L.N. 11 of 2017

Pharmacy and Poisons (Amendment) Regulation 2017

(Made by the Pharmacy and Poisons Board under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Secretary for Food and Health)

1. Commencement

(1) Subject to subsection (2), this Regulation comes into operation on the expiry of 6 months beginning on the day on which it is published in the Gazette.

(2) Sections 3(5), 4(5) and 5(5) come into operation on the expiry of 12 months beginning on the day on which this Regulation is published in the Gazette.

2. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 3, 4 and 5.

3. Schedule 1 amended (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply under regulations 3, 5, 6, 22 and 24)

(1) Schedule 1, Division A, after item "Alendronic acid; its salts"—

Add

"Alfacalcidol; its salts".

(2) Schedule 1, Division A, after item "Calcipotriol; its salts"—

Add

"Calcitriol; its salts".

(3) Schedule 1, Division A—

Repeal item "Paracetamol when contained in pharmaceutical products for human parenteral administration".

(4) Schedule 1, Division A, after item "Pertuzumab"—

Add

"Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin—

Acetic acid

Acetylcholine

Acetylcysteine

Adenosine

Adrenaline

Ambroxol

Amino acids

Aminophylline

Anti-D (rho) immunoglobulins

Anti-histamine substances

Atropine

Betiatide

Bicisate

Butetamate

Caffeine

Carnitine

Cations, the following, except in preparations containing any substance to which the Antibiotics Ordinance (Cap. 137) applies—

Calcium
Chromium
Copper
Iron
Magnesium
Manganese
Potassium
Selenium
Sodium, except sodium chloride 0.9%
Zinc
Choline
Cimetidine
Dextromethorphan
Dicycloverine
Difenidol
Diprophylline
Disofenin
Ephedrine
Exametazime
Fish oil
Fluorescein
Gallium
Gelatin
Glucosamine
Glucose
Glycerol

Glyceryl trinitrate
Guaifenesin
Heparin
Hyaluronic acid
Hyaluronidase
Hydroxyethyl starch
Hyoscine
Icodextrin
Indocyanine green
Iodine norcholesterol
Isosorbide
Lactic acid
Lecithin
Lignocaine
Mannitol
Mebrofenin
Medronic acid
Mesna
Methoxyphenamine
Methylene blue
Methylephedrine
Metronidazole
Noradrenaline
Olive oil
Omeprazole
Oxidronate

Papaverine
Paracetamol
Patent blue V
Pentetic acid
Pentoxifylline
Phenol
Phenylephrine
Piracetam
Procaine
Protamine
Ranitidine
Rhenium
Sodium pyrophosphate
Sodium tetradecyl sulfate
Sodium thiosulfate
Sorbitol
Soya oil
Stonefish antivenom
Succimer
Terbutaline
Tetrakis copper tetrafluoroborate
Tetrofosmin
Thallium
Tin
Triglycerides

Tuberculin

Vitamins

Xantinol nicotinate".

(5) Schedule 1, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

(a) After item "Rhenium"—

Add

"Sodium chloride 0.9%";

(b) After item "Vitamins"—

Add

"Water".

(6) Schedule 1, Division A, after item "Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10,000 international units of vitamin A"—

Add

"Vitamin D and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 1,000 international units of vitamin D".

(7) Schedule 1, Division A, before item "Voriconazole; its salts"—

Add

"Vitamin K and its salts when contained in pharmaceutical products, except products with recommended daily dose of 120 mcg or less of vitamin K1 or K2 or its salts".

4. Schedule 3 amended (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)

(1) Schedule 3, Division A, after item "Alendronic acid; its salts"—

Add

"Alfacalcidol; its salts".

(2) Schedule 3, Division A, after item "Calcipotriol; its salts"—

Add

"Calcitriol; its salts".

(3) Schedule 3, Division A—

Repeal item "Paracetamol when contained in pharmaceutical products for human parenteral administration".

(4) Schedule 3, Division A, after item "Pertuzumab"—

Add

"Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin—

Acetic acid

Acetylcholine

Acetylcysteine

Adenosine

Adrenaline

Ambroxol

Amino acids

Aminophylline

Anti-D (rho) immunoglobulins

Anti-histamine substances

Atropine

Betiatide

Bicisate

Butetamate

Caffeine

Carnitine

Cations, the following, except in preparations containing any substance to which the Antibiotics Ordinance (Cap. 137) applies—

Calcium

Chromium

Copper

Iron

Magnesium

Manganese

Potassium

Selenium

Sodium, except sodium chloride 0.9%

Zinc

Choline

Cimetidine

Dextromethorphan

Dicycloverine

Difenidol

Diprophylline
Disofenin
Ephedrine
Exametazime
Fish oil
Fluorescein
Gallium
Gelatin
Glucosamine
Glucose
Glycerol
Glyceryl trinitrate
Guaifenesin
Heparin
Hyaluronic acid
Hyaluronidase
Hydroxyethyl starch
Hyoscine
Icodextrin
Indocyanine green
Iodine norcholesterol
Isosorbide
Lactic acid
Lecithin
Lignocaine
Mannitol

Mebrofenin
Medronic acid
Mesna
Methoxyphenamine
Methylene blue
Methylephedrine
Metronidazole
Noradrenaline
Olive oil
Omeprazole
Oxidronate
Papaverine
Paracetamol
Patent blue V
Pentetic acid
Pentoxifylline
Phenol
Phenylephrine
Piracetam
Procaine
Protamine
Ranitidine
Rhenium
Sodium pyrophosphate
Sodium tetradecyl sulfate
Sodium thiosulfate

Sorbitol
Soya oil
Stonefish antivenom
Succimer
Terbutaline
Tetrakis copper tetrafluoroborate
Tetrofosmin
Thallium
Tin
Triglycerides
Tuberculin
Vitamins
Xantinol nicotinate".

(5) Schedule 3, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

(a) After item "Rhenium"—

Add

"Sodium chloride 0.9%";

(b) After item "Vitamins"—

Add

"Water".

(6) Schedule 3, Division A, after item "Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10,000 international units of vitamin A"—

Add

"Vitamin D and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 1,000 international units of vitamin D".

(7) Schedule 3, Division A, before item "Voriconazole; its salts"—

Add

"Vitamin K and its salts when contained in pharmaceutical products, except products with recommended daily dose of 120 mcg or less of vitamin K1 or K2 or its salts".

5. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, after item "Alendronic acid; its salts"—

Add

"Alfacalcidol; its salts".

(2) Schedule 10, section 2, Table, Part 1, Division A, after item "Calcipotriol; its salts"—

Add

"Calcitriol; its salts".

(3) Schedule 10, section 2, Table, Part 1, Division A—

Repeal item "Paracetamol when contained in pharmaceutical products for human parenteral administration".

(4) Schedule 10, section 2, Table, Part 1, Division A, after item "Pertuzumab"—

Add

"Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin—

Acetic acid

Acetylcholine

Acetylcysteine

Adenosine

Adrenaline

Ambroxol

Amino acids

Aminophylline

Anti-D (rho) immunoglobulins

Anti-histamine substances

Atropine

Betiatide

Bicisate

Butetamate

Caffeine

Carnitine

Cations, the following, except in preparations containing any substance to which the Antibiotics Ordinance (Cap. 137) applies—

Calcium

Chromium

Copper

Iron

Magnesium
Manganese
Potassium
Selenium
Sodium, except sodium chloride 0.9%
Zinc
Choline
Cimetidine
Dextromethorphan
Dicycloverine
Difenidol
Diprophylline
Disofenin
Ephedrine
Exametazime
Fish oil
Fluorescein
Gallium
Gelatin
Glucosamine
Glucose
Glycerol
Glyceryl trinitrate
Guaifenesin
Heparin
Hyaluronic acid

Hyaluronidase
Hydroxyethyl starch
Hyoscine
Icodextrin
Indocyanine green
Iodine norcholesterol
Isosorbide
Lactic acid
Lecithin
Lignocaine
Mannitol
Mebrofenin
Medronic acid
Mesna
Methoxyphenamine
Methylene blue
Methylephedrine
Metronidazole
Noradrenaline
Olive oil
Omeprazole
Oxidronate
Papaverine
Paracetamol
Patent blue V

Pentetic acid
Pentoxifylline
Phenol
Phenylephrine
Piracetam
Procaine
Protamine
Ranitidine
Rhenium
Sodium pyrophosphate
Sodium tetradecyl sulfate
Sodium thiosulfate
Sorbitol
Soya oil
Stonefish antivenom
Succimer
Terbutaline
Tetrakis copper tetrafluoroborate
Tetrofosmin
Thallium
Tin
Triglycerides
Tuberculin
Vitamins
Xantinol nicotinate".

(5) Schedule 10, section 2, Table, Part 1, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

(a) After item "Rhenium"—

Add

"Sodium chloride 0.9%";

(b) After item "Vitamins"—

Add

"Water".

(6) Schedule 10, section 2, Table, Part 1, Division A, after item "Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10 000 international units of vitamin A"—

Add

"Vitamin D and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 1 000 international units of vitamin D".

(7) Schedule 10, section 2, Table, Part 1, Division A, before item "Voriconazole; its salts"—

Add

"Vitamin K and its salts when contained in pharmaceutical products, except products with recommended daily dose of 120 mcg or less of vitamin K1 or K2 or its salts".

L.N. 11 of 2017
B1493

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

16 January 2017

Explanatory Note

This Regulation—

(a) adds 4 items to Division A of Schedule 1, and Division A of Schedule 3, to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***principal Regulations***);

(b) adds 1 item of a class relating to "pharmaceutical products for human parenteral administration" to those Divisions; and

(c) reallocates 1 existing item as an entry under the item mentioned in subparagraph (b) in those Divisions.

The effect is that the sale, supply, labelling and storage of substances in those items are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

2. This Regulation also—

(a) adds 4 items to Division A of Part 1 of the Poisons List set out in Schedule 10 to the principal Regulations;

(b) adds 1 item of a class relating to "pharmaceutical products for human parenteral administration" to that Division; and

(c) reallocates 1 existing item as an entry under the item mentioned in subparagraph (b) in that Division.

The effect is that, among other applicable requirements, substances in those items can only be sold on registered premises of an authorized seller of poisons by a registered pharmacist or in the presence and under the supervision of a registered pharmacist.