**L.N. 145 of 2019**

# Pharmacy and Poisons (Amendment) (No. 4) Regulation 2019

(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(8), (9), (10), (12) and (13), 4(8), (9), (10), (12) and (13) and 5(8), (9), (10), (12) and (13) come into operation on 18 October 2020.

**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 "Daclizumab"—

**Add**

"Dacomitinib; its salts".

(2) Schedule 1, Division A, after item "Efavirenz; its salts"—

**Add**

"Efinaconazole; its salts".

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

**Add**

"Erenumab".

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

**Add**

"Isavuconazole; its salts; its derivatives; their salts".

(5) Schedule 1, Division A, after item "Laropiprant; its salts"—

**Add**

"Latanoprostene bunod; its salts".

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

**Add**

"Lorlatinib; its salts".

(7) Schedule 1, Division A, after item "Nepafenac; its salts"—

**Add**

"Neratinib; its salts".

(8) Schedule 1, Division A, after item "Niflumic acid; its salts"—

**Add**

"Nifuratel; its salts

Nifuroxazide; its salts".

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

**Add**

"Nitrofural; its salts

Nitrofurantoin; its salts".

(10) Schedule 1, Division A, after item "Nitromethaqualone; its salts"—

**Add**

"Nitroxoline; its salts".

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

**Add**

"Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia".

(12) Schedule 1, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

**Repeal**

"Piracetam".

(13) Schedule 1, Division A, after item "Pipobroman"—

**Add**

"Piracetam; its salts".

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

**Add**

"Sugammadex; its salts; its esters; their salts".

**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 "Daclizumab"—

**Add**

"Dacomitinib; its salts".

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

**Add**

"Efinaconazole; its salts".

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

**Add**

"Erenumab".

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

**Add**

"Isavuconazole; its salts; its derivatives; their salts".

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

**Add**

"Latanoprostene bunod; its salts".

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

**Add**

"Lorlatinib; its salts".

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

**Add**

"Neratinib; its salts".

(8) Schedule 3, Division A, after item "Niflumic acid; its salts"—

**Add**

"Nifuratel; its salts

Nifuroxazide; its salts".

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

**Add**

"Nitrofural; its salts

Nitrofurantoin; its salts".

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

**Add**

"Nitroxoline; its salts".

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

**Add**

"Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia".

(12) Schedule 3, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

**Repeal**

"Piracetam".

(13) Schedule 3, Division A, after item "Pipobroman"—

**Add**

"Piracetam; its salts".

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

**Add**

"Sugammadex; its salts; its esters; their salts".

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

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

**Add**

"Dacomitinib; its salts".

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

**Add**

"Efinaconazole; its salts".

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

**Add**

"Erenumab".

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

**Add**

"Isavuconazole; its salts; its derivatives; their salts".

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

**Add**

"Latanoprostene bunod; its salts".

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

**Add**

"Lorlatinib; its salts".

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

**Add**

"Neratinib; its salts".

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

**Add**

"Nifuratel; its salts

Nifuroxazide; its salts".

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

**Add**

"Nitrofural; its salts

Nitrofurantoin; its salts".

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

**Add**

"Nitroxoline; its salts".

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

**Add**

"Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia".

(12) Schedule 10, section 2, Table, Part 1, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

**Repeal**

"Piracetam".

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

**Add**

"Piracetam; its salts".

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

**Add**

"Sugammadex; its salts; its esters; their salts".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

9 October 2019

## Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 15 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 15 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 consequentially amends the Divisions referred to in paragraph 1 to remove a sub-item from the item relating to "Pharmaceutical products for human parenteral administration".