

**L.N. 38 of 2017**

## **Pharmacy and Poisons (Amendment) (No. 2) Regulation 2017**

(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 “Auranofin”—

**Add**

“Avanafil; its salts”.

- (2) Schedule 1, Division A, after item “Bivalirudin; its salts”—

**Add**

“Blinatumomab”.

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

**Add**

“Daratumumab”.

- (4) Schedule 1, Division A, after item “Interferons”—

**Add**

“Iodine-131; its salts; when contained in pharmaceutical products”.

- (5) Schedule 1, Division A, after item “Mepivacaine; its salts”—

**Add**

“Mepolizumab”.

**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 “Auranofin”—

**Add**

“Avanafil; its salts”.

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

**Add**

“Blinatumomab”.

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

**Add**

“Daratumumab”.

- (4) Schedule 3, Division A, after item “Interferons”—

**Add**

“Iodine-131; its salts; when contained in pharmaceutical products”.

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

**Add**

“Mepolizumab”.

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

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

**Add**

“Avanafil; its salts”.

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

**Add**

“Blinatumomab”.

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

**Add**

“Daratumumab”.

- (4) Schedule 10, section 2, Table, Part 1, Division A, after item “Interferons”—

**Add**

“Iodine-131; its salts; when contained in pharmaceutical products”.

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

**Add**

“Mepolizumab”.

Dr. Constance CHAN  
Chairman,  
Pharmacy and Poisons Board

8 March 2017

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### **Explanatory Note**

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 5 items to—

- (a) Division A of its Schedule 1;
- (b) Division A of its Schedule 3; and
- (c) Division A of Part 1 of the Poisons List set out in its 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 5 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.