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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 7 November 2007

Proposed resolution under the Pharmacy and Poisons Ordinance

I forward for Members' consideration a proposed resolution which the Secretary for Food and Health will move at the Council meeting of 7 November 2007 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 4) Regulation 2007; and

(b) the Poisons List (Amendment) (No. 4) Regulation 2007.

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 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.

(Mrs Justina LAM)
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 17 October 2007, be approved –

(*a*) the Pharmacy and Poisons (Amendment)(No. 4) Regulation 2007; and

(*b*) the Poisons List (Amendment)(No. 4) Regulation 2007.

PHARMACY AND POISONS (AMENDMENT) (NO. 4) REGULATION 2007

(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. First Schedule amended

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

(*a*) by adding "Darunavir; its salts";

(*b*) by adding "Emtricitabine; its salts";

(*c*) by adding "Fosphenytoin; its salts";

(*d*) by adding "Sitagliptin; its salts";

(*e*) by adding "Tenofovir; its salts; its esters; their salts";

(*f*) by repealing "Tranexamic acid" and substituting "Tranexamic acid except when contained in toothpaste at 0.05% by weight".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Darunavir; its salts";

(*b*) by adding "Emtricitabine; its salts";

(*c*) by adding "Fosphenytoin; its salts";

(*d*) by adding "Sitagliptin; its salts";

(*e*) by adding "Tenofovir; its salts; its esters; their salts";

(*f*) by repealing "Tranexamic acid" and substituting "Tranexamic acid except when contained in toothpaste at 0.05% by weight".

Chairman,
Pharmacy and Poisons Board

17 October 2007

Explanatory Note

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

(*a*) to add 5 substances to the First and Third Schedules respectively 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*) to relax the control of tranexamic acid when it is contained in toothpaste at 0.05% by weight.

POISONS LIST (AMENDMENT) (NO. 4) REGULATION 2007

(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

(1) The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in Division A –

(*a*) in the item relating to "Antihistamine substances", by repealing "Loratadine" and substituting "Loratadine (except Loratadine; its salts; when contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis only)";

(*b*) by adding "Darunavir; its salts";

(*c*) by adding "Emtricitabine; its salts";

(*d*) by adding "Fosphenytoin; its salts";

(*e*) by adding "Sitagliptin; its salts";

(*f*) by adding "Tenofovir; its salts; its esters; their salts".

(2) The Schedule is amended, in Part II, in Division A, by adding –

"Loratadine; its salts; when contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis only".

Chairman,
Pharmacy and Poisons Board

17 October 2007

Explanatory Note

This Regulation amends the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B)("principal Regulations") –

(*a*) to add 5 substances in Division A of Part I of the Poisons List set out in the Schedule to the principal Regulations so that poisons containing those substances can only be sold on premises of authorized sellers of poisons by a registered pharmacist or in his presence and under his supervision; and

(*b*) to relax the control of Loratadine and its salts when they are contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis only so that their sale would not be required to be conducted on premises of authorized sellers of poisons by a registered pharmacist or in his presence and under his supervision.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 7 NOVEMBER 2007

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment)(No. 4) Regulation 2007
Poisons List (Amendment)(No. 4) Regulation 2007

Madam 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 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, dentist or a veterinary surgeon.

4. Arising from five applications for registration of pharmaceutical products, the Pharmacy and Poisons Board proposes to add five substances to Part I of the Poisons List and the First and Third Schedules to the Pharmacy and Poisons Regulations. Pharmaceutical products containing any of these substances must then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

5. In addition, the Pharmacy and Poisons Board proposes to relax the control of tranexamic acid when it is contained in toothpaste at 0.05% by weight. At present, tranexamic acid is classified in Part I of the Poisons List and in the First and Third Schedules to the Pharmacy and Poisons Regulations. That is to say, among other controls, they must be kept in a locked receptacle and sold on prescription in pharmacies in the presence and under the supervision of a registered pharmacist. Toothpaste containing tranexamic acid is used for the relief of gum bleeding caused by gingivitis. As gum bleeding is self-limiting, treatment with this toothpaste does not require the immediate attention of a dentist. We therefore propose reclassifying tranexamic acid when contained in toothpaste at 0.05% by weight as Part I poison, so that it can be sold without prescription. The control of other products containing tranexamic acid remains unchanged.

6. Besides, the Pharmacy and Poisons Board also proposes to relax the control of loratadine and its salts when contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis. loratadine and its salts are currently classified as Part I poisons, and can only be sold in pharmacies in the presence and under the supervision of a registered pharmacist. As allergic rhinitis is transient and can be self-diagnosed by patients, we propose reclassifying pharmaceutical products containing loratadine and its salts and labelled for the relief of the symptoms of allergic rhinitis only as Part II poisons, so that they can be sold by pharmacies as well as medicine companies, and their sale would not be required to be conducted in the presence and under the supervision of registered pharmacists.

7. We propose that these amendment regulations take immediate effect upon gazettal on 9 November 2007 to allow early control and sale of the relevant medicines.

8. 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.

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

Poisons List (Amendment) (No. 4) Regulation 2007

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2007

Supplementary Information to the Legislative Council

《2007年毒藥表（修訂）(第4號) 規例》
《2007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**
Darunavir; its salts (達蘆那韋 ； 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is used in combination with ritonavir or other antiretroviral agents for the treatment of human immunodeficiency virus (HIV) infection in antiretroviral treatment-experienced adult patients, such as those with HIV-1 strains resistant to more than one protease inhibitor. Its use should be decided by a doctor. 與利托那韋或其他抗逆轉錄病毒劑同時使用，適用於治療曾接受抗逆轉錄病毒治療的成年病人的愛滋病病毒感染，例如對超過一種蛋白質酶抑制劑有抗藥性的感染HIV-1型病毒患者。使用該葯與否，須由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Emtricitabine, its salts (恩曲他濱 ； 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is used in combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults. Its use should be decided by a doctor. 與其他抗逆轉錄病毒劑(例如非核苷逆轉錄酶抑制劑或蛋白質酶抑制劑) 同時使用，適用於治療成年病人的HIV-1型病毒感染。使用該葯與否，須由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
Fosphenytoin; its salts (磷苯妥英； 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for the control of status epilepticus of the tonic-clonic (grand mal) type, to prevent and treat seizures occurring in connection with neurosurgery and/or head trauma, as a substitute for oral phenytoin if oral drug administration is not possible and/or contraindicated. Its use should be decided by a doctor. 此葯適用於控制強直性陣攣性癲癇發作(癲癇大發作)的癲癇連續狀態，預防及治療與神經外科及／或頭部創傷有關的癲癇發作，及在不能口服藥物及／或口服藥物有禁忌的情況下，作爲口服苯妥英的代用品。使用該葯與否，須由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Sitagliptin; its salts (西格列汀 ； 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	Monotherapy: Sitagliptin is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Combination therapy: Sitagliptin is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin or a PPAR γ agonist (e.g., thiazolidinediones) when the single agent alone, with diet and exercise, does not provide adequate glycemic control. Its use should be decided by a doctor. 單一療法: 西格列汀適用於輔助節食及運動，以改善二型糖尿病患者的血糖控制。 混合療法:在單一藥物配合節食及運動仍無法提供足夠血糖控制的情況下，西格列汀混合甲福明或PPARγ促效劑(例如胰島素增敏劑)，適用於改善二型糖尿病患者的血糖控制。使用該葯與否，須由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** 原因
Tenofovir; its salts; its esters; their salts (替諾福韋 ； 其鹽類 ； 其酯類 ； 它們的鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is used in combination with other antiretroviral agents for the treatment of HIV-1 infection. Its use should be decided by a doctor 與其他抗逆轉錄病毒劑同時使用，以治療HIV-1型病毒感染。使用該葯與否，須由醫生決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Tranexamic acid when contained in toothpaste at 0.05% by weight 包含在牙膏中的以重量計算爲百分之0.05的氨甲環酸	Part I poison 第一部毒藥	Toothpaste containing tranexamic acid is used for the relief of gum bleeding caused by gingivitis. As gum bleeding is self-limiting, treatment with this toothpaste does not require the immediate attention of a dentist. The toothpaste can therefore be classified as a Part I poison and be sold without prescription by a pharmacist. Other products containing this drug continue to be Part I, First and Third Schedules poisons, i.e. prescription-only medicines. 含氨甲環酸的牙膏適用於由齒齦炎引起的牙肉流血。由於牙肉流血會自行痊癒，用含氨甲環酸的牙膏作治療牙肉流血不需要即時的牙科診斷。所以，這牙膏可被列爲第一部毒藥，在未有醫生處方的情況下由藥劑師售賣。 其他含氨甲環酸的藥品則仍然是第一部附表一及附表三毒藥，即醫生處方藥。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Loratadine and its salts when contained in pharmaceutical products labelled 'for the relief of the symptoms of allergic rhinitis only' 氯雷他定及其鹽類 (當含於標明「只作紓緩過敏性鼻炎症狀之用」的藥物內時)	Part II poison 第二部毒藥	Loratadine is used for the relief of the symptoms of allergic rhinitis and chronic idiopathic urticaria. As allergic rhinitis is transient and can be self-diagnosed by the patient, pharmaceutical products containing loratadine and its salts and labelled "for the relief of the symptoms of allergic rhinitis only" should be classified as part II poisons, so that they can be sold by medicine companies as well as pharmacies. 氯雷他定適用於紓援過敏性鼻炎及慢性原發性蕁麻疹的病徵。 因過敏性鼻炎爲短暫性，病人可自行診斷症狀，含氯雷他定及其鹽類而又標明「只作紓緩過敏性鼻炎症狀之用」的藥物可被列爲第二部毒藥，使其除藥房外也可在藥行發售。