立法會
Legislative Council

LC Paper No. LS123/08-09

Paper for the House Committee Meeting
on 9 October 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 21 October 2009. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009 and the Poisons List (Amendment) (No. 3) Regulation 2009 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board on 30 September 2009 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance).

2. Division A of the First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (the principal Regulations) 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 principal 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) (Part I of the Poisons List) 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.

4. The Amendment Regulations seek to -

(a) add two groups of substances namely, "Dexketoprofen; its salts"; and "Thiotic acid; its salts; its derivatives; when contained in pharmaceutical products", to Part I of the Poisons List and Division A of the First and Third Schedules to the principal Regulations; and

(b) amend four existing entries in Part I of the Poisons List and in the First and Third Schedules to the principal Regulations by adding a chemical description after each entry describing the analogues of each relevant kind of poison so that the analogues are also subject to the controls applicable to the relevant kinds of poisons themselves. The relevant

kinds of poisons are "Sibutramine; its salts", "Sildenafil; its salts", "Tadalafil; its salts" and "Vardenafil; its salts".

5. In addition, the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009 proposes to relax the control of "Orlistat; its salts" so that "Orlistat; its salts" when contained in pharmaceutical products the recommended daily dose of which contains not more than 60 mg of Orlistat or its salts to be taken three times a day (the relevant Orlistat pharmaceutical products) are excluded from Division A of the First and Third Schedules to the principal Regulations. No corresponding amendment is proposed in Part I of the Poisons List. The effect of this is that while the relevant Orlistat pharmaceutical products will be exempted from the restrictions imposed under the principal Regulations, they must be sold in pharmacies in the presence and under the supervision of registered pharmacists. According to the draft speech of the Secretary, the relevant Orlistat pharmaceutical products have been shown to be sufficiently safe and effective for use in the management of weight reduction without doctor's supervision.

6. In addition to his draft speech, the Secretary has provided supplementary information on the above substances. According to the information provided, "Dexketoprofen; its salts" is used for treatment of mild to moderate pain. "Thiotic acid; its salts; its derivatives; when contained in pharmaceutical products" is used for sensory disturbances in diabetic polyneuropathy. "Sibutramine; its salts", "Sildenafil; its salts", "Tadalafil; its salts" and "Vardenafil; its salts" are used for weight reduction or erectile dysfunction. The proposed amendments to those items as mentioned in paragraph 4(b) above are made in response to the recent emergence of products marketed for weight reduction or for enhancement of sexual function in men which were found on analysis to contain analogues of these drugs. The use of drugs containing the above substances should be decided by a medical practitioner.

7. 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 proposes that the Amendment Regulations take immediate effect upon gazettal on 23 October 2009 to allow early control and sale of the pharmaceutical products concerned (para. 7 of the draft speech).

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

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

Prepared by
YICK Wing-kin
Assistant Legal Adviser
Legislative Council Secretariat
6 October 2009