# *立法會*
# *Legislative Council*

LC Paper No. LS43/14-15

**Paper for the House Committee Meeting**
**on 27 February 2015**

**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 18 March 2015 to seek the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2015 (the Amendment Regulation) made by the Pharmacy and Poisons Board (the Board) on 9 February 2015 under section 29(1) of the Pharmacy and Poisons Ordinance (Cap. 138).

2. Under section 29(1)(k) [1] of Cap. 138, the Board may make regulations to provide for the regulation of the type of containers in which various poisons or pharmaceutical products or classes of poisons or pharmaceutical products may be stored or sold and for the labelling of containers in which such poisons or pharmaceutical products are sold.

3. Section 27(c) of Cap. 138 and regulation 15 of the Pharmacy and Poisons Regulations (Cap. 138A) require the containers of poisons to be labelled with particulars including the word "poison" or such other statement specified in the Fifth Schedule to Cap. 138A. Under paragraph 8 of the Fifth Schedule to Cap. 138A, the following medicines are required to be labelled with the words "Caution. This may cause drowsiness. If affected, do not drive or operate machinery." 「注意：此藥可使人昏昏欲睡，服後如有此情形，不得駕駛或動用機械。」: -

> Medicines made up ready for the internal treatment of human aliments containing any of the antihistamine substances (except Astemizole, Cetirizine, Desloratadine, Fexofenadine, Loratadine and Terfenadine), their salts or their compounds with any other substance.

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[1] Section 29(1)(k) of Cap. 138, as amended by section 23(12) of the Pharmacy and Poisons (Amendment) Ordinance 2015 (Ord. No. 2 of 2015) (Amendment Ordinance), extends the application of section 29(1)(k) to cover pharmaceutical products. Section 23(12) of the Amendment Ordinance came into operation on 6 February 2015 (L.N. 30 of 2015).

4. The Amendment Regulation proposes to amend paragraph 8 of the Fifth Schedule to Cap. 138A so that the container of a medicine containing Bilastine, its salts or its compounds with any other substance is not required to be labelled with the warning statement prescribed in that paragraph.

5. According to LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in February 2015, Bilastine is used for the symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Medicines containing Bilastine are proposed to be exempted from the labelling requirements of the caution statement related to drowsiness in the Fifth Schedule because the pharmacological properties of Bilastine indicate that the drug is a non-sedating, long acting histamine antagonist. Members may refer to Annex B to the LegCo Brief for details of the substance.

6. The Amendment Regulation, if approved by the Legislative Council, will come into operation on the day of its publication in the Gazette. According to the LegCo Brief, the Administration proposes gazettal on 20 March 2015 to allow early control and legitimate sale of the medicines containing Bilastine.

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

8. The Administration considers public consultation not necessary since the Amendment Regulation is made by the Board, which is a statutory authority comprising 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 Bilastine (paragraphs 4 and 7 of the LegCo Brief).

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

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24 February 2015