File Ref.: FHB/H/23/4

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO. 4) 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. 4) 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 a pharmaceutical product, the Board proposes adding the following substance to Division A of First Schedule (relating to the requirement to keep sales records), Division A of Third Schedule (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 Tenth Schedule (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) nusinersen; 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 substance.

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	6 July 2018
Date of Commencement	6 July 2018

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 Dan Chan, Assistant Secretary for Food and Health at 3509 8956.

Food and Health Bureau
July 2018

Pharmacy and Poisons (Amendment) (No. 4) 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 "Nortriptyline; its salts"—

Add

"Nusinersen; 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 "Nortriptyline; its salts"—

Add

"Nusinersen; its salts".

4. Schedule 10 amended (Poisons List)

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

Add

"Nusinersen; its salts".

Chairman,
Pharmacy and Poisons Board

27 June 2018

Explanatory Note

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

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

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2018

Supplementary Information to the Legislative Council

《2018年藥劑業及毒藥（修訂）（第4號）規例》

提交立法會的補充資料

Nusinersen; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used for the treatment of 5q spinal muscular atrophy. Side effects include headache, vomiting and back pain. Its use should be decided by a doctor based on the patient's conditions.
諾西那生；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5q脊髓性肌肉萎縮症。 副作用包括頭痛、嘔吐及背痛。 使用此藥物與否，須由醫生按病人情況決定。