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Paper for the House Committee Meeting
on 28 May 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 Legislative Council meeting on 9 June 2010. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 2010 and the Poisons List (Amendment) (No. 2) Regulation 2010 (collectively referred to as the Amendment Regulations) made by the Pharmacy and Poisons Board (the Board) on 19 May 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, 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 following two substances (the Substances) to Division A of Part I of the Poisons List and Division A of the First and Third Schedules to the principal Regulations:

(a) "Arsenic trioxide when contained in pharmaceutical products"; and

(b) "Canakinumab".

6. 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 pharmaceutical products containing the Substances. The supplementary information provided by the Secretary suggests that drugs containing the Substances are administered for the treatment of acute promyelocytic leukemia and cryopyrin-associated periodic syndromes respectively. Their use could result in side effects and must be decided and judged by a medical practitioner. Members may refer to the supplementary information for further details regarding the application of the Substances.

7. It is noted that the Chinese text of the Amendment Regulations renders the expression "Arsenic trioxide when contained in pharmaceutical products" as "三氧化二砷，但限於包含在藥劑製品內者". This is different from the Chinese text in a similar context in the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009 (L.N. 199 of 2009) where "硫辛酸；其鹽類；其衍生物；藥劑製品所包含者" is used. In response to the Legal Service Division's enquiry, the Department of Justice has explained that since the intention is to regulate arsenic trioxide only if it is contained in pharmaceutical products, "但限於包含在藥劑製品內者" is a better Chinese text than "藥劑製品所包含者" to reflect the policy intention. While acknowledging that "when" does not exactly correspond to "但限於" (which may be rendered as "but only if"), the Department of Justice takes the view that the textual difference would not cause any interpretation problem. While it is desirable that there is consistency in the drafting of provisions serving to reflect the same policy intent, we agree that as far as the proposed control over arsenic trioxide is concerned, the proposed Chinese text should not cause interpretation difficulties.

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 11 June 2010 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 discussed the Amendment Regulations.

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

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