# *立法會*
# *Legislative Council*

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Date : 26 February 2014

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

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**Council meeting of 19 March 2014**

**Proposed resolution under the Pharmacy and Poisons Ordinance**

The Secretary for Food and Health will move, at the Council meeting of 19 March 2014, a proposed resolution under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138). The proposed resolution is attached for Members' consideration. The President has directed that it be printed in the terms in which it was handed in on the Agenda of the Council.

2. The speech, in both Chinese and English, which the Secretary will deliver when moving the proposed resolution is also attached.

(Odelia LEUNG)
for Clerk to the Legislative Council

Encl.

# Pharmacy and Poisons Ordinance

## Resolution

(Under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138))

**Resolved** that the following Regulations, made by the Pharmacy and Poisons Board on 14 February 2014, be approved—

(a) the Pharmacy and Poisons (Amendment) Regulation 2014; and

(b) the Poisons List (Amendment) Regulation 2014.

# Pharmacy and Poisons (Amendment) Regulation 2014

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

**1. Pharmacy and Poisons Regulations amended**

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2 and 3.

**2. First Schedule amended (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply under regulations 3, 5, 6, 15, 19, 22, 23 and 24)**

(1) First Schedule, Chinese text, Division A, item "洋地黃的甙類；洋地黃的其他有效成份"—

**Repeal**

"成份"

**Substitute**

"成分".

(2) First Schedule, Division A—

(a) After item "Aminoglutethimide"—

**Add**

"5-Aminolevulinic acid; its salts; its derivatives; their salts";

(b) After item "Clozapine; its salts"—

**Add**

"Cobicistat; its salts";

(c) After item "Eltrombopag; its salts; its esters; their salts"—



**Add**

"Elvitegravir; its salts";

(d) After item "Lithium Sulphate"—

**Add**

"Lixisenatide";

(e) After item "Midodrine; its salts"—

**Add**

"Mifepristone; its salts; its esters; their salts";

(f) After item "Pentolinium; its salts"—

**Add**

"Perampanel";

(g) After item "Perindoprilat; its salts; its esters; their salts"—

**Add**

"Pertuzumab".

**3. Third Schedule amended (substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon)**

(1) Third Schedule, Division A—

**Repeal**

"**DIVISION A**".

(2) Third Schedule, after "**VETERINARY SURGEON**"—

**Add**

"**Division A**".

(3) Third Schedule, Division A—

(a) After item "Aminoglutethimide"—

**Add**

"5-Aminolevulinic acid; its salts; its derivatives; their salts";

(b) After item "Clozapine; its salts"—

**Add**

"Cobicistat; its salts";

(c) After item "Eltrombopag; its salts; its esters; their salts"—

**Add**

"Elvitegravir; its salts";

(d) After item "Lithium Sulphate"—

**Add**

"Lixisenatide";

(e) After item "Midodrine; its salts"—

**Add**

"Mifepristone; its salts; its esters; their salts";

(f) After item "Pentolinium; its salts"—

**Add**

"Perampanel";

(g) After item "Perindoprilat; its salts; its esters; their salts"—

**Add**

"Pertuzumab".



Chairman,
Pharmacy and Poisons Board

14 February 2014

## Explanatory Note

This Regulation—

(a) adds 7 substances to Division A of the First Schedule and Division A of the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***) so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations; and

(b) makes technical amendments to the 2 Schedules.

# Poisons List (Amendment) Regulation 2014

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

**1. Poisons List Regulations amended**

The Poisons List Regulations (Cap. 138 sub. leg. B) are amended as set out in section 2.

**2. Schedule amended (the Poisons List)**

The Schedule, Part I, Division A—

(a) After item "Aminoglutethimide"—

**Add**

"5-Aminolevulinic acid; its salts; its derivatives; their salts";

(b) After item "Clozapine; its salts"—

**Add**

"Cobicistat; its salts";

(c) After item "Eltrombopag; its salts; its esters; their salts"—

**Add**

"Elvitegravir; its salts";

(d) After item "Lithium Sulphate"—

**Add**

"Lixisenatide";

(e) After item "Midodrine; its salts"—

**Add**



"Mifepristone; its salts; its esters; their salts";

(f) After item "Pentolinium; its salts"—

**Add**

"Perampanel";

(g) After item "Perindoprilat; its salts; its esters; their salts"—

**Add**

"Pertuzumab".

Chairman,
Pharmacy and Poisons Board

14 February 2014

## Explanatory Note

This Regulation adds 7 substances to Division A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) 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 pharmacist's presence and under the pharmacist's supervision.

**SPEECH BY**
**THE SECRETARY FOR FOOD AND HEALTH**
**AT THE LEGISLATIVE COUNCIL**
**ON 19 MARCH 2014**

**Pharmacy and Poisons Ordinance (Cap. 138)**

**Pharmacy and Poisons (Amendment) Regulation 2013**
**Poisons List (Amendment) Regulation 2013**

Mr President,

I move that the motion under my name, as printed on the Agenda, be passed.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and monitoring system set up in accordance with the Pharmacy and Poisons Ordinance. The Ordinance maintains several Schedules under the Pharmacy and Poisons Regulations and a Poisons List under the Poisons List Regulations. Pharmaceutical products put under different parts of the Poisons List and different Schedules are subject to different levels of control in regard to the conditions of sale and keeping of records.

3. For the protection of public health, some pharmaceutical products can only be sold in pharmacies under the supervision of registered pharmacists and in their presence. For certain pharmaceutical products, proper records of the particulars of the sale must be kept, including the date of sale, the name and address of the purchaser, the name and quantity of the medicine and the purpose for which it is required. The sale of some pharmaceutical products must be authorized by prescription from a registered medical practitioner, dentist or veterinary surgeon.

4. Arising from an application for registration of seven pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following substances to Part I of the Poisons List and the

First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) 5-aminolevulinic acid; its salts; its derivatives; their salts;
(b) Cobicistat; its salts;
(c) Elvitegravir; its salts;
(d) Lixisenatide;
(e) Mifepristone; its salts; its esters; their salts;
(f) Perampanel; and
(g) Pertuzumab.

Pharmaceutical products containing the above seven substances must then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

5. For amendment regulations concerning the adding of the above seven substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations, we propose them to take immediate effect upon gazettal on 21 March 2014, to allow early control and sale of the relevant medicines.

6. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under the Ordinance to regulate pharmaceutical products. The Board comprises members engaged in the pharmacy, medical and academic professions. The Board considers the proposed amendments necessary in view of the potency, toxicity and potential side effects of the medicines concerned.

7. With these remarks, Mr President, I hope members could support the motion.

8. Thank you.