

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

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.