L.N. 184 of 2019

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2019

(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(7) and (9), 4(7) and (9) and 5(7) and (9) come into operation on 13 December 2020.

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 "Abciximab"—

Add

"Abemaciclib; its salts".

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

Add

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

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

Add

"; when contained in pharmaceutical products".

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

Add

"Gemtuzumab ozogamicin".

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

Add

"Larotrectinib; its salts".

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

Add

"Nicardipine; its salts".

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

Add

"Pentoxifylline; its salts".

(8) 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 "Icodextrin"—

Add

"Indigo carmine".

(9) 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"—

Repeal sub-item "Pentoxifylline".

(10) Schedule 1, Division A, item "Prostaglandins, the following and their derivatives", after sub-item "Dinoprostone"—

Add

"Epoprostenol".

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

Add

"Risankizumab".

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

Add

"Semaglutide".

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

Add

"Sodium zirconium cyclosilicate".

(14) Schedule 1, Chinese text, Division A, item "供注射入人體的藥劑製品，並包含 (作為有效成分) 以下物質或它們的鹽類，但與胰島素的混合物除外"—

Repeal

"與胰島素的混合物"

Substitute

"在與胰島素的混合物內者".

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 "Abciximab"—

Add

"Abemaciclib; its salts".

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

Add

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

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

Add

"; when contained in pharmaceutical products".

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

Add

"Gemtuzumab ozogamicin".

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

Add

"Larotrectinib; its salts".

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

Add

"Nicardipine; its salts".

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

Add

"Pentoxifylline; its salts".

(8) 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 "Icodextrin"—

Add

"Indigo carmine".

(9) 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"—

Repeal sub-item "Pentoxifylline".

(10) Schedule 3, Division A, item "Prostaglandins, the following and their derivatives", after sub-item "Dinoprostone"—

Add

"Epoprostenol".

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

Add

"Risankizumab".

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

Add

"Semaglutide".

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

Add

"Sodium zirconium cyclosilicate".

(14) Schedule 3, Chinese text, Division A, item "供注射入人體的藥劑製品，並包含 (作為有效成分) 以下物質或它們的鹽類，但與胰島素的混合物除外"—

Repeal

"與胰島素的混合物"

Substitute

"在與胰島素的混合物內者".

5. Schedule 10 amended (Poisons List)

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

Add

"Abemaciclib; its salts".

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

Add

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

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

Add

"; when contained in pharmaceutical products".

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

Add

"Gemtuzumab ozogamicin".

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

Add

"Larotrectinib; its salts".

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

Add

"Nicardipine; its salts".

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

Add

"Pentoxifylline; 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", after sub-item "Icodextrin"—

Add

"Indigo carmine".

(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"—

Repeal sub-item "Pentoxifylline".

(10) Schedule 10, section 2, Table, Part 1, Division A, item "Prostaglandins, the following and their derivatives", after sub-item "Dinoprostone"—

Add

"Epoprostenol".

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

Add

"Risankizumab".

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

Add

"Semaglutide".

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

Add

"Sodium zirconium cyclosilicate".

(14) Schedule 10, Chinese text, section 2, Table, Part 1, Division A, item "供注射入人體的藥劑製品，並包含 (作為有效成分) 以下物質或它們的鹽類，但與胰島素的混合物除外"—

Repeal

"與胰島素的混合物"

Substitute

"在與胰島素的混合物內者".

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

5 December 2019

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) to add new items and sub-items to, and remove certain sub-items from, the following schedules to the principal Regulations—

(a) Division A of Schedule 1 (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply);

(b) Division A of Schedule 3 (substances required to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon); and

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