立法會
Legislative Council

LC Paper No. LS48/12-13

Paper for the House Committee Meeting
on 10 May 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 on 22 May 2013 to seek the Council's approval of the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2013 and Poisons List (Amendment) (No. 3) Regulation 2013 (collectively the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 22 April 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 the following three substances -

(a) Aflibercept;
(b) Crizotinib; its salts; and
(c) Ruxolitinib; its salts

to Division A in each of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (PPR) and to Division A of Part I of the Poisons List in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (PLR).

4. The effect of the proposed amendments is to make the substances subject to different levels of control under the Ordinance. Substances listed in the First Schedule to PPR are subject to restrictions concerning their sale, supply, labelling and storage. Substances listed in the Third Schedule to PPR 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 PLR 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 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 PPR are used essentially for medicinal purposes.

5. According to the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in April 2013, the substances are respectively used for adults for the treatment of neovascular (wet) age-related macular degeneration (Aflibercept), for the treatment of patients with previously treated locally advanced or metastatic non-small cell lung cancer that is anaplastic lymphoma kinase positive (Crizotinib; its salts) and for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis (Ruxolitinib; its salts). Members may refer to Annex B to the LegCo Brief for supplementary information on the substances.

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 24 May 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 substances (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.

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