L.N. 191 of 2018

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2018

(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 "Brinzolamide; its salts"—

Add

"Brivaracetam; its salts".

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

Add

"Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both".

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

Add

"Durvalumab".

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

Add

"Emicizumab".

(5) Schedule 1, Division A, after item relating to "Guanidines"—

Add

"Guselkumab".

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

Add

"Inotuzumab ozogamicin".

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

Add

"Lignocaine; its salts; when in mixture with prilocaine or in mixture with the salts of prilocaine, and intended to be used for the treatment of premature ejaculation".

(8) Schedule 1, Division A—

Repeal item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"

Substitute

"Lignocaine; its salts; when in mixture with tetracaine (being an amino alcohol esterified with a derivative of benzoic acid) or in mixture with the salts of tetracaine".

(9) Schedule 1, Division A, after item "Methoxsalen"—

Add

"Methoxyflurane".

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

Add

"Niraparib; its salts".

(11) 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", after sub-item "Cimetidine"—

Add

"Citicoline".

(12) Schedule 1, Division A—

Repeal item "Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine".

(13) Schedule 1, Division A, after item "Vortioxetine; its salts"—

Add

"Voxilaprevir; its salts".

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 "Brinzolamide; its salts"—

Add

"Brivaracetam; its salts".

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

Add

"Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both".

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

Add

"Durvalumab".

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

Add

"Emicizumab".

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

Add

"Guselkumab".

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

Add

"Inotuzumab ozogamicin".

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

Add

"Lignocaine; its salts; when in mixture with prilocaine or in mixture with the salts of prilocaine, and intended to be used for the treatment of premature ejaculation".

(8) Schedule 3, Division A—

Repeal item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"

Substitute

"Lignocaine; its salts; when in mixture with tetracaine (being an amino alcohol esterified with a derivative of benzoic acid) or in mixture with the salts of tetracaine".

(9) Schedule 3, Division A, after item "Methoxsalen"—

Add

"Methoxyflurane".

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

Add

"Niraparib; its salts".

(11) 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", after sub-item "Cimetidine"—

Add

"Citicoline".

(12) Schedule 3, Division A—

Repeal item "Tetracaine (being an amino alcohol esterified with a derivative of benzoic acid); its salts in mixture with lignocaine or in mixture with the salts of lignocaine".

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

Add

"Voxilaprevir; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Brivaracetam; its salts".

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

Add

"Citicoline; its salts; when contained in pharmaceutical products intended to be used for the treatment of cognitive and neurological disorders associated with cerebrovascular disease or brain injury, or both".

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

Add

"Durvalumab".

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

Add

"Emicizumab".

(5) Schedule 10, section 2, Table, Part 1, Division A, after item relating to "Guanidines"—

Add

"Guselkumab".

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

Add

"Inotuzumab ozogamicin".

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

Add

"Methoxyflurane".

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

Add

"Niraparib; 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", after sub-item "Cimetidine"—

Add

"Citicoline".

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

Add

"Voxilaprevir; its salts".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

11 October 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to—

(a) add 10 items and 1 sub-item to Division A of Schedule 1 and Division A of Schedule 3;

(b) replace 2 existing items with a single one in Division A of Schedule 1 and Division A of Schedule 3; and

(c) add 9 items and 1 sub-item to Division A of Part 1 of the Poisons List set out in Schedule 10.

2. A substance specified in an item or sub-item in those Schedules is subject to requirements concerning sale, supply, labelling and storage. Among other applicable requirements—

(a) for a substance specified in an item or sub-item included in both Schedules 1 and 3—the sale, by retail, of the substance may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon; and

(b) for a substance specified in an item or sub-item in Part 1 of the Poisons List set out in Schedule 10—

(i) the sale, by retail, of the substance 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) the substance, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.