File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) REGULATION 2019

INTRODUCTION

The Pharmacy and Poisons Regulations ("the Regulations") (Cap. 138A) was made under section 29 of the Pharmacy and Poisons Ordinance ("the Ordinance") (Cap. 138). The Pharmacy and Poisons (Amendment) Regulation 2019 ("the Amendment Regulation") at **Annex A** is to amend Schedule 1, Schedule 3 and Schedule 10 to the Regulations.

JUSTIFICATIONS

General Background

2. The Pharmacy and Poisons Board ("the Board") is established under section 3 of the Ordinance. Under section 29(1B) of the Ordinance, the Board is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Regulations, subject to the approval of the Secretary for Food and Health and of the Poisons Committee, established under section 31 of the Ordinance.

Proposal of the Pharmacy and Poisons Board

3. Arising from applications for registration of two pharmaceutical products, the Board proposes adding the following new drug substances to Division A of Schedule 1 (relating to the requirement to keep sales records), Division A of Schedule 3 (relating to the requirements to supply in accordance with a prescription and to keep dispensing records) and Division A of Part I of the Poisons List set out in Schedule 10 (relating to the requirements for sales to be conducted in a pharmacy by a registered pharmacist or in his presence and under his supervision, and for the drug to be kept in a locked receptacle) to the Regulations:

(a) Brigatinib; its salts; and

(b) Letermovir; its salts; its esters; their salts.

4. Details of the above drugs (in paragraph 3) 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 drugs.

THE AMENDMENT REGULATION

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

LEGISLATIVE TIMETABLE

6. The legislative timetable shall be –

Publication in the Gazette	4 January 2019
Date of Commencement	4 January 2019

IMPLICATIONS OF THE PROPOSAL

7. The proposal shall impose appropriate control on pharmaceutical product which consists of the above drugs (in paragraph 3). It allows the pharmaceutical products to be sold in the market upon fulfillment of relevant regulations.

ENQUIRY

8. For any enquiries, please contact Mr. Dan Chan, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
January 2019

Pharmacy and Poisons (Amendment) Regulation 2019

(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 "Bretylium tosylate"—

Add

"Brigatinib; its salts".

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

Add

"Letermovir; its salts; its esters; their 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 "Bretylium tosylate"—

Add

"Brigatinib; its salts".

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

Add

"Letermovir; its salts; its esters; their salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Brigatinib; its salts".

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

Add

"Letermovir; its salts; its esters; their salts".

Chairman,
Pharmacy and Poisons Board

24 December 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 2 items to—

(a) Division A of Schedule 1;

(b) Division A of Schedule 3; and

(c) Division A of Part 1 of the Poisons List set out in Schedule 10.

2. The amendments relate to requirements concerning sale, supply, labelling and storage. Main effects of the amendments include—

(a) that the sale, by retail, of substances specified in the 2 items—

(i) may only be effected 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; and

(ii) may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon; and

(b) that the substances, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.

Pharmacy and Poisons (Amendment) Regulation 2019
Supplementary Information to the Legislative Council

《2019 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**	**Remarks** **備註**
Brigatinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib. Side effects include nausea, fatigue, vomiting, dyspnea and headache. Its use should be decided by a doctor based on the patient's conditions.
布格替尼; 其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療患有間變性淋巴瘤激酶呈陽性、轉移性非小細胞肺癌的成年患者，而且為曾接受克唑替尼後仍出現病情惡化或無法耐受。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括噁心、疲勞、嘔吐、呼吸困難及頭痛。 使用此藥物與否，須由醫生按病人情況決定。
Letermovir; its salts; its esters; their salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients of an allogeneic haematopoietic stem cell transplant. Side effects include nausea, diarrhoea and vomiting. Its use should be decided by a doctor based on the patient's conditions.
來特莫韋；其鹽類；其酯類；它們的鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於巨噬細胞病毒血清反應呈陽性，而且接受異體造血幹細胞移植的成人受贈者，以預防接受移植後出現巨噬細胞病毒再次激活及由巨噬細胞病毒所引致的疾病。 副作用包括噁心、腹瀉及嘔吐。

Drug Name 藥名	**Proposed Classification** 建議類別	**Remarks** 備註
		使用此藥物與否，須由醫生按病人情況決定。