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THE MEDICINES REGULATIONS 1984, AMENDMENT NO. 7

MICHAEL HARDIE BOYS, Governor-General

ORDER IN COUNCIL

At Wellington this 9th day of December 1996

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to section 105 of the Medicines Act 1981, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council and on the advice of the Minister of Health tendered after consultation with the organisations and bodies that appeared to the Minister to be representative of persons likely to be substantially affected, hereby makes the following regulations.

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Medicines Regulations 1984, Amendment No. 7, and shall be read together with and deemed part of the Medicines Regulations 1984* (hereinafter referred to as the principal regulations).

(2) These regulations shall come into force on the 28th day after the date of their notification in the *Gazette*.

*S.R. 1984/143 Amendment No. 1: 1985/228 Amendment No. 2: 1988/61 Amendment No. 3: 1990/221 Amendment No. 4: 1991/134 Amendment No. 5: 1992/43 Amendment No. 6: 1994/299 2. New First Schedule substituted—(1) The principal regulations are hereby amended by revoking the First Schedule, and substituting the First Schedule set out in the Schedule to these regulations.

(2) The following regulations are hereby consequentially revoked:

(a) The Medicines Regulations 1984, Amendment No. 1 (S.R. 1985/228):

(b) The Medicines Regulations 1984, Amendment No. 2 (S.R. 1988/61).

SCHEDULE

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS Reg. 2 "FIRST SCHEDULE

Every reference to a medicine in the Schedule applies whether the medicine is synthetic in origin or is from biological or mineral sources.

Unless specific reference is made otherwise, every reference applies also to medicines that are—

(a) Preparations and admixtures containing any proportion of any substance listed in the Schedule:

(b) Salts and esters of any substance listed in the Schedule:

(c) Preparations or extracts of biological materials listed in the Schedule:

(d) Salts or oxides of elements listed in the Schedule.

Where any reference is modified by a statement of the strength of the medicine, the strength is calculated using the free acid, base, alcohol, or element unless specifically stated otherwise.

Part I

Prescription Medicines

Abciximab Acarbose Acebutolol Acetarsol Acetazolamide Acetohexamide Acetrizoate sodium Acetylcarbromal Acetylcholine Acetyldigitoxin Acetylstrophanthidin Aciclovir; except when specified elsewhere in this Schedule Acipimox Acitretin Actinomycin D Adapalene Adenosine Adrenal extract; except for dermatological use in medicines containing 0.02% or less of ketosteroids Albendazole Albumin Alclofenac Alclometasone Alcuronium Aldosterone

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Alendronic acid Alfacalcidol Alglucerase Allergens Allopurinol Allyloestrenol Alphadolone Alphaxalone Alprazolam Alprenolol Alprostadil Alseroxylon Alteplase Altretamine Amantadine Amcinonide Amethocaine; for internal use; for ophthalmological use except when used in practice by a registered optometrist Amidopyrine Amidotrizoic acid Amifostine Amikacin Amiloride Aminocaproic acid Aminoglutethimide Aminometradine Aminophylline; except in liquid form for oral use Aminopterin Aminorex Aminosalicylic acid Amiodarone Amiphenazole Amisometradine Amitriptyline Amlodipine Ammonium bromide Amodiaquine Amorolfine Amoxapine Amoxycillin Amphotericin; except for buccal use Ampicillin Amrinone Amsacrine Anabolic steroids Anastrazole

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Ancrod and its immunoglobulin antidote Androgens Anistreplase Antigens Antimony Apomorphine Apraclonidine Apronal Aprotinin Arecoline Aristolochic acid and Aristolochiaceae species; except homoeopathic remedies Atenolol Atovaquone Atracurium Atropine; for ophthalmological use; for parenteral use except when used as an antidote in a device designed for self-injection Auranofin Aurothiomalate sodium Azacyclonol Azapetine Azapropazone Azaribine Azathioprine Azelastine Azithromycin Azlocillin Aztreonam Bacampicillin Bacitracin Baclofen Bamethan Bamiphylline; except in liquid form for oral use Barbiturates; except where specified in the Schedules to the Misuse of Drugs Act 1975 Beclamide Beclomethasone; except when specified elsewhere in this Schedule Bemegride Benactyzine Benazepril Bendrofluazide Benethamine penicillin Benoxaprofen Benperidol Benserazide Benzathine penicillin Benzatropine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Benzhexol Benzthiazide Benzylpenicillin Bepridil Beractant Beta carotene; in medicines containing more than 18 milligrams per recommended daily dose **Betahistine** Betamethasone Betaxolol **Bethanidine Bevantolol** Bezafibrate Bifonazole; except for dermatological use Biperiden Bisoprolol Bleomycin Blood clotting factors; except factor VIII Blood corpuscles Blood, whole Botulinum toxin Bretylium Bromazepam Bromocriptine Bromvaletone Budesonide; except when specified elsewhere in this Schedule Bumetanide Buphenine Bupivacaine Buserelin **Buspirone** Busulphan Butoconazole; except for dermatological use **Butorphanol** Cabergoline Calcipotriol Calcitonin Calcitriol Calcium carbimide Calcium polystyrene sulphonate Capreomycin Captopril Carbachol Carbamazepine Carbaryl; for external use in medicines containing more than 2% Carbenicillin Carbenoxolone; for internal use

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Carbidopa Carbimazole Carbocromen Carboplatin Carboprost Carbromal Carbutamide Carbuterol; for inhalation or parenteral use Carindacillin Carisoprodol Carmustine Carprofen Carvediol Cefaclor Cefamandole Cefazolin Cefepime Cefetamet Cefixime Cefodizime Cefonicid Cefoperazone Cefotaxime Cefotetan Cefotiam Cefoxitin Cefpirome Cefpodoxime Cefsulodin Ceftazidime Ceftibuten Ceftriaxone Cefuroxime Celiprolol Cephalexin Cephalothin Cephazolin Cephradine Ceruletide Chenodeoxycholic acid Chloral hydrate; except when specified elsewhere in this Schedule Chlorambucil Chloramphenicol Chlorazanil Chlordiazepoxide Chlormerodrin Chlormethiazole

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines—continued

Chlormezanone Chloroquine Chlorothiazide Chlorotrianisene Chlorphentermine Chlorpromazine Chlorpropamide Chlorprothixene Chlorquinaldol; for internal use Chlortetracycline Chlorthalidone Chlorzoxazone Chymopapain Ciclacillin Ciclopirox; except for dermatological use Cilastatin Cilazapril Cimetidine; except when specified elsewhere in this Schedule Cinchocaine; for parenteral use Cinchophen Cinoxacin Ciprofloxacin Cisapride Cisatracurium Cisplatin Cladribine Clarithromycin Clavulanic acid Clindamycin; except for dermatological use Clioquinol; for internal use Clobazam Clobetasol Clobetasone Clodronic acid Clofazimine Clofibrate Clomiphene Clomipramine Clonazepam Clonidine Clopamide Clorazepate Clorexolone Clotrimazole; except when specified elsewhere in this Schedule Cloxacillin Clozapine Co-dergocrine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines—continued

Co-trimoxazole Cobalt Colaspase Colchicine Colecalciferol; in medicines containing more than 25 micrograms per recommended daily dose Colestipol Colfosceril Colistin Collagen; for parenteral use Corticotrophin Cortisone and other steroidal hormones of the adrenal cortex; except when specified elsewhere in this Schedule; except adrenal extract for dermatological use in medicines containing 0.02% or less of ketosteroids Cryoprecipitate Crystal violet Curare Cyclandelate Cyclobenzaprine Cyclofenil Cycloheximide Cyclopenthiazide Cyclopentolate Cyclophosphamide Cyclopropane Cycloserine Cyclosporin Cycrimine Cyproterone Cytarabine Dacarbazine Dactinomycin Dalteparin Danaparoid Danazol Danthron Dantrolene Dapsone Daunorubicin Deanol Decamethonium Deflazacort Demacarium Demeclocycline Deoxycortone Deoxyribonuclease; except for external use Desferrioxamine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines—continued

Desflurane Desipramine Deslanoside Desmopressin Desogestrel Dexamethasone Dexfenfluramine Diatrizoic acid Diazepam Diazoxide Dibenzepin Dichloralphenazone Dichlorphenamide Diclofenac; except when specified elsewhere in this Schedule Dicloxacillin Didanosine Dienoestrol Diethylstilboestrol Diflucortolone Diflunisal Digitalis Digitoxin Digoxin Dihydroergotoxine Dihydrotachysterol Diltiazem Dimercaprol Dimethyl sulphoxide Dinoprost Dinoprostone Diphenidol Diphtheria toxoid Dipivefrin Diprophylline; except in liquid form for oral use Dipyridamole Dirithromycin Disopyramide Distigmine Disulfiram Disulphamide Ditiocarb Dobutamine Docetaxel Domperidone Dopamine Dopexamine Dornase

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued "FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Dorzolamide Dothiepin Doxantrazole Doxapram Doxazosin Doxepin Doxorubicin Doxycycline Droperidol Drostanolone Dydrogesterone Econazole; except when specified elsewhere in this Schedule Ecothiopate Ectylurea Edetic acid; in medicines containing more than 0.25% except in contact lens preparations Edoxudine Edrophonium Emepronium Enalapril Enoxacin Enoxaparin Enoximone Enprostil Epicillin Epirubicin Epoprostenol Ergocalciferol; in medicines containing more than 25 micrograms per recommended daily dose Ergometrine Ergot Ergotamine Ergotoxine Erythromycin Erythropoietin Esmolol Estramustine Ethacrynic acid Ethambutol Ethamivan Ethinyloestradiol Ethionamide Ethisterone Ethoglucid Ethoheptazine Ethosuximide Ethotoin

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Ethoxzolamide Ethyloestrenol Ethynodiol Etidronate Etodolac Etoposide Etretinate Famciclovir Famotidine; except when specified elsewhere in this Schedule Felodipine Fenbufen Fenclofenac Fenfluramine Fenoldopam Fenoprofen Fenoterol Fenpipramide Fenpiprane Fibrin Fibrinogen Fibrinolysin; except for external use Filgrastim Finasteride Flecainide Fleroxacin Floctafenine Fluanisone Flucloxacillin Fluconazole Flucytosine Fludarabine Fludrocortisone Flufenamic acid Flumazenil Flumethasone Flumethiazide Flunisolide; except when specified elsewhere in this Schedule Flunitrazepam Fluocinolone Fluocinolone acetonide Fluocinonide Fluocortolone Fluorides; for internal use in medicines containing more than 2.2 milligrams per dose form; for external use in medicines containing more than 2.5% of elemental fluorine Fluorometholone Fluorouracil

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued "FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Fluoxetine Fluoxymesterone Flupenthixol Fluphenazine Flurandrenolone Flurazepam Flurbiprofen Fluroxene Fluspirilene Flutamide Fluticasone Fluvastatin Folinic acid Follicle stimulating hormone Follitropin Formestane Formoterol Foscarnet Fosinopril Fotemustine Framycetin Frusemide Furaltadone Furazolidone Fusidic acid Gabapentin Gadodiamide Gadopentetic acid Galantamine Gallamine Ganciclovir Gemeprost Gemfibrozil Gentamicin Gestodene Gestonorone Gestrinone Gitalin Glibenclamide Gliclazide Glipizide Glisoxepide Glutathione; for parenteral use Glyceryl trinitrate; for parenteral use Glycopyrronium; for parenteral use Glymidine Gonadorelin

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines—continued

Gonadotrophic hormones Goserelin Gramicidin Granisetron Griseofulvin Guanabenz Guanethidine Hachimycin Haematin Haemophilus influenzae vaccine Halcinonide Halofantrine Halofenate Haloperidol Halothane Halquinol; for internal use Heparins; for internal use Hepatitis A vaccine Hepatitis B vaccine Hexachlorophane; in medicines containing more than 3% Hexamethonium Hexetidine; for internal use Hexobendine Hexoprenaline; for inhalation or parenteral use Histamine; in medicines containing more than 0.5% Homatropine; for ophthalmological or parenteral use Hydralazine Hydrargaphen; for internal use Hydrochlorothiazide Hydrocortisone; except when specified elsewhere in this Schedule Hydroflumethiazide Hydroxychloroquine Hydroxyphenamate Hydroxyurea Hydroxyzine Hyoscine; for ophthalmological or parenteral use Hyoscyamine; for ophthalmological or parenteral use Ibufenac Ibuprofen; except when specified elsewhere in this Schedule Ibuterol Idarubicin Idoxuridine; except for dermatological use in medicines containing 0.5% or less Ifosfamide Iloprost Imipenem Imipramine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines—continued

Immunoglobulins Indapamide Indinavir Indomethacin; except for external use in medicines containing 1% or less Indoprofen Indoramin Influenza and coryza vaccines; for parenteral use; for nasal administration Interferons Iodamide Iodised oil; for parenteral use Iodixanol Iodothiouracil Iodoxamic acid Iohexol Iomeprol Iopamidol Iopromide Iopronic acid Iothalamic acid Iotrolan Iotroxic acid Ioversol Ioxaglic acid Ipodate Ipratropium; except for nasal use Iprindole Iproniazid Isoaminile Isocarboxazid Isoconazole; except when specified elsewhere in this Schedule Isoetharine; for inhalation or parenteral use Isoflurane Isoniazid Isoprenaline; for inhalation or parenteral use Isoprinosine Isotretinoin Isoxicam Isoxsuprine Isradipine Itraconazole Kanamycin Ketamine Ketanserin Ketazolam Ketoconazole; except for dermatological use Ketoprofen; except when specified elsewhere in this Schedule Ketorolac

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines—continued

Ketotifen L-asparaginase Labetalol Lacidipine Lamivudine Lamotrigine Lanatosides Lansoprazole Latamoxef Lead Lenograstim Leucovorin Leuprorelin Levallorphan Levamisole Levobunolol Levodopa Levonorgestrel Lignocaine; for internal use by ingestion except in throat lozenges containing 30 milligrams or less per dose form; for ophthalmological use except when used in practice by a registered optometrist Lignocaine; for parenteral use except when used as a local anaesthetic in practice by a registered nurse or podiatrist or by a dental therapist Lincomycin Liothyronine Liquorice deglycyrrhizinised Lisinopril Lisuride Lithium Lofexidine Lomefloxacin Lomustine Loprazolam Loracarbef Lorazepam Lormetazepam Losartan Loxapine Lymecycline Mafenide Mannomustine Maprotiline Measles vaccine Mebanazine Mebendazole; in packs containing more than 600 milligrams Mebeverine Mebutamate

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Mecamylamine Mecasermin Mecillinam Meclocycline Meclofenamate Meclofenoxate Medroxyprogesterone Medrysone Mefenamic acid; except when specified elsewhere in this Schedule Mefloquine Mefruside Melphalan Meningococcal vaccine Menotrophin Mephentermine Mepindolol Mepivacaine Meptazinol Mercaptomerin Mercaptopurine Meropenem Mersalyl Mesalazine Mesna Mesterolone Mestranol Metaraminol Metergoline Metformin Methacholine Methallenoestril Methicillin Methimazole Methisazone Methixene Methocarbamol Methohexitone Methoin Methotrexate Methotrimeprazine Methoxsalen Methoxyflurane Methsuximide Methyclothiazide Methyldigoxin Methyldopa Methylergometrine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines—continued

Methylpentynol Methylprednisolone Methyltestosterone Methylthiouracil Methysergide Metoclopramide; except when specified elsewhere in this Schedule Metoprolol Metriphonate Metrizamide Metrizoic acid Metronidazole Metyrapone Mexiletine Mezlocillin Mianserin Miconazole; except when specified elsewhere in this Schedule Midazolam Midodrine Milrinone Minocycline Minoxidil; for internal use Misoprostol Mitoxantrone Mivacurium Moclobemide Molgramostim Molindone Mometasone Monobenzone Moperone Morazone Moricizine Motrazepam Motretinide Mumps vaccine Muromonab Mustine Mycophenolic acid Nabumetone Nadolol Nadroparin Nafarelin Naftidrofuryl Nalbuphine Nalidixic acid Nalorphine Naloxone

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Naltrexone Nandrolone Naproxen; except when specified elsewhere in this Schedule Natamycin Nebacumab Nedocromil Nefazodone Nefopam Neomycin Neostigmine Netilmicin Nialamide Nicardipine Nicergoline Nicofuranose Nicorandil Nicotine; for nasal administration; for inhalation Nifedipine Nifenazone Nilutamide Nimodipine Nimorazole Nisoldipine Nitrazepam Nitrendipine Nitrofurantoin Nitrogen mustard Nitroxoline Nizatidine; except when specified elsewhere in this Schedule Nomifensine Norethisterone Norfloxacin Norgestrel Nortriptyline Noxiptyline Nystatin; except when specified elsewhere in this Schedule Octamylamine Octreotide Oestradiol Oestrogens Oestrone Ofloxacin Olsalazine Omeprazole Ondansetron Opipramol Orciprenaline

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued "FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines-continued

Ornidazole Ornipressin Orphenadrine Ouabain Oxandrolone Oxaprozin Oxazepam Oxetacaine Oxitropium Oxolamine **Oxolinic** acid Oxpentifylline Oxprenolol Oxybuprocaine; except when used in practice by a registered optometrist Oxymetholone Oxyphenbutazone Oxyphenisatin Oxytetracycline Oxytocin Paclitaxel Pamidronate Pancreatic enzymes; in medicines containing more than 20,000 BP units of lipase activity Pancuronium Pantoprazole Paracetamol; in solid dose form containing more than 500 milligrams per dose unit Paraldehyde; in medicines containing more than 1% Paramethadione Paroxetine Pecazine Pefloxacin Pemoline Pempidine Penbutolol Penicillamine Pentagastrin Pentamidine Pentazocine Pentolinium Pentoxifylline Pergolide Perhexiline Pericyazine Perindopril Permethrin; in medicines containing more than 1% Perphenazine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines—continued

Phenacetin Phenaglycodol Phenelzine Phenformin Phenglutarimide Phenindione Phenisatin Phenoxybenzamine Phenoxymethylpenicillin Phensuximide Phentolamine Phenylbutazone Phenylephrine; for ophthalmological use in medicines containing more than 0.12% Phenylpropanolamine Phenytoin Phthalylsulphathiazole Physostigmine Picrotoxin Pilocarpine Pimozide Pinacidil Pindolol Pipecuronium Pipemidic acid Piperacillin Piperidine Pipothiazine Pirbuterol Pirenzipine Piretanide Piroxicam; except for external use in medicines containing 1% or less Pirprofen Pivampicillin Pizotifen Plasma Plasma protein fraction Plasmin Plasminogen activator Platelets Plicamycin Pneumococcal vaccine Podophyllum; in medicines containing more than 20% Polidexide Poliomyelitis vaccine Polymyxin Polyoestradiol

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines—continued

Polythiazide Potassium bromide Pravastatin Prazepam Prazosin Prednisolone Prednisone Prenalterol Prenylamine Prilocaine; for parenteral use except when used as a local anaesthetic in practice by a dental therapist Primaquine Primidone Probenecid Probucol Procainamide Procaine Procarbazine Prochlorperazine; except when specified elsewhere in this Schedule Procyclidine Progestogens Proglumide Proguanil Prolintane Promazine Promoxolane Propafenone Propanidid Propofol Propranolol Propyliodone Propylthiouracil Proquazone Proscillaridin Protamine sulphate; except when in insulins Prothionamide Prothipendyl Protirelin Protoveratrines Protriptyline Proxymetacaine; except when used in practice by a registered optometrist Pyrazinamide Pyridinolcarbamate Pyridostigmine Pyrimethamine Quazepam Quinagolide

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines—continued

Quinapril Quinidine Quinine; except when specified elsewhere in this Schedule; in medicines containing more than 50 milligrams per recommended daily dose Rabies vaccine Ramipril Ranitidine; except when specified elsewhere in this Schedule Rauwolfia Razoxane Remoxipride Reproterol; for inhalation or parenteral use Reserpine Retinol; in medicines containing more than 3000 micrograms per recommended daily dose Ribavirin Rifabutin Rifampicin Rifamycin Rimiterol; for inhalation or parenteral use Risperidone Ritodrine Rocuronium Rolitetracycline Ropivacaine Rosoxacin Roxithromycin Rubella vaccine Salbutamol; for inhalation or parenteral use Salmeterol Saquinavir Selegiline Sermorelin Sertraline Serum, dried human Sevoflurane Silver sulfadiazine; for external use in pack sizes containing more than 50 grams Simvastatin Sisomicin Sodium bromide Sodium cromoglycate; except for nasal and ophthalmological use Sodium ipodate Sodium nitroprusside Sodium polystyrene sulphonate Sodium tetradecyl sulphate; for parenteral use Sodium valproate Somatostatin

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines—continued

Somatropin Sotalol Sparfloxacin Sparteine Spectinomycin Spiramycin Spirapril Spironolactone Steroid hormones Streptodornase Streptokinase Streptomycin Strophanthin Styramate Sulbactam Sulconazole; except for dermatological use Sulfacetamide; except for ophthalmological use Sulfadiazine; except silver sulfadiazine for external use in pack sizes containing 50 grams or less Sulfadimidine Sulfadimethoxine Sulfadoxine Sulfafurazole Sulfaguanidine Sulfamerazine Sulfamethizole Sulfamethoxazole Sulfamethoxydiazine Sulfamethoxypyridazine Sulfametrole Sulfamoxole Sulfaphenazole Sulfapyridine Sulfasalazine Sulfathiazole Sulfinpyrazone Sulindac Sultamicillin Sulthiame Sumatriptan Suprofen Sutilains Suxamethonium Suxethonium T cell receptor antibody Tacrine Tamoxifen

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Tamsulosin Tazobactam Teicoplanin Temazepam Teniposide Tenoxicam Terazosin Terbinafine; except for dermatological use Terbutaline; for inhalation or parenteral use Terodiline Testosterone Tetanus antitoxin Tetanus toxoid Tetrabenazine Tetracosactrin Tetracycline Tetraethylammonium Tetroxoprim Theophylline; except in liquid form for oral use Thiethylperazine Thiocarlide Thioguanine Thiopentone Thiopropazate Thioproperazine Thioridazine Thiotepa Thiothixene Thiouracil Thrombin Thymoxamine Thyrotrophin Thyrotrophin-releasing factor Thyroxine Tiaprofenic acid Tiaramide Tibolone Ticarcillin Ticlopidine Tienilic acid Tiletamine Timolol Tinidazole Tinzaparin Tioconazole; except when specified elsewhere in this Schedule Tirilazad Tobramycin

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued "FIRST SCHEDULE—continued

PART I-continued

Prescription Medicines-continued

Tocainide Tolazamide Tolazoline Tolbutamide Tolmetin Tolrestat Torasemide Trandolapril Tranexamic acid Tranylcypromine Trazodone Treosulphan Tretamine Tretinoin Triacetyloleandomycin Triamcinolone; except when specified elsewhere in this Schedule Triamterene Triaziquone Triazolam Trichlormethiazide Tricloroethylene Triethylene thiophosphoramide Trifluoperazine Trifluperidol Triflupromazine Trimeprazine Trimetaphan Trimethoprim Trimipramine Trioxysalen Triperidol Triple antigen vaccine Triptorelin Tropicamide; except when used in practice by a registered optometrist Tropisetron Troxidone Tubocurarine Tulobuterol; for inhalation or parenteral use Typhoid vaccine Urapidil Urofollitropin Urokinase Ursodeoxycholic acid Vaccines; except oral vaccines specified elsewhere in this Schedule Valaciclovir Vancomycin Varicella vaccine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART I—continued

Prescription Medicines—continued

Vasopressin Vecuronium Venlafaxine Verapamil Veratrum Vidarabine Vigabatrin Viloxazine Vinblastine Vincamine Vincristine Vindesine Vinyl ether Vitamin A; in medicines containing more than 3000 micrograms per recommended daily dose Vitamin D; in medicines containing more than 25 micrograms per recommended daily dose Warfarin Xamoterol Xanthinol nicotinate Xipamide Zalcitabine Zidovudine Zimeldine Zinc; for internal use in medicines containing more than 25 milligrams per recommended daily dose Zopiclone Zoxazolamine Zuclopenthixol

Part II

Restricted Medicines

Adiphenine

Alcohol, absolute; except when compounded in a medicine

Ambutonium

Aminacrine

Amphotericin; for buccal use

Aspirin; in slow release forms; in enteric coated forms containing more than 300 milligrams per dose form

Astemizole

Atropine; for oral use in liquid form; in solid dose form containing more than 0.3 milligrams per dose or more than 1 milligram per recommended daily dose

Beclomethasone; in aqueous nasal sprays delivering 50 micrograms per actuation when the maximum recommended daily dose is no greater than 400 micrograms and the medicine has received the consent of the

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART II—continued

Restricted Medicines-continued

Minister or the Director-General to its distribution as a restricted medicine

Belladonna; for oral use in liquid form; in solid dose form containing more than 0.3 milligrams per dose or more than 1 milligram per recommended daily dose

Benzilonium

Bethanechol

Bismuth; for internal use

Brucine; in medicines containing 0.2% or more

Budesonide; in aqueous nasal sprays delivering 50 micrograms per actuation when the maximum recommended daily dose is no greater than 400 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a restricted medicine

Butyl nitrite

Caramiphen

Carbuterol; except for inhalation or parenteral use

Chloral hydrate; in medicines containing a total of 2 grams or less when sold to any 1 person on any 1 day

Ciclopirox; for dermatological use in medicines containing more than 1% Cimetidine; in medicines which have received the consent of the Minister

- or the Director-General to their distribution as restricted medicines and which are sold in the manufacturer's original pack containing not more than 14 days' supply and 200 milligrams or less per dose form
- Clindamycin; for dermatological use

Clotrimazole; for vaginal use in packs equivalent to one course of treatment

Colestyramine resin

Croton oil

Di-iodohydroxy quinoline; for vaginal use

Diclofenac; in solid dose form containing 25 milligrams or less per dose form in packs of not more than 30 tablets or capsules

Dithranol

Econazole; for vaginal use in packs equivalent to one course of treatment Ether; except when used as a vehicle for a topical dose form

Ethyl chloride

Famotidine; in medicines which have received the consent of the Minister or the Director-General to their distribution as restricted medicines and which are sold in the manufacturer's original pack containing not more than 14 days' supply and 10 milligrams or less per dose form Flavoxate

Flunisolide; in aqueous nasal sprays delivering 25 micrograms per actuation when the maximum recommended daily dose is no greater than 200 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a restricted medicine

Glycopyrronium; except for parenteral use

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART II—continued

Restricted Medicines—continued

Guanidine

Hexocyclium;

Hexoprenaline; except for inhalation or parenteral use

- Homatropine; for oral use in liquid form; in solid dose form containing more than 0.3 milligrams per dose or more than 1 milligram per recommended daily dose
- Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; for dermatological use in medicines containing 1% or less but more than 0.5% by weight of hydrocortisone base with no other active ingredient except an antifungal and in a quantity of 15 grams or less or 15 millilitres or less per container
- Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; in rectal medicines in cream or ointment form containing 1% or less by weight of hydrocortisone base and in combination with a local anaesthetic and in a quantity of not more than 35 grams per container
- Hydrocyanic acid; in medicines containing 1% or more
- Hyoscine; for transdermal use; for oral use in liquid form; in solid dose form containing more than 0.3 milligrams per dose or more than 1 milligram per recommended daily dose
- Hyoscyamine; for oral use in liquid form; in solid dose form containing more than 0.3 milligrams per dose or more than 1 milligram per recommended daily dose
- Ibuprofen; in liquid form for oral use in medicines which have received the consent of the Minister or the Director-General to their distribution as restricted medicines and which are sold in the manufacturer's original pack containing not more than 200 millilitres in volume and in strengths of 100 milligrams or less per 5 millilitres
- Insulins

Isoconazole; for vaginal use in packs equivalent to one course of treatment Isoetharine; except for inhalation or parenteral use

Isopropamide

Ketoprofen; in solid dose form containing 25 milligrams or less per dose form in packs of not more than 30 capsules or tablets

Levocabastine

Malathion; for external use in medicines containing more than 2%

Mepenzolate

Mercury

Methantheline

- Metoclopramide; when compounded with paracetamol in packs of not more than 10 tablets or capsules
- Miconazole; for buccal use; for vaginal use in packs equivalent to one course of treatment

Minoxidil; for external use

Mupirocin

Naproxen; in solid dose form containing the equivalent of 250 milligrams or less per dose form in packs of not more than 30 tablets or capsules

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART II—continued

Restricted Medicines-continued

Nicotinamide; in medicines containing more than 100 milligrams per dose form

Nicotinic acid; in medicines containing more than 100 milligrams per dose form

Nicotinyl alcohol; in medicines containing more than 100 milligrams per dose form

Nitrous oxide

Nizatidine; in medicines which have received the consent of the Minister or the Director-General to their distribution as restricted medicines and which are sold in the manufacturer's original pack containing not more than 14 days' supply

Nystatin; for buccal use; for vaginal use in packs equivalent to one course of treatment

Octyl nitrite

Oxybutynin

Oxyphencyclimine

Oxyphenonium

Papaverine

Paraldehyde; in medicines containing 1% or less

Penthienate

Podophyllum; in medicines containing 20% or less

Pralidoxime

Prampine

Prochlorperazine; for buccal use in medicines which have received the consent of the Minister or the Director-General to their distribution as restricted medicines and which are sold in the manufacturer's original pack containing not more than 10 tablets for the treatment of nausea associated with migraine

Propantheline

Propyphenazone

Quebracho

- Quinine; in medicines containing 200 milligrams or less per dose form in packs containing not more than 5 days' supply for the treatment of cramp
- Ranitidine; in medicines which have received the consent of the Minister or the Director-General to their distribution as restricted medicines and which are sold in the manufacturer's original pack containing not more than 14 days' supply

Reproterol; except for inhalation or parenteral use

Rimiterol; except for inhalation or parenteral use

Sabadilla

Salbutamol; except for inhalation or parenteral use

Savin oil

Staphisagria; for internal use in medicines containing 0.2% or more

Stramonium; for oral use in liquid form; in solid dose form containing more than 0.3 milligrams per dose or more than 1 milligram per recommended daily dose

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART II—continued

Restricted Medicines—continued

Strychnine

Sulfacetamide; for ophthalmological use

Terbutaline; except for inhalation or parenteral use

Terfenadine

Tiemonium

Tioconazole; for vaginal use in packs equivalent to one course of treatment Triamcinolone acetonide; for buccal use in packs containing 5 milligrams or less

Tricyclamol

Tridihexethyl

Tulobuterol; except for inhalation or patenteral use

Part III

Pharmacy-Only Medicines

Acetanilide; in medicines containing more than 0.5% Acetic acid, glacial Acetomenaphthone Acetylcysteine Aciclovir; for the treatment of herpes labialis Aconite; except for external use in medicines containing less than 0.02% Acriflavine Acrivastine Adrenaline Alcohol, isopropyl; in uncompounded medicines for external use Aloes; for internal use Aloin Aloxiprin Aminophylline; in liquid form for oral use Amyl nitrite; except when sold from outlets licensed under the Toxic Substances Regulations 1983 to sell sodium cyanide paste for the purpose of vertebrate pest control Antazoline Atropine; in solid dose form containing 0.3 milligrams or less per dose and 1 milligram or less per recommended daily dose; when used as an antidote in a device designed for self-injection; except when sold by licencees under the Toxic Substances Regulations 1983 Azatadine Azelaic acid Bamiphylline; in liquid form for oral use Belladonna; in solid dose form containing 0.8 milligrams or less per dose and 1 milligram or less per recommended daily dose Benorylate Bentiromide Benzocaine; for external use in medicines containing more than 2% Benzoyl peroxide; for external use in medicines containing more than 5% Benzydamine

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART III—continued

Pharmacy-Only Medicines-continued

Benzyl benzoate; for external use in medicines containing more than 2.5% Bephenium Bifonazole; for dermatological use Biphenylacetic acid Bisacodyl Bismuth; for external use Bithionol Boric acid; in medicines containing more than 2% Bromelains Bromhexine Brompheniramine Broxaldine Broxyquinoline Brucine; in medicines containing less than 0.2% Buclosamide Bufexamac Butoconazole; for dermatological use Calcium hypochlorite Calcium salicylate Camphor, ammoniated Camphorated oil Capsicum oleo-resin; for external use in medicines containing more than **î%** Carbetapentane; in medicines containing more than 0.5% Carboxymethylcysteine Cetirizine Chlophedianol Chlorbutol Chlorcyclizine Chlorpheniramine Chromium trioxide Ciclopirox; for dermatological use in medicines containing 1% or less Cinchocaine; for external use in medicines containing more than 2% Cinnamedrine Clemizole Clidinium Clotrimazole; for dermatological use Colocynth Coniine Controlled drugs that are medicines specified in Part VI of the Third Schedule to the Misuse of Drugs Act 1975 Copaiba balsam Copper; in medicines containing more than 5 milligrams per recommended daily dose Cotarnine Creosote; in medicines containing more than 10% Cresols; in medicines containing more than 1%

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART III—continued

Pharmacy-Only Medicines—continued

Cyanocobalamin; in medicines containing more than 50 micrograms per recommended daily dose

Cyclizine

Cyproheptadine

Deoxyribonuclease; for external use

Dextranomer

Dextrans

Dextromethorphan; in medicines containing more than 0.25%

Diamthazole

Dibromopropamidine; for ophthalmological use

Dichlofenthion

Dichlorophen

Diclofenac; for external use except for ophthalmological use

Dicophane

Dicyclomine

Diethylcarbamazine

Dimenhydrinate; except in a sealed container of not more than 12 tablets or capsules for the prevention of travel sickness and sold at a transport

terminal or aboard a ship or plane

Dimethothiazine

Diphenhydramine Diphenylpyraline

Diprophylline; in liquid form for oral use

Doxylamine

Econazole; for dermatological use

Emetine; in medicines containing more than 0.05%

Ephedra

Erythrityl tetranitrate

Ether; when used as a vehicle for a topical dose form

Factor VIII

Felbinac; for external use

Fluorescein

Fluorides; for internal use in medicines containing 2.2 milligrams or less per dose form; for external use in medicines containing 2.5% or less but more than 0.1% of elemental fluorine

Folic acid; in medicines containing more than 500 micrograms per recommended daily dose

Formaldehyde

Formic acid

Gamma benzene hexachloride

Gelsemium

Glucagon

Glutaraldehyde

Glyceryl trinitrate; except for parenteral use

Guaiphenesin; in medicines containing more than 2%

Hetastarch

Hexachlorophane; in medicines containing 3% or less but more than 0.75%

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS—continued

"FIRST SCHEDULE—continued

PART III—continued

Pharmacy-Only Medicines—continued

Hexamidine

Hippuric acid

Homatropine; in solid dose form containing 0.3 milligrams or less per dose and 1 milligram or less per recommended daily dose

Hyaluronic acid

Hydrargaphen; for external use

Hydrocortisone and hydrocortisone acetate but no other esters of hydrocortisone; for dermatological use in medicines containing 0.5% or less by weight of hydrocortisone base with no other active ingredient except an antifungal and in a quantity of 15 grams or less or 15 milliltres or less per container

Hydrocyanic acid; in medicines containing less than 1%

Hydrogen peroxide

Hydroiodic acid

Hydroquinone; in medicines containing more than 2%

Hydroxocobalamin; in medicines containing more than 50 micrograms per recommended daily dose

Hyoscine; in solid dose form containing 0.3 milligrams or less per dose and 1 milligram or less per recommended daily dose

Hyoscyamine; in solid dose form containing 0.3 milligrams or less per dose and 1 milligram or less per recommended daily dose

Ibuprofen; for external use

Ibuprofen; in solid dose form containing 200 milligrams or less per dose form

Ichthammol; in medicines containing more than 10%

Idoxuridine; for dermatological use in medicines containing 0.5% or less Indanazoline

Indomethacin; for external use in medicines containing 1% or less

Injectable medicines; except when specified elsewhere in this Schedule Inositol nicotinate

Iodic acid

Iodine; for external use in medicines containing more than 2.5%; for internal use in medicines containing 300 micrograms or more per recommended daily dose

Ipecacuanha; in medicines containing more than 0.05% of emetine Ipomoea

Ipratropium; for nasal use

Iron; in medicines containing more than 24 milligrams per recommended daily dose

Irrigation medicines; except for ophthalmological use; except when specified elsewhere in this Schedule

Isoconazole; for dermatological use

Isoprenaline; except for inhalation or parenteral use

Isosorbide dinitrate

Isosorbide mononitrate

Jaborandi; in medicines containing 0.5% or more

Jalap resin

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART III—continued

Pharmacy-Only Medicines—continued

Ketoconazole; for dermatological use Ketoprofen; for external use Krameria Lignocaine; for external use in medicines containing more than 2% Lindane Lobelia Lodoxamide; for ophthalmological use Loperamide Loratadine Magenta Mandelic acid Mannityl hexanitrate Mebendazole; in packs containing 600 milligrams or less Mebhydrolin Meclozine; except in a sealed container of not more than 12 tablets or capsules for the prevention of travel sickness and sold at a transport terminal or aboard a ship or plane Mefenamic acid; in solid dose form containing 250 milligrams or less per dose form in packs of not more than 20 tablets or capsules for the treatment of dysmenorrhoea Menadiol Mepyramine Mequitazine Mercurochrome Methdilazine Methoxamine Methoxyphenamine Methylene blue Miconazole; for dermatological use Monoacetin Monosulfiram Naphazoline; except for nasal use when sold at an airport Naproxen; in solid dose form containing 250 milligrams or less per dose form in packs of not more than 20 tablets or capsules for the treatment of dysmenorrhoea Niclosamide Nicotine; for transdermal use; in chewing gum Nitrofurazone Nitrous ether spirit Noradrenaline Noscapine Nux vomica Nystatin; for dermatological use Oxerutins Oxiconazole Oxymetazoline; except for nasal use when sold at an airport

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART III—continued

Pharmacy-Only Medicines—continued

Paracetamol; in liquid form; in solid dose form for oral use containing 500 milligrams or less per dose unit and in packs containing more than 10 grams

Paraformaldehyde

Pentaerythritol tetranitrate

Pentastarch

Phenazone

Phenazopyridine

Pheniramine

Phenol; in medicines containing more than 1%

Phenolphthalein

Phenoxyethanol; in medicines containing more than 2%

Phenylephrine; except for nasal use when sold at an airport; except for ophthalmological use

Phytomenadione

Picric acid

Piperazine

Piroctone; in medicines containing more than 1%

Piroxicam; for external use in medicines containing 1% or less

Polygeline

Pomegranate

- Potassium; except when specified elsewhere in this Schedule; for internal use in slow release or enteric coated forms; in medicines containing more than 100 milligrams per recommended dose except in medicines for oral rehydration therapy or for dialysis
- Pramocaine; for external use in medicines containing more than 2% Pregnancy test kits

Prilocaine; for external use in medicines containing more than 2%

Promethazine; except promethazine theoclate in a sealed container of not more than 12 tablets or capsules for the prevention of travel sickness and sold at a transport terminal or aboard a ship or plane

Propamidine

Pseudoephedrine

Pyrantel

Quassia

Ribonuclease

Salicylamide

Salicylic acid; for external use in medicines containing more than 12.5% Salsalate

Scillarins

Selenium; for external use in medicines containing more than 2.5%; for internal use in medicines containing more than 150 micrograms per recommended daily dose

Sennosides

Silver; except silver sulfadiazine for external use in pack sizes containing more than 50 grams

Sodium cromoglycate; for nasal and ophthalmological use

NEW FIRST SCHEDULE TO THE PRINCIPAL REGULATIONS-continued

"FIRST SCHEDULE—continued

PART III—continued

Pharmacy-Only Medicines-continued

Sodium hydroxide Sodium iodide Sodium nitrite Sodium perborate Sodium picosulphate Sodium salicylate Solcoseryl Squill; in medicines containing more than 1% Stannous chloride Stannous oxide Staphisagria; for external use; for internal use in medicines containing less than 0.2% Stramonium; in solid dose form containing 0.3 milligrams or less per dose and 1 milligram or less per recommended daily dose Sucralfate Sulconazole; for dermatological use Sulfadiazine, silver; for external use in pack sizes containing 50 grams or less Tannic acid Terbinafine; for dermatological use Terebene; except for external use Tetrachloroethylene Tetrahydrozoline Theobromine Theophylline; in liquid form for oral use Thiabendazole Thiomersal Thioxolone Tioconazole; for dermatological use Tramazoline Trichloroacetic acid Triprolidine Tuaminoheptane Vaccines, oral; except when specified elsewhere in this Schedule Viprynium Xylometazoline; except for nasal use when sold at an airport Yohimbine Zinc chloride; for external use

> MARIE SHROFF, 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, which come into force on the 28th day after the date of their notification in the Gazette, amend the Medicines Regulations 1984.

Regulation 2 substitutes new lists of prescription medicines, restricted medicines, and pharmacy-only medicines.

Issued under the authority of the Acts and Regulations Publication Act 1989. Date of notification in *Gazette:* 12 December 1996. These regulations are administered in the Ministry of Health.