立法會
Legislative Council

LC Paper No. LS1/08-09

Paper for the House Committee Meeting
on 10 October 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 22 October 2008. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2008 and the Poisons List (Amendment) (No. 4) Regulation 2008 (collectively referred to as the Amendment Regulations), both made by the Pharmacy and Poisons Board ("the Board") on 29 September 2008 pursuant to section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. The Amendment Regulations seek to amend the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) and Poison List Regulations (Cap. 138 sub. leg. B) (collectively referred to as the Regulations) to -

(a) relax the control on chewing gum and lozenges intended to be used in nicotine replacement therapy and containing more than 2 mg and not more than 4 mg (as opposed to those of not more than 2 mg the control of which is already relaxed under the existing Regulations) of Nicotine per piece; and patches for external application, also intended to be used in nicotine replacement therapy by removing them from Part I Poisons in the Schedule to the Poisons List Regulations. Instead these products are to be classified as Part II Poisons in the Schedule to the Poisons List Regulations so that they can be sold by pharmacies and medicine companies and their sale would not be required to be conducted in the presence and under the supervision of a registered pharmacist. According to the draft speech of the Secretary, these products have been found to be sufficiently safe to be available for self-selection by smokers who wish to quit smoking; and

(b) add six substances, namely, (i) Anidulafungin; its salts; its esters; their salts; (ii) Etravirine; (iii) Fosaprepitant; its salts; (iv) Fulvestrant; (v) Idursulfase; and (vi) Palonosetron; its salts to Division A of the First and Third Schedules to the Pharmacy and Posions Regulations and Division A of Part I of the Schedule to the Poisons List Regulations. The addition means that pharmaceutical products containing any of these six

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.

3. Members may wish to refer to the supplementary information provided by the Secretary for the respective application of the six substances.

4. The Board considers that the proposed amendments necessary in view of the potency, toxicity and potential side-effects of the medicines concerned.

5. The Administration intends the Amendment Regulations to come into operation on the day of publication in the Gazette after having been approved by the Legislative Council to allow early control and sale of the relevant substances. The Secretary has proposed 24 October 2008 as the date of gazettal.

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
TAM Shuk-fong, Clara
Assistant Legal Adviser
Legislative Council Secretariat
6 October 2008