L.N. 40 of 2016

Pharmacy and Poisons (Amendment) Regulation 2016

(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 "Bitolterol and its salts when contained in aerosol dispensers"—

Add

"Bivalirudin; its salts".

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

Add

"Delamanid; its salts".

(3) Schedule 1, Division A, after item "Dimepheptanol; its salts; its esters and ethers; their salts"—

Add

"Dimethyl fumarate when contained in pharmaceutical products".

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

Add

"Macitentan; its salts".

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

Add

"Nintedanib; its salts".

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

Add

"Paracetamol when contained in pharmaceutical products for human parenteral administration".

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

Add

"Ramucirumab".

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 "Bitolterol and its salts when contained in aerosol dispensers"—

Add

"Bivalirudin; its salts".

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

Add

"Delamanid; its salts".

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

Add

"Dimethyl fumarate when contained in pharmaceutical products".

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

Add

"Macitentan; its salts".

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

Add

"Nintedanib; its salts".

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

Add

"Paracetamol when contained in pharmaceutical products for human parenteral administration".

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

Add

"Ramucirumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Bivalirudin; its salts".

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

Add

"Delamanid; its salts".

(3) Schedule 10, section 2, Table, Part 1, Division A, after item "Dimepheptanol; its salts; its esters and ethers; their salts"—

Add

"Dimethyl fumarate when contained in pharmaceutical products".

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

Add

"Macitentan; its salts".

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

Add

"Nintedanib; its salts".

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

Add

"Paracetamol when contained in pharmaceutical products for human parenteral administration".

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

Add

"Ramucirumab".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

7 March 2016

Explanatory Note

This Regulation—

(a) adds 7 substances to Division A of Schedule 1 and Division A of Schedule 3 to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations; and

(b) adds 7 substances to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations so that, among other applicable requirements, those substances can only be sold 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.