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Paper for the House Committee Meeting
on 29 February 2008

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 12 March 2008. The motion seeks the Legislative Council's approval of the Pharmacy and Poisons (Amendment) Regulation 2008 and the Poisons List (Amendment) Regulation 2008 (collectively "the Amendment Regulations"), both made by the Pharmacy and Poisons Board on 15 February 2008 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the principal Ordinance").

2. According to the draft speech of the Secretary, the Amendment Regulations seek to add four substances, namely, "Alglucosidase alfa", "Aliskiren; its salts; its esters; their salts", "Laronidase" and "Posaconazole; its salts; its esters; their salts" to Division A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A), and Division A in Part I of the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) ("Part I of the Poisons List"). In addition, the Poisons List (Amendment) Regulation 2008 proposes to remove "Cetirizine" from Part I of the Poisons List.

3. The Secretary has provided, in addition to his draft speech, supplementary information on the above substances. According to the information provided, "Alglucosidase alfa" is used in patients with Pompe disease. "Alisikiren; its salts; its esters; their salts" is used for the treatment of essential hypertension. "Laronidase" is used for patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I and for patients with the Scheie form who have moderate to severe symptoms. "Posaconazole; its salts; its esters; their salts" is used for the treatment of various types of fungal infections in adults and for prophylaxis of invasive fungal infections in patients receiving remission-induction chemotherapy for acute myelogenous leukaemia or myelodysplastic syndromes. The use of the above four drugs should be decided by a medical practitioner. "Cetirizine", which is proposed to be removed from Part I of the Poisons List, is an antihistamine drug used for the relief of nasal and skin allergies.

4. The addition of the four substances mentioned above to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations means that pharmaceutical products containing any of these 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, with the support of prescriptions given by a registered medical practitioner, registered dentist or registered veterinary surgeon.

5. The effect of removing "Cetirizine" from Part I of the Poisons List is that the control of cetirizine will be relaxed in that antihistamine drugs containing cetirizine can be sold by authorised sellers of poisons on registered premises without involving a registered pharmacist, or by sellers of poisons whose names are entered on the list of persons kept under section 25 of the principal Ordinance. According to the Secretary's draft speech, the relaxation is proposed as nasal and skin allergies are transient and can be self-diagnosed by patients.

6. The Amendment Regulations are to come into operation on the day of publication in the Gazette after having been approved by the Legislative Council. The Secretary has proposed 14 March 2008 as the date of their gazettal to allow early control and sale of the relevant medicines.

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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