立法會
Legislative Council

LC Paper No. LS30/13-14

Paper for the House Committee Meeting
on 28 February 2014

Legal Service Division Report on
Proposed Resolution under section 29 of
the Pharmacy and Poisons Ordinance (Cap. 138)

The Secretary for Food and Health has given notice to move a motion at the Legislative Council meeting of 19 March 2014 to seek the Council's approval of the Pharmacy and Poisons (Amendment) Regulation 2014 (PPAR) and the Poisons List (Amendment) Regulation 2014 (PLAR) made by the Pharmacy and Poisons Board (the Board) on 14 February 2014 under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. Under section 29(1)(o) and (r) of Cap. 138, the Board may make regulations to regulate and control the selling, purchasing, compounding and dispensing of poisons and medicines and to prescribe a list of poisons to be called the Poisons List.

3. PPAR and PLAR seek to add the following seven substances -

(a) 5-Aminolevulinic acid; its salts; its derivatives; their salts;
(b) Cobicistat; its salts;
(c) Elvitegravir; its salts;
(d) Lixisenatide;
(e) Mifepristone; its salts; its esters; their salts;
(f) Perampanel; and
(g) Pertuzumab

to Division A in each of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138A) and to Division A of Part I of the Poisons List in the Schedule to the Poisons List Regulations (Cap. 138B).

4. The effect of the amendments is to make these seven substances subject to the different levels of control under Cap. 138. Substances listed in the First Schedule to Cap. 138A are subject to restrictions concerning their sale, supply, labelling and storage. Substances listed in the Third Schedule to Cap. 138A can only be sold upon a prescription given by a registered medical

practitioner, registered dentist or registered veterinary surgeon. Substances listed in Part I of the Poisons List in the Schedule to Cap. 138B can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the pharmacist's presence and under the pharmacist's supervision. The substances listed in Division A of Part I of the Poisons List and Divisions A in the First and Third Schedules to Cap. 138A are used essentially for medicinal purposes.

5. PPAR further makes a textual amendment to each of the First and Third Schedules to Cap. 138A. The amendments do not change the legal effect of any provisions of Cap. 138A.

6. According to paragraph 4 of the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in February 2014, the Board considers the amendments appropriate in view of the potency, toxicity and potential side effects of these substances. Members may refer to Annex B of that Brief for details of these substances.

7. PPAR and PLAR, if approved by the Legislative Council, will come into operation on the day of publication in the Gazette. The Administration proposes gazettal on 21 March 2014 to allow early control and sale of the medicines containing these substances.

8. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on PPAR and PLAR.

9. According to the Administration, public consultation is not considered necessary as PPAR and PLAR are made by the Board which is a statutory authority comprising members from the pharmacy, medical and academic professions established under Cap. 138 to regulate pharmaceutical products.

10. No difficulties relating to the legal and drafting aspects of PPAR and PLAR have been identified.

Prepared by

KAN Wan-yee, Wendy
Assistant Legal Adviser
Legislative Council Secretariat
26 February 2014