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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 21 October 2009

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 21 October 2009 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009; and

(b) the Poisons List (Amendment) (No. 3) Regulation 2009.

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 30 September 2009, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009; and

(*b*) the Poisons List (Amendment) (No. 3) Regulation 2009.

PHARMACY AND POISONS (AMENDMENT) (NO. 3) REGULATION 2009

(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 "Dexketoprofen; its salts";

(*b*) in the item relating to "Orlistat; its salts", by repealing "its salts" and substituting "its salts; except when contained in a pharmaceutical product of which the recommended dose is a quantity of the product that contains not more than 60 mg of orlistat or its salts, taken 3 times a day";

(*c*) in the item relating to "Sibutramine; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 1-[1-(4-Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine substituted to any degree or without substitution; its salts";

(*d*) in the item relating to "Sildenafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts";

(*e*) in the item relating to "Tadalafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,

4-*b*]indole-1,4-dione substituted to any degree or without substitution; its salts";

(*f*) by adding "Thioctic acid; its salts; its derivatives; when contained in pharmaceutical products";

(*g*) in the item relating to "Vardenafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 2-(2-ethoxyphenyl)-5-methyl-7-propylimidazo[5,1-*f*][1,2,4]triazin-4(3*H*)-one substituted to any degree or without substitution; its salts".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

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

(*b*) in the item relating to "Orlistat; its salts", by repealing "its salts" and substituting "its salts; except when contained in a pharmaceutical product of which the recommended dose is a quantity of the product that contains not more than 60 mg of orlistat or its salts, taken 3 times a day";

(*c*) in the item relating to "Sibutramine; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 1-[1-(4-Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine substituted to any degree or without substitution; its salts";

(*d*) in the item relating to "Sildenafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts";

(*e*) in the item relating to "Tadalafil; its salts", by repealing "its salts" and substituting "its salts; any compound

containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-*b*]indole-1,4-dione substituted to any degree or without substitution; its salts";

(*f*) by adding "Thioctic acid; its salts; its derivatives; when contained in pharmaceutical products";

(*g*) in the item relating to "Vardenafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 2-(2-ethoxyphenyl)-5-methyl-7-propylimidazo[5,1-*f*][1,2,4]triazin-4(3*H*)-one substituted to any degree or without substitution; its salts".

Chairman,
Pharmacy and Poisons Board

30 September 2009

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 2 substances to those Schedules so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the principal Regulations;

(*b*) to add certain chemical descriptions after the items relating to "Sibutramine; its salts", "Sildenafil; its salts",

"Tadalafil; its salts" and "Vardenafil; its salts" so that their analogues are also subject to the same control as those substances; and

(*c*) to relax the control of "Orlistat; its salts" so that "Orlistat; its salts", when contained in a pharmaceutical product of which the recommended dose is a quantity of the product that contains not more than 60 mg of orlistat or its salts, taken 3 times a day, is excluded from those Schedules.

POISONS LIST (AMENDMENT) (NO. 3) REGULATION 2009

(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. B) is amended, in Part I, in Division A –

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

(*b*) in the item relating to "Sibutramine; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 1-[1-(4-Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine substituted to any degree or without substitution; its salts";

(*c*) in the item relating to "Sildenafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts";

(*d*) in the item relating to "Tadalafil; its salts", by repealing "its salts" and substituting "its salts; any compound containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-*b*]indole-1,4-dione substituted to any degree or without substitution; its salts";

(*e*) by adding "Thioctic acid; its salts; its derivatives; when contained in pharmaceutical products";

(*f*) in the item relating to "Vardenafil; its salts", by repealing "its salts" and substituting "its salts; any compound

containing the chemical structure of 2-(2-ethoxyphenyl)-5-methyl-7-propylimidazo[5,1-*f*][1,2,4]triazin-4(3*H*)-one substituted to any degree or without substitution; its salts".

Chairman,
Pharmacy and Poisons Board

30 September 2009

Explanatory Note

This Regulation amends Division A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) –

(*a*) to add 2 substances so that, among other applicable requirements, 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; and

(*b*) to add certain chemical descriptions after the items relating to "Sibutramine; its salts", "Sildenafil; its salts", "Tadalafil; its salts" and "Vardenafil; its salts" so that their analogues are also subject to the same control as those substances.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 21 October 2009

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009
Poisons List (Amendment) (No. 3) Regulation 2009

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 authorised by prescription from a registered medical practitioner, dentist or veterinary surgeon.

4 Arising from an application for registration of two pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following two substances to Part I of the Poisons List and

the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Dexketoprofen; its salts; and
(b) Thiotic acid; its salts; its derivatives, when contained in pharmaceutical products.

Pharmaceutical products and formulations 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. In addition, the Pharmacy and Poisons Board proposes to relax the control of "orlistat when contained in pharmaceutical products the recommended daily dose of which contains not more than 60mg of orlistat or its salts to be taken three times a day." Upon detailed research, these pharmaceutical products have been shown to be sufficiently safe and effective for use in the management of weight reduction without doctor's supervision. Therefore, we propose to re-classify "orlistat when contained in pharmaceutical products the recommended daily dose of which contains not more than 60mg of orlistat or its salts to be taken three times a day" from Part I poisons and Part I First and Third Schedules poisons to Part I poisons only. Subject to regulation under the relevant provision, these pharmatceutical products must be sold in pharmacies in the presence and under the supervision of registered pharmacists.

6. In response to the recent emergence of products marketed for weight reduction or for enhancement of sexual function in men which were found on analysis to contain analogues of poisons subject to regulation under the Pharmacy and Poisons Regulations, the Pharmacy and Poisons Board also proposes to amend four existing entries in Part I of the Poisons List and in the First and Third Schedules to the Pharmacy and Poisons Regulations by adding a chemical description after each entry describing the analogues of each poison, such that the analogues are also subject to the controls applicable to the four poisons themselves. The four poisons are

"Sibutramine; its salts", "Sildenafil; its salts", "Tadalafil; its salts" and "Vardenafil; its salts."

7. We propose that these amendment regulations take immediate effect upon gazettal on 23 October 2009 to allow early control of pharmaceutical products containing these substances.

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, President, I move the motion.

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Poisons List (Amendment) (No. 3) Regulation 2009

Pharmacy and Poisons (Amendment) (No. 3) Regulation 2009

Supplementary Information to the Legislative Council

《2009年毒藥表（修訂）(第三號) 規例》

《2009年藥劑業及毒藥（修訂）(第三號) 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**
Dexketoprofen; its salts 右酮洛芬；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 treatment of mild to moderate pain. Common side effects include hypersensitivity, renal impairment and interactions with other drugs. It may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療輕度至中度痛症。常見的副作用包括對此藥過敏，腎功能受損及與其他藥物相沖。此藥物可能會稍爲增加患上心臟病(心肌梗塞)或中風的風險。使用該藥與否，須由醫生按病人的病情決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Thioctic acid; its salts; its derivatives, when contained in pharmaceutical products 硫辛酸；其鹽類；其衍生物，包含在藥劑製品內	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for sensory disturbances in diabetic polyneuropathy. Common side effects include pressure in the head and difficulty in breathing after rapid intravenous injection. It may also enhance the blood sugar lowering effect of antidiabetic drugs, therefore close monitoring of blood sugar levels is required especially at the start of therapy. This drug should only be used upon medical judgment on appropriate usage. (Note: thiotic acid is a naturally-occurring growth factor present in animal and plant tissues. It is also present, in small dosages, in some health food products for its antioxidant effect). 此藥物用於糖尿病性多神經病變所造成的感官障礙。常見的副作用包括急促進行靜脈注射後出現頭部壓力和呼吸困難。由於此藥物可增強降血糖藥的藥效，因此需要密切監察病人血糖水平，尤其在開始使用此藥物時。需經醫生清楚診斷適用時，才能使用此藥物。 (按：硫辛酸是一種自然存在的生長因子，存在於動物及植物中。由於它有抗氧功能，有些健康食品中亦含有低量的硫辛酸。)

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Orlistat; its salts, except when contained in pharmaceutical products the recommended daily dose of which contain not more than 60mg of orlistat or its salts to be taken three times a day 奧利司他；其鹽類；包含在建議每日劑量不多於60毫克奧利司他或其鹽類，每日服食三次的藥劑製品者除外。	From Part I, First and Third Schedules poison to Part I poison 由第一部附表一及附表三毒藥轉爲第一部毒藥	These pharmaceutical products have been shown to be sufficiently safe and effective for use in the management of weight reduction without doctor's supervision 這些藥劑製品被証實有足夠的安全性及效能，在沒有醫生指示的情況下用以控制體重的減輕。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Sibutramine; its salts; any compound containing the chemical structure of 1-[1-4(Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine, or substituted to any degree; their salts 西布曲明; 其鹽類; 任何含有 1-[1-(4-氯苯基)環丁烷基]-3-甲基丁烷-1-胺這一化學結構或其受到任何程度的取代的化合物; 其鹽類 Sildenafil; its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one, or substituted to any degree; their salts 昔多芬; 其鹽類; 任何含有 5-(2-乙氧苯基)-1-甲基-3-丙基-1*H*-吡唑并[4,3-*d*]嘧啶-7(6*H*)-酮這一化學結構或其受到任何程度的取代的化合物; 其鹽類 Tadalafil; its salts; any compound containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12,12a-hexahydropyrazino[1′,2′:1,6]pyrido[3,4-*b*]indole-1,4-dione, or substituted to any degree; their salts Tadalafil; 其鹽類; 任何含有 6-(5-苯并[1,3]二噁茂基)-2,3,6,7,12,12a-六氫吡嗪并[1’2’:1,6]吡啶并[3,4-*b*]吲哚-1,4-二酮這一化學結構或其受到任何程度的取代的化合物; 其鹽類 Vardenafil; its salts; any compound containing the chemical structure of 2-(2-ethoxyphenyl)-5-methyl-7-propylimidazo[5,1-*f*][1,2,4]triazin-4(3*H*)-one, or substituted to any degree; their salts 伐地那非; 其鹽類; 任何含有 2-(2-乙氧苯基)-5-甲基-7-丙基咪唑并[5,1-*f*][1,2,4]三嗪-4(3*H*)-酮這一化學結構或其受到任何程度的取代的化合物; 其鹽類	Part I First and Third Schedules poison 第一部附表一及附表三毒藥	Sibutramine, sildenafil, tadalafil and vardenafil and their salts are drugs used for weight reduction or erectile dysfunction. They are already classified as Part I First and Third Schedules poisons. The present amendment arises from the recent emergence of products marketed for weight reduction or for enhancement of sexual function in men, but have been found on analysis to contain analogues (i.e. compounds containing the basic chemical structure) of these drugs. Therefore it is necessary to list these analogues as Part I First and Third Schedules poisons. 西布曲明， 昔多芬， tadalafil 及伐地那非及它們的鹽類，是用於減輕體重或治療男性性功能障礙的藥。它們已經被分類爲第一部附表一及附表三毒藥。這次修訂是由於近期發現的，以減輕體重或壯陽作爲招來的產品，經化驗後被發現含有這些藥的類似物 (即與這些藥有著同一的基本化學結構)，所以有需要將這些藥的類似物也一併列入第一部附表一及附表三毒藥。