L.N. 194 of 2022

Pharmacy and Poisons (Amendment) (No. 5) 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. 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(3), 4(3) and 5(3), (14), (15), (16), (17), (18) and (19) come into operation on the expiry of 12 months beginning on the day on which this Regulation is published in the Gazette.

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, after item "Abiraterone; its salts"—

Add

"Abrocitinib; its salts".

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

Add

"Amivantamab".

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

Add

"Betahistine; its salts; except when contained in pharmaceutical products containing betahistine hydrochloride or betahistine mesilate (a) labelled with a maximum recommended daily dose of the pharmaceutical product having the equivalent of 48 mg of betahistine hydrochloride or 36 mg of betahistine mesilate; (b) stated for use only in patients of 18 years old or above for relief of vertigo symptoms only; and (c) to be sold in packs for a maximum of 5 days' use".

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

Add

"Calcifediol".

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

Add

"Cilgavimab".

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

Add

"Faricimab".

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

Add

"Finerenone; its salts".

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

Add

"Fostamatinib; its salts".

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

Add

"Glycerol phenylbutyrate".

(10) Schedule 1, Division A, after item "Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia"—

Add

"Onasemnogene abeparvovec".

(11) Schedule 1, Division A, after item "Rufinamide; its salts"—

Add

"Rurioctocog alfa pegol".

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

Add

"Sacituzumab govitecan".

(13) Schedule 1, Division A, after item "Tisagenlecleucel"—

Add

"Tixagevimab".

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, after item "Abiraterone; its salts"—

Add

"Abrocitinib; its salts".

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

Add

"Amivantamab".

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

Add

"Betahistine; its salts; except when contained in pharmaceutical products containing betahistine hydrochloride or betahistine mesilate (a) labelled with a maximum recommended daily dose of the pharmaceutical product having the equivalent of 48 mg of betahistine hydrochloride or 36 mg of betahistine mesilate; (b) stated for use only in patients of 18 years old or above for relief of vertigo symptoms only; and (c) to be sold in packs for a maximum of 5 days' use".

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

Add

"Calcifediol".

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

Add

"Cilgavimab".

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

Add

"Faricimab".

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

Add

"Finerenone; its salts".

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

Add

"Fostamatinib; its salts".

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

Add

"Glycerol phenylbutyrate".

(10) Schedule 3, Division A, after item "Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia"—

Add

"Onasemnogene abeparvovec".

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

Add

"Rurioctocog alfa pegol".

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

Add

"Sacituzumab govitecan".

(13) Schedule 3, Division A, after item "Tisagenlecleucel"—

Add

"Tixagevimab".

5. Schedule 10 amended (Poisons List)

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

Add

"Abrocitinib; its salts".

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

Add

"Amivantamab".

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

Add

"Betahistine; its salts".

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

Add

"Calcifediol".

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

Add

"Cilgavimab".

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

Add

"Faricimab".

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

Add

"Finerenone; its salts".

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

Add

"Fostamatinib; its salts".

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

Add

"Glycerol phenylbutyrate".

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

Add

"Onasemnogene abeparvovec".

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

Add

"Rurioctocog alfa pegol".

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

Add

"Sacituzumab govitecan".

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

Add

"Tixagevimab".

(14) Schedule 10, section 2, Table, Part 2, Division A, after item "Antihistamine substances not included in Part 1 of this List; their salts; their compounds with any other substance"—

Add

"Aspirin; its salts; when contained in pharmaceutical products".

(15) Schedule 10, section 2, Table, Part 2, Division A, after item "Clotrimazole; its salts; when contained in pharmaceutical products labelled only for the treatment of tinea pedis or tinea cruris, or both"—

Add

"Ethenzamide; its salts".

(16) Schedule 10, section 2, Table, Part 2, Division A, after item "Nicotine when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy"—

Add

"Paracetamol; its salts; when contained in pharmaceutical products".

(17) Schedule 10, section 2, Table, Part 2, Division A, before item "Phenols as defined in Part 1 of this List in substances containing less than 60%, weight in weight, of phenols; compounds of phenol with a metal in substances containing less than the equivalent of 60%, weight in weight, of phenols"—

Add

"Phenazone; its salts".

(18) Schedule 10, section 2, Table, Part 2, Division A, after item "Phenols as defined in Part 1 of this List in substances containing less than 60%, weight in weight, of phenols; compounds of phenol with a metal in substances containing less than the equivalent of 60%, weight in weight, of phenols"—

Add

"Propyphenazone; its salts".

(19) Schedule 10, section 2, Table, Part 2, Division A, before item "Terbinafine; its salts; when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as a single application and when labelled only for the treatment of tinea pedis or tinea cruris, or both"—

Add

"Salicylamide; its salts; when contained in pharmaceutical products".

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Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

17 October 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 (***Poisons List***); and

(d) Division A of Part 2 of the Poisons List.

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, or on the registered premises of a listed seller of poisons; 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 (except those added to Division A of Part 2 of the Poisons List), if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.