立法會
Legislative Council

LC Paper No. LS6/20-21

Paper for the House Committee Meeting
on 6 November 2020

Legal Service Division Report on
Subsidiary Legislation Gazetted on 30 October 2020

Tabling in LegCo **:** Council meeting of 4 November 2020

Amendment to be made by **:** Council meeting of 2 December 2020 (or that of 6 January 2021 if extended by resolution)

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2020 (L.N. 212)

L.N. 212 is made by the Pharmacy and Poisons Board ("PPB") under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) with the approval of the Secretary for Food and Health. It mainly amends the Pharmacy and Poisons Regulations (Cap. 138A) by adding the following 12 items of substances to Division A of Schedule 1, Division A of Schedule 3, and Division A of Part 1 of the Poisons List set out in Schedule 10 ("Poisons List"), to Cap. 138A:

(i) Acalabrutinib; its salts;
(ii) Agalsidase alfa;
(iii) Alpelisib; its salts;
(iv) Carglumic acid; its salts; its esters; their salts;
(v) Darolutamide; its salts;
(vi) Dinutuximab beta;
(vii) Human cytomegalovirus immunoglobulin;
(viii) Lutetium-177; its salts; when contained in pharmaceutical products;
(ix) Pegaspargase;
(x) Remdesivir; its salts;
(xi) Siponimod; its salts; its esters; their salts; and
(xii) Upadacitinib; its salts.

2. The main effect of L.N. 212 is that the above substances are subject to restrictions with respect to their sale, supply, labelling and storage, and that they can

only be sold by retail upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. Further, the inclusion of the above 12 items in the Poisons List means that they can only be sold on registered premises of an authorized seller of poisons by, or in the presence and under the supervision of, a registered pharmacist. In addition, L.N. 212 also amends the Chinese text of the above Schedules so as to refer to an existing item specified therein by its Chinese name instead of its English name.[1]

3. According to paragraph 4 of the Legislative Council ("LegCo") Brief (File Ref: FHB/H/23/5) issued by the Food and Health Bureau in October 2020, PPB considers the amendments appropriate in view of the potency, toxicity and potential side effects of the above substances. Members may refer to Annex B to the LegCo Brief for details of the above substances which are used to treat various medical conditions including leukemia, breast or prostate cancer, Severe Acute Respiratory Syndrome Coronavirus 2, multiple sclerosis and arthritis.

4. As advised by the Clerk to Panel on Health Services, the Administration has not consulted the Panel on L.N. 212.

5. L.N. 212 came into operation on the date of publication in the Gazette, i.e. 30 October 2020.

6. No difficulties have been identified in relation to the legal and drafting aspects of L.N. 212.

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[1] Please see sections 2(13), 3(13) and 4(13) of L.N. 212. The relevant item is Secukinumab (司庫奇尤單抗).