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Legislative Council

LC Paper No. LS65/13-14

Paper for the House Committee Meeting
on 27 June 2014

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 9 July 2014 to seek the Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2014 and the Poisons List (Amendment) (No. 2) Regulation 2014 (collectively known as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. Under section 29(1)(o) and (r) of Cap. 138, 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. The Amendment Regulations seek to add the following four substances to Division A in each of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138A) and to Division A of Part I of the Poisons List in the Schedule to the Poisons List Regulations (Cap. 138B) –

(a) Dapagliflozin; its salts;
(b) Regorafenib; its salts;
(c) Tofacitinib; its salts; and
(d) Vilanterol; its salts.

3. The effect of the amendments is to make the above four substances subject to the control or regulation under Cap. 138. In gist, substances which are included in the First Schedule to Cap. 138A are subject to restrictions concerning their sale, supply, labelling and storage. Further, substances which are included in the Third Schedule to Cap. 138A can be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. In addition, substances that are 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.

4. According to paragraph 4 of the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in June 2014, the Board considers the amendments appropriate in view of the potency, toxicity and potential side effects of the said four substances. Members may refer to Annex B of the Brief for further details.

5. The Amendment Regulations, if approved by the Legislative Council, will come into operation on the day of publication in the Gazette. According to the Brief, the Administration proposes gazettal on 11 July 2014 to allow early control and sale of the medicines containing the relevant substances.

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

7. According to the Administration, public consultation is not considered necessary as the Amendment Regulations are made by the Board, which is a statutory authority comprising members from the pharmacy, medical and academic professions established under Cap. 138 to regulate pharmaceutical products.

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

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