**L.N. 14 of 2020**

# Pharmacy and Poisons (Amendment) Regulation 2020

(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. Commencement**

(1) Subject to subsection (2), this Regulation comes into operation on the day on which it is published in the Gazette.

(2) Sections 3(1), (6) and (7), 4(1), (6) and (7) and 5(1), (6) and (7) come into operation on 14 February 2021.

**2. Pharmacy and Poisons Regulations amended**

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 3, 4 and 5.

**3. 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 "Cobimetinib; its salts"—

**Add**

"Codergocrine mesilate".

(2) Schedule 1, Division A, after item "Corynebacterium parvum"—

**Add**

"Crisaborole; its salts".

(3) Schedule 1, Division A, after item "Dopamine; its salts"—

**Add**

"Doravirine; its salts".

(4) Schedule 1, Division A, after item "Gadoxetic acid; its salts"—

**Add**

"Galcanezumab".

(5) Schedule 1, Division A, item "Lovastatin", after "Lovastatin"—

**Add**

"when contained in pharmaceutical products".

(6) Schedule 1, Division A, after item "Metoprolol; its salts"—

**Add**

"Metronidazole; its salts; its esters; their salts".

(7) Schedule 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"—

**Repeal sub-item "Metronidazole".**

(8) Schedule 1, Division A, after item "Recombinant human erythropoietin"—

**Add**

"Regadenoson; its salts".

(9) Schedule 1, Division A, after item "Styramate"—

**Add**

"Sucroferric oxyhydroxide".

(10) Schedule 1, Division A, after item "Tafluprost"—

**Add**

"Talazoparib; its salts".

(11) Schedule 1, Division A, after item "Tirofiban; its salts"—

**Add**

"Tisagenlecleucel".

**4. 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 "Cobimetinib; its salts"—

**Add**

"Codergocrine mesilate".

(2) Schedule 3, Division A, after item "Corynebacterium parvum"—

**Add**

"Crisaborole; its salts".

(3) Schedule 3, Division A, after item "Dopamine; its salts"—

**Add**

"Doravirine; its salts".

(4) Schedule 3, Division A, after item "Gadoxetic acid; its salts"—

**Add**

"Galcanezumab".

(5) Schedule 3, Division A, item "Lovastatin", after "Lovastatin"—

**Add**

"when contained in pharmaceutical products".

(6) Schedule 3, Division A, after item "Metoprolol; its salts"—

**Add**

"Metronidazole; its salts; its esters; their salts".

(7) Schedule 3, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"—

**Repeal sub-item "Metronidazole".**

(8) Schedule 3, Division A, after item "Recombinant human erythropoietin"—

**Add**

"Regadenoson; its salts".

(9) Schedule 3, Division A, after item "Styramate"—

**Add**

"Sucroferric oxyhydroxide".

(10) Schedule 3, Division A, after item "Tafluprost"—

**Add**

"Talazoparib; its salts".

(11) Schedule 3, Division A, after item "Tirofiban; its salts"—

**Add**

"Tisagenlecleucel".

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

(1) Schedule 10, section 2, Table, Part 1, Division A, after item "Cobimetinib; its salts"—

**Add**

"Codergocrine mesilate".

(2) Schedule 10, section 2, Table, Part 1, Division A, after item "Creosote obtained from wood"—

**Add**

"Crisaborole; its salts".

(3) Schedule 10, section 2, Table, Part 1, Division A, after item "Dopamine; its salts"—

**Add**

"Doravirine; its salts".

(4) Schedule 10, section 2, Table, Part 1, Division A, after item "Gadoxetic acid; its salts"—

**Add**

"Galcanezumab".

(5) Schedule 10, section 2, Table, Part 1, Division A, item "Lovastatin", after "Lovastatin"—

**Add**

"when contained in pharmaceutical products".

(6) Schedule 10, section 2, Table, Part 1, Division A, item "Metronidazole; its salts", after "salts"—

**Add**

"; its esters; their salts".

(7) Schedule 10, section 2, Table, Part 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"—

**Repeal sub-item "Metronidazole".**

(8) Schedule 10, section 2, Table, Part 1, Division A, after item "Recombinant human erythropoietin"—

**Add**

"Regadenoson; its salts".

(9) Schedule 10, section 2, Table, Part 1, Division A, after item "Styramate"—

**Add**

"Sucroferric oxyhydroxide".

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

**Add**

"Talazoparib; its salts".

(11) Schedule 10, section 2, Table, Part 1, Division A, after item "Tirofiban; its salts"—

**Add**

"Tisagenlecleucel".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

7 February 2020

## Explanatory Note

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

3. This Regulation also—

(a) amends 1 item in, and removes 1 sub-item from, Division A of Schedule 1 and Division A of Schedule 3; and

(b) amends 2 items in, and removes 1 sub-item from, Division A of Part 1 of the Poisons List set out in Schedule 10.