File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 5) REGULATION 2015

INTRODUCTION

The Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations") was made under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance"). The Pharmacy and Poisons (Amendment) (No. 5) Regulation 2015 ("the Amendment Regulation") at **Annex A** is to amend the First, Third and Tenth Schedules to the Regulations.

JUSTIFICATIONS

General Background

2. Under section 29(1B) of the Ordinance, the Pharmacy and Poisons Board ("the Board") set up under section 3 of the Ordinance is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Regulations, including the First Schedule and Third Schedule to the Regulations, 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 twelve 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 the Tenth Schedule to the Regulations:

(a) Dasabuvir; its salts
(b) Empagliflozin; its salts
(c) Ibrutinib; its salts
(d) Idelalisib; its salts
(e) Ledipasvir; its salts

(f) Linaclotide; its salts
(g) Obinutuzumab; its antibody drug conjugates
(h) Ombitasvir; its salts
(i) Paritaprevir; its salts
(j) Pomalidomide; its salts
(k) Rufinamide; its salts
(l) Vedolizumab

4. Details of the above substances are set out at **Annex B**. The Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the substances.

THE AMENDMENT REGULATION

5. The Amendment Regulation is to add the substances listed in paragraph 3 above to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	9 October 2015
Date of Commencement	9 October 2015

IMPLICATIONS OF THE PROPOSAL

7. The proposal will impose appropriate control on pharmaceutical products consisting of the above substances so that they can be sold in the market upon fulfillment of the relevant regulations.

ENQUIRY

8. 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
October 2015

Pharmacy and Poisons (Amendment) (No. 5) 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. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2, 3 and 4.

2. 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 "Darunavir; its salts"—

Add

"Dasabuvir; its salts".

(2) First Schedule, Division A, after item "Embutramide"—

Add

"Empagliflozin; its salts".

(3) First Schedule, Division A, after item "Ibritumomab tiuxetan"—

Add

"Ibrutinib; its salts".

(4) First Schedule, Division A, before item "Idursulfase"—

Add

"Idelalisib; its salts".

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

Add

"Ledipasvir; its salts".

(6) First Schedule, Division A, after item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"—

Add

"Linaclotide; its salts".

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

Add

"Obinutuzumab; its antibody drug conjugates".

(8) First Schedule, Division A, after item "Omalizumab"—

Add

"Ombitasvir; its salts".

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

Add

"Paritaprevir; its salts".

(10) First Schedule, Division A, after item "Polymethylenebistrimethylammonium salts"—

Add

"Pomalidomide; its salts".

(11) First Schedule, Division A, after item "Rotigotine; its salts"—

Add

"Rufinamide; its salts".

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

Add

"Vedolizumab".

3. 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 "Darunavir; its salts"—

Add

"Dasabuvir; its salts".

(2) Third Schedule, Division A, after item "Embutramide"—

Add

"Empagliflozin; its salts".

(3) Third Schedule, Division A, after item "Ibritumomab tiuxetan"—

Add

"Ibrutinib; its salts".

(4) Third Schedule, Division A, before item "Idursulfase"—

Add

"Idelalisib; its salts".

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

Add

"Ledipasvir; its salts".

(6) Third Schedule, Division A, after item "Lignocaine; its salts in mixture with tetracaine or in mixture with the salts of tetracaine"—

Add

"Linaclotide; its salts".

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

Add

"Obinutuzumab; its antibody drug conjugates".

(8) Third Schedule, Division A, after item "Omalizumab"—

Add

"Ombitasvir; its salts".

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

Add

"Paritaprevir; its salts".

(10) Third Schedule, Division A, after item "Polymethylenebistrimethylammonium salts"—

Add

"Pomalidomide; its salts".

(11) Third Schedule, Division A, after item "Rotigotine; its salts"—

Add

"Rufinamide; its salts".

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

Add

"Vedolizumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Dasabuvir; its salts".

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

Add

"Empagliflozin; its salts".

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

Add

"Ibrutinib; its salts".

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

Add

"Idelalisib; its salts".

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

Add

"Ledipasvir; its salts".

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

Add

"Linaclotide; its salts".

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

Add

"Obinutuzumab; its antibody drug conjugates".

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

Add

"Ombitasvir; its salts".

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

Add

"Paritaprevir; its salts".

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

Add

"Pomalidomide; its salts".

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

Add

"Rufinamide; its salts".

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

Add

"Vedolizumab".

Chairman,
Pharmacy and Poisons Board

29 September 2015

Explanatory Note

This Regulation—

(a) adds 12 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; and

(b) adds 12 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 may only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the presence and under the supervision of a registered pharmacist.

Annex B
附件 B

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2015

Supplementary Information to the Legislative Council

《2015年藥劑業及毒藥（修訂）（第5號）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**
Dasabuvir; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in a combination product with ombitasvir, paritaprevir and ritonavir for the treatment of patients with genotype 1 chronic hepatitis C virus infection including those with compensated cirrhosis. Side effects of the aforementioned combination product include fatigue, nausea, pruritus and insomnia. Its use should be decided by a doctor based on the patient's conditions.
達塞布韋；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物與奧比他韋、帕立瑞韋及利托那韋同用於一款混合型產品，治療屬基因一型的慢性丙型肝炎病毒感染，包括屬代償性肝硬化的患者。 上述混合型產品的副作用包括疲勞、噁心、瘙癢和失眠。 使用此藥物與否，須由醫生按病人情況決定。

Empagliflozin; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as monotherapy or add-on combination therapy. Side effects include urinary tract infection, pruritus, and increased urination. Its use should be decided by a doctor based on the patient's conditions.
恩格列淨；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於單一或附加綜合療法，治療糖尿病二型的成年患者，改善其血糖控制。 副作用包括尿道感染、瘙癢和排尿增加。 使用此藥物與否，須由醫生按病人情況決定。
Ibrutinib; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy, or as first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. Side effects include diarrhea, musculoskeletal pain, upper respiratory tract infection, rash, nausea, pyrexia, neutropenia and constipation. Its use should be decided by a doctor based on the patient's conditions.
伊布替尼；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於治療患有慢性淋巴細胞性白血病的成年病人，而該患者已經接受最少一次療法；或作為一線療法，用於出現17p刪除或TP53基因變異，不適合進行化學免疫療法的患者。 副作用包括腹瀉、肌肉及骨骼疼痛、上呼吸道感染、紅疹、噁心、發燒、中性粒細胞減少及便秘。 使用此藥物與否，須由醫生按病人情況決定。

Idelalisib; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukaemia for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. It is also used for the treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma and relapsed small lymphocytic lymphoma, who have received at least two prior systemic therapies. Side effects include pyrexia, nausea, pneumonia, diarrhoea, chills, fatigue and cough. Its use should be decided by a doctor based on the patient's conditions.
伊德利塞；其鹽類	附表十第一部、 附表一及 附表三毒藥	此藥物與利妥昔單抗同用於治療患有復發性慢性淋巴細胞白血病，而因其他合併症被認為適合單獨使用利妥昔單抗治療的患者。此藥物亦用於治療曾經接受最少兩款系統性治療，患有復發性濾泡性B細胞非霍奇金氏淋巴瘤，及復發性小淋巴細胞淋巴瘤的患者。 副作用包括發熱、噁心、肺炎、腹瀉、發冷、疲倦和咳嗽。 使用此藥物與否，須由醫生按病人情況決定。

Ledipasvir ; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in a combination product with sofosbuvir for the treatment of chronic hepatitis C genotype 1 infection in adults. Side effects include fatigue, headache, nausea, diarrhoea and insomnia. Its use should be decided by a doctor based on the patient's conditions.
來迪派韋；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物與索磷布韋同用於一款混合型產品，治療屬慢性丙型肝炎基因一型感染的成年患者。 副作用包括疲倦、頭痛、噁心、腹瀉和失眠。 使用此藥物與否，須由醫生按病人情況決定。
Linaclotide; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation in adults. Side effects include diarrhoea, viral gastroenteritis, abdominal pain, flatulence, abdominal distention and dizziness. Its use should be decided by a doctor based on the patient's conditions.
利那洛肽；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用於對症治療帶有便秘，屬中度至嚴重程度的腸易激綜合症的成年患者。 副作用包括腹瀉、病毒性胃腸炎、腹痛、腸胃氣脹、腹脹和頭暈。 使用此藥物與否，須由醫生按病人情況決定。

Obinutuzumab; its antibody drug conjugates	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in combination with chlorambucil for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia and with comorbidities making them unsuitable for full-dose fludarabine therapy. Side effects include neutropenia, thrombocytopenia, anaemia, diarrhoea and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
阿托珠單抗；其抗體藥物結合體	附表十第一部、 附表一及 附表三毒藥	此藥物與苯丁酸氮芥同用於治療患有未曾接受治療的慢性淋巴細胞性白血病並因有合併症而不適合接受全劑量氟達拉濱療法的成年病人。 副作用包括中性粒細胞減少、血小板減少、貧血、腹瀉和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Ombitasvir; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in a combination product with dasabuvir, paritaprevir and ritonavir for the treatment of patients with genotype 1 chronic hepatitis C virus infection including those with compensated cirrhosis. Side effects of the aforementioned combination product include fatigue, nausea, pruritus and insomnia. Its use should be decided by a doctor based on the patient's conditions.
奧比他韋；其鹽類	附表十第一部、 附表一及 附表三毒藥	此藥物與達塞布韋、帕立瑞韋及利托那韋同用於一款混合型產品，治療屬基因一型的慢性丙型肝炎病毒感染，包括屬代償性肝硬化的患者。 上述混合型產品的副作用包括疲勞、噁心、瘙癢和失眠。 使用此藥物與否，須由醫生按病人情況決定。

Paritaprevir; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in a combination product with dasabuvir, ombitasvir and ritonavir for the treatment of patients with genotype 1 chronic hepatitis C virus infection including those with compensated cirrhosis. Side effects of the aforementioned combination product include fatigue, nausea, pruritus and insomnia. Its use should be decided by a doctor based on the patient's conditions.
帕立瑞韋；其鹽類	附表十第一部、 附表一及 附表三毒藥	此藥物與達塞布韋、奧比他韋及利托那韋同用於一款混合型產品，治療屬基因一型的慢性丙型肝炎病毒感染，包括屬代償性肝硬化的患者。 上述混合型產品的副作用包括疲勞、噁心、瘙癢和失眠。 使用此藥物與否，須由醫生按病人情況決定。

Pomalidomide; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Side effects include pneumonia, neutropenia, thrombocytopenia, leucopenia, anaemia, cough, diarrhoea, nausea, constipation, bone pain, muscle pain, and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
泊馬度胺；其鹽類	附表十第一部、 附表一及 附表三毒藥	此藥物與地塞米松同用於治療患有復發性和難治性多發骨髓瘤的成年病人，而該患者曾之前接受最少兩款治療方案，包括來那度胺和硼替佐米，並在最後一次療程後証實病情惡化。 副作用包括肺炎、中性粒細胞減少、血小板減少、白細胞減少、貧血、咳嗽、腹瀉、噁心、便秘、骨痛、肌肉疼痛和發熱。 使用此藥物與否，須由醫生按病人情況決定。

Rufinamide; its salts	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older. Side effects include somnolence, headache, dizziness, nausea and vomiting. Its use should be decided by a doctor based on the patient's conditions.
蘆非醯胺；其鹽類	附表十第一部、附表一及附表三毒藥	此藥物用作輔助療法，治療4歲及以上患有Lennox-Gastaut綜合症導致癲癇的病人。 副作用包括嗜睡、頭痛、頭暈、噁心和嘔吐。 使用此藥物與否，須由醫生按病人情況決定。
Vedolizumab	Part I of Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with moderately to severely active ulcerative colitis, or Crohn's disease, who have an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha antagonist. Side effects include nasopharyngitis, headache and arthralgia. Its use should be decided by a doctor based on the patient's conditions.
維多珠單抗	附表十第一部、附表一及附表三毒藥	此藥物用於治療對傳統療法或alpha-腫瘤壞死因子對抗劑反應欠佳、失去反應、或不能耐受，患有中至嚴重情度活躍性潰瘍結腸炎或克羅恩病的成年患者。 副作用包括鼻咽炎、頭痛和關節痛。 使用此藥物與否，須由醫生按病人情況決定。