

**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”.

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- (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”.

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- (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 autoleucl”—

**Add**

“Inavalisib; 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**

“Serplulimab”.

- (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

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### 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.