立法會
Legislative Council

LC Paper No. LS117/20-21

Paper for the House Committee Meeting
on 10 September 2021

Legal Service Division Report on
Subsidiary Legislation Gazetted on 3 September 2021

Tabling in LegCo **:** Council meeting of 8 September 2021

Amendment to be made by **:** Council meeting of 6 October 2021 (or that of 27 October 2021 if extended by resolution)

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2021 (L.N. 218)

L.N. 218 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 amends the Pharmacy and Poisons Regulations (Cap. 138A) by:

(a) adding the following five substances to Division A of Schedule 1, Division A of Schedule 3, and Division A of Part 1 of the Table set out in section 2 of Schedule 10 ("Poisons List") to Cap. 138A:

(i) Belantamab mafodotin;
(ii) Cabotegravir; its salts;
(iii) Isatuximab;
(iv) Ofatumumab; and
(v) Risdiplam; its salts;

(b) adding a substance, namely "Allopurinol", to Division A of Schedule 1 and Division A of Schedule 3 to Cap. 138A; and

(c) adding a substance, namely "Phenazopyridine; its salts", to Division A of Part 1 of the Poisons List.

2. The effect of L.N. 218 is that the six substances set out in paragraph 1(a) and (b) above 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 six substances in paragraph 1(a) and (c) above 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.

3. According to paragraph 4 of the Legislative Council ("LegCo") Brief (File Ref.: FHB/H/23/8) issued by the Food and Health Bureau in August 2021, 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 for the treatment of various medical conditions including chronic primary or secondary gout, uric acid nephropathy, uric acid stone formation, multiple myeloma, Human Immunodeficiency Virus type 1 (HIV-1) infection, multiple sclerosis and spinal muscular atrophy.

4. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on L.N. 218.

5. Save for sections 3(1), 4(1) and 5(5) (amendments relating to Allopurinol, and Phenazopyridine and its salts) which come into operation on 3 September 2022, L.N. 218 came into operation on the day on which it was published in the Gazette (i.e. 3 September 2021). According to footnote 2 of the LegCo Brief, PPB recommends that the amendments in relation to Allopurinol, and Phenazopyridine and its salts commence 12 months after the date on which L.N. 218 is published in the Gazette in order to give affected registration certification holders of pharmaceutical products sufficient time to (a) recall the affected products from the market and (b) re-label the affected products to comply with the labelling requirements due to changes in sales control.

6. No difficulties have been identified in relation to the legal and drafting aspect of L.N. 218.

Prepared by

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