

## **LEGISLATIVE COUNCIL BRIEF**

### Antibiotics Ordinance (Cap. 137)

## **ANTIBIOTICS (AMENDMENT) REGULATION 2018**

### **INTRODUCTION**

The Director of Health (“the DoH”), in exercise of powers conferred by section 12 of the Antibiotics Ordinance (Cap. 137) (“the Ordinance”), made the Antibiotics (Amendment) Regulation 2018 (“the Amendment Regulation”) at **Annex A** to amend the First Schedule to the Antibiotics Regulations (Cap. 137A) (“the Regulations”).

### **JUSTIFICATIONS**

#### **General Background**

2. The Ordinance controls the sale and supply of certain antibiotic substances. Under section 4(1) of the Ordinance, only certain qualified persons are allowed to sell or otherwise supply any substance to which the Ordinance applies or any preparation of which any such substance is an ingredient or part. Section 4(2) of the Ordinance restricts the administration of such substance or preparation by certain qualified or licensed persons only. The indiscriminate use of such substances, commonly known as antibiotics, may give rise to the emergence of antibiotic-resistant bacteria in the community, and in turn, endanger public health. Therefore, it is necessary to restrict the use of such substances.

3. Section 12 of the Ordinance provides that the DoH may by regulation prescribe the substances and definitions to which this Ordinance applies. The Regulations have been made under section 12 of the Ordinance, which the First Schedule to the Regulations specifies the substances and their definitions to which the Ordinance applies.

## **Addition of Eprinomectin to the First Schedule**

4. The pharmaceutical industry has developed a new substance, namely Eprinomectin, which is an antibiotic agent derived from strains of *Streptomyces avermitilis* and is used for cats with, or at risk from mixed infestations by, cestodes, nematodes and ectoparasites. Eprinomectin is effective against gastrointestinal and extraintestinal nematodes. Details of the above substance are set out at **Annex B**.

5. To guard against the indiscriminate use of this new antibiotic, which can give rise to the emergence of Eprinomectin-resistant microbials, the DoH has decided that Eprinomectin should be added to the First Schedule to the Regulations so that the control specified in the Ordinance will apply. With the amendment, pharmaceutical products containing Eprinomectin can be sold and supplied only by certain persons, such as registered veterinary surgeons, or registered pharmacists with prescriptions signed by a registered veterinary surgeon.

## **THE AMENDMENT REGULATION**

6. The Amendment Regulation is to add the above antibiotic (in paragraph 4) to the First Schedule to the Regulations.

## **LEGISLATIVE TIMETABLE**

7. The legislative timetable will be –

Publication in the Gazette	26 January 2018
Date of Commencement	26 January 2018

## **IMPLICATIONS OF THE PROPOSAL**

8. 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.

## **CONSULTATION**

9. The Pharmacy and Poisons Board has been consulted and has recommended that Eprinomectin should be included in the First Schedule to the Regulations for the purpose of controlling its sale and supply.

## **ENQUIRY**

10. For any enquiries, please contact Mr Lam Fong-tat James, Assistant Secretary for Food and Health at 3509 8956.

**Food and Health Bureau**

**January 2018**

**Antibiotics (Amendment) Regulation 2018**

**Explanatory Note**

(Made by the Director of Health under section 12 of the Antibiotics Ordinance (Cap. 137))

This Regulation amends Schedule 1 to the Antibiotics Regulations (Cap. 137 sub. leg. A) by adding 1 antibiotic to the list of substances to which the Antibiotics Ordinance (Cap. 137) applies.

**1. Antibiotics Regulations amended**

The Antibiotics Regulations (Cap. 137 sub. leg. A) are amended as set out in section 2.

**2. Schedule 1 amended**

Schedule 1, after item 19A—

**Add**

“19B. Eprinomectin            An antibiotic agent derived from strains of *Streptomyces avermitilis*.”.



Director of Health

17 . . . 2018

**Antibiotics (Amendment) Regulation 2018****Supplementary Information to the Legislative Council****《2018年抗生素(修訂)規例》****提交立法會的補充資料**

<b>Name of Substance</b>	<b>Proposed Classification</b>	<b>Reasons</b>
Eprinomectin  依立諾克丁	Schedule 1  附表一	<p>This drug is used for cats with, or at risk from mixed infestations by, cestodes, nematodes and ectoparasites</p> <p>Sides effects include vomiting, itching and hair loss at the application site</p> <p>Its use should be decided by a veterinary surgeon based on the animal's conditions</p> <p>此藥物用於對條蟲、線蟲及體外寄生蟲患有混合感染或懷有混合感染風險的貓隻</p> <p>副作用包括嘔吐、瘙癢及引致使用藥物的部位脫毛</p> <p>使用此藥物與否,須由獸醫按動物的情況決定</p>