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Legislative Council

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Paper for the House Committee Meeting
on 17 February 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 (the Secretary) has given notice to move a motion at the Legislative Council meeting on 29 February 2012 to seek the Council's approval of the Pharmacy and Poisons (Amendment) Regulation 2012 and the Poisons List (Amendment) Regulation 2012 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance).

2. Section 29(1) of the Ordinance provides that, subject to the advice given by the Poisons Committee and the approval of the Legislative Council, the Board may make regulations to regulate and control the selling, purchasing, dispensing and compounding of poisons and medicines[1] and to prescribe a list of poisons (known as the Poisons List)[2]. Part I of the Poisons List in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) sets out 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.

3. Further, the First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (Regulations) contains a list of substances the sale, supply, labeling and storage of which are subject to certain restrictions. The Third Schedule to the same 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 essentially for medicinal purposes.

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[1] Section 29(1)(o) of the Ordinance
[2] Section 29(1)(r) of the Ordinance

4. The Amendment Regulations seek to add the twelve substances below to Division A of Part I of the Poisons List and of the said Schedules to the Regulations-

(a) Cabazitaxel; its salts; its esters; their salts
(b) Clofarabine; its salts; its esters; their salts
(c) Degarelix; its salts
(d) Eculizumab
(e) Febuxostat; its salts; its esters; their salts
(f) Fingolimod; its salts; its esters; their salts
(g) Lacosamide; its salts
(h) Liraglutide
(i) Natalizumab
(j) Prucalopride; its salts
(k) Ticagrelor; its salts; its esters; their salts
(l) Vernakalant; its salts

5. According to the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in February 2012, the Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the above substances. Members may refer to Annex B to the LegCo Brief for side effects that could be resulted from the use of the above substances, hence the use of them must be decided by a registered medical practitioner based on the patient's condition.

6. Further, an amendment to punctuation is made to the English text of Division A of Part II of the Schedule to the Poisons List Regulations.

7. 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 2 March 2012 when they will be published in the Gazette to allow early control and sale of the medicines containing the substances concerned.

8. The Panel on Health Services has not been consulted on the Amendment Regulations. According to the Administration, public consultation is not necessary since the amendments are proposed by the Board which is a statutory authority comprising members from the pharmacy, medical and academic professions to regulate pharmaceutical products.

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

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