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".

Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

10 February 2022

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.

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).