L.N. 193 of 2015

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2015

(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. First Schedule 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) First Schedule, Division A, after item "Darunavir; its salts"—

Add

"Dasabuvir; its salts".

(2) First Schedule, Division A, after item "Embutramide"—

Add

"Empagliflozin; its salts".

(3) First Schedule, Division A, after item "Ibritumomab tiuxetan"—

Add

"Ibrutinib; its salts".

(4) First Schedule, Division A, before item "Idursulfase"—

Add

"Idelalisib; its salts".

(5) First Schedule, Division A, after item "Lead, compounds of, with acids from fixed oils"—

Add

"Ledipasvir; its salts".

(6) First Schedule, Division A, after item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"—

Add

"Linaclotide; its salts".

(7) First Schedule, Division A, after item "Nortriptyline; its salts"—

Add

"Obinutuzumab; its antibody drug conjugates".

(8) First Schedule, Division A, after item "Omalizumab"—

Add

"Ombitasvir; its salts".

(9) First Schedule, Division A, after item "Paricalcitol; its salts; its esters; their salts"—

Add

"Paritaprevir; its salts".

(10) First Schedule, Division A, after item "Polymethylenebistrimethylammonium salts"—

Add

"Pomalidomide; its salts".

(11) First Schedule, Division A, after item "Rotigotine; its salts"—

Add

"Rufinamide; its salts".

(12) First Schedule, Division A, after item "Vecuronium; its salts"—

Add

"Vedolizumab".

3. Third Schedule 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) Third Schedule, Division A, after item "Darunavir; its salts"—

Add

"Dasabuvir; its salts".

(2) Third Schedule, Division A, after item "Embutramide"—

Add

"Empagliflozin; its salts".

(3) Third Schedule, Division A, after item "Ibritumomab tiuxetan"—

Add

"Ibrutinib; its salts".

(4) Third Schedule, Division A, before item "Idursulfase"—

Add

"Idelalisib; its salts".

(5) Third Schedule, Division A, after item "Laropiprant; its salts"—

Add

"Ledipasvir; its salts".

(6) Third Schedule, Division A, after item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"—

Add

"Linaclotide; its salts".

(7) Third Schedule, Division A, after item "Nortriptyline; its salts"—

Add

"Obinutuzumab; its antibody drug conjugates".

(8) Third Schedule, Division A, after item "Omalizumab"—

Add

"Ombitasvir; its salts".

(9) Third Schedule, Division A, after item "Paricalcitol; its salts; its esters; their salts"—

Add

"Paritaprevir; its salts".

(10) Third Schedule, Division A, after item "Polymethylenebistrimethylammonium salts"—

Add

"Pomalidomide; its salts".

(11) Third Schedule, Division A, after item "Rotigotine; its salts"—

Add

"Rufinamide; its salts".

(12) Third Schedule, Division A, after item "Vecuronium; its salts"—

Add

"Vedolizumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Dasabuvir; its salts".

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

Add

"Empagliflozin; its salts".

(3) Schedule 10, section 2, Table, Part I, Division A, after item "Ibritumomab tiuxetan"—

Add

"Ibrutinib; its salts".

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

Add

"Idelalisib; its salts".

(5) Schedule 10, section 2, Table, Part I, Division A, after item "Lead acetates; compounds of lead with acids from fixed oils"—

Add

"Ledipasvir; its salts".

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

Add

"Linaclotide; its salts".

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

Add

"Obinutuzumab; its antibody drug conjugates".

(8) Schedule 10, section 2, Table, Part I, Division A, after item "Omalizumab"—

Add

"Ombitasvir; its salts".

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

Add

"Paritaprevir; its salts".

(10) Schedule 10, section 2, Table, Part I, Division A, after item "Polymethylenebistrimethylammonium salts"—

Add

"Pomalidomide; its salts".

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

Add

"Rufinamide; its salts".

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

Add

"Vedolizumab".

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Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

29 September 2015

Explanatory Note

This Regulation—

(a) adds 12 substances to Division A of the First Schedule and Division A of the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations; and

(b) adds 12 substances to Division A of Part I of the Poisons List set out in Schedule 10 to the principal Regulations so that, among other applicable requirements, poisons containing those substances may only be sold 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.