立法會
Legislative Council

LC Paper No. LS1/13-14

Paper for the House Committee Meeting
on 4 October 2013

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

The Secretary for Food and Health has given notice to move a motion at the Legislative Council meeting of 16 October 2013 to seek the Council's approval of the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2013 and the Poisons List (Amendment) (No. 5) Regulation 2013 (collectively the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 23 September 2013 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance).

2. Under section 29(1)(o) and (r) of the Ordinance, the Board may make regulations to regulate and control the selling, purchasing, compounding and dispensing of poisons and medicines and to prescribe a list of poisons to be called the Poisons List.

3. The Amendment Regulations propose to add a substance, namely Glycopyrronium and its salts, to Division A in each of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (Cap. 138A) and to Division A of Part I of the Poisons List in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (Cap. 138B).

4. The effect of the proposed amendments is to make the substance subject to different levels of control under the Ordinance. Substances listed in the First Schedule to Cap. 138A are subject to restrictions concerning their sale, supply, labelling and storage. Substances listed in the Third Schedule to Cap. 138A can only be sold upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. Substances listed in Part I of the Poisons List in the Schedule to Cap. 138B can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the pharmacist's presence and under the pharmacist's supervision. The

substances listed in Division A of Part I of the Poisons List and Division A of the two said Schedules to Cap. 138A are used essentially for medicinal purposes.

5. According to Annex B of the LegCo Brief (File Ref.: FHB/H/23/4) issued by the Food and Health Bureau in September 2013, the substance is used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. The use of the substance should be decided by a doctor based on the patient's conditions.

6. The Amendment Regulations, if approved by the Legislative Council, will come into operation on the day of publication in the Gazette. The Administration proposes gazettal on 18 October 2013 to allow early control and sale of the medicines containing the substances.

7. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on the Amendment Regulations.

8. The Administration considers public consultation not necessary since the amendments are proposed by the Board which comprises members from the pharmacy, medical and academic professions. The Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the substance (paragraphs 4 and 7 of the LegCo Brief).

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

Prepared by

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