L.N. 135 of 2024

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2024

(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 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), 4(8) and 5(7) come into operation on the expiry of 6 months beginning on the day on which this Regulation is published in the Gazette.

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 "Atracurium besylate"—

Add

"Atropine; its salts; when contained in pharmaceutical products for human parenteral administration or pharmaceutical products intended to be used for slowing the progression of myopia".

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

Add

"Efanesoctocog alfa".

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

Add

"Eladocagene exuparvovec".

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

Add

"Etranacogene dezaparvovec".

(5) Schedule 1, Division A, after item "Everolimus; its salts; its esters; their salts"—

Add

"Evocalcet; its salts; its esters; their salts".

(6) Schedule 1, Division A, after item "Gallamine; its salts; its quaternary compounds"—

Add

"Gallium-68; its salts; when contained in pharmaceutical products".

(7) Schedule 1, Division A, after item "Gemtuzumab ozogamicin"—

Add

"Germanium-68; its salts; when contained in pharmaceutical products".

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

Add

"Glutathione; its salts; its derivatives; when contained in products for human parenteral administration".

(9) Schedule 1, Division A, after item "Iprindole; its salts"—

Add

"Iptacopan; its salts".

(10) 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 "Atropine".

(11) Schedule 1, Division A, after item "Romosozumab"—

Add

"Ropeginterferon alfa-2b".

(12) Schedule 1, Division A, after item "Rotigotine; its salts"—

Add

"Roxadustat; its salts".

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

Add

"Savolitinib; its salts".

(14) Schedule 1, Division A, before item "Somapacitan"—

Add

"Solriamfetol; its salts".

(15) Schedule 1, Division A, before item "Sutoprofen; its salts"—

Add

"Surufatinib; its salts".

(16) Schedule 1, Division A, after item "Tisagenlecleucel"—

Add

"Tislelizumab".

(17) Schedule 1, Division A, after item "Torasemide"—

Add

"Toripalimab".

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 "Atracurium besylate"—

Add

"Atropine; its salts; when contained in pharmaceutical products for human parenteral administration or pharmaceutical products intended to be used for slowing the progression of myopia".

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

Add

"Efanesoctocog alfa".

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

Add

"Eladocagene exuparvovec".

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

Add

"Etranacogene dezaparvovec".

(5) Schedule 3, Division A, after item "Everolimus; its salts; its esters; their salts"—

Add

"Evocalcet; its salts; its esters; their salts".

(6) Schedule 3, Division A, after item "Gallamine; its salts; its quaternary compounds"—

Add

"Gallium-68; its salts; when contained in pharmaceutical products".

(7) Schedule 3, Division A, after item "Gemtuzumab ozogamicin"—

Add

"Germanium-68; its salts; when contained in pharmaceutical products".

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

Add

"Glutathione; its salts; its derivatives; when contained in products for human parenteral administration".

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

Add

"Iptacopan; its salts".

(10) 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 "Atropine".

(11) Schedule 3, Division A, after item "Romosozumab"—

Add

"Ropeginterferon alfa-2b".

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

Add

"Roxadustat; its salts".

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

Add

"Savolitinib; its salts".

(14) Schedule 3, Division A, before item "Somapacitan"—

Add

"Solriamfetol; its salts".

(15) Schedule 3, Division A, before item "Sutoprofen; its salts"—

Add

"Surufatinib; its salts".

(16) Schedule 3, Division A, after item "Tisagenlecleucel"—

Add

"Tislelizumab".

(17) Schedule 3, Division A, after item "Torasemide"—

Add

"Toripalimab".

5. Schedule 10 amended (Poisons List)

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

Add

"Efanesoctocog alfa".

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

Add

"Eladocagene exuparvovec".

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

Add

"Etranacogene dezaparvovec".

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

Add

"Evocalcet; its salts; its esters; their salts".

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

Add

"Gallium-68; its salts; when contained in pharmaceutical products".

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

Add

"Germanium-68; its salts; when contained in pharmaceutical products".

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

Add

"Glutathione; its salts; its derivatives; when contained in products for human parenteral administration".

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

Add

"Iptacopan; its salts".

(9) 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 "Atropine".

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

Add

"Ropeginterferon alfa-2b".

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

Add

"Roxadustat; its salts".

(12) Schedule 10, section 2, Table, Part 1, Division A, after item "Savin, oil of"—

Add

"Savolitinib; its salts".

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

Add

"Solriamfetol; its salts".

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

Add

"Surufatinib; its salts".

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

Add

"Tislelizumab".

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

Add

"Toripalimab".

Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

8 October 2024

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add certain substances (***newly added substances***) to the following provisions (***specified provisions***)—

(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. After the amendments take effect—

(a) the sale, by retail, of the newly added substances—

(i) may only be effected on the 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) the newly added 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 correspondingly removes 1 sub-item from the specified provisions.