File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2018

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 2018 ("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 five pharmaceutical products, the Board proposes adding the following substances 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) desflurane
(b) isoflurane
(c) midostaurin; its salts
(d) sarilumab
(e) sevoflurane

4. Details of the above substances 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 drugs (in paragraph 3) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette	11 May 2018
Date of Commencement	11 May 2018 or 11 May 2019 (where applicable)[1]

IMPLICATIONS OF THE PROPOSAL

7. The proposal will impose appropriate control on pharmaceutical products consisting of the above substances 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
May 2018

[1] To allow the trade to have sufficient time to get prepared for the above changes in sale control, the Board recommends that for "desflurane", "isoflurane" and "sevoflurane", the commencement date of the proposed amendments should be twelve months after the date of gazettal; for "midostaurin; its salts" and "sarilumab", the commencement date of the proposed amendments should be the date of gazettal.

Pharmacy and Poisons (Amendment) (No. 3) 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. Commencement

(1) Subject to subsection (2), this Regulation comes into operation on the day on which it is published in the Gazette.

(2) Sections 3(1), (2) and (5), 4(1), (2) and (5) and 5(1), (2) and (5) come into operation on the expiry of 12 months beginning on the day on which this Regulation is published in the Gazette.

2. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 3, 4 and 5.

3. 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 "Desferrioxamine; its salts"—

Add

"Desflurane".

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

Add

"Isoflurane".

(3) Schedule 1, Division A, after item "Midodrine; its salts"—

Add

"Midostaurin; its salts".

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

Add

"Sarilumab".

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

Add

"Sevoflurane".

4. 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 "Desferrioxamine; its salts"—

Add

"Desflurane".

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

Add

"Isoflurane".

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

Add

"Midostaurin; its salts".

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

Add

"Sarilumab".

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

Add

"Sevoflurane".

5. Schedule 10 amended (Poisons List)

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

Add

"Desflurane".

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

Add

"Isoflurane".

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

Add

"Midostaurin; its salts".

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

Add

"Sarilumab".

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

Add

"Sevoflurane".

Chairman,
Pharmacy and Poisons Board

30 April 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 5 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 5 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 2018

Supplementary Information to the Legislative Council

《2018年藥劑業及毒藥(修訂)(第3號)規例》

提交立法會的補充資料

Desflurane	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used: - as an inhalation agent for induction of anaesthesia for inpatient and outpatient surgery in adults; - as an inhalation agent for maintenance of anaesthesia for inpatient and outpatient surgery in adults and in pediatric patients; - for maintenance of anaesthesia in infants and children after induction of anaesthesia with agents other than desflurane, and tracheal intubation. - Side effects include coughing, breathholding, nausea, vomiting and apnoea. Its use should be decided by a doctor based on the patient's conditions.
地氟烷	附表十的第一部，附表一及附表三毒藥	此藥物: - 用在住院和門診手術的成年病人作為誘導其麻醉的吸入劑; - 用在住院和門診手術的成年及兒科病人作為維持其麻醉的吸入劑; - 用於嬰兒及兒童，在其使用地氟烷以外的誘導麻醉及氣管插管後，作為維持其麻醉。 副作用包括咳嗽、屏氣、噁心、嘔吐及窒息。 使用此藥物與否，須由醫生按病人情況決定。

Isoflurane	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used - for induction and maintenance of general anaesthesia in both adults and children; - as a general inhalant anaesthetic agent and can be used for all types of veterinary surgery in cats, dogs, ornamental birds, reptiles, small mammals and horses. Side effects include respiratory depression, hypotension, arrhythmias, shivering, nausea, vomiting and ileus. Its use should be decided by a doctor or veterinary surgeon based on the patient's or animal's conditions.
異氟烷	附表十的第一部，附表一及附表三毒藥	此藥物用於: - 成人及兒童作為誘導及維持其全身麻醉; - 進行所有類型獸醫手術的貓、狗、觀賞鳥、爬行動物、小型哺乳動物及馬，作為其全身麻醉的吸入劑。 副作用包括呼吸抑制、低血壓、心律失常、顫抖、噁心、嘔吐及腸塞痛。 使用此藥物與否，須由醫生或獸醫按病人或動物情況決定。

Midostaurin; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used: - in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by maintenance therapy as single agent, for adult patients with newly diagnosed acute myeloid leukaemia who are FLT3 mutation-positive; - as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated haematological neoplasm, or mast cell leukaemia. Side effects include febrile neutropenia, nausea, exfoliative dermatitis, vomiting and diarrhoea. Its use should be decided by a doctor based on the patient's conditions.
米哚妥林；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物用於: - 具陽性FLT3突變之新確診為急性粒細胞性白血病成年患者，它與標準柔紅霉素和阿糖胞苷誘導治療及高劑量阿糖胞苷鞏固化療結合使用，及當病人在完全緩解後作為單一藥物的維持治療; - 患有入侵性系統性肥大細胞增生症，系統性肥大細胞增生症連帶血液系統腫瘤或肥大細胞白血病之成年患者治療用的單一療法。 副作用包括發熱性中性白細胞減少症、噁心、剝脫性皮炎、嘔吐及腹瀉。 使用此藥物與否，須由醫生按病人情況決定。

Sarilumab	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used in combination with methotrexate for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs. This drug can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate. Side effects include neutropenia, transaminases increased, injection site erythema, upper respiratory tract infection and urinary tract infection. Its use should be decided by a doctor based on the patient's conditions.
沙立蘆人單抗	附表十的第一部，附表一及附表三毒藥	此藥物與甲氨蝶呤結合使用於治療中度至嚴重活性類風濕關節炎的成年患者，並已對一種或多種緩解病情抗風濕病藥物的反應不佳或無法耐受。此藥物能在不耐受甲氨蝶呤或不適合使用甲氨蝶呤作治療的情況下作為單一療法。 副作用包括中性白細胞減少症、轉氨酶增加、注射部位紅斑、上呼吸道感染及尿道感染。 使用此藥物與否，須由醫生按病人情況決定。

Sevoflurane	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for induction and maintenance of general anaesthesia for in-patient and out-patient surgery in both adults and children. Side effects include agitation, bradycardia, hypotension, cough, nausea and vomiting. Its use should be decided by a doctor based on the patient's conditions.
七氟烷	附表十的第一部，附表一及附表三毒藥	此藥物用在住院和門診手術的成年及兒童病人，作為誘導及維持其全身麻醉。 副作用包括精神激昂、心搏過緩、低血壓、咳嗽、噁心及嘔吐。 使用此藥物與否，須由醫生按病人情況決定。