

PHARMACY AND POISONS ORDINANCE

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**RESOLUTION**

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

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RESOLVED that -

- (a) the Pharmacy and Poisons (Amendment)(No. 2) Regulation 2002; and
- (b) the Poisons List (Amendment)(No. 2) Regulation 2002, made by the Pharmacy and Poisons Board on 28 May 2002 be approved

**PHARMACY AND POISONS (AMENDMENT)(NO. 2) 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 by adding -

"Caspofungin; its salts  
Deferiprone; its salts  
Ganirelix; its salts".

**2. Articles exempted by regulation 8 from the  
provisions of the Ordinance and of these  
regulations**

The Second Schedule is amended, in Group II, in part A, in the  
entry relating to "Steroid compounds with androgenic or oestrogenic  
or progestational activity; their esters", by repealing "preparations  
intended to be taken orally for contraceptive purposes only which  
contain not more than 50 microgrammes of oestrogenic substance and not  
more than 5 milligrammes of progestational substance; multivitamin"  
and substituting -

"preparations intended to be taken orally for contraceptive  
purposes only which contain not more than the following per  
dose -

0.15 milligrammes Desogestrel;  
3.00 milligrammes Drospirenone;

0.05 milligrammes Ethinyloestradiol;  
0.10 milligrammes Gestodene;  
0.25 milligrammes Levonorgestrel;  
2.50 milligrammes Lynoestrenol;  
0.05 milligrammes Mestranol;  
1.00 milligrammes Norethisterone;  
0.25 milligrammes Norgestimate; and  
0.50 milligrammes Norgestrel,  
multivitamin".

- 3. 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 by adding -  
"Caspofungin; its salts  
Deferiprone; its salts  
Ganirelix; its salts".

(Dr P Y LAM)

Chairman,  
Pharmacy and Poisons Board

28 May 2002

**Explanatory Note**

This Regulation updates the First, Second and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) by -

- (a) adding 3 new substances to the First and Third Schedules respectively (sections 1 and 3); and
- (b) tightening the control of oral contraceptive products containing oestrogenic and progestational substances (section 2).

**POISONS LIST (AMENDMENT)(NO. 2) 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, by adding -

"Caspofungin; its salts  
Deferiprone; its salts  
Ganirelix; its salts".

(Dr P Y LAM)

Chairman,  
Pharmacy and Poisons Board

28 May 2002

**Explanatory Note**

This Regulation updates the Schedule to the Poisons List  
Regulations (Cap. 138 sub. leg.) by adding 3 substances to part A of  
Part I of the Poisons List.

**SPEECH BY  
THE SECRETARY FOR HEALTH AND WELFARE  
AT THE LEGISLATIVE COUNCIL  
ON 26 JUNE 2002**

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

**Poisons List (Amendment) (No. 2) Regulation 2002  
Pharmacy and Poisons (Amendment) (No. 2) Regulation 2002**

Madam President,

I move that the Poisons List (Amendment) (No. 2) Regulation 2002 and the Pharmacy and Poisons (Amendment) (No. 2) 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 a number of new medicines and tightening the control of oral contraceptive products containing oestrogenic and progestational substances.

5. The Pharmacy and Poisons Board proposes to add three 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. In addition, the Pharmacy and Poisons Board proposes to modify the exemption given to oral contraceptive products. At present, steroid compounds with androgenic or oestrogenic or progestational activity are prescription only medicines, but preparations intended to be taken orally for contraceptive purpose only which contain not more than 50 microgrammes of oestrogenic substance and not more than 5 milligrammes of progestational substance are exempted from such control, so that they can be sold freely over-the-counter. However, these exemption levels do not take into account the different potencies and side effects of individual steroid compounds. The Pharmacy and Poisons Board now proposes to specify the exemption level for individual steroid compound contained per dose in the oral contraceptive product. This is done by adopting the highest level of each steroid compound contained in each of the 35 oral contraceptive products currently registered in Hong Kong as the new exemption levels. Oral contraceptive products containing any steroid compound for which exemption levels have not been set, or containing an existing steroid compound at a level exceeding the exemption level, will be considered on a case by case basis if exemption is justified.

7. 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.

8. With these remarks, Madam President, I move the motion.



**Poisons List (Amendment) (No. 2) Regulation 2002**

**Pharmacy and Poisons (Amendment) (No. 2) Regulation 2002**

**Supplementary Information to the Legislative Council**

《2002年毒藥表（修訂）（第2號）規例》

《2002年藥劑業及毒藥（修訂）（第2號）規例》

提交立法會的補充資料

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
<b>Caspofungin</b> 卡泊芬淨	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This medicine is used for the treatment of invasive aspergillosis in patients who do not respond to other therapies. A doctor's decision is required for the use of this medicine.  此藥用作治療對其它療法無療效之侵襲性曲菌病。選用此藥需經醫生決定。

<b>Drug Name</b> 藥名	<b>Proposed Classification</b> 建議類別	<b>Reason</b> 原因
<b>Deferiprone</b> 去鐵酮	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 the treatment of iron overload in patients with thalassemia-major whom deferoxamine therapy is inadequate. This drug should only be used upon medical judgment on appropriate usage.</p> <p>此藥用於治療去鐵胺未有足夠療效之重型地中海貧血引致的鐵質過量症。需經醫生清楚診斷適用時，才能使用此藥物。</p>
<b>Ganirelix</b> 加尼瑞克	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 prevent premature luteinising hormone surges in women undergoing controlled ovarian hyperstimulation for assisted reproduction techniques. A doctor's decision is required for the use of this medicine.</p> <p>此藥用作預防女性進行輔助生育技術中，控制性高度刺激卵巢所引致的黃體激素過早急劇分泌。選用此藥需經醫生決定。</p>