File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap 138)

PHARMACY AND POISONS (AMENDMENT) (NO.3) 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) (No. 3) Regulation 2016 ("the Amendment Regulation") at **Annex A** is to amend 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 three pharmaceutical products, the Board proposes to add the following substances to Division A of First Schedule, Division A of Third Schedule and Division A of Part I of the Poisons List set out in Tenth Schedule to the Regulations:

(a) Edoxaban; its salts;
(b) Olaparib; its salts;
(c) Trametinib; its salts

4. Besides, the Board also proposes to repeal the existing entry of "Tenofovir; its salts; its esters; their salts" in Division A of First Schedule,

Division A of Third Schedule and Division A of Part I of the Poisons List set out in Tenth Schedule to the Regulations, and replace it by the new entry of "Tenofovir; its salts; its derivatives; their salts".

5. 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

6. The Amendment Regulation is to add the above drugs (in paragraph 3 to 4) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

7. The legislative timetable will be –

Publication in the Gazette	20 May 2016
Date of Commencement	20 May 2016

IMPLICATIONS OF THE PROPOSAL

8. 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

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

Food and Health Bureau
May 2016

Pharmacy and Poisons (Amendment) (No. 3) 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 "Eculizumab"—

Add

"Edoxaban; its salts".

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

Add

"Olaparib; its salts".

(3) Schedule 1, Division A—

Repeal item "Tenofovir; its salts; its esters; their salts"

Substitute

"Tenofovir; its salts; its derivatives; their salts".

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

Add

"Trametinib; its salts".

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 "Eculizumab"—

Add

"Edoxaban; its salts".

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

Add

"Olaparib; its salts".

(3) Schedule 3, Division A—

Repeal item "Tenofovir; its salts; its esters; their salts"

Substitute

"Tenofovir; its salts; its derivatives; their salts".

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

Add

"Trametinib; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Edoxaban; its salts".

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

Add

"Olaparib; its salts".

(3) Schedule 10, section 2, Table, Part 1, Division A—

Repeal item "Tenofovir; its salts; its esters; their salts"

Substitute

"Tenofovir; its salts; its derivatives; their salts".

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

Add

"Trametinib; its salts".

Chairman,
Pharmacy and Poisons Board

17·5·2016

Explanatory Note

This Regulation—

(a) adds 3 items 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***); and

(b) replaces the item relating to "Tenofovir" in those Divisions with another item.

The effect is that the sale, supply, labelling and storage of substances in those items are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

2. This Regulation also—

(a) adds 3 items to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations; and

(b) replaces the item relating to "Tenofovir" in that Division with another item.

The effect is that among other applicable requirements, substances in those items 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) (No.3) Regulation 2016

Supplementary Information to the Legislative Council

《2016年藥劑業及毒藥（修訂）（第3號）規例》

提交立法會的補充資料

Edoxaban; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in adults for the prevention of stroke and systemic embolism with nonvalvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack; and for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE. Side effects include anaemia, gastrointestinal haemorrhage, oral/pharyngeal haemorrhage, nausea, rash and vaginal haemorrhage. Its use should be decided by a doctor based on the patient's conditions.
艾多沙班；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物用於預防中風及全身性栓塞，患有非瓣膜心房纖維性顫動，並存在一個或多個風險因素，如充血性心臟衰竭、高血壓、年齡達75歲及以上、糖尿病、曾經中風或短暫缺血性發作的成年患者；亦用於治療患有深層靜脈血栓及肺部栓塞，和預防復發性深層靜脈血栓及肺部栓塞的成年患者。 副作用包括貧血、胃腸道出血、口咽部出血、噁心、皮疹、和陰道出血。 使用此藥物與否，須由醫生按病人情況決定。

Olaparib; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used as monotherapy for the maintenance treatment in adults with platinum-sensitive relapsed BRCA-mutated ovarian cancer who are in response to platinum-based chemotherapy. Side effects include decreased appetite, headache, dizziness, vomiting, diarrhoea, fatigue, anaemia, and neutropenia. Its use should be decided by a doctor based on the patient's conditions.
奧拉帕利；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物作為單一療法，用於維持性治療患有對鉑呈反應的復發性BRCA-突變型卵巢癌，並對鉑類化療呈現療效的成年患者。 副作用包括食慾下降、頭痛、頭暈、嘔吐、腹瀉、乏力、貧血和中性粒細胞減少症。 使用此藥物與否，須由醫生按病人情況決定。

Tenofovir; its salts; its derivatives; their salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used in combination with elvitegravir, cobicistat and emtricitabine for the treatment of adults and adolescents infected with human immunodeficiency virus-1 without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir. Side effects include nausea, headache, dizziness, diarrhoea, vomiting, abdominal pain, and fatigue. Its use should be decided by a doctor based on the patient's conditions.
替諾福韋；其鹽類；其衍生物；它們的鹽類	附表一、附表三及附表十的第一部毒藥	此藥物與艾維雷韋、cobicistat (沒有中文名稱)及恩曲他濱聯合使用，治療感染人類免疫力缺乏病毒一型，並對整合酶抑製劑類、恩曲他濱或替諾福韋，沒有任何已知有關抗藥性突變的成年及少年患者。 副作用包括噁心、頭痛、頭暈、腹瀉、嘔吐、腹痛、和疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Trametinib; its salts	Schedule 1, Schedule 3 and Part 1 of Schedule 10 poison	This drug is used as monotherapy or in combination with dabrafenib for the treatment of adults with unresectable or metastatic melanoma with a BRAF V600 mutation. Side effects include hypertension, haemorrhage, cough, dyspnoea, diarrhoea, nausea, vomiting, constipation, abdominal pain, alopecia, fatigue and pyrexia. Its use should be decided by a doctor based on the patient's conditions.
曲莫替尼；其鹽類	附表一、附表三及附表十的第一部毒藥	此藥物作為單一療法，或與達拉非尼聯合使用，治療BRAF V600突變而不能切除或轉移性黑色素瘤的成年患者。 副作用包括高血壓、出血、咳嗽、呼吸困難，腹瀉、噁心、嘔吐、便秘、腹痛、脫髮、疲勞和發熱。 使用此藥物與否，須由醫生按病人情況決定。