File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) REGULATION 2015

INTRODUCTION

The Pharmacy and Poisons Board made the Pharmacy and Poisons (Amendment) Regulation 2015 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"). The Amendment Regulation is at **Annex A**.

JUSTIFICATIONS

General Background

2. Under sections 29(l), (o) and (r) of the Ordinance, the Pharmacy and Poisons Board ("the Board") set up under section 3 is empowered to make regulations to regulate and control the sale of poisons and medicines, and to prescribe the Poisons List, subject to section 31 of the Ordinance and to the approval of the Secretary for Food and Health.

Proposal of the Pharmacy and Poisons Board

3. Arising from an application for registration of seventeen pharmaceutical products, the Board proposes to add the following substances to Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in Schedule 10 to the Pharmacy and Poisons Regulations ("PPR"):

(a) Afatinib; its salts
(b) Alogliptin; its salts
(c) Bilastine
(d) Brentuximab vedotin
(e) Canagliflozin; its salts
(f) Dabrafenib; its salts

(g) Decitabine; its salts
(h) Dolutegravir; its salts
(i) Enzalutamide; its salts
(j) Ipilimumab
(k) Ocriplasmin
(l) Radium-223; its salts; when contained in pharmaceutical products
(m) Riociguat; its salts
(n) Sofosbuvir; its salts
(o) Teriflunomide; its salts
(p) Trastuzumab; its antibody drug conjugates
(q) Zofenopril; its salts

4. Details of the above medicines are set out at **Annex B**. The registration of the above substance "Trastuzumab; its antibody drug conjugates" will replace the substance "Trastuzumab" in Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in Schedule 10 to the PPR.

5. Besides, in order to enhance the safety of the substance "Domperidone; its salts" in Division A of Part I of the Poisons List set out in Schedule 10 to the PPR, the substance will be added to Division A of the First Schedule and Division A of the Third Schedule. The change will come into operation on 15 May 2015.

6. The Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the substances.

THE AMENDMENT REGULATION

7. The Amendment Regulation is to add the above drugs (in para 3 to 5) to the PPR.

LEGISLATIVE TIMETABLE

8. The legislative timetable will be –

Publication in the Gazette	13 February 2015

Date of Commencement 13 February 2015
(Except for the amendment relating to "Domperidone; its salts" in para 5)

IMPLICAIONS OF THE PROPOSAL

9. The proposal will allow early control and legitimate sale of the relevant medicines as appropriate.

ENQUIRY

10. For any enquiries on the brief, please contact Mr Chow Tat-wing, Assistant Secretary for Food and Health at 3509 8956.

Food and Health Bureau
February 2015

Pharmacy and Poisons (Amendment) Regulation 2015

(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(9) and 4(9) come into operation on 15 May 2015.

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. First Schedule 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) First Schedule, Division A, after item "Adefovir; its salts; its esters; their salts"—

Add

"Afatinib; its salts".

(2) First Schedule, Division A, after item "Almitrine; its salts"—

Add

"Alogliptin; its salts".

(3) First Schedule, Division A, item relating to "Antihistamine substances", after item "Astemizole"—

Add

"Bilastine".

(4) First Schedule, Division A, after item "Botulinum toxin complexes"—

Add

"Brentuximab vedotin".

(5) First Schedule, Division A, after item "Calcipotriol; its salts"—

Add

"Canagliflozin; its salts".

(6) First Schedule, Division A, after item "Dabigatran etexilate; its salts"—

Add

"Dabrafenib; its salts".

(7) First Schedule, Division A, after item "Debrisoquine; its salts"—

Add

"Decitabine; its salts".

(8) First Schedule, Division A, after item "Docetaxel; its salts"—

Add

"Dolutegravir; its salts".

(9) First Schedule, Division A, before item "Donepezil; its salts"—

Add

"Domperidone; its salts".

(10) First Schedule, Division A, after item "Entecavir; its salts; its esters; their salts"—

Add

"Enzalutamide; its salts".

(11) First Schedule, Division A, after item "Interferons"—

Add

"Ipilimumab".

(12) First Schedule, Division A, after item "Nortriptyline; its salts"—

Add

"Ocriplasmin".

(13) First Schedule, Division A, after item "Ractopamine; its salts"—

Add

"Radium-223; its salts; when contained in pharmaceutical products".

(14) First Schedule, Division A, after item "Rimonabant; its salts"—

Add

"Riociguat; its salts".

(15) First Schedule, Division A, after item "Sodium nitroprusside"—

Add

"Sofosbuvir; its salts".

(16) First Schedule, Division A, after item "Terbutaline and its salts when contained in aerosol dispensers"—

Add

"Teriflunomide; its salts".

(17) First Schedule, Division A—

Repeal item "Trastuzumab"

Substitute

"Trastuzumab; its antibody drug conjugates".

(18) First Schedule, Division A, after item "Ziprasidone; its salts"—

Add

"Zofenopril; its salts".

4. Third Schedule 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) Third Schedule, Division A, after item "Adefovir; its salts; its esters; their salts"—

Add

"Afatinib; its salts".

(2) Third Schedule, Division A, after item "Almitrine; its salts"—

Add

"Alogliptin; its salts".

(3) Third Schedule, Division A, item relating to "Antihistamine substances", after item "Astemizole"—

Add

"Bilastine".

(4) Third Schedule, Division A, after item "Botulinum toxin complexes"—

Add

"Brentuximab vedotin".

(5) Third Schedule, Division A, after item "Calcipotriol; its salts"—

Add

"Canagliflozin; its salts".

(6) Third Schedule, Division A, after item "Dabigatran etexilate; its salts"—

Add

"Dabrafenib; its salts".

(7) Third Schedule, Division A, after item "Debrisoquine; its salts"—

Add

"Decitabine; its salts".

(8) Third Schedule, Division A, after item "Docetaxel; its salts"—

Add

"Dolutegravir; its salts".

(9) Third Schedule, Division A, before item "Donepezil; its salts"—

Add

"Domperidone; its salts".

(10) Third Schedule, Division A, after item "Entecavir; its salts; its esters; their salts"—

Add

"Enzalutamide; its salts".

(11) Third Schedule, Division A, after item "Interferons"—

Add

"Ipilimumab".

(12) Third Schedule, Division A, after item "Nortriptyline; its salts"—

Add

"Ocriplasmin".

(13) Third Schedule, Division A, after item "Ractopamine; its salts"—

Add

"Radium-223; its salts; when contained in pharmaceutical products".

(14) Third Schedule, Division A, after item "Rimonabant; its salts"—

Add

"Riociguat; its salts".

(15) Third Schedule, Division A, after item "Sodium nitroprusside"—

Add

"Sofosbuvir; its salts".

(16) Third Schedule, Division A, after item "Terbutaline and its salts when contained in aerosol dispensers"—

Add

"Teriflunomide; its salts".

(17) Third Schedule, Division A—

Repeal item "Trastuzumab"

Substitute

"Trastuzumab; its antibody drug conjugates".

(18) Third Schedule, Division A, after item "Ziprasidone; its salts"—

Add

"Zofenopril; its salts".

5. Schedule 10 amended (Poisons List)

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

Add

"Afatinib; its salts".

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

Add

"Alogliptin; its salts".

(3) Schedule 10, section 2, Table, Part I, Division A, item relating to "Antihistamine substances", after item "Azelastine"—

Add

"Bilastine".

(4) Schedule 10, section 2, Table, Part I, Division A, after item "Botulinum toxin complexes"—

Add

"Brentuximab vedotin".

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

Add

"Canagliflozin; its salts".

(6) Schedule 10, section 2, Table, Part I, Division A, after item "Dabigatran etexilate; its salts"—

Add

"Dabrafenib; its salts".

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

Add

"Decitabine; its salts".

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

Add

"Dolutegravir; its salts".

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

Add

"Enzalutamide; its salts".

(10) Schedule 10, section 2, Table, Part I, Division A, after item "Interferons"—

Add

"Ipilimumab".

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

Add

"Ocriplasmin".

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

Add

"Radium-223; its salts; when contained in pharmaceutical products".

(13) Schedule 10, section 2, Table, Part I, Division A, after item "Rimonabant; its salts"—

Add

"Riociguat; its salts".

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

Add

"Sofosbuvir; its salts".

(15) Schedule 10, section 2, Table, Part I, Division A, after item "Terconazole; its salts"—

Add

"Teriflunomide; its salts".

(16) Schedule 10, section 2, Table, Part I, Division A—

Repeal item "Trastuzumab"

Substitute

"Trastuzumab; its antibody drug conjugates".

(17) Schedule 10, section 2, Table, Part I, Division A, after item "Ziprasidone; its salts"—

Add

"Zofenopril; its salts".

Chairman,
Pharmacy and Poisons Board

9 February 2015

Explanatory Note

This Regulation—

(a) adds 17 substances to Division A of the First Schedule and Division A of the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations;

(b) adds 16 substances to Division A of Part I of the Poisons List set out in Schedule 10 to the principal Regulations so that, among other applicable requirements, poisons containing those substances can only be sold on any 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

(c) replaces the substance "Trastuzumab" in Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in Schedule 10 to the principal Regulations by "Trastuzumab; its antibody drug conjugates".

Pharmacy and Poisons (Amendment) Regulation 2015

Supplementary Information to the Legislative Council

《2015年藥劑業及毒藥（修訂）規例》
提交立法會的補充資料

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Afatinib; its salts	Part I, First and Third Schedules poison	This drug is used for the treatment of Epidermal Growth Factor Receptor (EGFR) tyrosine kinase inhibitor-naïve adult patients with locally advanced or metastatic non-small cell lung cancer with activating EGFR mutation(s). Side effects include paronychia, decreased appetite, dysgeusia, conjunctivitis, epistaxis, diarrhoea, stomatitis, rash, dry skin, muscle spasms, renal impairment/renal failure, pyrexia and weight decreased. Its use should be decided by a doctor based on the patient's conditions.
阿法替尼；其鹽類	第一部附表一及附表三毒藥	此藥物用於治療未曾使用過表皮生長因子受體酪氨酸激酶抑制劑，而患有局部晚期或轉移性附有表皮生長因子受體活躍突變的非小細胞肺癌的成年患者。 副作用包括甲溝炎、食慾下降、味覺障礙、結膜炎、流鼻血、腹瀉、口腔炎、皮疹、皮膚乾燥、肌肉痙攣、腎功能障礙/衰竭、發熱和體重下降。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Alogliptin; its salts	Part I, First and Third Schedules poison	This drug is used in a combination product with pioglitazone to improve glycemic control in adult patients with type 2 diabetes mellitus. When the drug is used in combination with pioglitazone, their side effects include anaemia, atrial fibrillation, congestive cardiac failure, vertigo, constipation, pyrexia, influenza, nasopharyngitis, blood creatinine increased, hepatic enzyme increased, dyslipidaemia, hypertriglyceridaemia, arthralgia, headache, paraesthesia, depression, insomnia, haematuria, dyspnoea and hypertension. Its use should be decided by a doctor based on the patient's conditions.
阿格列汀；其鹽類	第一部附表一及附表三毒藥	此藥物與吡格列酮同在於一款混合型產品，用作改善糖尿病二型成年患者的血糖控制。 此藥物與吡格列酮同用時的副作用包括貧血、心房顫動、充血性心臟衰竭、頭暈、便秘、發熱、感冒、鼻咽炎、血肌酐升高、肝酵素升高、血脂異常、高甘油三酯血症、關節痛、頭痛、感覺異常、抑鬱、失眠、血尿、呼吸困難和高血壓。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Bilastine; its salts; its esters; their salts	Part I, First and Third Schedules poison	This drug is used for the symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Side effects include oral herpes, increased appetite, anxiety, insomnia, tinnitus, vertigo, sinus arrhythmia, electrocardiogram QT prolonged, somnolence, headache, dyspnoea, nasal discomfort, abdominal pain, nausea, pruritus, fatigue, thirst, increased gamma-glutamyltransferase and increased alanine aminotransferase. Its use should be decided by a doctor based on the patient's conditions.
比拉斯汀；其鹽類; 其酯類; 它們的鹽類	第一部附表一及附表三毒藥	此藥物用於治療過敏性鼻炎及結膜炎（季節性和持續性）和蕁麻疹的引起的症狀。 副作用包括口腔疱疹、食慾增加、焦慮、失眠、耳鳴、眩暈、竇性心律不齊、心電圖QT延長、嗜睡、頭痛、呼吸困難、鼻腔不適、腹痛、噁心、皮膚瘙癢、疲勞、口渴、γ-谷氨酰轉移酶升高和丙氨酸轉移酶升高。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Brentuximab vedotin	Part I, First and Third Schedules poison	This drug is used for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma following autologous stem cell transplant (ASCT) or following at least 2 prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and with relapsed or refractory systemic anaplastic large cell lymphoma. Side effects include upper respiratory tract infection, herpes zoster, pneumonia, neutropenia, anaemia, thrombocytopenia, anaphylactic reaction, hyperglycaemia, dizziness, cough, dyspnoea, diarrhoea, nausea, vomiting, alopecia, rash, myalgia, arthralgia, fatigue and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
維布妥昔單抗	第一部附表一及附表三毒藥	此藥物用於治療復發或難治性CD30+型霍奇金氏淋巴瘤的成年患者，並當該患者經自身幹細胞移植，或當經歷最少兩類自身幹細胞移植或多項化療的療程均屬不合適的選項時使用，以及用於復發或難治性全身間變性大型細胞淋巴瘤的成年患者。 副作用包括上呼吸道感染、帶狀疱疹、肺炎、中性粒細胞減少、貧血、血小板減少、過敏性反應、高血糖、頭暈、咳嗽、呼吸困難、腹瀉、噁心、嘔吐、脫髮、紅疹、肌肉疼痛、關節疼痛、疲勞和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Canagliflozin; its salts	Part I, First and Third Schedules poison	This drug is used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Side effects include hypotension, impairment in renal function, hyperkalemia, hypoglycemia, hypersensitivity reactions, increased low-density lipoprotein, urinary tract infection, increased urination, thirst, constipation and nausea. Its use should be decided by a doctor based on the patient's conditions.
卡格列淨；其鹽類	第一部附表一及附表三毒藥	此藥物用作輔助飲食和運動，以改善糖尿病二型成年患者的血糖控制。 副作用包括低血壓、腎功能受損、高血鉀症，低血糖、過敏反應、增加低密度脂蛋白、尿道感染、小便增多、口渴、便秘和噁心。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Dabrafenib; its salts	Part I, First and Third Schedules poison	This drug is used in monotherapy for the treatment of adult patients with unresectable or metastatic melanoma with BRAF V600 mutation. Side effects include papilloma, cutaneous squamous cell carcinoma, hypersensitivity, panniculitis, decreased appetite, hypophosphataemia, headache, cough, nausea, vomiting, hyperkeratosis, alopecia, arthralgia, myalgia, renal failure, nephritis, pyrexia and fatigue. Its use should be decided by a doctor based on the patient's conditions.
達拉非尼；其鹽類	第一部附表一及附表三毒藥	此藥物單獨用於治療呈現BRAF V600突變屬不可切除或轉移性黑色素瘤的成年患者。 副作用包括乳頭狀瘤、皮膚鱗狀細胞癌、過敏反應、脂膜炎、食慾下降、低磷酸鹽血症、頭痛、咳嗽、噁心、嘔吐、角化過度、脫髮、關節痛、肌肉痛、腎功能衰竭、腎炎、發熱和疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Decitabine; its salts	Part I, First and Third Schedules poison	This drug is used for the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia, according to the World Health Organisation classification, who are not candidates for standard induction chemotherapy. Side effects include pneumonia, urinary tract infection, neutropenia, thrombocytopenia, anaemia, leukopenia, headache, epistaxis, diarrhea, vomiting, nausea and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
地西他濱；其鹽類	第一部附表一及附表三毒藥	此藥物用於治療65歲及以上的成年患者，患有被世界衛生組織分類為不合適接受正常入門化療，屬新斷症原發性或繼發性的急性骨髓性白血病。 副作用包括肺炎、尿道感染、中性粒細胞減少、血小板減少、貧血、白血球減少、頭痛、鼻出血、腹瀉、嘔吐、噁心和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Dolutegravir; its salts	Part I, First and Third Schedules poison	This drug is used in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus infected adults and adolescents above 12 years of age. Side effects include insomnia, headache, dizziness, nausea, diarrhoea, vomiting, abdominal pain, rash and fatigue. Its use should be decided by a doctor based on the patient's conditions.
多替拉韋；其鹽類	第一部附表一及附表三毒藥	此藥物與其他抗逆轉錄病毒藥物結合使用，治療患有人類缺乏免疫力病毒感染的成年和12歲以上的青少年患者。 副作用包括失眠、頭痛、頭暈、噁心、腹瀉、嘔吐、腹痛、皮疹和疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Domperidone; its salts 多潘立酮；其鹽類	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for relieving the symptoms of nausea and vomiting. Side effects include dry mouth, galactorrhoea, gynaecomastia, amenorrhoea, QT prolongation, serious ventricular arrhythmias, sudden cardiac death, nervousness, asthenia, headache, urinary retention, and abnormal liver function tests. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於紓緩噁心和嘔吐的症狀。 副作用包括口乾、乳溢、男性乳房發育、閉經、延長QT間距、嚴重室性心律不齊、突發性心臟猝死、精神緊張、乏力、頭痛、尿液滯流和肝功能測試異常。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Enzalutamide; its salts	Part I, First and Third Schedules poison	This drug is used for the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy. Side effects include neutropenia, leucopenia, visual hallucinations, anxiety, headache, cognitive disorder, memory impairment, seizure, hot flush, hypertension, pruritus and fractures. Its use should be decided by a doctor based on the patient's conditions.
恩扎盧胺；其鹽類	第一部附表一及附表三毒藥	此藥物用於治療正接受或已接受多西紫杉醇療程但病情仍惡化，屬轉移性不可切除前列腺癌的成年男子。 副作用包括中性粒細胞減少、白血球減少、視幻覺，焦慮、頭痛、認知障礙、記憶障礙、癲癇、潮熱、高血壓、瘙癢和骨折。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Ipilimumab	Part I, First and Third Schedules poison	This drug is used for the treatment of advanced unresectable or metastatic melanoma in adults. Side effects include sepsis, septic shock, tumour pain, anaemia, lymphopenia, hypersensitivity, hypopituitarism, hypothyroidism, decrease appetite, dehydration, peripheral sensory neuropathy, dizziness, blurred vision, eye pain, arrhythmia, hypotension, flushing, dyspnea, cough, diarrhea, vomiting, abnormal hepatic function, rash, pruritus, arthralgia and myalgia. Its use should be decided by a doctor based on the patient's conditions.
伊匹木單抗	第一部附表一及附表三毒藥	此藥物用於治療晚期不可切除或轉移性黑色素瘤的成年患者。 副作用包括膿毒症、感染性休克、腫瘤疼痛 、貧血、淋巴細胞減少、過敏反應、腦下垂體機能減退症、甲狀腺機能減退症、食慾下降、脫水、周邊感官神經病變、頭暈、視力模糊、眼痛、心律失常、低血壓、潮紅、呼吸困難、咳嗽、腹瀉、嘔吐、肝功能異常、皮疹、瘙癢、關節痛和肌痛。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Ocriplasmin	Part I, First and Third Schedules poison	This drug is used in adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. Side effects include vitreous floaters, eye pain, photopsia, vitreous haemorrhage, conjunctival haemorrhage, reduced visual acuity, visual impairment, retinal tear, retinal detachment, and increased intraocular pressure. Its use should be decided by a doctor based on the patient's conditions.
奧克纖溶酶	第一部附表一及附表三毒藥	此藥物用於治療玻璃體黃斑牽引，包括相關的黃斑裂孔直徑為小於或等於400微米的成年患者。 副作用包括玻璃體漂浮物、眼痛、閃光幻覺，玻璃體出血、眼結膜出血、視力降低、視力障礙、視網膜撕裂、視網膜脫落和眼內壓增高。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Radium-223; its salts; when contained in pharmaceutical products	Part I, First and Third Schedules poison	This drug is used for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. Side effects include thrombocytopenia, neutropenia, pancytopenia, leukopenia, diarrhoea, vomiting, nausea and injection site reactions. Its use should be decided by a doctor based on the patient's conditions.
鐳-223；其鹽類; 限於包含在藥劑製品者	第一部附表一及附表三毒藥	此藥用於治療患有不可切除前列腺癌、帶有骨性轉移症狀及沒有已知內臟轉移的成年患者。 副作用包括血小板減少、中性粒細胞減少、全血細胞減少、白血球減少、腹瀉、嘔吐、噁心和注射部位反應。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Riociguat; its salts	Part I, First and Third Schedules poison	This drug is used for the treatment of adult patients with WHO Functional Class II to III with inoperable chronic thromboembolic pulmonary hypertension (CTEPH), persistent or recurrent CTEPH after surgical treatment or pulmonary arterial hypertension to improve exercise capacity. Side effects include dizziness, headache, dyspepsia, diarrhoea, nausea, vomiting, peripheral oedema, gastroenteritis, anaemia, palpitations, hypotension, haemoptysis, epistaxis and nasal congestion. Its use should be decided by a doctor based on the patient's conditions.
利奧西呱；其鹽類	第一部附表一及附表三毒藥	此藥物用於治療屬世界衞生組織II及III功能級別，並不能進行手術的慢性血栓栓塞性肺高血壓症〔CTEPH〕，或手術治療後的持續或復發性CTEPH，或肺動脈高血壓症的成年患者，使提高其運動能力。 副作用包括頭暈、頭痛、消化不良、腹瀉、噁心、嘔吐、周邊水腫、腸胃炎、貧血、心悸、低血壓、咳血、流鼻血和鼻塞。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Sofosbuvir; its salts	Part I, First and Third Schedules poison	This drug is used in combination with other medicinal products for the treatment of chronic hepatitis C in adults. Side effects include nasopharyngitis, haemoglobin decreased, anaemia, neutropenia, lymphocyte count decreased, platelet count decreased, decreased appetite, insomnia, headache, dizziness, dyspnoea, cough, nausea, diarrhea, vomiting, rash, arthralgia, myalgia, fatigue, and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
索磷布韋；其鹽類	第一部附表一及附表三毒藥	此藥物與其他藥物結合使用於治療慢性丙型肝炎的成年患者。 副作用包括鼻咽炎、血紅蛋白減少、貧血、中性粒細胞減少、淋巴細胞數量減少、血小板數量減少、食慾下降、失眠、頭痛、頭暈、呼吸困難、咳嗽、噁心、腹瀉、嘔吐、紅疹、關節疼痛、肌肉疼痛、疲倦和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Teriflunomide; its salts	Part I, First and Third Schedules poison	This drug is used for the treatment of adult patients with relapsing remitting multiple sclerosis. Side effects include influenza, upper respiratory tract infection, urinary tract infection, neutropenia, anxiety, paraesthesia, hypertension, diarrhoea, nausea, alopecia and musculoskeletal pain. Its use should be decided by a doctor based on the patient's conditions.
特立氟胺；其鹽類	第一部附表一及附表三毒藥	此藥用於治療復發性緩解型多發性硬化症的成年患者。 副作用包括流行性感冒、上呼吸道感染、尿道感染、中性粒細胞減少、焦慮、感覺異常、高血壓、腹瀉、噁心、禿頭、和肌肉骨骼疼痛。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Trastuzumab; its antibody drug conjugates	Part I, First and Third Schedules poison	This drug is used for the treatment of patients with HER2-positive metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Side effects include neutropenia, anemia, thrombocytopenia, left ventricular dysfunction, increased lacrimation, dry eyes, dyspepsia, stomatitis, peripheral edema, chills, nodular regenerative hyperplasia, portal hypertension, drug hypersensitivity, urinary tract infection, increased blood alkaline phosphatase, increased transaminases, hypokalemia, myalgia, arthralgia, dysgeusia, dizziness, insomnia, pneumonitis, dyspnoea, pruritus, rash and hypertension. Its use should be decided by a doctor based on the patient's conditions.
曲妥珠單抗；其抗體藥物結合體	第一部附表一及附表三毒藥	此藥物用於治療曾接受曲妥珠單抗和紫杉烷的獨立或合併療程的HER2呈陽性反應的轉移性乳癌患者。 副作用包括中性粒細胞減少、貧血、血小板減少症、左心室功能失常、淚液分泌增加、眼乾、消化不良、口腔炎、周邊水腫、發冷、結節再生性增生、門靜脈血壓過高、藥物過敏、尿道感染、血液鹼性磷酸酶升高、轉氨酶升高、低血鉀、肌肉疼痛、關節疼痛、味覺障礙、頭暈、失眠、肺炎、呼吸困難、皮膚瘙癢、皮疹和高血壓。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	**Proposed Classification** 建議類別	**Reasons** 原因
Zofenopril; its salts	Part I, First and Third Schedules poison	This combination drug with hydrochlorothiazide is used for the treatment of mild to moderate essential hypertension in patients whose blood pressure is not adequately controlled on Zofenopril alone. Side effects include dizziness, headache, cough, nausea, vomiting and fatigue. Its use should be decided by a doctor based on the patient's conditions.
佐芬普利；其鹽類	第一部附表一及附表三毒藥	此藥物與氫氯噻嗪作為混合藥物用於治療不能單獨以佐芬普利有效控制血壓，屬輕度至中度原發性高血壓的病人。 副作用包括頭暈、頭痛、咳嗽、噁心、嘔吐和疲勞。 使用此藥物與否，須由醫生按病人情況決定。