

L. N. 202 of 1999

PHARMACY AND POISONS (AMENDMENT) REGULATION 1999

(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. Commencement

This Regulation shall come into operation on a day to be appointed by the Pharmacy and Poisons Board by notice in the Gazette.

2. Regulation substituted

Regulation 3 of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) is repealed and the following substituted---

"3. Application of section 22 restricted to the First Schedule

Section 22 shall only apply to those poisons included in Part I of the Poisons List as set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg.) which are also included in the First Schedule but not included in the Third Schedule."

3. Substances falling within the Poisons

List to which special restrictions apply under regulations 3 and 5

The First Schedule is amended in Part A---

(a) in the entry relating to "Antihistamine substances" by adding---

"Fexofenadine";

(b) by repealing the entry of the substance "Atellin";

(c) in the entry relating to "Contrast media" by adding---

"Iomeprol";

(d) in the entry relating to "Etoposide" by adding "; its esters" at the end;

(e) by repealing the entry of the substance "Omeprazole";

(f) in the entry relating to "Prostaglandins" by adding---

"Latanoprost";

(g) in the entry relating to "Suprarenal gland" by adding after

"1%" ---

"and except beclomethasone and its salts when contained in aerosol dispensers";

(h) by adding---

"Abciximab

Acamprosate; its salts

Acemetacin; its salts

Aciclovir; its salts

Adapalene; its salts; its esters
Aldesleukin
Anastrozole; its salts
Atorvastatin; its salts
Atovaquone
Basiliximab; its salts
Benserazide; its salts
Bicalutamide; its salts
Brimonidine; its salts
Broncho-Vaxom
Candesartan; its salts; its esters; their salts
Carbidopa; its salts
Celecoxib; its salts
Cerivastatin; its salts
Chlofenamic acid; its salts
Chloroquine; its salts
Cidofovir; its salts
Ciprofibrate; its salts
Cisatracurium besylate
Clopidogrel; its salts
Corticotropin; its salts
Dalteparin; its salts
Dapsone
Dihydroergotamine; its salts, simple or complex
Distigmine; its salts
Donepezil; its salts
Enoxaparin; its salts
Entacapone; its salts
Famciclovir; its salts
Flumethrin; its salts
Gemcitabine; its salts
Glimepiride; its salts
Granisetron; its salts
Grepafloxacin; its salts; its esters
Hydroxychloroquine; its salts
Ibandronic acid; its salts
Imidapril; its salts
Imiquimod; its salts

Irbesartan; its salts
Irinotecan; its salts
Lamivudine; its salts
Lanreotide; its salts
Letrozole
Mangafodipir; its salts
Meloxicam; its salts
Mibefradil; its salts
Mexipril; its salts
Montelukast; its salts
Mivomab-CD3
Mycophenolic acid; its salts; its esters
Naratriptan; its salts
Nefazodone; its salts
Neostigmine; its salts
Nevirapine; its salts
Nimesulide; its salts
Nisoldipine
Olanzapine; its salts
Orlistat; its salts
Penciclovir; its salts
Pentamidine; its salts
Pizotifen; its salts
Pramipexole; its salts
Primaquine; its salts
Proguanil; its salts
Pyridostigmine; its salts
Pyrimethamine
Quetiapine; its salts
Rabeprazole; its salts
Raloxifene; its salts
Reboxetine; its salts
Remifentanyl; its salts
Repaglinide; its salts; its esters
Reteplase
Reviparin; its salts
Riluzole; its salts
Rivastigmine; its salts

Ropinirole; its salts
Ropivacaine; its salts
Saquinavir; its salts
Sodium aurothiomalate
Tacrolimus
Tazarotene; its salts
Tiludronic acid; its salts
Tinzaparin; its salts
Tirofiban; its salts
Tolcapone; its salts
Tolterodine; its salts
Topiramate; its salts
Topotecan; its salts
Trimetrexate; its salts
Trovafloxacin; its salts; its derivatives; their salts
Valaciclovir; its salts
Valsartan; its salts
Vinorelbine; its salts
Xylazine; its salts
Zafirlukast
Zolmitriptan; its salts".

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

The Second Schedule is amended in Part A of Group II, in the entry relating to "Sodium fluoride" by repealing "dentifrices containing not more than 0.3% of sodium fluoride" and substituting "dentifrices containing not more than 0.33% of sodium fluoride".

5. 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 entry relating to "Antihistamine substances" by adding--- "Fexofenadine";
- (b) by repealing the entry of the substance "Atellin";
- (c) in the entry relating to "Contrast media" by adding---

"Iomeprol";

(d) in the entry relating to "Etoposide" by adding "; its esters" at the end;

(e) by repealing the entry of the substance "Omeprazole";

(f) in the entry relating to "Prostaglandins" by adding---

"Latanoprost";

(g) in the entry relating to "Suprarenal gland" by adding after "1%"---

"and except beclomethasone and its salts when contained in aerosol dispensers";

(h) by adding---

"Abciximab

Acamprosate; its salts

Acemetacin; its salts

Aciclovir; its salts

Adapalene; its salts; its esters

Aldesleukin

Anastrozole; its salts

Atorvastatin; its salts

Atovaquone

Basiliximab; its salts

Benserazide; its salts

Bicalutamide; its salts

Brimonidine; its salts

Broncho-Vaxom

Candesartan; its salts; its esters; their salts

Carbidopa; its salts

Celecoxib; its salts

Cerivastatin; its salts

Chlofenamic acid; its salts

Chloroquine; its salts

Cidofovir; its salts

Ciprofibrate; its salts

Cisatracurium besylate

Clopidogrel; its salts

Corticotropin; its salts

Dalteparin; its salts

Dapsone

Dihydroergotamine; its salts, simple or complex

Distigmine; its salts

Donepezil; its salts

Enoxaparin; its salts
Entacapone; its salts
Famciclovir; its salts
Flumethrin; its salts
Gemcitabine; its salts
Glimepiride; its salts
Granisetron; its salts
Grepafloxacin; its salts; its esters
Hydroxychloroquine; its salts
Ibandronic acid; its salts
Imidapril; its salts
Imiquimod; its salts
Irbesartan; its salts
Irinotecan; its salts
Lamivudine; its salts
Lanreotide; its salts
Letrozole
Mangafodipir; its salts
Meloxicam; its salts
Mibefradil; its salts
Mexipril; its salts
Montelukast; its salts
Mivomab-CD3
Mycophenolic acid; its salts; its esters
Naratriptan; its salts
Nefazodone; its salts
Neostigmine; its salts
Nevirapine; its salts
Nimesulide; its salts
Nisoldipine
Olanzapine; its salts
Orlistat; its salts
Penciclovir; its salts
Pentamidine; its salts
Pizotifen; its salts
Pramipexole; its salts
Primaquine; its salts
Proguanil; its salts

Pyridostigmine; its salts
Pyrimethamine
Quetiapine; its salts
Rabeprazole; its salts
Raloxifene; its salts
Reboxetine; its salts
Remifentanyl; its salts
Repaglinide; its salts; its esters
Reteplase
Reviparin; its salts
Riluzole; its salts
Rivastigmine; its salts
Ropinirole; its salts
Ropivacaine; its salts
Saquinavir; its salts
Sodium aurothiomalate
Tacrolimus
Tazarotene; its salts
Tiludronic acid; its salts
Tinzaparin; its salts
Tirofiban; its salts
Tolcapone; its salts
Tolterodine; its salts
Topiramate; its salts
Topotecan; its salts
Trimetrexate; its salts
Trovafloxacin; its salts; its derivatives; their salts
Valaciclovir; its salts
Valsartan; its salts
Vinorelbine; its salts
Xylazine; its salts
Zafirlukast
Zolmitriptan; its salts".

6. 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 "Cetirizine, Fexofenadine," after "Astemizole,".

T. A. SAW

Chairman

25 June 1999

Explanatory Note

This Regulation repeals and substitutes regulation 3 of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) to clarify the application of section 22 of the Pharmacy and Poisons Ordinance (Cap. 138).

2. The Regulation also updates various Schedules to the principal Regulations which update includes---

(a) in the First and Third Schedules---

(i) adding a number of new substances;

(ii) upgrading the control of "Etoposide" by including also its esters;

(iii) substituting "Muromonab-CD3" for "Atellin" in order to tie with the internationally accepted nomenclature for that substance;

(iv) relaxing the control of "Omeprazole";

(v) relaxing the control of "beclomethasone and its salts when contained in aerosol dispensers" (an active principle of "Suprarenal gland");

(b) in the Second Schedule, relaxing the control of "Sodium fluoride" so as to allow dentifrices containing not more than 0.33% of "sodium fluoride" to be sold to the public without any restrictions; and

(c) in the Fifth Schedule, exempting "Cetirizine" and "Fexofenadine" from the relevant statutory labelling requirement.