

L.N. 13 of 2026

Pharmacy and Poisons (Amendment) Regulation 2026

(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, item “Antisera, antitoxins, immunoglobulins and vaccines”, paragraph (a), after sub-item “Bacillus Calmette-Guérin (BCG)”—

Add

“Digoxin-specific antibody fragments”.

(2) Schedule 1, Division A, after item “Atracurium besylate”—

Add

“Atrasentan; its salts; its esters; their salts”.

(3) Schedule 1, Division A, after item “Avelumab”—

Add

“Axicabtagene ciloleucel”.

(4) Schedule 1, Division A, before item “Carisoprodol”—

Add

“Cariprazine; its salts”.

(5) Schedule 1, Division A, after item “Dasatinib; its salts”—
Add
“Datopotamab deruxtecan”.

(6) Schedule 1, Division A, after item “Dornase alfa”—
Add
“Dorzagliatin; its salts”.

(7) Schedule 1, Division A, after item “Fulvestrant”—
Add
“Fulzerasib; its salts”.

(8) Schedule 1, Division A, after item “Ganirelix; its salts”—
Add
“Garadacimab”.

(9) Schedule 1, Division A, after item “Inaticabtagene autoleucel”—
Add
“Inavolisib; its salts”.

(10) Schedule 1, Division A, after item “Roxadustat; its salts”—
Add
“Rozanolixizumab”.

(11) Schedule 1, Division A, after item “Sermorelin; its salts”—
Add
“Serplulimab”.

(12) Schedule 1, Division A, after item “Tafluprost”—
Add
“Tafolecimab”.

(13) Schedule 1, Division A, after item “Vonoprazan; its salts”—

Add

“Vorasidenib; its salts”.

(14) Schedule 1, Division A, after item “Zomepirac; its salts”—

Add

“Zongertinib; its 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, item “Antisera, antitoxins, immunoglobulins and vaccines”, paragraph (a), after sub-item “Bacillus Calmette-Guérin (BCG)”—

Add

“Digoxin-specific antibody fragments”.

(2) Schedule 3, Division A, after item “Atracurium besylate”—

Add

“Atrasentan; its salts; its esters; their salts”.

(3) Schedule 3, Division A, after item “Avelumab”—

Add

“Axicabtagene ciloleucel”.

(4) Schedule 3, Division A, before item “Carisoprodol”—

Add

“Cariprazine; its salts”.

(5) Schedule 3, Division A, after item “Dasatinib; its salts”—
Add
“Datopotamab deruxtecan”.

(6) Schedule 3, Division A, after item “Dornase alfa”—
Add
“Dorzagliatin; its salts”.

(7) Schedule 3, Division A, after item “Fulvestrant”—
Add
“Fulzerasib; its salts”.

(8) Schedule 3, Division A, after item “Ganirelix; its salts”—
Add
“Garadacimab”.

(9) Schedule 3, Division A, after item “Inaticabtagene autoleucel”—
Add
“Inavolisib; its salts”.

(10) Schedule 3, Division A, after item “Roxadustat; its salts”—
Add
“Rozanolixizumab”.

(11) Schedule 3, Division A, after item “Sermorelin; its salts”—
Add
“Serplulimab”.

(12) Schedule 3, Division A, after item “Tafluprost”—
Add
“Tafolecimab”.

(13) Schedule 3, Division A, after item “Vonoprazan; its salts”—

Add

“Vorasidenib; its salts”.

(14) Schedule 3, Division A, after item “Zomepirac; its salts”—

Add

“Zongertinib; its salts”.

4. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, item “Antisera, antitoxins, immunoglobulins and vaccines”, paragraph (a), after sub-item “Bacillus Calmette-Guérin (BCG)”—

Add

“Digoxin-specific antibody fragments”.

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

Add

“Atrasentan; its salts; its esters; their salts”.

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

Add

“Axicabtagene ciloleucel”.

(4) Schedule 10, section 2, Table, Part 1, Division A, before item “Carisoprodol”—

Add

“Cariprazine; its salts”.

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

Add

“Datopotamab deruxtecan”.

(6) Schedule 10, section 2, Table, Part 1, Division A, after item “Dornase alfa”—

Add

“Dorzagliatin; its salts”.

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

Add

“Fulzerasib; its salts”.

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

Add

“Garadacimab”.

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

Add

“Inavolisib; its salts”.

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

Add

“Rozanolixizumab”.

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

Add

“Serpulimab”.

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

Add

“Tafolecimab”.

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

Add

“Vorasidenib; its salts”.

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

Add

“Zongertinib; its salts”.

Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

27 January 2026

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) 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.