L.N. 172 of 2016

Pharmacy and Poisons (Amendment) (No. 5) 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 "Aldesleukin"—

Add

"Alectinib; its salts".

(2) Schedule 1, Division A, before item "Aprepitant; its salts"—

Add

"Apremilast; its salts".

(3) Schedule 1, Division A, after item "Carbutamide"—

Add

"Carfilzomib; its salts".

(4) Schedule 1, Division A, after item "Elosulfase alfa"—

Add

"Elotuzumab".

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

Add

"Osimertinib; its salts".

(6) Schedule 1, Division A, after item "Paclitaxel"—

Add

"Palbociclib; its salts".

(7) Schedule 1, Division A—

Repeal item "Pantoprazole; its salts"

Substitute

"Pantoprazole; its salts; except when contained in oral preparations with 20 mg or less per solid dosage unit, indicated with the maximum daily dose of 20 mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days".

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 "Aldesleukin"—

Add

"Alectinib; its salts".

(2) Schedule 3, Division A, before item "Aprepitant; its salts"—

Add

"Apremilast; its salts".

(3) Schedule 3, Division A, after item "Carbutamide"—

Add

"Carfilzomib; its salts".

(4) Schedule 3, Division A, after item "Elosulfase alfa"—

Add

"Elotuzumab".

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

Add

"Osimertinib; its salts".

(6) Schedule 3, Division A, after item "Paclitaxel"—

Add

"Palbociclib; its salts".

(7) Schedule 3, Division A—

Repeal item "Pantoprazole; its salts"

Substitute

"Pantoprazole; its salts; except when contained in oral preparations with 20 mg or less per solid dosage unit, indicated with the maximum daily dose of 20 mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days".

4. Schedule 10 amended (Poisons List)

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

Add

"Alectinib; its salts".

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

Add

"Apremilast; its salts".

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

Add

"Carfilzomib; its salts".

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

Add

"Elotuzumab".

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

Add

"Osimertinib; its salts".

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

Add

"Palbociclib; its salts".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

18 November 2016

Explanatory Note

This Regulation—

(a) adds 6 items 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***); and

(b) replaces the item relating to "Pantoprazole" in those Divisions with another item.

The effect is that the sale, supply, labeling and storage of substances in those items are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

2. This Regulation also adds 6 items to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations. The effect is that, among other applicable requirements, substances in those items 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.