

LEGISLATIVE COUNCIL BRIEF

Antibiotics Ordinance (Chapter 137)

Antibiotics (Amendment) Regulation 2009

INTRODUCTION

On 22 January 2009, the Director of Health, in exercise of powers conferred by section 12 of the Antibiotics Ordinance (Cap.137) (“the Ordinance”), made the regulation at Annex A to update Schedule 1 to the Antibiotics Regulations (Cap.137A)(“the Regulations”).

JUSTIFICATIONS

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 Director of Health may by regulation prescribe the substances and definitions to which this Ordinance applies. The Regulations have been made under section 12 of the Ordinance. Schedule 1 to the Regulations specifies the substances and their definitions to which the Ordinance applies.

Addition of Daptomycin to Schedule 1

4. The pharmaceutical industry has developed a new substance, namely Daptomycin, which is an antibiotic agent derived from *Streptomyces roseosporus*. Daptomycin is used for the treatment of infections caused by certain sensitive bacteria. The supplementary information of Daptomycin is at **Annex B.**

5. To guard against the indiscriminate use of this new antibiotic, which can give rise to the emergence of Daptomycin-resistant bacteria in the community, and thus endanger public health, the Director of Health has decided that Daptomycin should be added to Schedule 1 to the Regulations so that the control specified in the Ordinance will apply to it. With the amendment, pharmaceutical products containing Daptomycin can be sold and supplied only by certain persons, such as registered medical practitioners, dentists, veterinary surgeons, or registered pharmacists with prescriptions signed by a registered medical practitioner, a dentist or a veterinary surgeon.

THE AMENDMENT REGULATION

6. This Amendment Regulation amends Schedule 1 to the Regulations by adding one antibiotic to the list of substances to which the Ordinance applies.

LEGISLATIVE TIMETABLE

7. The Amendment Regulation will be published in the Gazette on 30 January 2009 and tabled in the Legislative Council on 4 February 2009 for negative vetting.

IMPLICATIONS OF THE PROPOSAL

8. The Amendment Regulation is in conformity with the Basic Law, including the provisions concerning human rights. It has no additional financial or staffing implications. It has no productivity, environmental or sustainability implications.

9. The Amendment Regulation does not affect the current binding effect of the Ordinance and its subsidiary legislation.

PUBLIC CONSULTATION

10. The Pharmacy and Poisons Board have been consulted and have recommended that Daptomycin should be included in Schedule 1 to the Regulations for the purpose of controlling its sale and supply.

PUBLICITY

11. A Legislative Council Brief has been issued on 29 January 2009.

OTHERS

12. For any enquiries on this brief, please contact Mr Anthony CHAN, Chief Pharmacist, Department of Health, at 2319 8500.

**Food and Health Bureau
29 January 2009**

File Ref.: FH/H/21/10

ANTIBIOTICS (AMENDMENT) REGULATION 2009

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

1. Commencement

This Regulation comes into operation on 4 March 2009.

2. Schedule 1 amended

Schedule 1 to the Antibiotics Regulations (Cap. 137 sub. leg. A) is amended by adding –

“18A. Daptomycin An antibiotic agent derived from *Streptomyces roseosporus*.”.

Director of Health

January 2009

Explanatory Note

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

Antibiotics (Amendment) Regulation 2009**Supplementary Information of Daptomycin**

Drug Name	Proposed Classification	Reason
Daptomycin	First Schedule	<p>This drug is used to treat adults with the following bacterial infections:</p> <p class="list-item-l1">(a) complicated infections of the skin or in the layers of flesh under the skin (soft tissues);</p> <p class="list-item-l1">(b) right-sided infective endocarditis (infection of the lining or the valves of the right side of the heart) caused by the bacterium <i>Staphylococcus aureus</i>;</p> <p class="list-item-l1">(c) bacteraemia (infection of the blood) caused by <i>Staphylococcus aureus</i>.</p> <p>Its use should be decided by a doctor.</p>