立法會
Legislative Council

LC Paper No. LS56/08-09

Paper for the House Committee Meeting
on 17 April 2009

Legal Service Division Report on
Proposed Resolution under section 29 of the
Pharmacy and Poisons Ordinance (Cap. 138)

The Secretary for Food and Health (the Secretary) has given notice to move a motion at the Council meeting on 29 April 2009. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) Regulation 2009 and the Poisons List (Amendment) Regulation 2009 (collectively referred to as the Amendment Regulations); both made by the Pharmacy and Poisons Board (the Board) on 6 April 2009 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. According to the draft speech of the Secretary, the Amendment Regulations seek to add "Feline immunodeficiency virus vaccine", "Metaflumizone; its salts", "Methylnaltrexone; its salts", "Nepafenac; its salts", "Ractopamine; its salts" and "Rivaroxaban; its salts" (collectively referred to as the substances) to Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (the principal Regulations) and Division A in Part I of the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (Part I of the Poisons List). Arising from an application for registration of six pharmaceutical products, the Board proposes to add the substances to the principal Regulations and Part I of the Poisons List.

3. The Secretary has provided, in addition to his draft speech, supplementary information on the substances. According to the information provided, the vaccine containing "Feline immunodeficiency virus" is administered to cats for the prevention of infections caused by the virus. "Metaflumizone; its salts" is used alone to treat or prevent flea infestations in cats. It is also used together with another drug amitraz to treat or prevent tick and flea infestations in dogs. It can also be used as part of a treatment strategy for the control of flea allergy dermatitis (an allergic reaction of cats or dogs to flea bits). "Methylnaltrexone; its salts" is used to treat the constipation caused by the administration of morphine or morphine-like painkillers. "Nepafenac; its salts" is used to treat the pain and inflammation associated with cataract surgey. "Ractopamine; its salts" is used to mix into feedstuff for feeding grown swine (i.e. swine from 68 kg to 109 kg body weight) to increase the rate of weight gain, improve feed efficiency and increase carcass leanness. "Rivaroxaban; its salts" is used to

prevent the formation of clots in the veins (venous thromboembolism, VTE) in adults who are undergoing surgery to replace a hip or knee.

4. In addition, the Amendment Regulations also seek to amend the Second Schedule to the principal Regulations so that preparations intended for external application only containing testosterone or its esters are no longer exempt from the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations. These preparations are used for the treatment of testosterone deficiency in men.

5. The addition of the substances to the First and Third Schedules to the principal Regulations means that the sale, supply, labelling and storage of the substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations. On the other hand, the addition of the substances to Part I of the Poisons List means that pharmaceutical products containing the substances must be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in his presence and under his supervision, with the support of prescriptions given by a registered medical practitioner, registered dentist or registered veterinary surgeon. The Pharmacy and Poisons Board considers the proposed amendments necessary in view of the potency, toxicity and potential side effects of the medicine concerned.

6. The Amendment Regulations are to come into operation on the day of publication in the Gazette after having been approved by the Legislative Council. The Secretary has proposed 30 April 2009 as the date of gazettal to allow early control and sale of the medicines concerned.

7. Neither the public nor the Panel on Health Services has been consulted on the Amendment Regulations.

8. No difficulties relating to the legal and drafting aspects of the Amendment Regulations have been identified.

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14 April 2009