File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 7) REGULATION 2018

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. 7) Regulation 2018 ("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 an application for registration of a pharmaceutical product, the Board proposes adding the following new drug substance 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) Apalutamide; its salts.

4. Details of the above drug (in paragraph 3) is 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	23 November 2018
Date of Commencement	23 November 2018

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 product 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
November 2018

Pharmacy and Poisons (Amendment) (No. 7) Regulation 2018

(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 "Antithymocyte Immunoglobulin"—

Add

"Apalutamide; 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 "Antithymocyte Immunoglobulin"—

Add

"Apalutamide; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Apalutamide; its salts".

Chairman,
Pharmacy and Poisons Board

6 November 2018

Explanatory Note

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

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

附件B
Annex B

Pharmacy and Poisons (Amendment) (No. 7) Regulation 2018

Supplementary Information to the Legislative Council

《2018年藥劑業及毒藥（修訂）（第7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**
Apalutamide; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with non-metastatic, castration-resistant prostate cancer. Side effects include fatigue, hypertension, rash, diarrhoea, and nausea. Its use should be decided by a doctor based on the patient's conditions.
阿帕他胺；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非轉移性不可切除前列腺癌的成年人士。 副作用包括疲勞、高血壓、皮疹、腹瀉，以及噁心。 使用此藥物與否，須由醫生按病人情況決定。