衞生署藥物辦公室
牌照及監察科
香港灣仔皇后大道東248號
大新金融中心20樓2001-2002室

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
Room 2001-2002, 20/F, Dah Sing Financial Centre,
248 Queen's Road East, Wan Chai, Hong Kong

本署檔號 Our Ref.: DH DO/LC/1-10/1
電　　話 Tel.: (852) 2961 8028
圖文傳真 Fax: (852) 3107 0221

28 June 2024

To: All Listed Sellers of Poisons

Dear Sirs,

Amendment to the Pharmacy and Poisons Regulations

Your attention is drawn to the Gazette amendment to the Pharmacy and Poisons Regulations (Cap. 138A) published on 28 June 2024.

With effect from **28 June 2024**, the following amendment was made to Schedule 1 and Part 1 of the Poisons List in Schedule 10 (P1S1):

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

With effect from **28 June 2024**, the following amendment was made to Schedule 3 (S3):

Added:

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

With effect from **28 June 2024**, the following amendment was made to the Chinese text in Part 2 of the Poisons List in Schedule 10 (P2):

"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", **added** " (撲熱息痛)".

Please pay attention to the above amendments and comply with the legal requirements accordingly.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)

We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority

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28 June 2024

To: All Listed Sellers of Poisons

Dear Sirs,

Amendment to the Pharmacy and Poisons Regulations

Your attention is drawn to the Gazette amendment to the Pharmacy and Poisons Regulations (Cap. 138A) published on 28 June 2024.

With effect from **28 June 2025**, the following amendments will be made to Part 1 of the Poisons List in Schedule 10 (P1):

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

Added:

"; 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".

With effect from **28 June 2025**, the following amendments will be made to Schedule 2 (S2):

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

Everything in column 2 repealed, substituted with:

"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".

With effect from **28 June 2025**, the following amendments will be made to Part 2 of the Poisons List in Schedule 10 (P2):

Added:

"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".

Please pay attention to the above amendments and comply with the legal requirements accordingly.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)

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28 June 2024

To: All Authorized Sellers of Poisons

Dear Sirs,

Amendment to the Pharmacy and Poisons Regulations

Your attention is drawn to the Gazette amendment to the Pharmacy and Poisons Regulations (Cap. 138A) published on 28 June 2024.

With effect from **28 June 2024**, the following amendments were made to Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10 (P1S1S3):

Substances added:

a. Atogepant;
b. Bexarotene; its salts;
c. Epcoritamab;
d. Lecanemab;
e. Perflubutane;
f. Ritlecitinib; its salts; and
g. Somapacitan.

With effect from **28 June 2024**, the following amendment was made to Schedule 1 and Part 1 of the Poisons List in Schedule 10 (P1S1):

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

With effect from **28 June 2024**, the following amendment was made to Schedule 3 (S3):

Added:

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

With effect from **28 June 2024**, the following amendments were made to the Chinese text in Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10 (P1S1S3):

a. Repealed "醯" and substituted with "酰" for sub-item "乙醯半胱氨酸" under 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";
b. Repealed "醯" and substituted with "酰" for sub-item "乙醯膽鹼" under 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";

c. Repealed sub-item "對乙醯氨基酚" under 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" and substituted with "對乙酰氨基酚(撲熱息痛)"; and

d. Repealed "醯" and substituted with "酰" for "蘆非醯胺；其鹽類".

With effect from **28 June 2024**, the following amendment was made to the Chinese text in Part 2 of the Poisons List in Schedule 10 (P2):

"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", **added**" (撲熱息痛)".

Please pay attention to the above amendments and comply with the legal requirements accordingly. Please also consult your pharmacist with respect to the pharmaceutical products affected.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)

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28 June 2024

To: All Authorized Sellers of Poisons

Dear Sirs,

Amendment to the Pharmacy and Poisons Regulations

Your attention is drawn to the Gazette amendment to the Pharmacy and Poisons Regulations (Cap. 138A) published on 28 June 2024.

With effect from **28 June 2025**, the following amendments will be made to Schedule 1 and Part 1 of the Poisons List in Schedule 10 (P1S1):

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

Added:

"; 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".

With effect from **28 June 2025**, the following amendments will be made to Schedule 3:

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

Repealed:

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

Substituted with:

"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".

With effect from **28 June 2025**, the following amendments will be made to Schedule 2 (S2): Item "Androgenic, oestrogenic and progestational substances, the following", sub-item relating to "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters"—
Everything in column 2 repealed, substituted with:
"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".

With effect from **28 June 2025**, the following amendments will be made to Part 2 of the Poisons List in Schedule 10 (P2):
Added:
"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".

Please pay attention to the above amendments and comply with the legal requirements accordingly. Please also consult your pharmacist with respect to the pharmaceutical products affected.

Yours faithfully,

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for Assistant Director (Drug)

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28 June 2024

To: All Licensed Wholesale Dealers
All Licensed Pharmaceutical Manufacturers

Dear Sirs,

Amendment to the Pharmacy and Poisons Regulations

Your attention is drawn to the Gazette amendment to the Pharmacy and Poisons Regulations (Cap. 138A) published on 28 June 2024.

With effect from **28 June 2024**, the following amendments were made to Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10 (P1S1S3):

Substances added:

a. Atogepant;
b. Bexarotene; its salts;
c. Epcoritamab;
d. Lecanemab;
e. Perflubutane;
f. Ritlecitinib; its salts; and
g. Somapacitan.

With effect from **28 June 2024**, the following amendment was made to Schedule 1 and Part 1 of the Poisons List in Schedule 10 (P1S1):

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

With effect from **28 June 2024**, the following amendment was made to Schedule 3 (S3):

Added:

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

With effect from **28 June 2024**, the following amendments were made to the Chinese text in Schedule 1, Schedule 3 and Part 1 of the Poisons List in Schedule 10 (P1S1S3):

a. Repealed "醯" and substituted with "酰" for sub-item "乙醯半胱氨酸" under 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";
b. Repealed "醯" and substituted with "酰" for sub-item "乙醯膽鹼" under 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";

c. Repealed sub-item "對乙醯氨基酚" under 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" and substituted with "對乙酰氨基酚(撲熱息痛)"; and

d. Repealed "醯" and substituted with "酰" for "蘆非醯胺；其鹽類".

With effect from **28 June 2024**, the following amendment was made to the Chinese text in Part 2 of the Poisons List in Schedule 10 (P2):

"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", **added**" (撲熱息痛)".

Please pay attention to the above amendments and comply with the legal requirements accordingly.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)

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28 June 2024

To: All Licensed Wholesale Dealers
All Licensed Pharmaceutical Manufacturers

Dear Sirs,

Amendment to the Pharmacy and Poisons Regulations

Your attention is drawn to the Gazette amendment to the Pharmacy and Poisons Regulations (Cap. 138A) published on 28 June 2024.

With effect from **28 June 2025**, the following amendments will be made to Schedule 1 and Part 1 of the Poisons List in Schedule 10 (P1S1):

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

Added:

"; 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".

With effect from **28 June 2025**, the following amendments will be made to Schedule 3:

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

Repealed:

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

Substituted with:

"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".

With effect from **28 June 2025**, the following amendments will be made to Schedule 2 (S2):
Item "Androgenic, oestrogenic and progestational substances, the following", sub-item relating to "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters"—
Everything in column 2 repealed, substituted with:
"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".

With effect from **28 June 2025**, the following amendments will be made to Part 2 of the Poisons List in Schedule 10 (P2):
Added:
"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".

Please pay attention to the above amendments and comply with the legal requirements accordingly.

Yours faithfully,

(Grant NG)
for Assistant Director (Drug)