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Paper for the House Committee Meeting
on 7 January 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 19 January 2011 to seek the Council's approval of the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2010 and the Poisons List (Amendment) (No. 5) Regulation 2010 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 28 December 2010 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 required to be sold by retail only 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 those whose uses are essentially medicinal.

5. The Amendment Regulations seek to:

(a) add the four 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:

(i) "Besifloxacin; its salts; its esters; their salts";
(ii) "Eltrombopag; its salts; its esters; their salts";
(iii) "Enrofloxacin; its salts; its esters";
(iv) "Pazopanib; its salts"; and

(b) amend the Chinese name of the substance "Bupropion" (which already exists under Division A of Part I of the Poisons List and Division A of the First and Third Schedules to the principal Regulations) from "苯丙胺"[1] to its correct translation "安非他酮".

6. According to paragraph 3 of the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in December 2010, 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)(i), (ii) and (iv) above could result in side effects and must be decided and monitored by a medical practitioner. In the case of Enrofloxacin, its salts and esters, their use should be judged by a veterinary surgeon.

7. It is noted that in the proposed section 3(2) of the Pharmacy and Poisons (Amendment) (No.5) Regulation 2010 (PPAR), which seeks to add the four substances set out in paragraph 5(a) above to Division A of the Third Schedule to the principal Regulations, the Chinese text contains the reference to "中文文本", but no such reference appears in the corresponding English text. Upon enquiry by the Legal Service Division, the Administration accepts that the words "中文文本" should not be there but does not consider it necessary to delete them because those words would not affect the meaning of the Chinese version of section 3(2). While it is desirable that there is consistency between the English and Chinese versions of the PPAR, we agree that as far as the

[1] Upon enquiry by the Legal Service Division, the Administration has clarified that "苯丙胺" refers to another substance, "alpha-Methylphenethylamine", which is already regulated under Division A of Part I of the Poisons List and Division A of the First and Third Schedules to the principal Regulations.

Chinese version of the PPAR is concerned, the proposed Chinese text would not cause interpretation difficulties because the expression "中文文本" is superfluous.

8. The Amendment Regulations are to come into operation on the date of publication in the Gazette after having been approved by the Legislative Council. The Secretary proposes that the Amendment Regulations take immediate effect upon gazettal on 21 January 2011 to allow early control and sale of the medicines concerned (paragraphs 5 and 7 of the LegCo Brief).

9. According to paragraph 6 of the LegCo Brief, the Administration does not consider public consultation necessary as the Amendment Regulations are made by the Board which is a statutory authority comprising members from the pharmacy, medical and academic professions. The Panel on Health Services has not been consulted on the Amendment Regulations.

10. Subject to Members' views on the drafting issue referred to in paragraph 7 above, no difficulties relating to the legal and drafting aspects of the Amendment Regulations have been identified.

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