L.N. 105 of 2024

Pharmacy and Poisons (Amendment) (No. 3) 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. 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(1), 4, 5(1) and 6(1) and (14) 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 to 6.

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, item "Androgenic, oestrogenic and progestational substances, the following", sub-item "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters", after "esters"—

Add

"; except when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following—

0.15 mg of Desogestrel;

3.00 mg of Drospirenone;

0.05 mg of Ethinyloestradiol;

0.10 mg of Gestodene;

0.25 mg of Levonorgestrel;

2.50 mg of Lynoestrenol;

0.05 mg of Mestranol;

1.00 mg of Norethisterone;

0.25 mg of Norgestimate; and

0.50 mg of Norgestrel".

(2) Schedule 1, Division A, after item "Atezolizumab"—

Add

"Atogepant".

(3) Schedule 1, Division A, after item "Bevacizumab"—

Add

"Bexarotene; its salts".

(4) Schedule 1, Division A, item "Cannabinol and its tetrahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item", after "tetrahydro"—

Add

"or hexahydro".

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

Add

"Epcoritamab".

(6) Schedule 1, Division A, after item "Lead, compounds of, with acids from fixed oils"—

Add

"Lecanemab".

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

Add

"Perflubutane".

(8) Schedule 1, Division A, after item "Risperidone"—

Add

"Ritlecitinib; its salts".

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

Add

"Somapacitan".

(10) 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，但在與胰島素的混合物內者除外", sub-item "乙醯半胱氨酸"—

Repeal

"醯"

Substitute

"酰".

(11) 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，但在與胰島素的混合物內者除外", sub-item "乙醯膽鹼" —

Repeal

"醯"

Substitute

"酰".

(12) 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，但在與胰島素的混合物內者除外", sub-item "對乙醯氨基酚" —

Repeal

"對乙醯氨基酚"

Substitute

"對乙酰氨基酚(撲熱息痛)".

(13) Schedule 1, Chinese text, Division A, item "蘆非醯胺；其鹽類" —

Repeal

"醯"

Substitute

"酰".

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

Schedule 2, Group II, Division A, item "Androgenic, oestrogenic and progestational substances, the following", sub-item relating to "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters" —

Repeal everything in column 2

Substitute

"Multivitamin preparations (with or without minerals) containing not more than the following in each dosage form—

0.01 mg of Ethinyloestradiol; and

2.50 mg of Methyltestosterone".

5. 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, item "Androgenic, oestrogenic and progestational substances, the following", sub-item "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters"—

Repeal

"Steroid compounds with androgenic or oestrogenic or progestational activity; their esters"

Substitute

"Steroid compounds with androgenic or oestrogenic or progestational activity; their esters; except when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following—

0.15 mg of Desogestrel;

3.00 mg of Drospirenone;

0.05 mg of Ethinyloestradiol;

0.10 mg of Gestodene;

0.25 mg of Levonorgestrel;

2.50 mg of Lynoestrenol;

0.05 mg of Mestranol;

1.00 mg of Norethisterone;

0.25 mg of Norgestimate; and

0.50 mg of Norgestrel".

(2) Schedule 3, Division A, after item "Atezolizumab"—

Add

"Atogepant".

(3) Schedule 3, Division A, after item "Bevacizumab"—

Add

"Bexarotene; its salts".

(4) Schedule 3, Division A, after item "Cannabidiol; its salts; when contained in pharmaceutical products"—

Add

"Cannabinol and its tetrahydro or hexahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item".

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

Add

"Epcoritamab".

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

Add

"Lecanemab".

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

Add

"Perflubutane".

(8) Schedule 3, Division A, after item "Risperidone"—

Add

"Ritlecitinib; its salts".

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

Add

"Somapacitan".

(10) 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，但在與胰島素的混合物內者除外", sub-item "乙醯半胱氨酸"—

Repeal

"醯"

Substitute

"酰".

(11) 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，但在與胰島素的混合物內者除外", sub-item "乙醯膽鹼"—

Repeal

"醯"

Substitute

"酰".

(12) 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，但在與胰島素的混合物內者除外", sub-item "對乙醯氨基酚" —

Repeal

"對乙醯氨基酚"

Substitute

"對乙酰氨基酚(撲熱息痛)".

(13) Schedule 3, Chinese text, Division A, item "蘆非醯胺；其鹽類" —

Repeal

"醯"

Substitute

"酰".

6. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, item "Androgenic, oestrogenic and progestational substances, the following", sub-item "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters", after "esters"—

Add

"; except when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following—

0.15 mg of Desogestrel;

3.00 mg of Drospirenone;

0.05 mg of Ethinyloestradiol;

0.10 mg of Gestodene;

0.25 mg of Levonorgestrel;

2.50 mg of Lynoestrenol;

0.05 mg of Mestranol;

1.00 mg of Norethisterone;

0.25 mg of Norgestimate; and

0.50 mg of Norgestrel".

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

Add

"Atogepant".

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

Add

"Bexarotene; its salts".

(4) Schedule 10, section 2, Table, Part 1, Division A, item "Cannabinol and its tetrahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item", after "tetrahydro"—

Add

"or hexahydro".

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

Add

"Epcoritamab".

(6) Schedule 10, section 2, Table, Part 1, Division A, after item "Lead acetates; compounds of lead with acids from fixed oils"—

Add

"Lecanemab".

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

Add

"Perflubutane".

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

Add

"Ritlecitinib; its salts".

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

Add

"Somapacitan".

(10) 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，但在與胰島素的混合物內者除外", sub-item "乙醯半胱氨酸"—

Repeal

"醯"

Substitute

"酰".

(11) 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，但在與胰島素的混合物內者除外", sub-item "乙醯膽鹼"—

Repeal

"醯"

Substitute

"酰".

(12) 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，但在與胰島素的混合物內者除外", sub-item "對乙醯氨基酚" —

Repeal

"對乙醯氨基酚"

Substitute

"對乙酰氨基酚 (撲熱息痛)".

(13) Schedule 10, Chinese text, section 2, Table, Part 1, Division A, item "蘆非醯胺；其鹽類" —

Repeal

"醯"

Substitute

"酰".

(14) Schedule 10, section 2, Table, Part 2, Division A, after item "Salicylamide; its salts; when contained in pharmaceutical products"—

Add

"Steroid compounds with androgenic or oestrogenic or progestational activity; their esters; when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following—

0.15 mg of Desogestrel;

3.00 mg of Drospirenone;

0.05 mg of Ethinyloestradiol;

0.10 mg of Gestodene;

0.25 mg of Levonorgestrel;

2.50 mg of Lynoestrenol;

0.05 mg of Mestranol;

1.00 mg of Norethisterone;

0.25 mg of Norgestimate; and

0.50 mg of Norgestrel".

(15) Schedule 10, Chinese text, section 2, Table, Part 2, Division A, item "對乙酰氨基酚；其鹽類；但限於包含在藥劑製品內者", after "對乙酰氨基酚" —

Add

"(撲熱息痛)".

Amy CHIU Pui-yin
Chairman,
Pharmacy and Poisons Board

25 June 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 Division A of Schedule 1, Division A of Schedule 3 and Division A of Part 1 of the Poisons List set out in Schedule 10 (***Poisons List***) (see sections 3(2) to (9), 5(2) to (9) and 6(2) to (9) of this Regulation).

2. After the amendments take effect—

(a) 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) 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 A of Group II of Schedule 2 to Cap. 138A so that, after the amendment takes effect, certain oral contraceptive preparations (***specified preparations***) are no longer exempt from the restrictions under the Pharmacy and Poisons Ordinance (Cap. 138) and Cap. 138A. A related amendment is also made to Division A of Part 2 of the Poisons List by this Regulation and the specified preparations would then be regulated under Cap. 138A as

poisons in the Poisons List (see sections 4 and 6(14) of this Regulation).

4. Corresponding amendments, and minor or technical amendments, are also made to Cap. 138A by this Regulation (see sections 3(1) and (10) to (13), 5(1) and (10) to (13) and 6(1), (10) to (13) and (15) of this Regulation).

5. This Regulation, other than sections 3(1), 4, 5(1) and 6(1) and (14) (***remaining provisions***), comes into operation on the day on which it is published in the Gazette. The remaining provisions will come into operation on the expiry of 12 months beginning on that day.