

立法會
Legislative Council

LC Paper No. LS69/11-12

**Paper for the House Committee Meeting
on 1 June 2012**

**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 13 June 2012 to seek the Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2012 and the Poisons List (Amendment) (No. 2) Regulation 2012 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 22 May 2012 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance).

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

3. Part I of the Poisons List as set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (PLR) contains a list of substances which, unless exempted, can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in his presence and under his supervision. Substances listed in Division A of Part I are used essentially for medicinal purposes.

4. The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (PPR) contains a list of substances the sale, supply, labelling and storage of which are subject to certain restrictions. The Third Schedule to PPR contains a list of substances that can be sold only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. Substances listed in Divisions A in these two Schedules are used essentially for medicinal purposes.

5. Arising from an application for registration of eleven pharmaceutical products, the Amendment Regulations seek to add the following eleven substances to Division A of Part I of the Schedule to PLR and Divisions A of the First and Third Schedules to PPR -

- (a) Abiraterone; its salts;
- (b) Apixaban; its salts;
- (c) Asenapine; its salts; its isomers;
- (d) Belimumab;
- (e) Dexlansoprazole; its salts;
- (f) Gimeracil; its salts;
- (g) Linagliptin; its salts;
- (h) Oteracil; its salts;
- (i) Panitumumab;
- (j) Retigabine; its salts; and
- (k) Rilpivirine; its salts.

6. Further, "Domperidone; its salts" will be added to Division A of Part I of the Schedule to PLR.

7. According to the LegCo Brief (File Ref.: FHB/H/23/4) issued by the Food and Health Bureau in May 2012, the Board considers the amendments appropriate in view of the potency, toxicity and potential side effects of the substances. Members may refer to Annex B of that Brief for details of these medicines.

8. If the Legislative Council approves the Amendment Regulations, the Administration will arrange gazettal so that the amendments mentioned in paragraph 5 above will take effect on 15 June 2012 to allow early control and sale of the relevant medicines. The amendment described in paragraph 6 above will take effect on 15 August 2012.

9. The Panel on Health Services has not been consulted on the Amendment Regulations. 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 the Ordinance to regulate pharmaceutical products.

10. No difficulties have been identified in the legal or drafting aspects of the Amendment Regulations.

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