File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2020

INTRODUCTION

The Pharmacy and Poisons Regulations ("the Regulations") (Cap. 138A) were made under section 29 of the Pharmacy and Poisons Ordinance ("the Ordinance") (Cap. 138). The Pharmacy and Poisons (Amendment) (No. 3) Regulation 2020 ("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 an ongoing review of sales control of pharmaceutical products and applications for registration of pharmaceutical products, the Board proposes –

(a) adding "Erdafitinib; its salts" and "Romosozumab" 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; and

(b) adding "Ibuprofen" to Part A of Schedule 1 and Schedule 3 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 proposes amending the relevant Schedules to the Regulations in accordance to paragraph 3.

LEGISLATIVE TIMETABLE

6. The legislative timetable shall be –

Publication in the Gazette	19 June 2020
Date of Commencement	19 June 2020

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
June 2020

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2020

(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 "Eptifibatide; its salts"—

Add

"Erdafitinib; its salts".

(2) Schedule 1, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Hyoscine"—

Add

"Ibuprofen".

(3) Schedule 1, Division A, after item "Romiplostim"—

Add

"Romosozumab".

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 "Eptifibatide; its salts"—

Add

"Erdafitinib; its salts".

(2) Schedule 3, Division A, item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin", after sub-item "Hyoscine"—

Add

"Ibuprofen".

(3) Schedule 3, Division A, after item "Romiplostim"—

Add

"Romosozumab".

4. Schedule 10 amended (Poisons List)

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

Add

"Erdafitinib; its salts".

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

Add

"Romosozumab".

Chairman,
Pharmacy and Poisons Board

11 June 2020

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 those 2 new 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.

3. The Regulation also adds 1 sub-item to an item in Division A of Schedule 1 and Division A of Schedule 3, which sub-item is already in Division A of Part 1 of the Poisons List.

Annex B

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2020
Supplementary Information to the Legislative Council

《2020 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
Erdafitinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma, that has: - susceptible FGFR3 or FGFR2 genetic alterations, and - progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Side effects include stomatitis, fatigue, diarrhea, dry mouth and decreased appetite. Its use should be decided by a doctor based on the patient's conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
厄達替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	此藥物用於治療易受FGFR3或FGFR2遺傳改變及之前接受至少一款鉑類化療(包括十二個月內的新輔助性或輔助性鉑類化療)期間或之後出現病情惡化的局部晚期或轉移性泌尿道上皮癌的成年患者。 副作用包括口腔炎、疲勞、腹瀉、口乾及食慾下降。 使用此藥物與否，須由醫生按病人情況決定。
Ibuprofen	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison (to be put under the entry of "Pharmaceutical products for human parenteral administration containing the	This drug in the form of injection is used for the treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age. Side effects include thrombocytopenia, neutropenia, bronchopulmonary dysplasia, oliguria and fluid retention. Its use should be decided by a doctor based on the patient's conditions.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
	following or their salts, as active ingredients, except in mixture with insulin –" in Schedule 1 and Schedule 3 only as "Ibuprofen; its salts" is already a Part 1 Poison)	
布洛芬	附表10的第1部，附表1及附表3毒藥 (由於"布洛芬；其鹽類"已屬於第1部毒藥，因此，有關物質只需列於附表1及附表3的以下條文內："供注射入人體的藥劑製品，並包含(作為有	此注射劑藥物用於治療小於34週胎齡的早產嬰兒的血液動力學顯注存開性動脈導管。 副作用包括血小板減少症、中性白細胞減少症、支氣管肺發育不良、少尿及水腫。 使用此藥物與否，須由醫生按病人情況決定。

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
	效成分)以下物質或它們的鹽類，但與胰島素的混合物除外 - "	
Romosozumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. Side effects include arthralgia, headache, muscle spasms, edema peripheral and asthenia. Its use should be decided by a doctor based on the patient's conditions.
羅莫組單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於有高骨折風險(界定為有骨質疏鬆性骨折病史或多種骨折風險因素)的絕經後婦女或對其他可用的骨質疏鬆症療程無效或不耐受的骨質疏鬆症治療。

Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
		副作用包括關節痛、頭痛、肌肉痙攣、周邊水腫及無力。 使用此藥物與否，須由醫生按病人情況決定。