

立法會
Legislative Council

LC Paper No. LS44/19-20

**Legal Service Division Report on
Subsidiary Legislation Gazetted on 14 February 2020**

Tabling in LegCo : Council meeting of 19 February 2020

Amendment to be made by : Council meeting of 18 March 2020 (or that of 22 April 2020 if extended by resolution)

Pharmacy and Poisons (Amendment) Regulation 2020 (L.N. 14)

L.N. 14 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 nine items of substances¹ to Division A of Schedule 1 and Division A of Schedule 3 to Cap. 138A;
- (b) adding eight items of substances² to Division A of Part 1 of the Poisons List set out in Schedule 10 to Cap. 138A ("Poisons List");
- (c) amending the existing item of substance "Lovastatin" to "Lovastatin when contained in pharmaceutical products" in Division A of Schedules 1 and 3 to Cap. 138A and the Poisons List;
- (d) amending the existing item of substance "Metronidazole; its salts" to "Metronidazole; its salts; its esters; their salts" in the Poisons List; and
- (e) removing one sub-item "Metronidazole" from the item relating to "Pharmaceutical products for human parenteral administration" in Division A of Schedules 1 and 3 to Cap. 138A and the Poisons List.

¹ The nine items are: (a) Codergocrine mesilate; (b) Crisaborole; its salts; (c) Doravirine; its salts; (d) Galcanezumab; (e) Metronidazole; its salts; its esters; their salts; (f) Regadenoson; its salts; (g) Sucroferric oxyhydroxide; (h) Talazoparib; its salts; and (i) Tisagenlecleucel.

² The eight items of substances are same with those set out in footnote 1 except item (e) Metronidazole; its salts; its esters; their salts which has been included in the Poisons List by way of amending the existing item of substance "Metronidazole; its salts" in the List.

2. The effect of L.N. 14 is that the newly added 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 newly added substances in the Poisons List means that they can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the presence and under the supervision of a registered pharmacist.

3. According to paragraph 5 of the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in February 2020, PPB considers the amendments appropriate in view of the potency, toxicity and potential side effects of the substances. Members may refer to Annex B to the LegCo Brief for details of the substances.

4. As advised by the Clerk to the Panel on Health Services, the Administration has not consulted the Panel on L.N. 14.

5. Save for sections 3(1), (6) and (7), 4(1), (6) and (7), and 5(1), (6) and (7) (collectively "the remaining sections"), L.N. 14 came into operation on the day on which it was published in the Gazette, i.e. 14 February 2020. The remaining sections, which relate to the addition of substances "Codergocrine mesilate" and "Metronidazole; its salts; its esters; their salts" and the amendments referred to in paragraph 1(d) and (e) above, come into operation on 14 February 2021. According to footnote 2 of the LegCo Brief, the commencement of the remaining sections in February 2021 would give affected registration certification holders sufficient time to recall the affected products from the market and to re-label the affected products to comply with the labelling requirements due to changes in sales control.

Dangerous Drugs Ordinance (Amendment of Second Schedule) Order 2020 (L.N. 15)

6. L.N. 15 is made by the Secretary for Security under section 50(2) of the Dangerous Drugs Ordinance (Cap. 134) to amend the list of hospitals and institutions ("prescribed hospitals") as specified in the Second Schedule to Cap. 134 by:

- (a) removing two institutions (i.e. Hong Kong Kidney Foundation Limited (Kowloon City Dialysis Centre; and Po Leung Kuk Fuk Wai Home for the Elderly) from the Schedule due to their closure; and
- (b) adding four institutions (i.e. Alpine Nursing Home, Evergreen (Kwai Chung Estate) Nursing Home, Evergreen (On Tai) Nursing Home Cum Day Care Centre and Grand Residence) to the Schedule.

7. Under section 22(1)(e) and (f) of Cap. 134, a registered pharmacist or an approved person employed or engaged at a prescribed hospital and whose duties

include the dispensing or supply of medicines for that hospital; and a sister in charge of a ward, theatre or other department in a prescribed hospital may, subject to other provisions of Cap. 134, possess and supply a dangerous drug, so far as may be necessary for the practice or exercise of his/her profession, function or employment. Under section 22(2), the matron of a prescribed hospital may possess and supply a dangerous drug so far as may be necessary for the purposes of the hospital and in his/her capacity as matron thereof.

8. Members may refer to the LegCo Brief (no reference number provided) issued by the Narcotics Division of the Security Bureau on 12 February 2020 for further information.

9. As advised by the Clerks to the Panel on Health Services and the Panel on Security, the Administration has not consulted the Panels on L.N. 15.

10. L.N. 15 comes into operation on 24 April 2020.

Concluding observations

11. No difficulties have been identified in the legal and drafting aspects of the above items of subsidiary legislation.

Prepared by

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