**L.N. 161 of 2025**

# Pharmacy and Poisons (Amendment) (No. 4) Regulation 2025

(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 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—

**Repeal**

"Anlotinib; its salts".

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

**Add**

"Catequentinib (Anlotinib); its salts".

(3) Schedule 1, Division A, after item "Losartan; its salts"—

**Add**

"Lotilaner; its salts".

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

**Add**

"Marstacimab".

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

**Add**

"Mirogabalin; its salts; its esters; their salts".

(6) Schedule 1, Division A, before item "Pibrentasvir; its salts"—

**Add**

"Phospholipid fraction; when contained in pharmaceutical products intended to be used as pulmonary surfactant for the treatment of respiratory distress syndrome".

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

**Add**

"Teprotumumab".

**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—

**Repeal**

"Anlotinib; its salts".

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

**Add**

"Catequentinib (Anlotinib); its salts".

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

**Add**

"Lotilaner; its salts".

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

**Add**

"Marstacimab".

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

**Add**

"Mirogabalin; its salts; its esters; their salts".

(6) Schedule 3, Division A, before item "Pibrentasvir; its salts"—

**Add**

"Phospholipid fraction; when contained in pharmaceutical products intended to be used as pulmonary surfactant for the treatment of respiratory distress syndrome".

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

**Add**

"Teprotumumab".

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

(1) Schedule 10, section 2, Table, Part 1, Division A—

**Repeal**

"Anlotinib; its salts".

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

**Add**

"Catequentinib (Anlotinib); its salts".

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

**Add**

"Lotilaner; its salts".

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

**Add**

"Marstacimab".

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

**Add**

"Mirogabalin; its salts; its esters; their salts".

(6) Schedule 10, section 2, Table, Part 1, Division A, before item "Pibrentasvir; its salts"—

**Add**

"Phospholipid fraction; when contained in pharmaceutical products intended to be used as pulmonary surfactant for the treatment of respiratory distress syndrome".

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

**Add**

"Teprotumumab".

Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

14 July 2025

## Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) to add certain substances (***newly added substances***) to the following provisions—

(a) Division A of Schedule 1;

(b) Division A of Schedule 3;

(c) Division A of Part 1 of the Poisons List set out in Schedule 10.

2. After the amendments take effect—

(a) 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) 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.

3. The Regulation also makes a minor amendment to the principal Regulations, changing the reference to the substance "Anlotinib" to "Catequentinib (Anlotinib)".