L.N. 212 of 2020

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2020

(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 "Abiraterone; its salts"—

Add

"Acalabrutinib; its salts".

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

Add

"Agalsidase alfa".

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

Add

"Alpelisib; its salts".

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

Add

"Carglumic acid; its salts; its esters; their salts".

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

Add

"Darolutamide; its salts".

(6) Schedule 1, Division A, after item "Dimethyl fumarate when contained in pharmaceutical products"—

Add

"Dinutuximab beta".

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

Add

"Human cytomegalovirus immunoglobulin".

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

Add

"Lutetium-177; its salts; when contained in pharmaceutical products".

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

Add

"Pegaspargase".

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

Add

"Remdesivir; its salts".

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

Add

"Siponimod; its salts; its esters; their salts".

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

Add

"Upadacitinib; its salts".

(13) Schedule 1, Chinese text, Division A—

(a) **Repeal item "Secukinumab";**

(b) after item "司美魯肽"—

Add

"司庫奇尤單抗".

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 "Abiraterone; its salts"—

Add

"Acalabrutinib; its salts".

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

Add

"Agalsidase alfa".

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

Add

"Alpelisib; its salts".

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

Add

"Carglumic acid; its salts; its esters; their salts".

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

Add

"Darolutamide; its salts".

(6) Schedule 3, Division A, after item "Dimethyl fumarate when contained in pharmaceutical products"—

Add

"Dinutuximab beta".

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

Add

"Human cytomegalovirus immunoglobulin".

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

Add

"Lutetium-177; its salts; when contained in pharmaceutical products".

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

Add

"Pegaspargase".

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

Add

"Remdesivir; its salts".

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

Add

"Siponimod; its salts; its esters; their salts".

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

Add

"Upadacitinib; its salts".

(13) Schedule 3, Chinese text, Division A—

(a) **Repeal item "Secukinumab";**

(b) after item "司美魯肽"—

Add

"司庫奇尤單抗".

4. Schedule 10 amended (Poisons List)

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

Add

"Acalabrutinib; its salts".

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

Add

"Agalsidase alfa".

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

Add

"Alpelisib; its salts".

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

Add

"Carglumic acid; its salts; its esters; their salts".

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

Add

"Darolutamide; its salts".

(6) Schedule 10, section 2, Table, Part 1, Division A, after item "Dimethyl fumarate when contained in pharmaceutical products"—

Add

"Dinutuximab beta".

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

Add

"Human cytomegalovirus immunoglobulin".

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

Add

"Lutetium-177; its salts; when contained in pharmaceutical products".

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

Add

"Pegaspargase".

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

Add

"Remdesivir; its salts".

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

Add

"Siponimod; its salts; its esters; their salts".

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

Add

"Upadacitinib; its salts".

(13) Schedule 10, Chinese text, section 2, Table, Part 1, Division A—

(a) **Repeal item "Secukinumab";**

(b) after item "司美魯肽"—

Add

"司庫奇尤單抗".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

23 October 2020

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; and

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

2. The specified provisions relate to requirements concerning sale, supply, labelling and storage. The Regulation adds 12 items to the specified provisions. Main effects of the amendments include—

(a) that the sale, by retail, of substances specified in those 12 new 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. The Regulation also amends the Chinese text of the specified provisions to refer to an existing item by its Chinese name instead of its English name.