

**L.N. 41 of 2020**

**Pharmacy and Poisons (Amendment) (No. 2) 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. 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 “Bupropion; its salts”—

**Add**

“Burosumab”.

(2) Schedule 1, Division A, after item “Entecavir; its salts; its esters; their salts”—

**Add**

“Entrectinib; its salts”.

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

**Add**

“Lisdexamfetamine; its salts”.

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

**Add**

“Lutetium (<sup>177</sup>Lu) oxodotreotide; its salts”.

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

**Add**

“Polatuzumab vedotin”.

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

**Add**

“Prasterone; its salts; when contained in pharmaceutical products”.

**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 “Bupropion; its salts”—

**Add**

“Burosumab”.

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

**Add**

“Entrectinib; its salts”.

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

**Add**

“Lisdexamfetamine; its salts”.

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

**Add**

“Lutetium (<sup>177</sup>Lu) oxodotreotide; its salts”.

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

**Add**

“Polatuzumab vedotin”.

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

**Add**

“Prasterone; its salts; when contained in pharmaceutical products”.

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

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

**Add**

“Burosumab”.

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

**Add**

“Entrectinib; its salts”.

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

**Add**

“Lisdexamfetamine; its salts”.

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

**Add**

“Lutetium ( $^{177}\text{Lu}$ ) oxodotreotide; its salts”.

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

**Add**

“Polatuzumab vedotin”.

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

**Add**

“Prasterone; its salts; when contained in pharmaceutical products”.

Dr. Constance CHAN  
Chairman,  
Pharmacy and Poisons Board

1 April 2020

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### **Explanatory Note**

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 6 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 6 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.