

**L.N. 19 of 2022**

**Pharmacy and Poisons (Amendment) (No. 2)  
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. 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(4), 5(4) and 6(4) come into operation on 18 February 2023.

**2. Pharmacy and Poisons Regulations amended**

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 3 to 6.

**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 “Caspofungin; its salts”—

**Add**

“Cedazuridine; its salts”.

- (2) Schedule 1, Division A, after item “Eptifibatide; its salts”—

**Add**

“Eptinezumab”.

- (3) Schedule 1, Division A, after item “Icatibant; its salts; its esters; their salts”—

**Add**

“Icosapent ethyl when contained in pharmaceutical products indicated for the reduction of the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization”.

- (4) Schedule 1, Division A, after item “Prindolol; its salts”—

**Add**

“Probenecid”.

- (5) Schedule 1, Division A, after item “Selexipag; its salts”—

**Add**

“Selinexor; its salts”.

**4. Schedule 2 amended (articles exempted by regulation 8 from the provisions of the Ordinance and of these regulations)**

Schedule 2, Group II, Division A, after the item relating to “Sodium fluoride”—

**Add**

“Tranexamic acid                      Topical preparations containing not more than 3% of tranexamic acid as cosmetic products not intended for the treatment of human ailments”.

5. **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 “Caspofungin; its salts”—  
**Add**  
“Cedazuridine; its salts”.
- (2) Schedule 3, Division A, after item “Eptifibatide; its salts”—  
**Add**  
“Eptinezumab”.
- (3) Schedule 3, Division A, after item “Icatibant; its salts; its esters; their salts”—  
**Add**  
“Icosapent ethyl when contained in pharmaceutical products indicated for the reduction of the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization”.
- (4) Schedule 3, Division A, after item “Prindolol; its salts”—  
**Add**  
“Probenecid”.
- (5) Schedule 3, Division A, after item “Selexipag; its salts”—  
**Add**  
“Selinexor; its salts”.

**6. Schedule 10 amended (Poisons List)**

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

**Add**

“Cedazuridine; its salts”.

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

**Add**

“Eptinezumab”.

- (3) Schedule 10, section 2, Table, Part 1, Division A, after item “Icatibant; its salts; its esters; their salts”—

**Add**

“Icosapent ethyl when contained in pharmaceutical products indicated for the reduction of the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization”.

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

**Add**

“Probenecid”.

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

**Add**

“Selinexor; its salts”.

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Ronald LAM Man-kin  
Chairman,  
Pharmacy and Poisons Board

10 February 2022

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### Explanatory Note

This Regulation amends the following provisions of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (*principal Regulations*)—

- (a) Division A of Schedule 1;
- (b) Division A of Group II of Schedule 2;
- (c) Division A of Schedule 3; and
- (d) Division A of Part 1 of the Poisons List set out in Schedule 10.

2. The substances listed in Division A of Schedule 1, Division A of Schedule 3 and Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations (*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 may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon.

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3. The Regulation also adds an article containing tranexamic acid to Division A of Group II of Schedule 2 to the principal Regulations, such that the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations do not apply to the article (but if the article is a pharmaceutical product, certain provisions of the principal Regulations relating to the regulation of pharmaceutical products still apply to the article).