

L.N. 177 of 2024

**Pharmacy and Poisons (Amendment) (No. 5) Regulation
2024**

(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. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2 to 5.

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 “Aclidinium; its salts”—

Add

“Adagrasib; its salts”.

(2) Schedule 1, Division A, item relating to “Alkaloids”—

Repeal the sub-item relating to “Nicotine”

Substitute

“Nicotine (except 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); any compound containing the chemical structure of 3-(1-methylpyrrolidin-2-yl)pyridine substituted to any degree or without substitution”.

- (3) Schedule 1, Division A, after item “Capecitabine; its salts”—
Add
“Capivasertib; its salts”.
- (4) Schedule 1, Division A, after item “Dalteparin; its salts”—
Add
“Danicopan; its salts”.
- (5) Schedule 1, Division A, after item “Dehydroemetine; its salts”—
Add
“Delafloxacin; its salts; its esters; their salts”.
- (6) Schedule 1, Division A, after item “Efinaconazole; its salts”—
Add
“Elacestrant; its salts”.
- (7) Schedule 1, Division A, after item “Eladocagene exuparvovec”—
Add
“Elapegademase”.
- (8) Schedule 1, Division A, after item “Furethidine; its salts”—
Add
“Futibatinib; its salts”.
- (9) Schedule 1, Division A, after item “Labetalol; its salts”—
Add
“Labuvirtide”.
- (10) Schedule 1, Division A, after item “Lonazolac; its salts”—

Add

“Loncastuximab tesirine”.

- (11) Schedule 1, Division A, after item “Molybdate (99Mo); its salts; when contained in pharmaceutical products”—

Add

“Momelotinib; its salts”.

- (12) Schedule 1, Division A, after item “Nirmatrelvir; its salts”—

Add

“Nirsevimab”.

- (13) Schedule 1, Division A, after item “Octreotide; its salts”—

Add

“Odevixibat; its salts; its esters; their salts”.

- (14) Schedule 1, Division A, after item “Pegfilgrastim”—

Add

“Pegunigalsidase alfa”.

- (15) Schedule 1, Division A, after item “Repaglinide; its salts; its esters”—

Add

“Repotrectinib; its salts”.

- (16) Schedule 1, Division A, after item “Saxagliptin; its salts”—

Add

“Sebelipase alfa”.

- (17) Schedule 1, Division A, after item “Talazoparib; its salts”—

Add

Section 3

“Talquetamab”.

- (18) Schedule 1, Division A, after item “Tremelimumab”—

Add

“Treosulfan; its salts”.

- (19) Schedule 1, Division A, after item “Vortioxetine; its salts”—

Add

“Vosoritide”.

- (20) Schedule 1, Division A, after item “Voxilaprevir; its salts”—

Add

“Vutrisiran; its salts”.

3. Schedule 2 amended (articles exempted by regulation 8 from the provisions of the Ordinance and of these regulations)

Schedule 2, Group II, Division B, item “Nicotine”—

Repeal everything in column 2

Substitute

“Tobacco in any conventional smoking product (as defined by section 2(1) of the Smoking (Public Health) Ordinance (Cap. 371))”.

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 “Aclidinium; its salts”—

Add

“Adagrasib; its salts”.

Section 4

- (2) Schedule 3, Division A, after item “Capecitabine; its salts”—

Add

“Capivasertib; its salts”.

- (3) Schedule 3, Division A, after item “Dalteparin; its salts”—

Add

“Danicopan; its salts”.

- (4) Schedule 3, Division A, after item “Dehydroemetine; its salts”—

Add

“Delafloxacin; its salts; its esters; their salts”.

- (5) Schedule 3, Division A, after item “Efinaconazole; its salts”—

Add

“Elacestrant; its salts”.

- (6) Schedule 3, Division A, after item “Eladocagene exuparvovec”—

Add

“Elapegademase”.

- (7) Schedule 3, Division A, after item “Fulvestrant”—

Add

“Futibatinib; its salts”.

- (8) Schedule 3, Division A, after item “Labetalol; its salts”—

Add

“Labuvirtide”.

- (9) Schedule 3, Division A, after item “Lonazolac; its salts”—

Add

“Loncastximab tesirine”.

- (10) Schedule 3, Division A, after item “Molybdate (99Mo); its salts; when contained in pharmaceutical products”—

Add

“Momelotinib; its salts”.

- (11) Schedule 3, Division A, after item “Nirmatrelvir; its salts”—

Add

“Nirsevimab”.

- (12) Schedule 3, Division A, after item “Octreotide; its salts”—

Add

“Odevixibat; its salts; its esters; their salts”.

- (13) Schedule 3, Division A, after item “Pegfilgrastim”—

Add

“Pegunigalsidase alfa”.

- (14) Schedule 3, Division A, after item “Repaglinide; its salts; its esters”—

Add

“Repotrectinib; its salts”.

- (15) Schedule 3, Division A, after item “Saxagliptin; its salts”—

Add

“Sebelipase alfa”.

- (16) Schedule 3, Division A, after item “Talazoparib; its salts”—

Add

“Talquetamab”.

Section 5

- (17) Schedule 3, Division A, after item “Tremelimumab”—

Add

“Treosulfan; its salts”.

- (18) Schedule 3, Division A, after item “Vortioxetine; its salts”—

Add

“Vosoritide”.

- (19) Schedule 3, Division A, after item “Voxilaprevir; its salts”—

Add

“Vutrisiran; its salts”.

5. Schedule 10 amended (Poisons List)

- (1) Schedule 10, section 2, Table, Part 1, Division A, after item “Aclidinium; its salts”—

Add

“Adagrasib; its salts”.

- (2) Schedule 10, section 2, Table, Part 1, Division A, item relating to “Alkaloids”—

Repeal the sub-item relating to “Nicotine”**Substitute**

“Nicotine (except 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); any compound containing the chemical structure of 3-(1-methylpyrrolidin-2-yl)pyridine substituted to any degree or without substitution”.

Section 5

- (3) Schedule 10, section 2, Table, Part 1, Division A, after item “Capecitabine; its salts”—

Add

“Capivasertib; its salts”.

- (4) Schedule 10, section 2, Table, Part 1, Division A, after item “Dalteparin; its salts”—

Add

“Danicopan; its salts”.

- (5) Schedule 10, section 2, Table, Part 1, Division A, after item “Dehydroemetine; its salts”—

Add

“Delafloxacin; its salts; its esters; their salts”.

- (6) Schedule 10, section 2, Table, Part 1, Division A, after item “Efinaconazole; its salts”—

Add

“Elacestrant; its salts”.

- (7) Schedule 10, section 2, Table, Part 1, Division A, after item “Eladocagene exuparvovec”—

Add

“Elapegademase”.

- (8) Schedule 10, section 2, Table, Part 1, Division A, after item “Furethidine; its salts”—

Add

“Futibatinib; its salts”.

- (9) Schedule 10, section 2, Table, Part 1, Division A, after item “Labetalol; its salts”—

Add

“Labuvirtide”.

Section 5

- (10) Schedule 10, section 2, Table, Part 1, Division A, after item “Lonazoloc; its salts”—

Add

“Loncastuximab tesirine”.

- (11) Schedule 10, section 2, Table, Part 1, Division A, after item “Molybdate (99Mo); its salts; when contained in pharmaceutical products”—

Add

“Momelotinib; its salts”.

- (12) Schedule 10, section 2, Table, Part 1, Division A, after item “Nirmatrelvir; its salts”—

Add

“Nirsevimab”.

- (13) Schedule 10, section 2, Table, Part 1, Division A, after item “Octreotide; its salts”—

Add

“Odevixibat; its salts; its esters; their salts”.

- (14) Schedule 10, section 2, Table, Part 1, Division A, after item “Pegfilgrastim”—

Add

“Pegunigalsidase alfa”.

- (15) Schedule 10, section 2, Table, Part 1, Division A, after item “Repaglinide; its salts; its esters”—

Add

“Repotrectinib; its salts”.

- (16) Schedule 10, section 2, Table, Part 1, Division A, after item “Saxagliptin; its salts”—

Add

“Sebelipase alfa”.

- (17) Schedule 10, section 2, Table, Part 1, Division A, after item “Talazoparib; its salts”—

Add

“Talquetamab”.

- (18) Schedule 10, section 2, Table, Part 1, Division A, after item “Tremelimumab”—

Add

“Treosulfan; its salts”.

- (19) Schedule 10, section 2, Table, Part 1, Division A, after item “Vortioxetine; its salts”—

Add

“Vosoritide”.

- (20) Schedule 10, section 2, Table, Part 1, Division A, after item “Voxilaprevir; its salts”—

Add

“Vutrisiran; its salts”.

- (21) Schedule 10, section 2, Table, Part 2, Division A, item relating to “Pharmaceutical products retailed in the form as supplied by the manufacturer”, paragraph (e)—

Repeal the sub-item relating to “Nicotine”

Substitute

“Nicotine (except 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); any compound containing the chemical structure of

3-(1-methylpyrrolidin-2-yl)pyridine substituted to any degree or without substitution”.

Ronald LAM Man-kin
Chairman,
Pharmacy and Poisons Board

9 December 2024

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (*Cap. 138A*) to add certain substances (*newly added substances*) to the following 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 (*Poisons List*).

2. 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; 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. In addition, this Regulation amends Division B of Group II of Schedule 2 to Cap. 138A so that tobacco (except tobacco in certain smoking products) is no longer exempt from the restrictions under the Pharmacy and Poisons Ordinance (Cap. 138) and Cap. 138A.

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2024

Explanatory Note
Paragraph 4

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4. This Regulation also amends Division A of Part 2 of the Poisons List to tighten the control over certain compounds relating to Nicotine.