

立法會
Legislative Council

LC Paper No. LS40/14-15

**Paper for the House Committee Meeting
on 27 February 2015**

**Legal Service Division Report on
Subsidiary Legislation Gazetted on 13 February 2015**

Tabling in LegCo : Council meeting of 25 February 2015

Amendment to be made by : Council meeting of 25 March 2015 (or that of 15 April 2015 if extended by resolution)

Pharmacy and Poisons (Amendment) Regulation 2015 (L.N. 34)

L.N. 34 is made by the Pharmacy and Poisons Board (the Board) under section 29(1B)¹ of the Pharmacy and Poisons Ordinance (Cap. 138) with the approval of the Secretary for Food and Health. It:—

- (a) adds 17 substances to Division A of the First Schedule and Division A of the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138A) to make the substances subject to the restrictions imposed under Cap. 138 and Cap. 138A. Substances included in the First Schedule to Cap. 138A are subject to restrictions concerning their sale, supply, labelling and storage. Substances included in the Third Schedule to Cap. 138A can only be sold by retail upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon;
- (b) adds 16 substances to Division A of Part I of the Poisons List set out in Schedule 10 to Cap. 138A so that, among other applicable requirements, poisons containing those substances 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; and

¹ Section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) provides that the Board may, subject to the approval of the Secretary for Food and Health and section 31, by regulation, amend (a) the Poisons List; or (b) any list, in a regulation made under subsection (1), of any substances or articles to which a provision in Cap. 138 applies or which are exempt from any such provision. This subsection (1B) was added by section 23(20) of the Pharmacy and Poisons (Amendment) Ordinance 2015 (Ord. No. 2 of 2015) which came into operation on 6 February 2015.

- (c) replaces the substance "Trastuzumab" in Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in Schedule 10 to Cap. 138A by "Trastuzumab; its antibody drug conjugates".

2. According to paragraph 6 of the LegCo Brief (File Ref: FHB/H/23/4) issued by the Food and Health Bureau in February 2015, the Board considers the amendments appropriate in view of the potency, toxicity and potential side effects of the substances. It also considers that it is necessary to add "Domperidone; its salts" (which is currently included in Division A of Part I of the Poisons List) to Division A of the First Schedule and Division A of the Third Schedule to Cap. 138A in order to enhance safety by subjecting it to more restrictions concerning its sale, supply, labelling and storage. Members may refer to Annex B of the LegCo Brief for details of the substances.

3. L.N. 34 (except sections 3(9) and 4(9) relating to "Domperidone; its salts") came into operation on the day of publication in the Gazette, i.e. 13 February 2015. Sections 3(9) and 4(9) of L.N. 34 will come into operation on 15 May 2015.

4. As advised by the Clerk to the Panel on Health Services, the Panel has not been consulted on L.N. 34.

5. No difficulties have been identified in the legal and drafting aspects of L.N. 34.

Prepared by

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24 February 2015