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Legislative Council

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Paper for the House Committee Meeting
on 4 December 2009

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 16 December 2009. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2009 and the Poisons List (Amendment) (No. 4) Regulation 2009 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 24 November 2009 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, storage and transport 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 to the principal Regulations are those whose uses are essentially medicinal.

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 for essentially medicinal purposes.

5. The Amendment Regulations seek to add the 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) "Allergen extract of Dermatophagoides pteronyssinus";
(b) "Mertiatide; its salts; its esters; their salts";
(c) "Prasugrel; its salts";
(d) "Racecadotril; its salts";
(e) "Trafluprost"; and

(f) "Trabectedin; its salts; its esters".

6. In relation to the item relating to "Antisera, antitoxins, immunoglobulins and vaccines" in Division A of Part I of the Poisons List and Division A of the First and Third Schedules to the principal Regulations, the Amendment Regulations propose to–

(a) add "Bordetella species" and "Canine infectious disease" to paragraph (b) of the item so that it would also cover antisera, antitoxins, immunoglobulins and vaccines directed against "Bordetella species" or "Canine infectious disease"; and

(b) add a reference to "viruses" to paragraph (b) of the item so that the description of that paragraph covers viruses as well as diseases and organisms.

7. According to the draft speech of the Secretary (para. 7), the Board considers that the proposed amendments are necessary in view of the potency, toxicity and potential side effects of the pharmaceutical products concerned. Members may refer to the supplementary information provided by the Secretary 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 (f) could result in severe allergic reaction or other side effects and must be decided and monitored by a medical practitioner. In the case of vaccines directed against "Bordetella species" or "Canine infectious disease", the use of the vaccines should be monitored by a veterinary surgeon.

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 18 December 2009 to allow early control and sale of the pharmaceutical products concerned (para. 6 of the draft speech).

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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