

**L.N. 210 of 2018**

**Pharmacy and Poisons (Amendment) (No. 6) Regulation  
2018**

(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. 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, after item “Acebutolol; its salts”—

**Add**

“Aceclofenac; its salts”.

(2) Schedule 1, Division A, before item “Allergen extract of Dermatophagoides pteronyssinus”—

**Add**

“Allergen extract of Dermatophagoides farinae”.

(3) Schedule 1, Division A, after item “Avanafil; its salts”—

**Add**

“Avelumab”.

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

**Add**

“Benralizumab”.

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- (5) Schedule 1, Division A, after item “Bicalutamide; its salts”—  
**Add**  
“Bictegravir; its salts”.
- (6) Schedule 1, Division A, before item “Bromocriptine; its salts”—  
**Add**  
“Brodalumab”.
- (7) Schedule 1, Division A, after item “Duloxetine; its salts”—  
**Add**  
“Dupilumab”.
- (8) Schedule 1, Division A, after item “Linezolid; its salts”—  
**Add**  
“Lipegfilgrastim”.
- (9) Schedule 1, Division A, after item “Olaparib; its salts”—  
**Add**  
“Olaratumab”.
- (10) Schedule 1, Division A, after item “Piminodine; its salts”—  
**Add**  
“Pimobendan; its salts”.
- (11) Schedule 1, Division A, after item “Pomalidomide; its salts”—  
**Add**  
“Ponatinib; its salts”.

- (12) Schedule 1, Division A, after item “Poractant alfa”—

**Add**

“Porfimer; 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, after item “Acebutolol; its salts”—

**Add**

“Aceclofenac; its salts”.

- (2) Schedule 3, Division A, before item “Allergen extract of Dermatophagoides pteronyssinus”—

**Add**

“Allergen extract of Dermatophagoides farinae”.

- (3) Schedule 3, Division A, after item “Avanafil; its salts”—

**Add**

“Avelumab”.

- (4) Schedule 3, Division A, after item “Benoxaprofen; its salts”—

**Add**

“Benralizumab”.

- (5) Schedule 3, Division A, after item “Bicalutamide; its salts”—

**Add**

“Bictegravir; its salts”.

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- (6) Schedule 3, Division A, before item “Bromocriptine; its salts”—  
**Add**  
“Brodalumab”.
- (7) Schedule 3, Division A, after item “Duloxetine; its salts”—  
**Add**  
“Dupilumab”.
- (8) Schedule 3, Division A, after item “Linezolid; its salts”—  
**Add**  
“Lipegfilgrastim”.
- (9) Schedule 3, Division A, after item “Olaparib; its salts”—  
**Add**  
“Olaratumab”.
- (10) Schedule 3, Division A, after item “Pimecrolimus”—  
**Add**  
“Pimobendan; its salts”.
- (11) Schedule 3, Division A, after item “Pomalidomide; its salts”—  
**Add**  
“Ponatinib; its salts”.
- (12) Schedule 3, Division A, after item “Poractant alfa”—  
**Add**  
“Porfimer; its salts”.

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

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

**Add**

“Aceclofenac; its salts”.

- (2) Schedule 10, section 2, Table, Part 1, Division A, before item “Allergen extract of Dermatophagoides pteronyssinus”—

**Add**

“Allergen extract of Dermatophagoides farinae”.

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

**Add**

“Avelumab”.

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

**Add**

“Benralizumab”.

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

**Add**

“Bictegravir; its salts”.

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

**Add**

“Brodalumab”.

Section 4

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

**Add**

“Dupilumab”.

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

**Add**

“Lipegfilgrastim”.

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

**Add**

“Olaratumab”.

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

**Add**

“Pimobendan; its salts”.

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

**Add**

“Ponatinib; its salts”.

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

**Add**

“Porfimer; its salts”.

Dr. Constance CHAN  
Chairman,  
Pharmacy and Poisons Board

22 October 2018

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### **Explanatory Note**

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 12 items to—

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

2. The amendments relate to requirements concerning sale, supply, labelling and storage. Main effects of the amendments include—

- (a) that the sale, by retail, of substances specified in the 12 items—
  - (i) may only be effected on 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) that the substances, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.