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. 3) Regulation 2002; and

(b) the Poisons List (Amendment)(No. 3) Regulation 2002,

made by the Pharmacy and Poisons Board on 17 June 2002, be approved.

PHARMACY AND POISONS (AMENDMENT)(NO. 3) 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 relating to "Suprarenal gland" by repealing "and except beclomethasone and its salts when contained in aerosol dispensers" and substituting "; except beclomethasone and its salts when contained in aerosol dispensers and except clobetasone butyrate when contained in preparations intended for external application only at not more than 0.05%";

(b) by adding –

"Dexmedetomidine; its salts

Rasburicase; 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 relating to "Suprarenal gland" by repealing "and except beclomethasone and its salts when contained in aerosol dispensers" and substituting "; except beclomethasone and its salts when contained in aerosol dispensers and except clobetasone butyrate when

contained in preparations intended for external application only at not more than 0.05%";

(b) by adding –

"Dexmedetomidine; its salts

Rasburicase; its salts".

3. Indication of statement prescribed by regulation 15 for the purposes of section 27(c) of the Ordinance

The Fifth Schedule is amended in item 8 by adding "Desloratadine," after "Cetirizine,".

Chairman,
Pharmacy and Poisons Board

17 June 2002

Explanatory Note

This Regulation amends the First, Third and Fifth Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) –

(a) to relax the control of clobetasone butyrate when contained in preparations intended for external application only at not more than 0.05%;

(b) to add 2 new substances to the First and Third Schedules; and

(c) to exempt Desloratadine from the labelling requirement stated in item 8 of the Fifth Schedule.

POISONS LIST (AMENDMENT)(NO. 3) 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)

4. The Poisons List

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

"Dexmedetomidine; its salts

Rasburicase; its salts".

Chairman,
Pharmacy and Poisons Board

17 June 2002

Explanatory Note

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) to add 2 new substances to part A of Part I of the Poisons List.

SPEECH BY
THE SECRETARY FOR HEALTH, WELFARE AND FOOD
AT THE LEGISLATIVE COUNCIL
ON 10 JULY 2002

Pharmacy and Poisons Ordinance (Cap 138)

Poisons List (Amendment) (No. 3) Regulation 2002
Pharmacy and Poisons (Amendment) (No. 3) Regulation 2002

Madam President,

I move that the Poisons List (Amendment) (No. 3) Regulation 2002 and the Pharmacy and Poisons (Amendment) (No. 3) 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 two new medicines and modifying the control on another two existing medicines.

5. The Pharmacy and Poisons Board proposes to add two 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 relax the control of Clobetasone butyrate when contained in preparations intended for external application only at not more than 0.05% so that its sale does not require the support of a prescription but still has to be sold by authorized sellers of poisons under the direct supervision of registered pharmacists. Having regard to the experience related to the use of this drug, the Board is satisfied that this drug is sufficiently safe to be made available without prescription.

7. Moreover, the Board proposes to exempt Desloratadine from the statutory labelling requirement stated in item 8 of the Fifth Schedule to the Pharmacy and Poisons Regulations so that the container of these substances is not required to carry a warning that this drug may cause drowsiness. The proposed relaxation on the labelling requirement is based on the ground that Desloratadine is itself low-sedating.

8. 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.

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

Poisons List (Amendment) (No. 3) Regulation 2002

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2002

Supplementary Information to the Legislative Council

《2002年毒藥表（修訂）（第 3 號）規例》

《2002年藥劑業及毒藥（修訂）（第 3 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**
Dexmedetomidine 右美托咪定	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to sedate patients under an intensive care setting who require ventilation assistance. It requires professional medical knowledge for safe and effective administration. 此藥用於需要呼吸輔助之深切治療部病人作鎮靜劑使用，其安全及有效使用需要專業醫學知識。
Rasburicase **(無)**	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This medicine is used to prevent acute renal failure in patients with blood cancer after the start of cancer therapy. Professional medical knowledge is required for the use of this medicine. 此藥用作預防血癌病人的急性腎衰竭。 選用此藥需要專業醫學知識。