成年患者。 副作用包括腹瀉、疲勞、噁心、便秘及咳嗽。 使用此藥物與否，須由醫生按病人情況決定。
Inclisiran; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid-lowering therapies in patients who are unable to reach LDL-C goals with the maximum tolerated dose of a statin, or

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
英克司蘭；其鹽類	附表10的第1部，附表1及附表3毒藥	- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. Side effects include injection site reaction, injection site pain, injection site erythema and injection site rash. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於原發性高膽固醇血症（雜合家族性及非家族性）或混合性血脂異常的成年患者，作為輔助飲食： - 對於使用最大耐受劑量的他汀治療後，低密度脂蛋白膽固醇仍無法達到目標水平的患者，可以聯合他汀或他汀及其他降脂療法使用，或 - 對於他汀不耐受或存在使用禁忌的患者，可以單獨或聯合與其他降脂療法使用。

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		副作用包括注射部位反應、注射部位疼痛、注射部位紅斑及注射部位皮疹。 使用此藥物與否，須由醫生按病人情況決定。
Lanadelumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for routine prevention of recurrent attacks of hereditary angioedema in patients aged 12 years and older. Side effects include injection site reactions, hypersensitivity, dizziness, rash maculo-papular and myalgia. Its use should be decided by a doctor based on the patient's conditions.
拉那蘆人單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於12歲及以上患者作為遺傳性血管性水腫反復發作的常規性預防。 副作用包括注射部位反應、過敏反應、眩暈、斑丘疹及肌肉痛。 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**
Ozanimod; its salts 奧扎莫德；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 relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Side effects include upper respiratory infection, orthostatic hypotension, urinary tract infection, back pain and hypertension. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療復發性多發性硬化症的成年人士，包括臨床孤立綜合徵、復發緩解型疾病及活動性繼發漸進型的疾病。 副作用包括上呼吸道感染、直立性低血壓、尿道炎、背痛及高血壓。 使用此藥物與否，須由醫生按病人情況決定。
Ravulizumab	Part 1 of Schedule 10, Schedule 1 and	This drug is used for:

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
瑞利珠單抗	Schedule 3 poison 附表10的第1部，附表1及附表3毒藥	- the treatment of adult patients with paroxysmal nocturnal hemoglobinuria. - the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy. Side effects include upper respiratory tract infection, headache, diarrhoea, nausea and vomiting. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於： - 治療陣發性夜間血紅蛋白尿的成年患者； - 治療有非典型溶血性尿毒症綜合徵的成年患者及一個月大及以上的兒童患者，以抑制補體介導的血栓性微血管病。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括上呼吸道感染、頭痛、腹瀉、噁心及嘔吐。 使用此藥物與否，須由醫生按病人情況決定。
Tildrakizumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Side effects include upper respiratory tract infections, headache, gastroenteritis, nausea and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.
替卓組單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於治療適合接受全身系統性療程，患有中度至嚴重程度斑塊型銀屑病的成年人士。 副作用包括上呼吸道感染、頭痛、胃腸炎、噁心及腹瀉。 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
Trifarotene; its salts; its esters; their salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present. Side effects include application site irritation, application site pruritus and sunburn. Its use should be decided by a doctor based on the patient's conditions.
曲法羅汀；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	此藥物用於治療12歲及以上患者面部及/或軀幹皮膚的痤瘡，而該痤瘡出現許多粉刺，丘疹和膿疱。 副作用包括應用部位刺激、施用部位瘙癢及曬傷。 使用此藥物與否，須由醫生按病人情況決定。