

立法會
Legislative Council

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Tel : 2869 9205
Date : 24 October 2002
From : Clerk to the Legislative Council
To : All Members of the Legislative Council

Council meeting of 13 November 2002

Proposed resolution under the Pharmacy and Poisons Ordinance

I forward for Members' consideration a proposed resolution which the Secretary for Health, Welfare and Food will move at the Council meeting of 13 November 2002 under the Pharmacy and Poisons Ordinance relating to:

- (a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2002; and
- (b) the Poisons List (Amendment) (No. 4) Regulation 2002.

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 draft speech, in both English and Chinese versions, which the Secretary will deliver when moving the proposed resolution, and the supplementary information provided by the Secretary, are also attached.

(Ray CHAN)
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 -

- (a) the Pharmacy and Poisons (Amendment)(No. 4) Regulation 2002; and
- (b) the Poisons List (Amendment)(No. 4) Regulation 2002, made by the Pharmacy and Poisons Board on 2002, be approved.

PHARMACY AND POISONS (AMENDMENT)(NO. 4) REGULATION 2002

(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. Substances falling within the Poisons List to which special restrictions apply under regulations 3 and 5

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) is amended in part A -

(a) in the item beginning from "Prostaglandins, the following and their derivatives -" and ending at "their salts; their esters", by adding under "Misoprostol" -

"Travoprost

Unoprostone";

(b) by adding -

"Fondaparinux; its salts

Levosimendan; its salts

Parecoxib; its salts

Valdecoxib; its salts".

2. 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

The Third Schedule is amended in part A -

(a) in the item beginning from "Prostaglandins, the following and their derivatives -" and ending at "their salts; their esters", by adding under "Misoprostol" -

"Travoprost

Unoprostone";

(b) by adding -

"Fondaparinux; its salts

Levosimendan; its salts

Parecoxib; its salts

Valdecoxib; its salts".

(Dr Margaret CHAN)
Chairman,
Pharmacy and Poisons Board

22 October 2002

Explanatory Note

This Regulation amends the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) by adding 6 substances to the First and Third Schedules respectively.

POISONS LIST (AMENDMENT)(NO. 4) REGULATION 2002

(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. The Poisons List

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) is amended, in Part I, in part A -

- (a) in the item beginning from "Prostaglandins, the following and their derivatives -" and ending at "their salts; their esters", by adding under "Misoprostol" -

"Travoprost

Unoprostone";

- (b) by adding -

"Fondaparinux; its salts

Levosimendan; its salts

Parecoxib; its salts

Valdecoxib; its salts".

(Dr Margaret CHAN)
Chairman,
Pharmacy and Poisons Board

22 October 2002

Explanatory Note

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) by adding 6 substances to part A of Part I of the Poisons List.

- 1.
2. **Poisons List (Amendment) (No. 4) Regulation 2002**
3. **Pharmacy and Poisons (Amendment) (No. 4) Regulation 2002**
4. **Supplementary Information to the Legislative Council**
5. **《2002年毒藥表（修訂）（第4號）規例》**
6. **《2002年藥劑業及毒藥（修訂）（第4號）規例》**
7. **提交立法會的補充資料**

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Fondaparinux; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for prevention of blood clotting in patients undergoing major surgery of the lower limbs. It requires specialist medical knowledge for safe and effective use. 此藥用於下肢接受大型手術的病人以預防血栓塞。其安全及有效使用需要專科醫學知識。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Levosimendan; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This drug is used for the short-term treatment of severe chronic heart failure when conventional treatment is not sufficient. This drug should only be used when the need is established by a medical diagnosis. Use of this medicine requires careful medical monitoring.</p> <p>此藥在其它常用藥物未能有足夠療效時，用作嚴重慢性心臟衰竭的短期治療。此藥物需經醫生清楚診斷並確定有需要時才能使用。醫護人員在使用此藥時需要小心觀察病人。</p>
Parecoxib; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This medicine is used for short-term treatment of pain caused by surgical operations. A doctor's decision is required for the use of this medicine.</p> <p>此藥用作手術後之痛症的短暫性治療。選用此藥需經醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Travoprost	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This medicine is used to decrease pressure in the eye in glaucoma when other therapies are not tolerated or are inadequate. A doctor's decision is required for the use of this drug.</p> <p>此藥在病人不能耐受其它藥物或其它藥物未能有足夠療效時，治療青光眼作減眼壓用。選用此藥需由醫生決定。</p>
Unoprostone	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This medicine is used to decrease pressure in the eye in glaucoma when other therapies are not tolerated or are inadequate. A doctor's decision is required for the use of this drug.</p> <p>此藥在病人不能耐受其它藥物或其它藥物未能有足夠療效時，治療青光眼作減眼壓用。選用此藥需由醫生決定。</p>
Valdecoxib; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三 毒藥	<p>This medicine is used to treat signs and symptoms of arthritis and uncomplicated period pain. A doctor's decision is required for the use of this medicine because of its possible side effect of causing severe allergy.</p> <p>此藥用作治療關節炎之症狀及非合併症的經痛。由於此藥可以引致嚴重的敏感，故選用此藥需經醫生決定。</p>

**SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 13 NOVEMBER 2002**

Pharmacy and Poisons Ordinance (Cap 138)

**Poisons List (Amendment) (No. 4) Regulation 2002
Pharmacy and Poisons (Amendment) (No. 4) Regulation 2002**

Madam President,

I move that the Poisons List (Amendment) (No. 4) Regulation 2002 and the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2002 as set out under my name in the paper circulated to Members be approved.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and inspection system set up in accordance with the Pharmacy and Poisons Ordinance. The Ordinance maintains a Poisons List under the Poisons List Regulations and several Schedules under the Pharmacy and Poisons Regulations. Pharmaceutical products put on 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, a registered dentist or a registered veterinary surgeon.

4. The Amendment Regulations now before Members seek to amend the Poisons List in the Poisons List Regulations and the Schedules to the Pharmacy and Poisons Regulations, for the purpose of imposing control on six new medicines.

5. The Pharmacy and Poisons Board proposes to add six new medicines to Part I of the Poisons List, and the First and Third Schedules to the Pharmacy and Poisons Regulations so that pharmaceutical products containing any of them must be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under section 3 of the Ordinance to regulate the registration and control of 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, Madam President, I move the motion.

Poisons List (Amendment) (No. 4) Regulation 2002

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2002

Supplementary Information to the Legislative Council

《 2002年毒藥表 (修訂)(第 4 號) 規例 》

《 2002年藥劑業及毒藥 (修訂)(第 4 號) 規例 》

提交立法會的補充資料

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Fondaparinux; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for prevention of blood clotting in patients undergoing major surgery of the lower limbs. It requires specialist medical knowledge for safe and effective use. 此藥用於下肢接受大型手術的病人以預防血栓塞。其安全及有效使用需要專科醫學知識。

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Levosimendan; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This drug is used for the short-term treatment of severe chronic heart failure when conventional treatment is not sufficient. This drug should only be used when the need is established by a medical diagnosis. Use of this medicine requires careful medical monitoring.</p> <p>此藥在其它常用藥物未能有足夠療效時，用作嚴重慢性心臟衰竭的短期治療。此藥物需經醫生清楚診斷並確定有需要時才能使用。醫護人員在使用此藥時需要小心觀察病人。</p>
Parecoxib; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This medicine is used for short-term treatment of pain caused by surgical operations. A doctor's decision is required for the use of this medicine.</p> <p>此藥用作手術後之痛症的短暫性治療。選用此藥需經醫生決定。</p>
Travoprost	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This medicine is used to decrease pressure in the eye in glaucoma when other therapies are not tolerated or are inadequate. A doctor's decision is required for the use of this drug.</p> <p>此藥在病人不能耐受其它藥物或其它藥物未能有足夠療效時，治療青光眼作減眼壓用。選用此藥需由醫生決定。</p>

Drug Name 藥名	Proposed Classification 建議類別	Reason 原因
Unoprostone	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This medicine is used to decrease pressure in the eye in glaucoma when other therapies are not tolerated or are inadequate. A doctor's decision is required for the use of this drug.</p> <p>此藥在病人不能耐受其它藥物或其它藥物未能有足夠療效時，治療青光眼作減眼壓用。選用此藥需由醫生決定。</p>
Valdecoxib; its salts	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	<p>This medicine is used to treat signs and symptoms of arthritis and uncomplicated period pain. A doctor's decision is required for the use of this medicine because of its possible side effect of causing severe allergy.</p> <p>此藥用作治療關節炎之症狀及非合併症的經痛。由於此藥可以引致嚴重的敏感，故選用此藥需經醫生決定。</p>