L.N. 232 of 2022

Pharmacy and Poisons (Amendment) (No. 6) Regulation 2022

(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. 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 "Anidulafungin; its salts; its esters; their salts"—

Add

"Anifrolumab".

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

Add

"Avalglucosidase alfa".

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

Add

"Cemiplimab".

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

Add

"Migalastat; its salts".

(5) Schedule 1, Division A, after item "Obinutuzumab; its antibody drug conjugates"—

Add

"Ocrelizumab".

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

Add

"Pitolisant; its salts".

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

Add

"Pretomanid; its salts".

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

Add

"Tafasitamab".

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 "Anidulafungin; its salts; its esters; their salts"—

Add

"Anifrolumab".

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

Add

"Avalglucosidase alfa".

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

Add

"Cemiplimab".

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

Add

"Migalastat; its salts".

(5) Schedule 3, Division A, after item "Obinutuzumab; its antibody drug conjugates"—

Add

"Ocrelizumab".

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

Add

"Pitolisant; its salts".

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

Add

"Pretomanid; its salts".

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

Add

"Tafasitamab".

4. Schedule 10 amended (Poisons List)

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

Add

"Anifrolumab".

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

Add

"Avalglucosidase alfa".

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

Add

"Cemiplimab".

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

Add

"Migalastat; its salts".

(5) Schedule 10, section 2, Table, Part 1, Division A, after item "Obinutuzumab; its antibody drug conjugates"—

Add

"Ocrelizumab".

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

Add

"Pitolisant; its salts".

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

Add

"Pretomanid; its salts".

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

Add

"Tafasitamab".

L.N. 232 of 2022
B4925

Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

2 December 2022

Explanatory Note

This Regulation amends the following provisions of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***specified provisions***)—

(a) Division A of Schedule 1;

(b) Division A of Schedule 3;

(c) Division A of Part 1 of the Poisons List set out in Schedule 10.

2. The substances listed in the specified provisions are subject to specific requirements concerning sale, supply, labelling and storage. The Regulation adds certain substances to the specified provisions. Main effects of the amendments include—

(a) that 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) that 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.