File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2019

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 2019 ("the Amendment Regulation") at **Annex A** is to amend Schedule 1, Schedule 3 and Schedule 10 to the Regulations.

JUSTIFICATIONS

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 **"Brexpiprazole; its salts"** and **"Ertugliflozin; its 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 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 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	15 March 2019
Date of Commencement	15 March 2019

IMPLICATIONS OF THE PROPOSAL

7. The proposal shall impose appropriate control on pharmaceutical products which consist of the above drugs (in paragraph 3). The proposal 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
March 2019

Pharmacy and Poisons (Amendment) (No. 3) 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

"Brexpiprazole; its salts".

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

Add

"Ertugliflozin; 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 "Bretylium tosylate"—

Add

"Brexpiprazole; its salts".

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

Add

"Ertugliflozin; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Brexpiprazole; its salts".

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

Add

"Ertugliflozin; its salts".

Chairman,
Pharmacy and Poisons Board

1 March 2019

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.

Annex B
附件 B

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2019
Supplementary Information to the Legislative Council

《2019 年藥劑業及毒藥(修訂)(第 3 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**
Brexpiprazole; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adults for the treatment of schizophrenia. Side effects include dyspepsia, diarrhoea, weight gain, akathisia and tremor. The use of the drug should be decided by a doctor based on the patient's conditions.
布瑞哌唑；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於治療精神分裂症的成年患者。 副作用包括消化不良、腹瀉、體重增加、靜坐不能及震顫。 使用此藥物與否，須由醫生按病人情況決定。

Annex B
附件 B

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
Ertugliflozin; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in adults of the age of 18 years or older with type 2 diabetes mellitus, as an adjunct to diet and exercise to improve glycaemic control – • as monotherapy in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications; and • in addition to other medicinal products for the treatment of diabetes. Side effects include vulvovaginal mycotic infection and other female genital mycotic infections, hypoglycaemia, increased urination, vulvovaginal pruritus and thirst. The use of the drug should be decided by a doctor based on the patient's conditions.
艾托格列淨；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於十八歲或以上的二型糖尿病成年患者，作為飲食及運動的輔助，以改善血糖控制： • 作為因不耐受或禁忌症以致不適合使用甲福明的患者的單一治療；

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		• 並與其他治療糖尿病的藥物一併使用。 副作用包括外陰陰道真菌感染和其他女性生殖器真菌感染、低血糖症、排尿增加、外陰陰道瘙癢及口渴。 使用此藥物與否，須由醫生按病人情況決定。