File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 2) 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. 2) 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 applications for registration of six pharmaceutical products, the Board proposes adding the following drugs 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 –

(a) Burosumab;
(b) Entrectinib; its salts;
(c) Lisdexamfetamine; its salts;
(d) Lutetium (177Lu) oxodotreotide; its salts;
(e) Polatuzumab vedotin; and
(f) Prasterone; its salts; when contained in pharmaceutical products.

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	17 April 2020
Date of Commencement	17 April 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
April 2020

Pharmacy and Poisons (Amendment) (No. 2) 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 "Bupropion; its salts"—

Add

"Burosumab".

(2) Schedule 1, Division A, after item "Entecavir; its salts; its esters; their salts"—

Add

"Entrectinib; its salts".

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

Add

"Lisdexamfetamine; its salts".

(4) Schedule 1, Division A, after item "Lurasidone; its salts"—

Add

"Lutetium (177Lu) oxodotreotide; its salts".

(5) Schedule 1, Division A, after item "Plerixafor; its salts"—

Add

"Polatuzumab vedotin".

(6) Schedule 1, Division A, after item "Pramipexole; its salts"—

Add

"Prasterone; its salts; when contained in pharmaceutical products".

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 "Bupropion; its salts"—

Add

"Burosumab".

(2) Schedule 3, Division A, after item "Entecavir; its salts; its esters; their salts"—

Add

"Entrectinib; its salts".

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

Add

"Lisdexamfetamine; its salts".

(4) Schedule 3, Division A, after item "Lurasidone; its salts"—

Add

"Lutetium (177Lu) oxodotreotide; its salts".

(5) Schedule 3, Division A, after item "Plerixafor; its salts"—

Add

"Polatuzumab vedotin".

(6) Schedule 3, Division A, after item "Pramipexole; its salts"—

Add

"Prasterone; its salts; when contained in pharmaceutical products".

4. Schedule 10 amended (Poisons List)

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

Add

"Burosumab".

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

Add

"Entrectinib; its salts".

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

Add

"Lisdexamfetamine; its salts".

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

Add

"Lutetium (177Lu) oxodotreotide; its salts".

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

Add

"Polatuzumab vedotin".

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

Add

"Prasterone; its salts; when contained in pharmaceutical products".

Chairman,
Pharmacy and Poisons Board

1 April 2020

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 6 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 6 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. 2) Regulation 2020
Supplementary Information to the Legislative Council

《2020 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**
Burosumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of X-linked hypophosphatemia in adult and pediatric patients 1 year of age and older. Side effects include: Pediatric: Headache, injection site reaction, vomiting, pyrexia and pain in extremity. Adult: Back pain, headache, tooth infection, dizziness and constipation. Its use should be decided by a doctor based on the patient's conditions.
布羅索人單抗	附表10的第1部，附表1及附表3毒藥	此藥物用於治療患有X連結低磷血症的成年及一歲或以上的兒童病人。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
		副作用包括： 兒童：頭痛、注射部位反應、嘔吐、發熱及四肢疼痛。 成人：背痛、頭痛、牙齒感染、眩暈及便秘。 使用此藥物與否，須由醫生按病人情況決定。
Entrectinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of: 1. Adult patients with metastatic non-small cell lung cancer whose tumors are ROS1-positive. 2. Adult and pediatric patients 12 years of age and older with solid tumors that: ・have a neurotrophic tyrosine receptor kinase gene fusion without a known acquired resistance mutation, ・are metastatic or where surgical resection is likely to result in severe morbidity, and ・have either progressed following treatment or have no satisfactory alternative therapy.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
恩曲替尼；其鹽類	附表10的第1部，附表1及附表3毒藥	Side effects include fatigue, constipation, dizziness, diarrhea and nausea. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有： 1. ROS1呈陽性的轉移性非小細胞肺癌的成人患者。 2. 實體腫瘤並出現以下情況的成人及十二歲或以上兒童患者： - 出現神經營養受體酪氨酸激酶基因融合，並且沒有已知的後天抗藥性突變，； - 腫瘤屬於轉移性，或接受外科手術切除很可能導致重症；及 - 曾於接受療程後仍出現病情惡化或沒有合適的治療選項。 副作用包括疲勞、便秘、眩暈、腹瀉及噁心。 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**
Lisdexamfetamine; its salts 利右苯丙胺；其鹽類	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表10的第1部，附表1及附表3毒藥	This drug is used for the treatment of attention deficit hyperactivity disorder. Side effects include anorexia, anxiety, decreased weight, diarrhoea and dizziness. Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療專注力不足/過度活躍症。 副作用包括食慾缺乏、焦慮、體重下降、腹瀉及眩暈。 使用此藥物與否，須由醫生按病人情況決定。
Lutetium (177Lu) oxodotreotide; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours in adults. Side effects include thrombocytopenia, lymphopenia, decreased appetite, nausea and fatigue.

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Remarks** **備註**
鐿[177Lu]奧索度曲肽；其鹽類	附表10的第1部，附表1及附表3毒藥	Its use should be decided by a doctor based on the patient's conditions. 此藥物用於治療不可切除或轉移性、漸進性、高度分化（G1及G2）生長抑素受體呈陽性的胃腸胰神經內分泌腫瘤的成年患者。 副作用包括血小板減少症、淋巴球減少症、食慾下降、噁心及疲勞。 使用此藥物與否，須由醫生按病人情況決定。
Polatuzumab Vedotin	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used in combination with bendamustine and rituximab for the treatment of previously treated adult patients with diffuse large B-cell lymphoma who are not candidates for hematopoietic stem cell transplant. Side effects include anaemia, thrombocytopenia, neutropenia, fatigue and diarrhoea. 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**
維泊妥組單抗	附表10的第1部，附表1及附表3毒藥	此藥物與苯達莫司汀及利妥昔單抗結合使用，用於治療不適合進行造血幹細胞移植，並曾接受瀰漫性大型B-細胞淋巴瘤治療的成年患者。 副作用包括貧血、血小板減少症、中性白細胞減少症、疲勞及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。
Prasterone; its salts; when contained in pharmaceutical products	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	This drug is used for the treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms. Side effects include application site discharge, abnormal pap smear and weight fluctuation. 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**
普拉睪酮；其鹽類；但限於包含在藥劑製品內者	附表10的第1部，附表1及附表3毒藥	此藥物用於治療患有中度至嚴重症狀的絕經後婦女的外陰和陰道萎縮。 副作用包括應用部位分泌物、異常子宮頸抹片檢查及體重波動。 使用此藥物與否，須由醫生按病人情況決定。