

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) REGULATION 2020

INTRODUCTION

The Pharmacy and Poisons Regulations (“the Regulations”) (Cap. 138A) was made under section 29 of the Pharmacy and Poisons Ordinance (“the Ordinance”) (Cap. 138). The Pharmacy and Poisons (Amendment) 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 adding the following 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 I 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 –

- (a) Codergocrine mesilate;
- (b) Crisaborole; its salts;
- (c) Doravirine; its salts;
- (d) Galcanezumab; and
- (e) Lovastatin when contained in pharmaceutical products;
- (f) Metronidazole; its salts; its esters; their salts;
- (g) Regadenoson; its salts;
- (h) Sucroferric oxyhydroxide;
- (i) Talazoparib; its salts; and
- (j) Tisagenlecleucel.

4. In addition, the Board proposes –

- (a) repealing the existing entry of “lovastatin” in Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10;
- (b) repealing the existing entry of “metronidazole; its salts” in Part 1 of the Poisons List in Schedule 10; and
- (c) repealing the existing entry of “metronidazole” under “Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin —” from Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10.

5. Details of the above drugs (in paragraphs 3 and 4) 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

6. The Amendment Regulation proposes amending the relevant

Schedules to the Regulations in accordance to paragraphs 3 and 4.

LEGISLATIVE TIMETABLE

7. The legislative timetable shall be –

Publication in the Gazette	14 February 2020
Date of Commencement	14 February 2020 ¹ or 14 February 2021 ²

IMPLICATIONS OF THE PROPOSAL

8. The proposal shall impose appropriate control on pharmaceutical products which consist of the above drugs (in paragraphs 3 and 4). The proposal allows the pharmaceutical products to be sold in the market upon fulfillment of relevant regulations.

ENQUIRY

9. For any enquiries, please contact Mr. Dan Chan, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
February 2020

¹ For the drugs in paragraphs 3(b)-(e), 3(g)-(j) and 4(a).

² For the drugs in paragraphs 3(a), 3(f), 4(b) and 4(c), 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) 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(1), (6) and (7), 4(1), (6) and (7) and 5(1), (6) and (7) come into operation on 14 February 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, after item “Cobimetinib; its salts”—
Add
“Codergocrine mesilate”.
- (2) Schedule 1, Division A, after item “Corynebacterium parvum”—
Add
“Crisaborole; its salts”.
- (3) Schedule 1, Division A, after item “Dopamine; its salts”—
Add
“Doravirine; its salts”.

- (4) Schedule 1, Division A, after item “Gadoxetic acid; its salts”—
Add
“Galcanzumab”.
- (5) Schedule 1, Division A, item “Lovastatin”, after “Lovastatin”—
Add
“when contained in pharmaceutical products”.
- (6) Schedule 1, Division A, after item “Metoprolol; its salts”—
Add
“Metronidazole; its salts; its esters; their salts”.
- (7) Schedule 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 “Metronidazole”.
- (8) Schedule 1, Division A, after item “Recombinant human erythropoietin”—
Add
“Regadenoson; its salts”.
- (9) Schedule 1, Division A, after item “Styramate”—
Add
“Sucroferric oxyhydroxide”.
- (10) Schedule 1, Division A, after item “Tafluprost”—
Add
“Talazoparib; its salts”.
- (11) Schedule 1, Division A, after item “Tirofiban; its salts”—
Add
“Tisagenlecleucel”.

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 “Cobimetinib; its salts”—
Add
“Codergocrine mesilate”.
 - (2) Schedule 3, Division A, after item “Corynebacterium parvum”—
Add
“Crisaborole; its salts”.
 - (3) Schedule 3, Division A, after item “Dopamine; its salts”—
Add
“Doravirine; its salts”.
 - (4) Schedule 3, Division A, after item “Gadoxetic acid; its salts”—
Add
“Galcanezumab”.
 - (5) Schedule 3, Division A, item “Lovastatin”, after “Lovastatin”—
Add
“when contained in pharmaceutical products”.
 - (6) Schedule 3, Division A, after item “Metoprolol; its salts”—
Add
“Metronidazole; its salts; its esters; their salts”.
 - (7) Schedule 3, 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 “Metronidazole”.**
- (8) Schedule 3, Division A, after item “Recombinant human erythropoietin”—
Add
“Regadenoson; its salts”.
 - (9) Schedule 3, Division A, after item “Styramate”—
Add
“Sucroferric oxyhydroxide”.
 - (10) Schedule 3, Division A, after item “Tafluprost”—
Add
“Talazoparib; its salts”.
 - (11) Schedule 3, Division A, after item “Tirofiban; its salts”—
Add
“Tisagenlecleucel”.
5. **Schedule 10 amended (Poisons List)**
- (1) Schedule 10, section 2, Table, Part 1, Division A, after item “Cobimetinib; its salts”—
Add
“Codergocrine mesilate”.
 - (2) Schedule 10, section 2, Table, Part 1, Division A, after item “Creosote obtained from wood”—
Add
“Crisaborole; its salts”.
 - (3) Schedule 10, section 2, Table, Part 1, Division A, after item “Dopamine; its salts”—
Add

“Doravirine; its salts”.

- (4) Schedule 10, section 2, Table, Part 1, Division A, after item “Gadoxetic acid; its salts”—

Add

“Galcanezumab”.

- (5) Schedule 10, section 2, Table, Part 1, Division A, item “Lovastatin”, after “Lovastatin”—

Add

“when contained in pharmaceutical products”.

- (6) Schedule 10, section 2, Table, Part 1, Division A, item “Metronidazole; its salts”, after “salts”—

Add

“; its esters; their salts”.

- (7) 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 “Metronidazole”.

- (8) Schedule 10, section 2, Table, Part 1, Division A, after item “Recombinant human erythropoietin”—

Add

“Regadenoson; its salts”.

- (9) Schedule 10, section 2, Table, Part 1, Division A, after item “Styramate”—

Add

“Sucroferric oxyhydroxide”.

- (10) Schedule 10, section 2, Table, Part 1, Division A, after item “Tafluprost”—

Add

“Talazoparib; its salts”.

- (11) Schedule 10, section 2, Table, Part 1, Division A, after item “Tirofiban; its salts”—

Add

“Tisagenlecleucel”.

Chairman,
Pharmacy and Poisons Board

7 February 2020

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add certain items to—

- (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 amendments relate to requirements concerning sale, supply, labelling and storage. Main effects of the amendments include—

- (a) that the sale, by retail, of substances specified in those 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. This Regulation also—

- (a) amends 1 item in, and removes 1 sub-item from, Division A of Schedule 1 and Division A of Schedule 3; and
- (b) amends 2 items in, and removes 1 sub-item from, Division A of Part 1 of the Poisons List set out in Schedule 10.

Pharmacy and Poisons (Amendment) Regulation 2020
Supplementary Information to the Legislative Council

《2020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
Codergocrine mesilate 現時沒有中文名稱	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 an adjunct in the symptomatic treatment of mild to moderate dementia in the elderly. Side effects include abdominal cramps, nausea, vomiting, headache and nasal congestion. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於患有輕度至中度痴呆的老年人，作為對症治療的輔助。 副作用包括腹部絞痛、噁心、嘔吐、頭痛及鼻塞。 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
Crisaborole; its salts 克立硼羅；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 topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. Side effects include application site pain. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於局部治療患有輕度至中度異位性皮膚炎的兩歲及以上患者。 副作用包括應用部位疼痛。 使用此藥物與否，須由醫生按病人情況決定。
Doravirine; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor class. Side effects include abnormal dreams, insomnia, headache, dizziness and somnolence.

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
多拉韋林；其鹽類	附表10的第1部，附表1及附表3毒藥	<p>Its use should be decided by a doctor based on the patient's conditions.</p> <p>此藥物與其他抗逆轉錄病毒藥物結合使用，用於治療感染人類免疫力缺乏病毒一型，並且沒有證據顯示過去或現在對非核苷逆轉錄酶抑制劑類產生抗藥性的成年患者。</p> <p>副作用包括異常的夢、失眠症、頭痛、眩暈及嗜眠。</p> <p>使用此藥物與否，須由醫生按病人情況決定。</p>
Galcanezumab 加卡奈組單抗	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表10的第1部，附	<p>This drug is used for the prophylaxis of migraine in adults who have at least 4 migraine days per month.</p> <p>Side effects include injection site pain, injection site reactions, vertigo, constipation and pruritus.</p> <p>Its use should be decided by a doctor based on the patient's conditions.</p> <p>此藥物用於每月至少有四日偏頭痛的成年患者，以預防偏頭痛。</p>

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
	表1及附表3毒藥	副作用包括注射部位疼痛、注射部位反應、眩暈、便秘及瘙癢。 使用此藥物與否，須由醫生按病人情況決定。
Lovastatin when contained in pharmaceutical products 洛伐他汀，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 used to reduce cholesterol in the treatment of hyperlipidaemias, particularly in hypercholesterolaemias (type IIa) and mixed (type IIb) hyperlipidaemia. It is also given for cardiovascular risk reduction in both primary and secondary prevention of ischaemic heart disease. Side effects include gastrointestinal disturbances. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於降低高脂血症的膽固醇，特別是在IIa和IIb型高脂蛋白血症。在用於缺血性心臟病的一級或二級預防中可降低心血管風險。 副作用包括腸胃失調。 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
<p>Metronidazole; its salts; its esters; their salts</p> <p>甲硝唑；其鹽類；其酯類；它們的鹽類</p>	<p>Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison</p> <p>附表10的第1部，附表1及附表3毒藥</p>	<p>This drug is used in adults and children for the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or are suspected to be the cause.</p> <p>Side effects include gastrointestinal disturbances, nausea, taste disorders, anorexia, vomiting and diarrhoea.</p> <p>Its use should be decided by a doctor based on the patient's conditions.</p> <p>此藥物用於預防和治療已確定或懷疑由厭氧細菌引起的感染的成年人及兒童。</p> <p>副作用包括腸胃失調、噁心、味覺失調、缺乏食慾、嘔吐及腹瀉。</p> <p>使用此藥物與否，須由醫生按病人情況決定。</p>
<p>Regadenoson; its salts</p>	<p>Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison</p>	<p>This drug is for diagnostic use only.</p> <p>This drug is a selective coronary vasodilator for use in adults as a pharmacological stress agent for:</p>

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
瑞加諾生；其鹽類	附表10的第1部，附表1及附表3毒藥	<ul style="list-style-type: none"> • radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress. • the measurement of fractional flow reserve of a single coronary artery stenosis during invasive coronary angiography, when repeated FFR measurements are not anticipated. <p>Side effects include headache, dizziness, cough, nausea and vomiting.</p> <p>Its use should be decided by a doctor based on the patient's conditions.</p> <p>此藥物只作診斷用途。</p> <p>此藥物是一種選擇性冠狀血管擴張劑，用於成人作為藥理性應激劑：</p> <ul style="list-style-type: none"> • 當患者無法進行足夠運動壓力時，用作放射性核素心肌灌注顯像。 • 進行入侵性冠狀動脈造影時量度單個冠狀動脈狹窄的血流儲備分數，而無需重複量度血流儲備分數。

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		副作用包括頭痛，眩暈，咳嗽，噁心及嘔吐。 使用此藥物與否，須由醫生按病人情況決定。
Sucroferric oxyhydroxide 現時沒有中文名稱	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 phosphate binder used for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis. Side effects include diarrhea and discolored faeces. Its use should be decided by a doctor based on the patient's conditions. 此藥物是一種磷酸鹽結合劑，用於使用透析的慢性腎臟疾病成年患者，以控制其血清磷水平。 副作用包括腹瀉及糞便變色。 使用此藥物與否，須由醫生按病人情況決定。
Talazoparib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated HER2-negative locally advanced or metastatic breast cancer.

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
他拉唑帕利；其鹽類	附表10的第1部，附表1及附表3毒藥	<p>Side effects include fatigue, anaemia, nausea, neutropenia and headache.</p> <p>Its use should be decided by a doctor based on the patient's conditions.</p> <p>此藥物用於治療患有致病性或疑似致病性生殖系BRCA基因突變第二型人類表皮生長因子受體呈陰性的局部晚期或轉移性乳癌的成年患者。</p> <p>副作用包括疲勞、貧血、噁心、中性白細胞減少症及頭痛。</p> <p>使用此藥物與否，須由醫生按病人情況決定。</p>
Tisagenlecleucel	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	<p>This drug is used for the treatment of:</p> <ul style="list-style-type: none"> • Paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia that is refractory, in relapse post-transplant or in second or later relapse. • Adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy. <p>Side effects include viral infections, febrile neutropenia, cytokine release</p>

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
替沙侖賽	附表10的第1部，附表1及附表3毒藥	<p>syndrome, decreased appetite and delirium.</p> <p>Its use should be decided by a doctor based on the patient's conditions.</p> <p>此藥物用於治療：</p> <ul style="list-style-type: none"> • 患有難治性、移植後復發或第二次或以後復發的B-細胞急性淋巴母細胞性白血病的兒童及二十五歲以下年輕成年患者。 • 在接受兩種或以上全身系統性療程後復發或難治性的瀰漫性大型B-細胞淋巴瘤的成年患者。 <p>副作用包括病毒感染、發熱性中性白細胞減少症、細胞活素釋放綜合症、食慾下降及譫妄。</p> <p>使用此藥物與否，須由醫生按病人情況決定。</p>