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Legislative Council

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Paper for the House Committee Meeting
on 24 June 2011

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

The Secretary for Food and Health (the Secretary) has given notice to move a motion at the Legislative Council meeting on 6 July 2011 to seek the Council's approval of the Pharmacy and Poisons (Amendment) Regulation 2011 and the Poisons List (Amendment) Regulation 2011 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 13 June 2011 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance).

2. Under section 29 of the Ordinance, the Board may, subject to the approval of the Legislative Council, make regulations in relation to, among other matters, the selling, dispensing, labelling and storage of medicines and poisons.

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

4. Part I of the Poisons List as contained in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (Part I of the Poisons List) sets out a list of substances which 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 of the Poisons List are used essentially for medicinal purposes.

5. The Amendment Regulations seek to add the eight substances listed below to Division A of Part I of the Poisons List and Division A of the First and Third Schedules to the principal Regulations:

(a) "Clozapine; its salts";
(b) "Corifollitropin alfa";
(c) "Denosumab";
(d) "Fenticonazole; its salts";
(e) "Prulifloxacin; its salts; its esters; their salts";
(f) "Rasagiline; its salts";
(g) "Roflumilast; its salts"; and
(h) "Romiplostim".

6. The Poisons List (Amendment) Regulation 2011 seeks to relax the control of "Terbinafine; its salts". Under the proposal, "Terbinafine; its salts; when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as a single application and when labelled for the treatment of tinea pedis and/or tinea cruris only" will be subject to regulation under Part II of the Poisons List, i.e., the substance concerned can only be sold by authorized sellers of poisons on registered premises or by listed sellers of poisons. "Terbinafine; its salts" which does not fall within the above description will continue to be regulated under Part I of the Poisons List.

7. According to paragraph 3 of the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in June 2011, the Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the substances concerned. Members may refer to the supplementary information at Annex B to the LegCo Brief for the respective application of the above substances. According to the information provided, the administration of drugs containing the substances set out in paragraph 5(a) to (h) above could result in side effects and must be decided by a registered medical practitioner based on the patient's condition.

8. According to paragraphs 5 and 7 of the LegCo Brief, subject to the Legislative Council's approval of the Amendment Regulations, the Administration intends to bring them into operation on 8 July 2011 when they are published in the Gazette to allow early control and sale of the medicines containing the substances concerned.

9. The Panel on Health Services has not been consulted on the Amendment Regulations.

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

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