File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 4) REGULATION 2017

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. 4) Regulation 2017 ("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 a pharmaceutical product, the Board proposes adding the following substance 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) Venetoclax; its salts

4. Details of the above substance 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 above drug (in paragraph 3) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	7 July 2017
Date of Commencement	7 July 2017

IMPLICATIONS OF THE PROPOSAL

7. The proposal will impose appropriate control on pharmaceutical products consisting of the above substance 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
July 2017

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2017

(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 "Vemurafenib; its salts"—

Add

"Venetoclax; 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)

Schedule 3, Division A, after item "Vemurafenib; its salts"—

Add

"Venetoclax; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Venetoclax; its salts".

Chairman,
Pharmacy and Poisons Board

4 July 2017

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add Venetoclax and its salts (***Venetoclax***) to—

(a) Division A of its Schedule 1;

(b) Division A of its Schedule 3; and

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

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

(a) that the sale, by retail, of Venetoclax—

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

Annex B

附件B

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2017

Supplementary Information to the Legislative Council

《2017年藥劑業及毒藥（修訂）（第4號）規例》

提交立法會的補充資料

Venetoclax; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of adult patients with chronic lymphocytic leukemia with 17p deletion who have received at least one prior therapy. Side effects include neutropenia, diarrhoea, nausea, anaemia, thrombocytopenia, upper respiratory tract infection and fatigue. Its use should be decided by a doctor based on the patient's conditions.
維奈克拉；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慢性淋巴細胞白血病及出現17P缺失，並曾接受過至少一次療程的成年患者。 副作用包括中性粒細胞減少、腹瀉、噁心、貧血、血小板減少、上呼吸道感染和疲勞。 使用此藥物與否，須由醫生按病人情況決定。