立法會
Legislative Council

LC Paper No. CB(3) 533/12-13

Ref. : CB(3)/M/OR

Tel : 3919 3300

Date : 30 April 2013

From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 22 May 2013

Proposed resolution under the Pharmacy and Poisons Ordinance

The Secretary for Food and Health will move, at the Council meeting of 22 May 2013, 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 22 April 2013, be approved—

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2013; and

(b) the Poisons List (Amendment) (No. 3) Regulation 2013.

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2013

(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)

First Schedule, Division A—

Add in alphabetical order

"Aflibercept

Crizotinib; its salts

Ruxolitinib; its salts".

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)

Third Schedule, Division A—

Add in alphabetical order

"Aflibercept

Crizotinib; its salts

Ruxolitinib; its salts".

Chairman,
Pharmacy and Poisons Board

22 April 2013

Explanatory Note

This Regulation adds 3 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.

Poisons List (Amendment) (No. 3) Regulation 2013

(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—

Add in alphabetical order

"Aflibercept

Crizotinib; its salts

Ruxolitinib; its salts".

Chairman,
Pharmacy and Poisons Board

22 April 2013

Explanatory Note

This Regulation adds 3 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 22 MAY 2013

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment)(No. 3) Regulation 2013
Poisons List (Amendment)(No. 3) 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 Schedules and different parts of the Poisons List 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 authorised by prescription from a registered medical practitioner, dentist or veterinary surgeon.

4. Arising from an application for registration of three pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following three substances to the First and Third Schedules

to the Pharmacy and Poisons Regulations and Part I of the Poisons List:

(a) Aflibercept;
(b) Crizotinib; its salts;
(c) Ruxolitinib; its salts.

Pharmaceutical products containing the above 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 three substances to the First and Third Schedules to the Pharmacy and Poisons Regulations and Part I of the Poisons List, we propose them to take immediate effect upon gazettal on 24 May 2013, to allow early control and sale of the relevant medicine.

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 medicine concerned.

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

8. Thank you.