立法會
Legislative Council

LC Paper No. LS62/05-06

Paper for the House Committee Meeting
on 12 May 2006

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

The Secretary for Health, Welfare and Food ("the Secretary") has given notice to move a motion at the Council meeting on 17 May 2006. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2006 and the Poisons List (Amendment) (No. 2) Regulation 2006, both made by the Pharmacy and Poisons Board ("the Board") on 24 April 2006 pursuant to section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. According to the draft speech of the Secretary, the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2006 and the Poisons List (Amendment) (No. 2) Regulation 2006 seek to:

(a) add 4 new drugs/medicines, i.e. Everolimus, its salts, its esters and their salts, Omalizumab, Pegvisomant and its salts and Solifenacin, its salts, its esters and their salts to part A of the First and Third Schedules to the Pharmacy and Poisons Regulations and part A of Part I of the Schedule to the Poisons List Regulations; and

(b) remove lozenges of nicotine, intended to be used in nicotine replacement therapy and containing not more than 2 mg of nicotine per piece ("nicotine lozenges") from part A of the First Schedule to the Pharmacy and Poisons Regulations and reclassify them from part A of Part I of the Schedule to the Poison List Regulations to part A of Part II of that Schedule.

3. The Secretary has provided, in addition to his draft speech, supplementary information on the 4 new drugs/medicines. Their addition means that pharmaceutical products containing any of these 4 substances must be sold in pharmacies by or under the supervision of a registered pharmacist and in his presence, with the support of prescriptions given by a registered medical practitioner, registered dentist or registered veterinary surgeon.

4. The removal of nicotine lozenges from part A of the First Schedule to the Pharmacy and Poisons Regulations and their reclassification in the Poison List means that instead of being kept in locked receptacle and sold in pharmacies in the presence and under the supervision of a registered pharmacist with sale records kept, they can be sold in pharmacies and in other medicines retail outlets, and no pharmacist supervision or record-keeping of sale is required. Thereafter, the control on the nicotine lozenges tallies with the control on chewing gums containing not more than 2 mg of nicotine per piece. There is sufficient medical evidence showing that there is no material difference between them in terms of potency, toxicity and potential side effects.

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

6. The two Amendment Regulations shall come into operation on the day when they are proposed to be published in the Gazette on 19 May 2006 after being approved by the Legislative Council.

7. The Panel on Health Services has not been consulted on the two Amendment Regulations.

8. The two Amendment Regulations are in order from the legal point of view.

Prepared by

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