

LC Paper No. LS84/08-09

Paper for the House Committee Meeting on 12 June 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 Legislative Council meeting on 24 June 2009. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2009 and the Poisons List (Amendment) (No. 2) Regulation 2009 (the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 3 June 2009 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance).

2. The First Schedule to Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) contains a list of substances to which certain restrictions with respect to the sale, supply, labelling and storage apply. Division A of the Third Schedule to the Pharmacy and Poisons Regulations contains a list of substances required to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon.

3. Part I of the Poisons List as contained in the Poisons List Regulations (Cap. 138 sub. leg. B) sets out a list of substances which can be sold only on registered premises of an authorized seller of poisons by a registered pharmacist or in his presence and under his supervision (section 21 of the Ordinance).

4. Arising from an application for registration of nine pharmaceutical products, the Board proposes to add the following nine substances to the First and Third Schedules to the Pharmacy and Poisons Regulations and Division A of Part I of the Poisons List Regulations -

- (a) Abatacept;
- (b) Feline calicivirus;
- (c) Feline Chlamydia psittaci;
- (d) Feline leukemia virus;

- (e) Feline panleukopenia virus;
- (f) Feline rhinotracheitis virus;
- (g) Cinacalcet; its salts;
- (h) Fesoterodine, its salts; its esters; their salts; and
- (i) Temsirolimus; its salt; its esters.

5. In addition to his draft speech, the Secretary has provided a supplementary information note on the use of the above substances for members' reference.

6. The Board is established under section 3 of the Ordinance and entrusted with the function of, amongst other things, regulating pharmaceutical products. According to the draft speech of the Secretary, the Board considers the proposed amendment necessary in view of the potency, toxicity and potential side effects of the medicine concerned (para. 7 of the draft speech).

7. If the motion is passed on 24 June 2009, the Amendment Regulations will be published in the Gazette on 26 June 2009 and the Secretary proposes that the Amendment Regulations come into operation on that day to allow early control and sale of the relevant medicine (para. 6 of the draft speech).

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

9. No difficulties relating to the drafting of the proposed Amendment Regulations has been identified.

Prepared by

Kitty Cheng Assistant Legal Adviser Legislative Council Secretariat 9 June 2009