L.N. 252 of 2020

Pharmacy and Poisons (Amendment) (No. 5) 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. 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(2), (5), (8) and (11) come into operation on 11 December 2021.

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, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b), after sub-item "Rubella"—

Add

"Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)".

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

Add

"Brolucizumab".

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

Add

"Capmatinib; its salts".

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

Add

"Icatibant; its salts; its esters; their salts".

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

Add

"Lemborexant; its salts".

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

Add

"Ripretinib; its salts".

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

Add

"Satralizumab".

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

Add

"Trospium chloride".

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, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b), after sub-item "Rubella"—

Add

"Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)".

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

Add

"Brolucizumab".

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

Add

"Capmatinib; its salts".

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

Add

"Icatibant; its salts; its esters; their salts".

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

Add

"Lemborexant; its salts".

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

Add

"Ripretinib; its salts".

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

Add

"Satralizumab".

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

Add

"Trospium chloride".

5. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b), after sub-item "Rubella"—

Add

"Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)".

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

Add

"Azelaic acid".

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

Add

"Brolucizumab".

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

Add

"Capmatinib; its salts".

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

Add

"Diprophylline; its salts".

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

Add

"Icatibant; its salts; its esters; their salts".

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

Add

"Lemborexant; its salts".

(8) 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 "Diprophylline".

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

Add

"Ripretinib; its salts".

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

Add

"Satralizumab".

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

Add

"Trospium chloride".

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

(a) item "氰氟蟲腙；其鹽類";

(b) item "氰苯哌酸；其鹽類";

(c) item "4-氰基-1-甲基-4-苯基哌啶；其鹽類";

(d) item "4-氰基-2-二甲胺基-4，4-二苯基丁烷；其鹽類"—

Repeal the items.

(13) Schedule 10, Chinese text, section 2, Table, Part 1, Division A, after item "氮芥及二氯乙胺於N位被取代的任何其他衍生物；它們的鹽類"—

Add

"氰氟蟲腙；其鹽類

氰苯哌酸；其鹽類

4-氰基-1-甲基-4-苯基哌啶；其鹽類

4-氰基-2-二甲胺基-4，4-二苯基丁烷；其鹽類".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

8 December 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 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 (except for Azelaic acid and Diprophylline and its salts); 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.

3. The Regulation also updates the arrangement order of certain substances in the Chinese text of Division A of Part 1 of the Poisons List set out in Schedule 10.