1983/132

THE RESTRICTED DRUGS REGULATIONS 1964, AMENDMENT NO. 19

DAVID BEATTIE, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington this 25th day of July 1983

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to the Restricted Drugs Act 1960, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

ANALYSIS

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Restricted Drugs Regulations 1964, Amendment No. 19, and shall be

read together with and deemed part of the regulations heretofore known as the Poisons Regulations 1964* (hereinafter referred to as the principal regulations).

(2) These regulations shall come into force on the 1st day of August 1983.

2. Altering Title of principal regulations and amending regulations—(1) The principal regulations may hereafter be cited as the Restricted Drugs Regulations 1964.

(2) The Title of the principal regulations, and the Titles of the regulations specified in the First Schedule to these regulations, are hereby consequentially amended, in each case, by omitting the word "Poisons", and substituting the words "Restricted Drugs".

3. Interpretation—(1) Regulation 2 (1) of the principal regulations is hereby amended by omitting the definitions of the terms "commercial user" (as substituted by regulation 2 (1) of the Restricted Drugs Regulations 1964, Amendment No. 12), "prohibited substance", and "restricted drug".

(2) Every reference in the principal regulations to a poison (other than a prescription poison) or a poisonous substance shall be deemed to be a reference to a restricted drug.

(3) Every reference in the principal regulations to a prescription poison shall be deemed to be a reference to a prescription drug.

4. Restricted drugs—The principal regulations are hereby amended by revoking regulation 3, and substituting the following regulation:

"3. The substances named, and every substance of a class described, in the First Schedule and the Second Schedule to these regulations are hereby declared to be restricted drugs."

5. Prescription drugs—The principal regulations are hereby amended by revoking regulation 7, and substituting the following regulation:

"7. The substances named, and every substance of a class described, in the Seventh Schedule to these regulations are hereby declared to be prescription drugs which may be sold by retail only pursuant to a prescription of a medical practitioner, dentist, or veterinary surgeon:

"Provided that—

"(a) No animal remedy that is sold as a food supplement or food premix and contains any substance named, or any substance of a class described, in the Seventh Schedule to these regulations, other than tetracycline, chlortetracycline, oxytetracycline, or erythromycin, shall be a prescription drug; and

"(b) No pesticide registered under the Pesticides Act 1979 shall be a prescription drug."

*S.R. 1964/64
Amendment No. 1: S.R. 1966/84
Amendment No. 2: S.R. 1967/250
Amendment No. 3: S.R. 1969/95
Amendment No. 4: S.R. 1969/193
Amendment No. 5: S.R. 1971/55
Amendment No. 6: S.R. 1972/53
Amendment No. 7: S.R. 1972/163
Amendment No. 8: S.R. 1973/111
Amendment No. 9: S.R. 1974/93
Amendment No. 10: S.R. 1974/133
Amendment No. 11: S.R. 1975/25
Amendment No. 12: S.R. 1977/130
Amendment No. 13: S.R. 1978/52
Amendment No. 14: S.R. 1979/37
Amendment No. 15: S.R. 1979/273
Amendment No. 16: S.R. 1981/120
Amendment No. 17: S.R. 1982/32
Amendment No. 18: S.R. 1982/248

6. Three new regulations (relating to advertising) substituted in principal regulations—The principal regulations are hereby amended by revoking regulations 21 to 23, and substituting the following regulations:

"21. **Restriction on advertising**—No advertisement relating to any restricted drug or prescription drug shall state or suggest, either expressly or by implication, that that drug is not habit forming.

"22. **Name and address of advertiser to be stated**—Every advertisement relating to a restricted drug or a prescription drug shall state the true name and the address of the place of business of the advertiser.

"23. **Advertisement for prescription drug**—(1) Every advertisement relating to a prescription drug shall contain a conspicuous statement that the substance advertised is a prescription drug:

"Provided that in any price list or similar publication it shall be sufficient if a prescription drug is indicated by the designation 'P.D.'.

"(2) Subject to subclause (3) of this regulation, nothing in subclause (1) of this regulation shall apply in respect of a prescription drug for the period of 1 month immediately following the date on which it becomes a prescription drug, if, at that date, the drug was part of the existing stock-in-trade in New Zealand of any person lawfully carrying on business there.

"(3) For the purposes of subclause (2) of this regulation, any goods purchased before the date on which a substance becomes a prescription drug, for importation into New Zealand, shall be deemed to be part of the purchaser's stock-in-trade in New Zealand.

"(4) In any proceedings for an offence against subclause (1) of this regulation in which subclause (2) of this regulation is pleaded in defence, the burden of proof that the provision of that subclause is applicable shall lie on the person charged."

7. Labelling—(1) Regulation 37 (1) of the principal regulations is hereby amended by revoking paragraph (d), and substituting the following paragraph:

"(d) The only word or words in that line of the label or panel, except that the word or words may, and where the substance or preparation is packed or labelled in New Zealand or for the New Zealand market shall, be immediately followed by the letters and numbers:

S.1 ... to indicate a restricted drug named in the First Schedule to these regulations

S.2 ... to indicate a restricted drug named in the Second Schedule to these regulations

P.D ... to indicate a prescription drug."

(2) Regulation 38 (a) of the principal regulations is hereby amended by revoking subparagraphs (i) to (v), and substituting the following subparagraphs:

"(i) A drug named, or any drug of a class described, in the First Schedule or the Second Schedule to these regulations, the words 'RESTRICTED DRUG':

"(ii) A prescription drug, the words 'PRESCRIPTION DRUG'; and ".

(3) Regulation 40 (c) of the principal regulations is hereby amended by omitting the word "Fourth".

8. Markings on container—Regulation 55 of the principal regulations is hereby amended by omitting the words "and, if containing any of the poisons or poisonous substances named or described in the Sixth Schedule hereto, shall have the true name or description of the poison or poisonous substance marked thereon in easily legible letters".

9. Records to be kept in certain cases—Regulation 58 of the principal regulations is hereby amended by—

(a) Omitting from paragraph (b) the words "or in Part I of the Third Schedule hereto":

(b) By revoking paragraph (e).

10. New Schedules and Part of Schedule substituted in principal regulations—The principal regulations are hereby amended—

(a) By revoking the First Schedule, and substituting the First Schedule set out in the Second Schedule to these regulations:

(b) By revoking the Second Schedule, and substituting the Second Schedule set out in the Third Schedule to these regulations:

(c) By revoking Part I of the Seventh Schedule, and substituting the Part I set out in the Fourth Schedule to these regulations.

11. Revocations—(1) The principal regulations are hereby amended by revoking the following provisions:

Regulations 4, 5, 6, 8, 9, 10, 11, 11A (as inserted by regulation 4 of the Poisons Regulations 1964, Amendment No. 9), 26, 27, and 28; paragraphs (b) and (g) (as added by regulation 4 of the Restricted Drugs Regulations 1964, Amendment No. 13) of subclause (5), and subclause (7) of regulation 29; and regulations 32, 33, 39, 44, 45, 47, 48, 49, 51, 51A (as inserted by regulation 7 (1) of the Restricted Drugs Regulations 1964, Amendment No. 9), 54 (2) (as added by regulation 7 (2) of the Restricted Drugs Regulations 1964, Amendment No. 9), 55, 63, and 64:

The Third Schedule, the Fourth Schedule, the Fifth Schedule, the Sixth Schedule, Part II of the Seventh Schedule (as substituted by regulation 18 (1) of the Restricted Drugs Regulations 1964, Amendment No. 3), and the Eighth Schedule.

(2) The regulations specified in the Fifth Schedule to these regulations are hereby revoked.

12. Transitional provision—Until the 1st day of January 1984, it shall not be necessary to comply with the provisions of the principal regulations relating to labelling as amended by these regulations if those provisions as they were before these regulations were made are complied with.

SCHEDULES

FIRST SCHEDULE

Reg. 2 (2)

REGULATIONS OF WHICH THE TITLE IS CHANGED

Title	Statutory Regulations Serial Number
The Poisons Regulations 1964, Amendment No. 1 ..	1966/84
The Poisons Regulations 1964, Amendment No. 2 ..	1967/250
The Poisons Regulations 1964, Amendment No. 3 ..	1969/95
The Poisons Regulations 1964, Amendment No. 4 ..	1969/193
The Poisons Regulations 1964, Amendment No. 5 ..	1971/55
The Poisons Regulations 1964, Amendment No. 6 ..	1972/53
The Poisons Regulations 1964, Amendment No. 7 ..	1972/163
The Poisons Regulations 1964, Amendment No. 8 ..	1973/111
The Poisons Regulations 1964, Amendment No. 9 ..	1974/93
The Poisons Regulations 1964, Amendment No. 10	1974/133
The Poisons Regulations 1964, Amendment No. 11	1975/25
The Poisons Regulations 1964, Amendment No. 12	1977/130
The Poisons Regulations 1964, Amendment No. 13	1978/52
The Poisons Regulations 1964, Amendment No. 14	1979/37
The Poisons Regulations 1964, Amendment No. 15	1979/273
The Poisons Regulations 1964, Amendment No. 16	1981/120
The Poisons Regulations 1964, Amendment No. 17	1982/32
The Poisons Regulations 1964, Amendment No. 18	1982/248

SECOND SCHEDULE

Reg. 10 (a)

NEW FIRST SCHEDULE SUBSTITUTED IN PRINCIPAL REGULATIONS

Reg. 3

"FIRST SCHEDULE

RESTRICTED DRUGS

Aconite, alkaloids of; their salts, except substances containing less than 0.02 percent of the alkaloids of aconite.

Adiphenine; its salts.

Ambutonium; its salts.

Anticholinergic agents not elsewhere mentioned in the Schedules to these regulations.

Antimony; its compounds; preparations of antimony; except oxides or antimony sulphides containing less than 0.5 percent of arsenic impurity.

Apomorphine; its salts; except substances containing less than 0.2 percent of apomorphine.

Atropine; its salts; except substances containing less than 0.15 percent of atropine; and except when contained in an auto injection device for use as an antidote.

SECOND SCHEDULE—*continued*

Barium sulphate.
Belladonna, alkaloids of; their salts; except substances containing less than 0.15 percent of the alkaloids of belladonna calculated as hyoscyamine.
Benzilonium; its salts.
Bethanechol chloride.
Bithionol, except when labelled exclusively for animal use.
Brucine, its salts; except substances containing less than 0.2 percent of brucine.
Bufexamac, in preparations for external use containing not more than 5 percent of bufexamac.

Camphorated oil.
Caramiphen.
Carbachol.
Chloral hydrate; its molecular compounds and complexes; except those mentioned elsewhere in the Schedules to these regulations, where not more than 2 grams of these substances is present in the total amount of any preparations sold to a person on any 1 day.
Chlorinated naphthalenes.
Colchicine; its salts; except substances containing less than 0.5 percent of colchicine.
Coniine; its salts; except substances containing less than 0.1 percent of coniine.
Cotarnine; its salts; except substances containing less than 0.2 percent of cotarnine.
Croton oil.
Cyclohexylamine.
Cyclopentolate.

Dextranomer.
Dextromethorphan; its salts; except substances containing less than 1.5 percent of dextromethorphan.
Diatrizoic acid; its salts.
Dicyclomine.
Diphemanil; its salts.
Dithienylallylamines; dithienylalkylallylamines; their salts.

Emetine; its salts; except in ipecacuanha and extracts and tinctures of ipecacuanha and except substances containing less than 1 percent of emetine.
Ethylene dichloride.

Flavoxate; its salts.
Fluorides; in preparations for topical use by man containing 2.5 percent or less of elementary fluorine; except substances containing fluorides in proportion equivalent to 0.1 percent or less of elementary fluorine.
Fluoroacetanilide.

Gelsemium, alkaloids of; their salts; except substances containing less than 0.1 percent of the alkaloids of gelsemium.
Glycopyrronium; its salts.
Guaiphenesin; except in preparations containing less than 1 percent of guaiphenesin.

SECOND SCHEDULE—*continued*

Guanidines, the following: polymethylene diguanidines, diparaanisylphenetyl guanidine.

Hexocyclium; its salts.
Homatropine; its salts; except substances containing less than 0.15 percent of homatropine.
Hydrocyanic acid; when included in preparations for use as medicines or applications for man; except substances containing less than 0.1 percent of hydrocyanic acid (HCN); cyanids; when included in preparations for use as medicines or applications for man; except substances containing less than the equivalent of 0.1 percent, weight in weight of hydrocyanic acid (HCN).
Hydroquinone; except in preparations containing 2 percent or less of hydroquinone.
Hyoscine; its salts; except substances containing less than 0.15 percent of hyoscine; and except in preparations for transdermal delivery.
Hyoscyamine; its salts; except substances containing less than 0.15 percent of hyoscyamine.

Idoxuridine; in preparations containing not more than 0.5 percent of idoxuridine for external use other than as an eye preparation.
Iodamide; its salts.
Iodoxamic acid; its salts.
Iopronic acid; its salts.
Iotroxic acid; its salts.
Ioxaglic acid; its salts.
Isopropamide; its salts.

Jaborandi, alkaloids of; their salts; except substances containing less than 0.5 percent of the alkaloids of jaborandi.

Lead; compounds of; with acids from fixed oils; except in machine spread plasters.
Lead; soluble salts of; except in substances containing less than 4 percent of lead salts.
Lobelia; alkaloids of; their salts; except preparations in the form of cigarettes, smoking mixtures, or fumigants for the relief of asthma; and except substances containing less than 0.5 percent of the alkaloids of lobelia.
Loperamide; its salts.

Mepenzolate.
Metanitrophenol; orthonitrophenol; paranitrophenol.
Methantheline; its salts.
Methyridine.
Metrizoic acid; its salts.

Noradrenaline; its salts.
Nux vomica; except substances containing less than 0.2 percent of strychnine.

Oxybutynin; its salts.
Oxyphencyclimine.
Oxyphenonium; its salts.

SECOND SCHEDULE—*continued*

Papaverine; its salts; except substances containing less than 1 percent of papaverine.
Paraldehyde; in solutions containing 1 percent or less of paraldehyde.
Penthienate.
Phenazone; except in preparations for external use and in preparations adapted for internal use and containing not more than 200 mg of phenazone in each adult dose.
Phenothiazine.
Pipenzolate.
Pomegranate; alkaloids of; their salts; except pomegranate bark; and except substances containing less than 0.5 percent of the alkaloids of pomegranate.
Prampine.
Propantheline; its salts.
Propylphenazone.

Quebracho; alkaloids of; their salts.

Radiographic contrast media.

Sabadilla; alkaloids of; their salts; except substances containing less than 1 percent of the alkaloids of sabadilla.
Savin; oil of.
Selenium; and compounds of selenium; except—
(a) In preparations for external use containing not more than 2.5 percent of selenium:
(b) In substances containing 3 parts per million or less of selenium:
(c) In preparations for internal use, where the recommended daily dose does not exceed 150 micrograms of selenium:
(d) In preparations for the treatment of metals.
Solanaceous alkaloids; their salts not otherwise included in this Schedule; except preparations in the form of cigarettes, smoking mixtures, or fumigants for the relief of asthma containing stramonium and except substances containing less than 0.15 percent of solanaceous alkaloids calculated as hyoscyamine.
Stavesacre; alkaloids of; their salts; except lotions for external use, soaps and ointments; and except substances containing less than 0.2 percent of the alkaloids of stavesacre.
Sutilains; except when listed elsewhere in the Schedules to these regulations.

Tansy, oil of.
Tiemonium; its salts.
Tricyclamol.
Tropicamide.
Tridihexethyl; its salts.

Yohimbe, alkaloids of; their salts.

Zinc phosphide."

Reg. 10 (b)

THIRD SCHEDULE

NEW SECOND SCHEDULE SUBSTITUTED IN PRINCIPAL REGULATIONS

Reg. 3

"SECOND SCHEDULE

RESTRICTED DRUGS

Aconite, alkaloids of; their salts; in substances containing less than 0.02 percent of the alkaloids of aconite.
Adrenal extract; in dermatological preparations containing not more than 0.02 percent of ketosteroids.
Adrenalin.
Aminophylline.
Amyl nitrite.
Anaesthetics, local; except those mentioned elsewhere in the Schedules to these regulations, and except in preparations for external use containing not more than 2 percent of any local anaesthetic.
Anthelmintics, when contained in preparations for use in man; except those mentioned elsewhere in the Schedules to these regulations.
Antihistamines; except—

(a) Those mentioned elsewhere in the Schedules to these regulations; and

(b) Tablets of dimenhydrinate and tablets of promethazine chlorotheophyllinate, if sold—

(i) In a sealed container containing not more than 2 tablets and labelled with or accompanied by printed directions for use for the prevention or alleviation of travel sickness; and

(ii) At an aerodrome, railway station, bus station, or wharf, or in an aircraft or a ship.

Apomorphine; its salts; in substances containing less than 0.2 percent of apomorphine.
Aspirin; in enteric coated and slow-release preparations.
Atropine; its salts; in substances containing less than 0.15 percent of atropine; and when contained in an auto injection device for use as an antidote.
Azobenzene.

Bamifylline hydrochloride.
Belladonna; alkaloids of; their salts; in substances containing less than 0.15 percent of the alkaloids of belladonna calculated as hyoscyamine.
Bentiromide.
Benzene hexachloride; except substances containing 2 percent or less of benzene hexachloride.
Benzoyl peroxide; in preparations for human therapeutic use containing 10 percent or less of benzoyl peroxide.
Bephenium hydroxynaphthoate.
Bioallethrin; for human therapeutic use.
Brobenzoxaldine.
Bromelains.
Bromhexine; its salts.
Brucine; its salts; in substances containing less than 0.2 percent of brucine.
Buclosamide.

THIRD SCHEDULE—*continued*

Cadmium; substances containing cadmium.
Carbaryl; in preparations for human use containing 2 percent or less of carbaryl.
Carbetapentane.
Carbuterol; its salts; except when contained in preparations packed under pressure.
Chlorhexidine; in preparations for human internal use.
Chloroform, except in substances containing less than 2.5 percent of chloroform.
Choline theophyllinate.
Clotrimazole; in dermatological preparations.
Colchicine; its salts; in substances containing less than 0.5 percent of colchicine.
Coniine; its salts; in substances containing less than 0.1 percent of coniine.
Cotarnine; its salts; in substances containing less than 0.2 percent of cotarnine.
Coumaphos.
Creosote, obtained from wood; except in substances containing less than 50 percent of creosote obtained from wood.
Cresols; except in preparations containing not more than 1 percent of cresols.
Cyanocobalamin (vitamin B_{12}); except in preparations containing 50 micrograms or less of cyanocobalamin per daily dose; and except in foods.

Diethylcarbamazine citrate; when contained in preparations for use in man.
Diethylene glycol; diethylene glycol monoethyl ether.
Digitalis; glycosides of; in substances containing less than 1 unit of activity (as defined in the British Pharmacopoeia) in 2 grammes of the substance.
Di-iodohydroxyquinoline; in dermatological preparations.
Dimethothiazine mesylate.
Disalicylic acid.
Dithranol.

Econazole; its salts; in dermatological preparations.
Elatin.
Emetine; its salts; in substances containing less than 1 percent and more than 0.05 percent of emetine.
Ephedra; alkaloids of; their derivatives; except nasal drops and nasal sprays containing less than 1 percent of the alkaloids of ephedra.
Erythrityl tetranitrate.
Ether; except in preparations containing less than 1 percent of ether.
Ethyl chloride.

Fenoterol; its salts; in preparations for oral use; except liquids or aerosol preparations.
Fluorides; in preparations for internal use by man containing 2.2 milligrams or less of fluorides per dosage unit; and in substances containing fluorides in proportion equivalent to 0.1 percent of elementary fluorine.
Folic acid; except in preparations containing 300 micrograms or less of folic acid per daily dose; and except in foods.
Formic acid; except substances containing less than 5 percent of formic acid.

THIRD SCHEDULE—*continued*

Gelsemium; alkaloids of; their salts; in substances containing less than 0.1 percent of the alkaloids of gelsemium.
Glyceryl trinitrate; except for parenteral use.
Glutaraldehyde; for human therapeutic use.

Haloprogin.
Heparin; in substances used for topical applications.
Hexachlorobenzene; in preparations containing more than 2 percent of hexachlorobenzene.
Hexachlorophane; in preparations containing more than 0.75 percent but not more than 3 percent of hexachlorophane.
Homatropine; its salts; in substances containing less than 0.15 percent of homatropine.
Hydrocortisone; hydrocortisone acetate; in dermatological applications containing not more than 0.5 percent by weight of hydrocortisone base and in a quantity not exceeding 15 grams or 15 millilitres per container.
Hydrocyanic acid in substances containing less than 0.1 percent of hydrocyanic acid (HCN); cyanides in substances containing less than the equivalent of 0.1 percent, weight in weight, of hydrocyanic acid (HCN); double cyanides of mercury and zinc.
Hydrogen peroxide; in solutions containing 8 percent or more of hydrogen peroxide.
Hydroxocobalamin (Vitamin B_{12a}, and B_{12b}) for human use, except in foods.
Hydroxyquinoline; and its halogenated and alkyl derivatives and their salts in forms for external human use.
Hyoscine; its salts; in substances containing less than 0.15 percent of hyoscine; and in preparations for transdermal delivery.
Hyoscyamine; its salts; in substances containing less than 0.15 percent of hyoscyamine.

Indanazoline; its salts.
Intrinsic factor; for human use; except in foods.
Iodine and solutions thereof containing more than 2.6 percent of iodine.
Ipratropium; its salts; in preparations for nasal inhalation.
Isoconazole; its salts; in dermatological preparations.
Isoetharine; its salts.
Isoprenaline; its salts.

Jaborandi; alkaloids of; their salts; in substances containing less than 0.5 percent and more than 0.025 percent of the alkaloids of jaborandi.

Lobelia, alkaloids of; their salts; in substances containing less than 0.5 percent and more than 0.1 percent of the alkaloids of lobelia.

Maldison; in preparations for human use containing 2 percent or less of maldison.
Mannityl hexanitrate.
Mebendazole; for human therapeutic use; where not more than 600 milligrams is present in the total amount of any preparation sold to a person on any 1 day.

THIRD SCHEDULE—*continued*

Mercury ammoniated; in preparations for human therapeutic use containing 2.5 percent or less of mercury.
Mercury; its salts; its compounds, except oxides of mercury and ammoniated mercury; in preparations for human therapeutic use containing more than 0.01 percent but no more than 0.1 percent of mercury.
Mercury oxides; in preparations for human therapeutic use containing 1 percent or less of mercury.
Methoxamine; its salts.
Methoxyphenamine; its salts.
Methyl salicylate; when not compounded with other substances.
Miconazole; its salts; in dermatological preparations.

Naphazoline; its salts.
Niclosamide; when contained in preparations for use in man.
Nitric acid; except substances containing less than 9 percent, weight in weight, of nitric acid ($HN0_3$).
Nitrobenzene; except substances containing less than 0.1 percent of nitrobenzene, or soaps containing less than 1 percent of nitrobenzene.
Nitrofurazone.
Noscapine; its salts.
Nux vomica; in substances containing less than 0.2 percent of strychnine.

Orciprenaline.
Organic tin compounds.
Orthocaine; its salts.
Oxymetazoline; its salts.

Papaverine; its salts; in substances containing less than 1 percent of papaverine.
Paracetamol.
Pentaerythritol tetranitrate.
Phenazone; in preparations adapted for internal use and containing not more than 200 mg of phenazone in each adult dose.
Phenols; except in preparations containing 1 percent or less of phenols.
Phenylephrine; its salts; except when contained in preparations for use as nasal sprays or nebulisers.
Phenylpropanolamine; its salts; when contained in an appliance for inhalation in which this substance or any salt thereof is absorbed in inert solid material or when in liquid preparations containing not more than 0.5 percent of this substance or any salt thereof.
Picric acid; except substances containing less than 5 percent of picric acid.
Piperazine; its salts; when contained in preparations for use in man.
Podophyllum; extracts and tinctures of podophyllum; podophyllin.
Polynoxylin.
Pomegranate; alkaloids of; their salts; in substances containing less than 0.5 percent of the alkaloids of pomegranate.
Potassium nitrite; except substances included in the Third Schedule to these regulations; and except in preparations containing less than 0.25 percent of the substance.
Propylhexedrine; its salts; when contained in an appliance for inhalation.
Pseudoephedrine; its salts.
Pyrantel; its salts; when contained in preparations for use in man.
Pyrethrins I and II.

THIRD SCHEDULE—*continued*

Sabadilla; alkaloids of; their salts; in substances containing less than 1 percent of the alkaloids of sabadilla.
Salbutamol; its salts and esters; except when mentioned elsewhere in the Schedules to these regulations.
Salicylic acid; in preparations containing more than 40 percent of salicylic acid.
Selenium; and its compounds; for internal use, where the recommended adult daily dose does not exceed 150 micrograms of selenium; except in substances containing 3 parts per million or less of selenium.
Silver nitrate.
Sodium hyaluronate.
Sodium nitrite; except in preparations containing less than 0.25 percent of the substance.
Solanaceous alkaloids; their salts; not otherwise included in this Schedule, in substances containing less than 0.15 percent of solanaceous alkaloids calculated as hyoscyamine.
Sorbide; its salts.
Stavesacre; alkaloids of; their salts; in substances containing less than 0.2 percent of the alkaloids of stavesacre.
Sucralfate.
Sulphuric acid, except substances containing less than 9 percent, weight in weight, of sulphuric acid (H_2SO_4).

Terbutaline; its salts.
Tetrachloroethylene.
Tetrahydrozoline; its salts.
Theophylline; its salts.
Thiabendazole; its salts; for human use.
Tioconazole; in dermatological preparations.
Tramazoline; its salts.
Trimeprazine; its salts; in preparations containing 0.05 percent or less of trimeprazine.

Viprynium embonate; when contained in preparations for use in man.

Xylometazoline.

Zinc chloride."

Reg. 10 (c) FOURTH SCHEDULE

NEW PART I SUBSTITUTED IN SEVENTH SCHEDULE TO PRINCIPAL REGULATIONS

"Part I

Acebutolol; its salts.
Acetarsol.
Acetazolamide.
Acetylcarbromal.
Acetyldigitoxin.
Acetylstrophanthidin.
Acyclovir.

FOURTH SCHEDULE—*continued*

Alclofenac.
Allergens for human use.
Allopurinol.
Alprazolam.
Alprenolol; derivatives of.
Amantadine; its salts.
Amethocaine; its salts; except when mixed with other substances.
Amidopyrine; its salts.
Amikacin; its salts.
Amiloride; its salts.
Aminoacridine; its salts; except in preparations for external use.
Amiodarone; its salts.
Para-aminobenzene sulphonamide; its salts; derivatives of para-aminobenzene sulphonamide having another radical or radicals substituted for one or both of the hydrogen atoms of—
(i) the para-amino group; or
(ii) the sulphonamide group; or
(iii) both of these groups; the salts of such derivatives:
Excluding, however, ready packed preparations labelled and described as being exclusively for the prevention and treatment of coccidiosis in poultry.
Aminocaproic acid; its salts and esters.
Aminometradine.
Aminopterin sodium.
Aminosalicylic acid; its salts and esters.
Amisometradine.
Amitriptyline; its salts.
Amoxapine; its salts.
Anaesthetics, local; for internal use by ingestion.
Anaesthetics, local; in preparations for ophthalmic use; except when sold to a registered optician for the purpose of use in his practice as an optician.
Ancrod; its immunoglobulin antidote.
Androgens, oestrogens, progestogens, either natural or synthetic, their derivatives, and preparations of them or their derivatives.
Anticonvulsant agents.
Antidepressants, including cyclic and other compounds having a similar type of action, monoamine oxidase inhibitors (hydrazine and non-hydrazine derivatives) and other thymoleptics.
Anti-diabetic substances for oral use.
Antihuman lymphocyte globulin.
Antimicrobial substances being:
(a) Substances produced by bacteria, fungi, or protozoa; or
(b) Substances the chemical properties of which are identical with or similar to, any substance within paragraph (a) above; or
(c) Salts or derivatives or salts of derivatives of substances within paragraph (a) or paragraph (b) above; or
(d) Substances within paragraphs (a), (b), or (c) above, mixed with one or more other materials; except—
(i) Penicillin or salts of penicillin up to 100,000 units when incorporated in a base of liquid or semi-solid consistency and contained in a collapsible tube, disposable syringe, or any other

FOURTH SCHEDULE—*continued*

device approved by the Animal Remedies Board fitted with a nozzle designed for insertion into the teat for the treatment of bovine mastitis; or

(ii) Penicillin or salts of penicillin up to 5,000,000 units when contained in a collapsible tube, disposable syringe, or any other device approved by the Animal Remedies Board; or

(iii) Tylosin or salts of tylosin when in soluble powder form or injectable form for the treatment of diseases of poultry; or

(iv) Tiamulin hydrogen fumarate, when in soluble powder form and incorporated in animal feed additives for the treatment of diseases of poultry, or growth promotion in poultry or pigs.

Apronal.
Aprotinin.
Atenolol; its salts.
Atracurium; its salts.
Auranofin.
Azacyclonol; its salts.
Azaperone.
Azapetine; its salts.
Azapropazone.
Azaribine.
Azathioprine.
Azlocillin; its salts.

Baclofen; its salts.
Bamethan; its salts.
Barbituric acid; its salts; derivatives of barbituric acid; their salts; that are not included in the Schedules to the Misuse of Drugs Act 1975; compounds with any other such substance of barbituric acid or of its salts or of its derivatives or of their salts; except solutions containing not more than 0.5 percent of the substances in this group.
Beclamide; its salts.
Benactyzine; its salts.
Bendrofluzide.
Benoxaprofen; its salts.
Benserazide; its salts.
Benthiazide.
Benzhexol; its salts.
Benzodiazepine; its derivatives.
Benzoyl peroxide, in preparations for human therapeutic use containing more than 10 percent of benzoyl peroxide.
Benztropine; its salts.
Benzydamine; its salts.
Beta-adrenergic receptor blocking agents.
Betahistine; its salts.
Bezafibrate.
Biperidin; its salts.
Bretylium tosylate.
Bromazepam.
Bromocriptine.
Bromvaletone.

FOURTH SCHEDULE—*continued*

Bronchodilators; in preparations for inhalation.
Broxyquinoline, in forms for internal use in humans.
Budesonide.
Bufexamac, except in preparations for external use containing not more than 5 percent of bufexamac.
Bumetanide.
Buphenine; its salts.
Buprenorphine; its salts.
Busulphan.
Butorphanol.

Calcitonin.
Calcium disodium edetate.
Calcitriol.
Captopril.
Carazolol.
Carbamazepine.
Carbaryl; in preparations for human use containing more than 2 percent of carbaryl.
Carbenoxolone; compounds of carbenoxolone except in any topical application.
Carbimazole.
Carboxymethylcysteine.
Carbromal.
Carbutamide.
Cardiac glycosides.
Carisoprodol.
Carmustine.
Carprofen.
Cefotiam; its salts.
Cefoperazone; its salts.
Cefsulodin; its salts.
Ceftriaxone.
Ceruletide.
Chenodeoxycholic acid.
Chlorambucil.
Chloral hydrate; its molecular compounds and complexes; except those mentioned elsewhere in the Schedules to these regulations.
Chlorazanil.
Chlordiazepoxide.
Chlorisondamine chloride.
Chlormerodrin.
Chlormethiazole; its salts.
Chlormezanone.
Chlorothiazide.
Chlorphentermine.
Chlorpropamide.
Chlorprothixene.
Chlorthalidone.
Chlorzoxazone.
Cholestyramine.
Cholinesterase inhibitors; in preparations for use as medicines or applications for man.

FOURTH SCHEDULE—*continued*

Chromonar; its salts.
Cimetidine.
Cinoxacin.
Clobazam.
Clofazimine.
Clofibrate; its salts.
Clomipramine; its salts.
Clomiphene; its salts and esters.
Clonidine; its salts.
Clopamide.
Clorexolone; its salts.
Clotrimazole; except in dermatological preparations.
Cobalt; its salts and compounds, in preparations intended for use as medicines for man; except radioactive forms of cobalt and their salts and compounds, and Cyanocobalamin (Vitamin B_{12}) and its derivatives.
Colestipol; its salts.
Cortisone and steroid suprarenal cortical hormones, either natural or synthetic, their derivatives, and preparations of them or their derivatives; except hydrocortisone and hydrocortisone acetate when contained in a dermatological application containing not more than 0.5 percent by weight of hydrocortisone base, and in a quantity not exceeding 15 grams or 15 millilitres per container; and except adrenal extract, in dermatological preparations containing not more than 0.02 percent of ketosteroids.
Coumarins, heparins, phenindiones, and similar anti-coagulants except heparins when included in substances used for topical applications.
Crocus Sativus for human use.
Curare; alkaloids of; curare bases.
Cyclandelate.
Cyclobenzaprine; its salts.
Cyclofenil.
Cyclopenthiazide.
Cyclophosphamide.
Cyclopropane.
Cycrimine; its salts.
Cytotoxic drugs used in the treatment of malignant disease (antimitotic agents, antinucleic agents, antineoplastic agents, and folic acid antagonists).

Dacarbazine; its salts.
Dantrolene; its salts.
Dapsone.
Deanol; its salts.
Decamethonium; its salts.
Demecarium bromide.
Desipramine; its salts.
Desmopressin.
Desogestrel.
Diazepam; its salts.
Dibenzepin; its salts.
Dichloralphenazone.
Dichlorphenamide; its salts.

FOURTH SCHEDULE—*continued*

Diclofenac; its salts.
Diflunisal.
Digitalis, glycosides of; except substances containing less than 1 unit of activity (as defined in the British Pharmacopoeia), in 2 grams of the substance.
Digitalis leaf.
Digitoxin.
Digoxin.
Di-iodohydroxyquinoline; except in dermatological preparations.
Dimercaprol.
Dimethyl sulphoxide.
Dinitrocresols; dinitronaphthols; dinitrophenols; dinitrothymols.
Diphenidol.
Dipyridamole.
Disodium etidronate.
Disopyramide; its salts.
Distigmine; its salts.
Disulfiram; its salts.
Disulphamide.
Dipivefrin; its salts.
Dobutamine; its salts.
Domperidone.
Dopamine; its salts.
Dothiepin hydrochloride.
Doxapram; its salts.
Doxepin; its salts.
Droperidol; its salts.

Ecothiopate iodide.
Econazole; its salts; except in dermatological preparations.
Ectylurea.
Edrophonium chloride.
Emepronium bromide.
Ergot; extracts of ergot; tinctures of ergot; alkaloids of ergot; salts of alkaloids of ergot.
Ethacrynic acid; its salts.
Ethambutol; its salts.
Ethamivan.
Ethionamide.
Ethoheptazine.
Ethosuximide.
Ethoxzolamide.
Ethynodiol diacetate.
Etretinate.

Fenbufen.
Fenclofenac.
Fenfluramine; its salts and esters.
Fenoprofen; its salts.
Fenoterol; its salts; in liquid and aerosol preparations.
Fenpipramide.
Fenpiprane.

FOURTH SCHEDULE—*continued*

Fenticlor; its salts; except in preparations for external use.
Floctafenine; its salts.
Fluanisone.
Flucytosine.
Flufenamic acid.
Flumethiazide.
Flumoperone; its salts and esters.
Flunitrazepam.
Fluorides, in preparations for internal use by man, containing more than 2.2 milligrams of fluorides per dosage unit, and in preparations for topical use by man containing fluorides in proportion equivalent to more than 2.5 percent of elementary fluorine.
5-Fluorocytosine.
Fluorouracil; its salts.
Flupenthixol; its esters.
Flurbiprofen.
Fluspirilene.
Flutamide.
Frusemide.
Furaltadone, except when included in preparations for the treatment of diseases of pigs and poultry.
Furazolidone, except when included in preparations for the treatment of diseases of pigs and poultry.

Gallamine; its salts; its quaternary compounds.
Ganglionic blocking agents and antihypertensive agents.
Gitalin.
Gliclazide.
Glipizide.
Glisoxepide.
Glyceryl trinitrate, for parenteral use.
Glymidine.
Gonadotrophic hormones; for parenteral use.
Guanethidine; its salts.

Halofenate.
Haloperidol.
Halothane.
Hepatitis B vaccine.
Hexachlorophane; in preparations containing more than 3 percent of hexachlorophane.
Hexamethonium bromide.
Hexetidine; except in preparations for external use.
Hexobendine; its salts.
Hexoprenaline; its salts.
Hydantoin; its derivatives.
Hydrallazine; its salts.
Hydrargaphen; except in preparations for external use.
Hydrochlorothiazide.
1 a-Hydroxycholecalciferol.
Hydroflumethiazide.
Hydroxychloroquine.

FOURTH SCHEDULE—*continued*

Hydroxyphenamate.
Hydroxyquinoline and its halogenated and alkyl derivatives and their salts in forms for human use; except in preparations for external use.
Hydroxyzine; its salts.
Hypothalamus; the active principles (including thyrotrophin releasing factor).

Ibufenac.
Ibuprofen; its salts.
Ibuterol; its salts.
Idoxuridine; except in preparations containing not more than 0.5 percent of idoxuridine for external use other than as an eye preparation.
Imipramine; its salts.
Indomethacin.
Indoprofen.
Indoramin hydrochloride.
Influenza vaccines for parenteral or intra-nasal administration.
Iodothiouracil sodium.
Ipratropium; its salts; except in preparations for human therapeutic use for nasal inhalation.
Iprindole; its salts.
Iproniazid; its salts and esters.
Isocarboxazid.
Isoconazole; its salts; except in dermatological preparations.
Isoflurane.
Isoniazid; its salts and esters.
Isotretinoin.
Isoxsuprine; its salts.

Ketamine; its salts.
Ketoconazole; its salts.
Ketoprofen; its salts.
Ketotifen; its salts.

Labetalol; its salts.
Lanatoside A, B, C, and D.
Levallorphan.
Levodopa.
Lignocaine hydrochloride; for internal use by ingestion.
Lithium; its salts and compounds; in preparations for internal use.
Lomustine.
Lorazepam; its salts.
Lormetazepam; its salts.
Loxapine.
Lysine acetyl salicylate.

Magenta; except in preparations for external use.
Maldison; in preparations for human use containing more than 2 percent of maldison.
Mannomustine.
Maprotiline; its salts.
Mazindol.
Measles virus vaccine.

FOURTH SCHEDULE—*continued*

Mebanazine.
Mebendazole; for human therapeutic use; except where contained in a preparation described in the Second Schedule to these regulations.
Mebeverine Hydrochloride.
Mebutamate.
Mecamylamine; its salts.
Meclocycline; its salts.
Meclofenamate; its salts.
Meclofenoxate; its salts.
Mecloqualone.
Mefenamic acid.
Mephentermine; its salts.
Mepindolol; its salts.
Mercaptomerin; its salts.
Mercaptopurine.
Mercuramide with theophylline.
Mercury, ammoniated, except in medicines containing 2.5 percent or less of mercury.
Mercury; its salts; its compounds, except oxides of mercury and ammoniated mercury; in medicines containing more than 1 percent of mercury.
Mercury oxides; except medicines containing 1 percent or less of mercury.
Mercuric sulphide, red, for oral use.
Mersalyl.
Metaraminol; its salts.
Methacholine; its salts.
Methimazole.
Methisazone.
Methixene; its salts.
Methocarbamol.
Methohexitone; its salts.
Methoin.
Methoxyflurane.
8-methoxypsoralen.
Methsuximide.
Methyclothiazide.
Methyldopa; its salts.
Methylpentynol; derivatives of methylpentynol.
Methylthiouracil.
Methysergide.
Metildigoxin.
Metoclopramide.
Metoprolol.
Metriphonate; in preparations for use in man.
Metrizamide.
Metronidazole.
Mexiletine; its salts.
Mezlocillin; its salts.
Mianserin; its salts.
Miconazole; its salts; except in dermatological preparations.
Midazolam.
Minoxidil.
Molindone; its salts.
Monobenzone.

FOURTH SCHEDULE—*continued*

Motretinide.
Moxalactam; its salts.
Mustine; its salts; its derivatives.

Naftidrofuryl; its salts.
Nalbuphine; its salts.
Nalidixic acid; its salts.
Nalorphine; its salts.
Naloxone.
Naproxen.
Nefopam; its salts.
Neostigmine; its salts.
Neuromuscular blocking agents.
Nialamide.
Nicofuranose.
Nicotinic acid; its derivatives; in preparations containing more than 100 mg nicotinic acid and its derivatives per dose; for internal human therapeutic use.
Nicotinyl alcohol; when intended for human therapeutic use and containing more than 100 milligrams per dosage unit.
Nifedipine.
Nifenazone.
Nitrazepam; its salts.
Nimorazole; its salts.
Nitrofurantoin.
Nitroxoline.
Nomifensine.
Norfloxicin.
Nortriptyline; its salts.
Noxiptiline; its salts.

Octamylamine; its salts.
Opipramol; its salts.
Oral diuretics of the following classes:
    Aminouracil derivatives:
    Mercurials:
    Sulphonamide derivatives:
    Thiazide derivatives:
    Triazine derivatives.
Ornidazole.
Ornipressin.
Orphenadrine; its salts.
Ouabain.
Oxazepam; its salts.
Oxethazaine.
Oxolamine; its salts.
Oxolinic acid.
Oxphenisatin acetate.
Oxprenolol.
Oxybuprocaine; its salts.
Oxyphenbutazone.

FOURTH SCHEDULE—*continued*

Pancuronium; its salts.
Paraldehyde; except solutions containing not more than 1 percent of paraldehyde.
Paramethadione.
Pecazine; its salts.
Pemoline.
Pempidine; its salts.
Penicillamine.
Pentazocine.
Pentifylline.
Pentoxifylline.
Pentolinium tartrate.
Perhexiline maleate.
Phenacetin; for human therapeutic use.
Phenaglycodal.
Phenelzine; its salts.
Phenformin; its salts.
Phenglutarimide.
Phenisatin.
Phenothiazine, derivatives of; their salts except dimethothiazine, methdilazine, promethazine, trimeprazine; their salts; and their molecular compounds.
Phenoxybenzamine.
Phensuximide.
Phentermine; its salts.
Phentolamine; its salts.
Phenylbutazone; its derivatives.
Phenylcinchoninic acid; its salts; its esters.
1-phenyl-2, 3-dimethyl-4 (2'-phenyl-3'-methyl-morpholino-methyl-pyrazolone -(5): its salts.
Phenylpropanolamine; its salts, except when contained in an appliance for inhalation in which the poison is absorbed in inert solid material or when contained in preparations containing 0.5 percent or less of phenylpropanolamine.
Physostigmine; its salts.
Picrotoxin.
Pimozide.
Pindolol; its salts.
Piperidine benzilate.
Pirenzepine; its salts.
Piroxicam.
Pirprofen.
Pituitary gland, the active principles of.
Pizotifen.
Pneumoccocal vaccine.
Polydexide; its salts; for human therapeutic use.
Potassium perchlorate; for human therapeutic use.
Practolol.
Prazepam.
Prenalterol; its salts.
Probenecid.
Probucol.
Procainamide; its salts and esters.

FOURTH SCHEDULE—*continued*

Procyclidine; its salts.
Proglumide.
Proguanil; its salts.
Prolintane.
Promazine; its salts.
Promoxolone.
Propanidid.
Propranolol.
Propylhexedrine; its salts; except when contained in an appliance for inhalation.
Propylthiouracil.
Proquazone.
Proscillaridin.
Prostaglandins.
Prothionamide.
Prothipendyl hydrochloride.
Protoveratrine "A".
Protriptyline; its salts.
Psychomotor stimulants.
Pyrazinamide.
Pyridinolcarbamate.
Pyrimethamine.

Quazepam.
Quinaldofur.
Quinidine; its salts and esters.
Quinine; and its salts in formulations for human therapeutic use.

Rabies vaccine.
Ranitidine; its salts.
Rauwolfia species; alkaloids of rauwolfia; their salts.
Razoxane.
Ritodrine; its salts.
Rosoxaxin.

Salbutamol; its salts and esters when contained in an appliance for inhalation or for parenteral use.
Salicylcinchoninic acid; its salts; its esters.
Sodium aurothiomalate.
Sodium cromoglycate; other cromoglycates.
Sodium nitroprusside; its salts, for human therapeutic use.
Sodium valproate.
Sparteine; its salts; its derivatives.
Streptokinase.
Strophanthin.
Styramate.
Sulindac.
Sulphametrole.
Sulphamoxole.
Sulphinpyrazone; its salts.
Sulphonal; alkyl sulphonals.
Suprofen.
Sutilains; in preparations for internal or parenteral human use.

FOURTH SCHEDULE—*continued*

Suxamethonium; its salts.
Suxethonium; its salts.
Synthetic anti-malarials: excluding quinine.

Tacrine; its salts.
Tamoxifen.
Teniposide; its salts.
Testosterone; its esters.
Tetraethylammonium chloride.
Tetrabenazine.
Tetroxoprin.
Thiocarlide; its salts.
Thiotepa.
Thiothixene.
Thiouracil.
Thyroid; its preparations; its synthetic derivatives.
Tiaprofenic acid; its salts.
Tiaramide; its salts.
Tiletamine; its salts.
Tilidine.
Timolol; its salts.
Tinidazole.
Tioconazole, except in dermatological preparations.
Tocainide; its salts.
Tolazoline; its salts.
Tolmetin; its salts.
Tranexamic acid; its salts and esters.
Tranylcypromine; its salts.
Tretinoin.
Triamterene.
Triaziquone; its salts.
Triazolam.
Tribromoethyl alcohol.
Trichlormethiazide.
Triethylene melamine.
Trifluperidol; its salts; its esters.
Trimeprazine; its salts; except in preparations containing 0.05 percent or less of trimeprazine.
Trimetaphan; its salts.
Trimethoprim.
Trioxsalen.
Troxidone.
Tuberculostatic agents.
Tubocurarine; its salts.

Urokinase.

Vasopressin.
Verapamil hydrochloride.
Veratrum, alkaloids of; their salts.
Vidarabine; its salts.
Viloxazine.

FOURTH SCHEDULE—*continued*

Vitamin A, preparations for human use if the recommended daily dose exceeds 3,000 micrograms.
Vitamin D, preparations for human use if the recommended daily dose exceeds 25 micrograms.

Xanthinol nicotinate.
Xipamide.

Zimelidine; its salts.
Zinc, for internal human therapeutic use, in preparations containing 15 milligrams or more of elemental zinc per dose.
Zoxazolamine; its salts."

Reg. 11 (2)

FIFTH SCHEDULE

REGULATIONS REVOKED

Title	Statutory Regulations Serial Number
The Restricted Drugs Regulations 1964, Amendment No. 1: regulations 8 to 14 and the Schedules ..	1966/84
The Restricted Drugs Regulations 1964, Amendment No. 2: regulations 5 to 17 and the Schedules ..	1967/250
The Restricted Drugs Regulations 1964, Amendment No. 3: regulations 3 and 8 to 19 and the Schedules	1969/95
The Restricted Drugs Regulations 1964, Amendment No. 4: regulations 4 to 10 and the Schedules ..	1969/193
The Restricted Drugs Regulations 1964, Amendment No. 5: regulations 3 and 5 to 13 and the Schedules	1971/55
The Restricted Drugs Regulations 1964, Amendment No. 6: regulations 3 to 12 and the Schedules ..	1972/53
The Restricted Drugs Regulations 1964, Amendment No. 7: regulation 3 and the Schedule	1972/163
The Restricted Drugs Regulations 1964, Amendment No. 8: regulation 3	1973/111
The Restricted Drugs Regulations 1964, Amendment No. 9: regulations 4 and 7 to 19 and the Schedules	1974/93
The Restricted Drugs Regulations 1964, Amendment No. 10	1974/133
The Restricted Drugs Regulations 1964, Amendment No. 11: regulations 3 to 13 and the Schedules ..	1975/25
The Restricted Drugs Regulations 1964, Amendment No. 12: regulations 2 to 6, 9, 10, and 12 to 22 and the Schedules	1977/130
The Restricted Drugs Regulations 1964, Amendment No. 13: regulations 2, 4, 5, and 7 to 17 and the Schedules	1978/52
The Restricted Drugs Regulations 1964, Amendment No. 14	1979/37
The Restricted Drugs Regulations 1964, Amendment No. 15:	1979/273
The Restricted Drugs Regulations 1964, Amendment No. 16: regulations 2 to 4 and 6 to 16 and the Schedules	1981/120
The Restricted Drugs Regulations 1964, Amendment No. 17: regulations 2 to 5 and 7 to 17 and the Schedules	1982/32
The Restricted Drugs Regulations 1964, Amendment No. 18	1982/248

P. G. MILLEN,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations are consequential upon the bringing into force of the Toxic Substances Act 1979 and the Restricted Drugs Amendment Act 1978. They rename the Poisons Regulations 1964 as the Restricted Drugs Regulations 1964, and limit the scope of those regulations to "medical poisons" pending the bringing into force of the Medicines Act 1981. The opportunity has also been taken to add some substances to, and remove others from, the various Schedules.

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