File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) REGULATION 2016

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) Regulation 2016 ("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, 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 applications for registration of seven 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) Bivalirudin; its salts
(b) Delamanid; its salts
(c) Dimethyl fumarate; when contained in pharmaceutical products
(d) Macitentan; its salts
(e) Nintedanib; its salts

(f) Paracetamol; when contained in pharmaceutical products for human parenteral administration
(g) Ramucirumab

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 mentioned in paragraph 3 above to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	11 March 2016
Date of Commencement	11 March 2016

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, please contact Mr Lam Fong-tat James, Assistant Secretary for Food and Health at 3509 8956.

Food and Health Bureau
March 2016

Pharmacy and Poisons (Amendment) Regulation 2016

(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. 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 "Bitolterol and its salts when contained in aerosol dispensers"—

Add

"Bivalirudin; its salts".

(2) Schedule 1, Division A, after item "Dehydroemetine; its salts"—

Add

"Delamanid; its salts".

(3) Schedule 1, Division A, after item "Dimepheptanol; its salts; its esters and ethers; their salts"—

Add

"Dimethyl fumarate when contained in pharmaceutical products".

(4) Schedule 1, Division A, after item "Lysuride; its salts"—

Add

"Macitentan; its salts".

(5) Schedule 1, Division A, after item "Nimodipine"—

Add

"Nintedanib; its salts".

(6) Schedule 1, Division A, after item "Pantoprazole; its salts"—

Add

"Paracetamol when contained in pharmaceutical products for human parenteral administration".

(7) Schedule 1, Division A, after item "Ramipril; its salts"—

Add

"Ramucirumab".

3. 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 "Bitolterol and its salts when contained in aerosol dispensers"—

Add

"Bivalirudin; its salts".

(2) Schedule 3, Division A, after item "Dehydroemetine; its salts"—

Add

"Delamanid; its salts".

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

Add

"Dimethyl fumarate when contained in pharmaceutical products".

(4) Schedule 3, Division A, after item "Lysuride; its salts"—

Add

"Macitentan; its salts".

(5) Schedule 3, Division A, after item "Nimodipine"—

Add

"Nintedanib; its salts".

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

Add

"Paracetamol when contained in pharmaceutical products for human parenteral administration".

(7) Schedule 3, Division A, after item "Ramipril; its salts"—

Add

"Ramucirumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Bivalirudin; its salts".

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

Add

"Delamanid; its salts".

(3) Schedule 10, section 2, Table, Part 1, Division A, after item "Dimepheptanol; its salts; its esters and ethers; their salts"—

Add

"Dimethyl fumarate when contained in pharmaceutical products".

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

Add

"Macitentan; its salts".

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

Add

"Nintedanib; its salts".

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

Add

"Paracetamol when contained in pharmaceutical products for human parenteral administration".

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

Add

"Ramucirumab".

Chairman,
Pharmacy and Poisons Board

7 March 2016

Explanatory Note

This Regulation—

(a) adds 7 substances to Division A of Schedule 1 and Division A of Schedule 3 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 7 substances to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations so that, among other applicable requirements, those substances can 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.

Pharmacy and Poisons (Amendment) Regulation 2016

Supplementary Information to the Legislative Council

《2016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
Bivalirudin; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug should be administered with acetylsalicylic acid and clopidogrel, and is used in adult patients undergoing percutaneous coronary intervention (PCI), including patients with ST-segment elevation myocardial infarction undergoing primary PCI; or with unstable angina/non-ST segment elevation myocardial infarction planned for urgent or early intervention. Side effects include thrombocytopenia, major haemorrhage at any site and hypersensitivity. Its use should be decided by a doctor based on the patient's conditions.
比伐蘆定；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物必須與乙酰水楊酸和氯吡多同服，用於接受透皮式冠狀動脈介入治療(PCI)，包括患有ST段提升心肌梗塞而接受原發性PCI的病人；或患有不穩定型心絞痛/非ST段提升心肌梗塞，而計劃進行緊急或早期介入治療的成年患者。 副作用包括血小板減少、任何部位大量出血及過敏反應。 使用此藥物與否，須由醫生按病人情況決定。

Delamanid; its salts 德拉馬尼；其鹽類	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	This drug is used as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. Side effects include reticulocytosis, hypokalaemia, insomnia, headache, tremor, tinnitus, palpitations, vomiting, nausea, asthenia and QT interval prolongation. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於當耐藥性或耐受性原因而不能設計其他有效治療方案，作為合適混合療程方案的其中部分，治療患有肺部多樣耐藥性結核病的成年患者。 副作用包括網狀細胞過多症、低鉀血症、失眠、頭痛、顫抖、耳鳴、心悸、嘔吐、噁心、乏力和QT段延長。 使用此藥物與否，須由醫生按病人情況決定。
Dimethyl fumarate; when contained in pharmaceutical products 富馬酸二甲酯；限於包含在藥劑製品者	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	This drug is used for the treatment of adult patients with relapsing remitting multiple sclerosis. Side effects include flushing, diarrhoea, nausea and abdominal pain. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有復發性緩解型多發性硬化症的成年患者。 副作用包括潮紅、腹瀉、噁心和腹痛。 使用此藥物與否，須由醫生按病人情況決定。

Macitentan; its salts 馬昔騰坦；其鹽類	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	This drug is used as monotherapy or in combination, for the long-term treatment of pulmonary arterial hypertension in adult patients of WHO Functional Class II to III. Side effects include nasopharyngitis, bronchitis, anaemia and headache. Its use should be decided by a doctor based on the patient's conditions. 此藥物可以單獨或結合其他藥物使用，用於長期治療屬世界衞生組織功能級別II及III型的肺動脈高血壓症的成年患者。 副作用包括鼻咽炎、支氣管炎、貧血和頭痛。 使用此藥物與否，須由醫生按病人情況決定。
Nintedanib; its salts 尼達尼布；其鹽類	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	This drug is used in adult patients for the treatment of idiopathic pulmonary fibrosis. Side effects include diarrhoea, nausea, abdominal pain and hepatic enzyme increased. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有特發性肺纖維化的成年患者。 副作用包括腹瀉、噁心、腹痛和肝酵素升高。 使用此藥物與否，須由醫生按病人情況決定。

Paracetamol; when contained in pharmaceutical products for human parenteral administration	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for short-term treatment of moderate pain, especially following surgery, and short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible. Side effects include hypotension, increased levels of hepatic transaminases and malaise. Its use should be decided by a doctor based on the patient's conditions.
對乙醯氨基酚；限於包含在供人注射用途的藥劑製品者	附表十的第一部，附表一及附表三毒藥	此藥物用於確實有臨牀迫切需要使用靜脈注射途徑治療痛症或體溫過高，及/或不能使用其它輸藥途徑時候，作為短期治療中度痛症，尤其在手術後；或短期治療發熱。 副作用包括血壓下降、肝轉氨酶升高和身體不適。 使用此藥物與否，須由醫生按病人情況決定。

Ramucirumab 雷莫蘆單抗	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附表一及附表三毒藥	This drug is used in adult patients in combination with paclitaxel for the treatment of advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy; and as monotherapy for whom treatment in combination with paclitaxel is not appropriate. Side effects include neutropenia, leukopenia, thrombocytopenia, hypoalbuminaemia, hypertension, gastrointestinal haemorrhage, diarrhoea, proteinuria, peripheral oedema and abdominal pain. Its use should be decided by a doctor based on the patient's conditions. 此藥物可以結合紫杉醇用於治療經鉑和氟尿嘧啶類藥物化療後病情惡化的晚期胃癌或胃食道交界腺癌；亦可以單獨用於不適宜結合紫杉醇治療的成年患者。 副作用包括中性粒細胞減少、白細胞減少、血小板減少、低白蛋白血症、高血壓、胃腸道出血、腹瀉、蛋白尿、周邊水腫和腹痛。 使用此藥物與否，須由醫生按病人情況決定。