

## 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 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.