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Legislative Council

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Paper for the House Committee Meeting
on 5 December 2008

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 17 December 2008. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2008 and the Poisons List (Amendment) (No. 5) Regulation 2008 (collectively referred to as the Amendment Regulations), both made by the Pharmacy and Poisons Board (the Board) on 25 November 2008 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 "Dabigatran etexilate; its salts", "Laropiprant; its salts" and "Vildagliptin; 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). The addition is the result of an application for registration of three pharmaceutical products containing the substances.

3. The Secretary has provided, in addition to his draft speech, supplementary information on the substances. According to the information provided, "Dabigatran etexilate; its salts" is used in adults who have had an operation to replace a hip or knee to prevent the formation of blood clots in the veins. "Laropiprant; its salts" is used together with Niacin in patients with dyslipdaemia (abnormally high levels of fat in the blood) in addition to diet and exercise. "Vildagliptin; its salts" is used to treat type 2 diabetes mellitus (non-insulin-dependant diabetes) together with another antidiabetes medicine (as "dual therapy") when the patient's diabetes is insufficiently controlled by other medicine taken alone. The use of each of the substances should be decided by a medical practitioner.

4. The addition of the substances to the First and Third Schedules to the principal Regulations means that the sale, supply, labeling 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.

5. 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 19 December 2008 as the date of gazettal to allow early control and sale of the medicines concerned.

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

7. 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
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