立法會
Legislative Council

LC Paper No. LS8/2022

Paper for the House Committee Meeting
on 25 February 2022

Legal Service Division Report on
Subsidiary Legislation Gazetted on 18 February 2022

Tabling in LegCo : Council meeting of 23 February 2022

Amendment to be made by : Council meeting of 23 March 2022 (or that of 27 April 2022 if extended by resolution)

Fixed Penalty (Smoking Offences) (Amendment) Regulation 2022 (L.N. 18)

The Smoking (Public Health) (Amendment) Ordinance 2021 (Ord. No. 39 of 2021) ("the Amendment Ordinance") amends, among other things, the Smoking (Public Health) Ordinance (Cap. 371) to prohibit the smoking or carrying of an activated alternative smoking product (in addition to conventional smoking products) in areas designated as no smoking areas or in public transport carriers. The Amendment Ordinance was passed by the Legislative Council ("LegCo") on 21 October 2021 and will come into operation on 30 April 2022.

2. L.N. 18 is made by the Secretary for Food and Health under section 16 of the Fixed Penalty (Smoking Offences) Ordinance (Cap. 600). It amends the Fixed Penalty (Smoking Offences) Regulation (Cap. 600A) by:

(a) amending Form 1 in the Schedule to consequentially reflect the amendments made under the Amendment Ordinance in relation to the offence of smoking in designated no smoking areas or in public transport carriers under section 7(1) of Cap. 371 to the effect that the fixed penalty notice in Form 1 in respect of the offence covers alternative smoking products; and

(b) updating the payment instructions in Forms 1 and 2 in the Schedule by removing the specified postal address of the Treasury, and adding its hotline and official website.

3. According to paragraph 10 of the LegCo Brief (File Ref.: FH CR 3/52/581/89) issued by the Food and Health Bureau and the Department of Health on 16 February 2022, as L.N. 18 contains amendments consequential

to the Amendment Ordinance and amendments to update the payment instructions, no public consultation is considered necessary.

4. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on L.N. 18.

5. L.N. 18 comes into operation on 30 April 2022.

Pharmacy and Poisons (Amendment) (No. 2) Regulation 2022 (L.N. 19)

6. L.N. 19 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) Cedazuridine; its salts;
(ii) Eptinezumab;
(iii) Icosapent ethyl when contained in pharmaceutical products indicated for the reduction of the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization;
(iv) Probenecid; and
(v) Selinexor; its salts; and

(b) adding an item, namely "Tranexamic acid, topical preparations containing not more than 3% of tranexamic acid as cosmetic products not intended for the treatment of human ailments", to Division A of Group II "Special Exemptions" of Schedule 2.

7. The main effects of L.N. 19 are that:

(a) the five substances set out in paragraph 6(a) 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 five substances in Part 1 of 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; and

(b) Cap. 138 and Cap. 138A do not apply to substances or articles that are or contain the item as mentioned in paragraph 6(b) above, except where the substance or article is a pharmaceutical product within the meaning of Cap. 138.

8. According to paragraph 4 of the LegCo Brief (File Ref.: FHB/H/23/4) issued by the Food and Health Bureau in February 2022, PPB considers the amendments appropriate in view of the potency, toxicity and potential side effects of the substances mentioned in paragraph 6(a) and (b) above. Members may refer to Annex B to the LegCo Brief for details of those substances, which are used to treat or prevent various medical conditions including myelodysplastic syndromes, migraine, myocardial infarction, hyperuricaemia associated with chronic gout and multiple myeloma.

9. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on L.N. 19.

10. Save for sections 3(4), 5(4) and 6(4) (amendments relating to Probenecid) which come into operation on 18 February 2023, L.N. 19 came into operation on the day on which it was published in the Gazette (i.e. 18 February 2022). According to footnote 2 of the LegCo Brief, PPB recommends that the amendments in relation to Probenecid commence 12 months after the date on which L.N. 19 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 arising from the changes in sales control.

Toys and Children's Products Safety Ordinance (Amendment of Schedules 1 and 2) Notice 2022 (L.N. 20)

11. L.N. 20 is made by the Secretary for Commerce and Economic Development under section 37 of the Toys and Children's Products Safety Ordinance (Cap. 424) to update certain safety standards for toys and six classes of children's products[1] as specified in Schedules 1 and 2 to Cap. 424 respectively.

12. Under sections 3 and 5 of Cap. 424, no person shall manufacture, import or supply any toy or children's product unless the toy or product complies with all the applicable requirements in at least one relevant safety standard specified in Schedule 1 or Schedule 2 to Cap. 424 respectively.[2]

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[1] The six classes of children's products are "baby walking frames", "bottle teats", "bunk beds for domestic use", "children's high chairs and multi-purpose high chairs for domestic use", "children's paints" and "children's safety harnesses".

[2] Sections 3(1) and 5(3) of Cap. 424 provide that goods in transit, goods in the course of transhipment or goods manufactured for export are not subject to the said statutory requirement.

13. According to paragraph 3 of the LegCo Brief (File Ref.: CITB CR 08/18/3) issued by the Commerce, Industry and Tourism Branch of the Commerce and Economic Development Bureau in February 2022, the revision introduced in L.N. 20 is to apply the standards updated by the standards institutions since the last amendment to the two Schedules in October 2021. According to paragraph 8 of the LegCo Brief, the Administration consulted some 50 major trade associations and organizations advocating children welfare in December 2021 and posted a gist of the proposed updates on the relevant Government websites. The Administration has received four submissions, which did not raise any objection in principle to the proposal.

14. As advised by the Clerks to the Panel on Economic Development and the Panel on Commerce and Industry, the Panels have not been consulted on L.N. 20.

15. L.N. 20 comes into operation on 1 September 2022.

Concluding observations

16. No difficulties have been identified in the legal and drafting aspects of L.N. 18 to L.N. 20.

Prepared by

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