File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 2) 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) (No. 2) 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 a pharmaceutical product, the Board proposes adding "Baloxavir; its salts; its esters and ethers; their salts" 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.

4. Details of the above drug (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 drug.

THE AMENDMENT REGULATION

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

LEGISLATIVE TIMETABLE

6. The legislative timetable shall be –

Publication in the Gazette	18 January 2019
Date of Commencement	18 January 2019

IMPLICATIONS OF THE PROPOSAL

7. The proposal shall impose appropriate control on pharmaceutical product which consists of the above drug (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) (No. 2) 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)

Schedule 1, Division A, after item "Baclofen"—

Add

"Baloxavir; its salts; its esters and ethers; 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)

Schedule 3, Division A, after item "Baclofen"—

Add

"Baloxavir; its salts; its esters and ethers; their salts".

4. Schedule 10 amended (Poisons List)

Schedule 10, section 2, Table, Part 1, Division A, after item "Baclofen"—

Add

"Baloxavir; its salts; its esters and ethers; their salts".

Chairman,
Pharmacy and Poisons Board

8 January 2019

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add "Baloxavir; its salts; its esters and ethers; their salts" (***Baloxavir***) 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 Baloxavir—

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

Annex B

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2019
Supplementary Information to the Legislative Council

《2019 年藥劑業及毒藥（修訂）（第 2 號）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**
Baloxavir; its salts; its esters and ethers; their salts 現時沒有中文名稱[1]	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部，附	This drug is used for the treatment of acute uncomplicated influenza in patients who are 12 years of age and older, and who have been symptomatic for no more than 48 hours. Side effects include diarrhoea, bronchitis, nausea, nasopharyngitis and headache. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療12歲及以上，出現感冒症狀不超過48小時的急性及

[1] 根據世界衞生組織「國際非專利藥品名稱」（International Nonproprietary Name for Pharmaceutical Substances），「Baloxavir; its salts;

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
	表一及附表三毒藥	沒有併發症的流行性感冒患者。 副作用包括腹瀉、支氣管炎、噁心、鼻咽炎及頭痛。 使用此藥物與否，須由醫生按病人情況決定。

its esters and ethers; their salts」現時沒有正式的中文名稱。