立法會
Legislative Council

LC Paper No. LS6/07-08

Paper for the House Committee Meeting
on 2 November 2007

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 7 November 2007. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2007 and the Poisons List (Amendment) (No. 4) Regulation 2007, both made by the Pharmacy and Poisons Board ("the Board") on 17 October 2007 pursuant to section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. The Pharmacy and Poisons (Amendment) (No. 4) Regulation 2007 and the Poisons List (Amendment) (No. 4) Regulation 2007 seek to:

(a) add 5 new drugs/medicines, i.e. Darunavir and its salts, Emtricitabine and its salts, Fosphenytoin and its salts, Sitagliptin and its salts and Tenofovir, its salts, its esters and their salts to Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations and Division A of Part I of the Schedule to the Poisons List Regulations. Their addition means that pharmaceutical products containing any of these 5 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;

(b) amend the item "Tranexamic acid" in Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations by adding "except when contained in toothpaste at 0.05% by weight". The effect of such amendment is to relax the control of tranexamic acid when it is contained in toothpaste at 0.05% by weight by removing it from the First and Third Schedules to the Pharmacy and Poisons Regulations. It is classified as Part I poison and can be sold without prescription. The control of other products containing tranexamic acid remains unchanged i.e. they must be kept in a locked receptacle and sold on prescription in pharmacies in the presence and under the supervision of a registered pharmacist; and

(c) relax the control of loratadine and its salts when contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis by excluding them from Part I poisons, which can only be sold in pharmacies in the presence and under the supervision of a registered pharmacist, and reclassifying them as Part II poisons, so that they can be sold by pharmacies as well as medicine companies, and their sale would not be required to be conducted in the presence and under the supervision of registered pharmacists.

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

4. The Legal Service Division has written to the Food and Health Bureau for clarification of the policy intent of relaxing the control of tranexamic acid when contained in toothpaste at 0.05% by weight only and the control over toothpaste which contains tranexamic acid at less than 0.05% by weight. The reply from the Administration is attached as Annex.

5. The two Amendment Regulations shall come into operation on the day when they are published in the Gazette after being approved by the Legislative Council to allow relaxation of control, early control and sale of the relevant medicines. According to the Secretary for Food and Health's draft speech, the date of gazettal will be 9 November 2007.

6. The Panel on Health Services has not discussed the two Amendment Regulations.

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

Encl

Prepared by

Monna LAI
Assistant Legal Adviser
Legislative Council Secretariat
30 October 2007

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Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
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Your ref.: LS/R/1/07-08

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26 October 2007

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Hong Kong

Dear Ms Lai,

Thank you for your letter dated 25 October, enquiring about the proposed resolution under section 29 of the Pharmacy and Poisons Ordinance.

The Department of Health's registration records show that at present only toothpaste containing tranexamic acid at 0.05% by weight has been registered in Hong Kong. If in future someone develops a kind of toothpaste that contains tranexamic acid at other percentage weight, he will have to provide clinical evidence to substantiate the safety and efficacy of that toothpaste. If he or the Pharmacy and Poisons Board would like to relax the control of that toothpaste, the relevant legislation has to be amended.

Yours sincerely,

(Patrick SIU)
for Secretary for Food and Health

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