立法會
Legislative Council

LC Paper No. LS33/09-10

Paper for the House Committee Meeting
on 8 January 2010

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 Council meeting on 20 January 2010. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2009 and the Poisons List (Amendment) (No. 5) Regulation 2009 (collectively referred to as the Amendment Regulations), both made by the Pharmacy and Poisons Board (the Board) on 28 December 2009 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. The Amendment Regulations seek to add the following four substances to Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (principal Regulations) and Division A of Part I of the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) (Part I of the Poisons List) respectively -

(a) Lenalidomide; its salts;
(b) Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia;
(c) Tocilizumab; and
(d) Ustekinumab.

3. The addition of the above substances to the First and Third Schedules to the principal Regulations means that the sale, supply, labeling and storage of the pharmaceutical products containing substances are subject to certain restrictions. On the other hand, the addition of these substances to Part I of the Poisons List means that pharmaceutical products containing the substances must 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 the respective Division A of the First and Third Schedules to the principal Regulations and of Part I of the Poisons List are those whose uses are essentially medicinal.

4. The Secretary has provided, in addition to his draft speech, supplementary information on the respective uses of the above substances for members' reference. According to the information provided, the use of pharmaceutical products containing these substances should be decided by a medical practitioner.

5. According to the draft speech of the Secretary, the Board considers that the proposed amendments necessary in view of the potency, toxicity and potential side effects of the medicine concerned.

6. The Administration intends the Amendment Regulations to come into operation on the day of publication in the Gazette after having been approved by the Legislative Council. The Secretary has proposed 22 January 2010 as the date of gazettal to allow early control and sale of the substances.

7. Neither the public nor the Panel on Health Services has been consulted on the Amendment Regulations.

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

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