Classification of Medicines

Pursuant to section 106(1) of the Medicines Act 1981, I, Dr Don Mackie, Chief Medical Officer, Clinical Leadership, Protection and Regulation Business Unit, Ministry of Health, acting under delegated authority, hereby declare the following:

1. The medicines listed in Schedule 1 to this notice are classified as prescription medicines.
2. The medicines listed in Schedule 2 to this notice are classified as restricted medicines.
3. The medicines listed in Schedule 3 to this notice are classified as pharmacy-only medicines.

Every reference to a medicine in this notice 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 notice.
b. salts and esters of any substance listed in the notice.
c. preparations or extracts of biological materials listed in the notice.
d. salts or oxides of elements listed in the notice.

Unless specific reference is made otherwise, every reference to a medicine applies:

i. if the medicine is in an injection or eye preparation, to any concentration of that medicine; and
ii. if the medicine is not in an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram.

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.

Schedule 1

Prescription Medicines

Abiraterone acetate

Aclidinium bromide

Afamelanotide

Afatanib dimaleate

Aflibercept

Alogliptin

Amorolfine; except when specified elsewhere in this notice; except in preparations for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Amyl nitrite; except when sold to a person who holds a controlled substances licence (issued under section 95B of the Hazardous Substances and New Organisms Act 1996) authorising the person to possess cyanide; except when sold to an exempt laboratory covered by a Hazardous Substances and New Organisms Act 1996 approved code of practice

Apixaban

Articaine; except when used as a local anaesthetic in practice by a dental therapist registered with the Dental Council

Asenapine

Avanafil

Axitinib

Azelastine; except when specified elsewhere in this notice

Belatacept

Belimumab

Bendamustine hydrochloride

Besifloxacin hydrochloride

Besifloxacine

Boceprevir

Cabazitaxel

Canagliflozin

Catumaxomab

Ceftaroline fosamil

Cholera vaccine; except in the form of an oral liquid containing Vibrio cholerae when sold in a pharmacy by a registered pharmacist

Clotrimazole; except in medicines for vaginal or external use

Cobicistat

Collagenase clostridium histolyticum

Crizotinib

Crofelemer

Cyclizine; except when specified elsewhere in this notice

Dabrafenib mesilate

Dapagliflozin propanediol

Degarelix

Denosumab

Diclofenac; in preparations for the treatment of solar keratosis; except when specified elsewhere in this notice; except in preparations for external use other than for the treatment of solar keratosis

Dimethyl fumarate

Diphtheria, tetanus and pertussis (acellular, component) vaccine; except when administered in a single dose to a person 18 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health

Dolutegravir

Dronedarone

Econazole; except in medicines for vaginal or dermal use

Eculizumab

Elvitegravir

Empagliflozin

Enobosarm

Enzalutamide

Eribulin mesylate

Febuxostat

Ferric carboxymaltose

Fidaxomicin

Fingolimod

Follistatin

Ghrelin

Glycopyrronium

Guaiphenesin; for oral use in medicines containing more than 2% or 200 milligrams per dose form except when specified elsewhere in this notice; except for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer’s original pack containing not more than 10 days’ supply

Hexarelin

Icatibant

Human growth hormone secretagogues

Indacaterol

Influenza vaccine; except when administered to a person 18 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health

Ingenol mebutate

Insulin-like growth factors; except where specified elsewhere in this notice

Ipamorelin

Ipilimumab

Isoconazole; except in medicines for vaginal or dermal use

Ivacaftor

Ledipasvir

Linagliptin

Lixisenatide

Loteprednol

Loteprednol etabonate

Lovastatin; except when present as an unmodified, naturally occurring substance in a food that has not been subject to a manufacturing process other than heating, freezing, drying, preserving, bottling, canning or packaging in retort pouches

Lurasidone

Macitentan

Melanocyte stimulating compounds

Meningococcal vaccine; except when administered to a person 16 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health

Mercurochrome; except when specified elsewhere in this notice

Micafungin

Miconazole; except when specified elsewhere in this notice; except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Mirabegron

Nitisinone

Nitrous Oxide; when supplied for inhalation

Nomegestrol

Nystatin; except when specified elsewhere in this notice; except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Obinutuzumab

Ocriplasmin

Ofatumumab

Olodaterol

Omeprazole; except when specified elsewhere in this notice

Oseltamivir; except when specified elsewhere in this notice

Pantoprazole; except when specified elsewhere in this notice

Pasireotide

Pasireotide diaspartate

Pertuzumab

Pitavastatin

Plerixafor

Pradofloxacin

Pralatrexate

Prucalopride

Pseudoephedrine

Ranitidine; except when specified elsewhere in this notice; except in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

Regorafenib

Remestemcel-L

Retapamulin

Retigabine

Ridaforolimus

Rifaximin

Rilpivirine

Riociguat

Romidepsin

Rupatadine

Ruxolitnib

Sapropterin

Selective androgen receptor modulators

Sildenafil and its structural analogues; except sildenafil in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35–70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand

Simeprevir

Sofosbuvir

Tafluprost

Taliglucerase alfa

Telaprevir

Terbinafine; except in medicines for dermal use

Teriflunomide

Tesamorelin

Ticagrelor

Tioconazole; except in medicines for vaginal or dermal use

Trametinib dimethyl sulfoxide

Tolvaptan

Trastuzumab emtansine

Trimethoprim; except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16–65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections

Tuberculin

Umeclidinium bromide

Vandetanib

Varicella vaccine; except when administered for the prevention of herpes zoster (shingles) to a person 50 years of age or over by a registered pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health

Vedolizumab

Velaglucerase alfa

Vemurafenib

Vilanterol

Vismodegib

Vorinostat

Vortioxetine

Zoster immunoglobulin, human

Schedule 2

Restricted Medicines

Adrenaline; in medicines containing 1% or less except in medicines for injection containing 0.02% or less

Brompheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Chlorpheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Ciclopirox; for external use in medicines containing more than 2%; in preparations for application to the nails containing more than 8%

Cimetidine; in medicines for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner that are sold in the manufacturer's original pack containing not more than 14 days' supply

Cyclizine; for oral use other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Dexchlorpheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Diclofenac; in solid dose form in medicines containing 25 milligrams or less and more than 12.5 milligrams per dose form in packs containing not more than 30 tablets or capsules

Diphenhydramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Doxylamine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Famciclovir; in divided solid dosage forms for oral use containing 500 milligrams or less for the treatment of recurrent herpes labialis when sold in the manufacturer's original pack containing up to 3 dosage units

Guaiphenesin; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing more than 10 days' supply but not more than 30 days' supply

Hyoscine butylbromide; for oral use in medicines containing not more than 20 milligrams per dose form and in packs containing not more than 10 tablets or capsules for the relief of muscle spasm of the gastrointestinal tract

Lansoprazole; in divided solid dosage forms for oral use containing 15 milligrams or less with a maximum daily dose of 15 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over or the relief of heartburn when sold in the manufacturer's original pack containing not more than 14 dosage units

Meclozine; in a pack size of up to 10 dosage units for the treatment of anxiety or insomnia

Mepyramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Miconazole; for the treatment of oral candidiasis; for vaginal use

Nystatin; for the treatment of oral candidiasis; for vaginal use

Oseltamivir; in solid dosage forms for oral use containing 75 milligrams in a pack size of up to 10 dosage units for the treatment or prophylaxis of influenza in adults and children aged 13 years and older who have been exposed to the influenza virus

Pheniramine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the

manufacturer's original pack containing not more than 10 dosage units

Promethazine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Trimeprazine; for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Schedule 3

Pharmacy-only Medicines

Amorolfine; in preparations for topical use except in preparations for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Azelastine; for nasal use; in topical eye preparations containing 0.05% or less

Beclomethasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age in aqueous nasal sprays delivering up to 50 micrograms per actuation when the maximum recommended daily dose is no greater than 400 micrograms (200 micrograms per nostril) in a pack containing 200 actuations or less

Budesonide; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age in aqueous nasal sprays delivering up to 50 micrograms per actuation and when the maximum recommended daily dose is no greater than 400 micrograms (200 micrograms per nostril) in a pack containing 200 actuations or less

Cetirizine; for oral use except in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply

Ciclopirox; for external use in medicines containing 2% or less except when for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board; in preparations for application to the nails containing 8% or less

Clotrimazole; for external use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Diclofenac; in solid dose form in medicines containing 12.5 milligrams or less per dose form in packs containing not more than 30 tablets or capsules and with a recommended daily dose of not more than 75 milligrams

Econazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Famotidine; for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in the manufacturer's original pack containing not more than 14 days' supply

Fexofenadine; for oral use except for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply

Fluticasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age when in aqueous nasal sprays delivering up to 50 micrograms per actuation with a maximum recommended daily dose of 200 micrograms (as a single dose) in a pack containing 200 actuations or less

Ibuprofen; for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; except in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units

Ipomoea; except ipomoea batatas

Isoconazole; for dermal use except when sold in practice by a podiatrist registered with the Podiatrists Board

Ketoconazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board; except in medicines for treatment of the scalp containing 1% or less

Loratadine; for oral use except in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply

Mercurochrome; in preparations for external use containing 2% or less

Miconazole; for external use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Mometasone; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age in aqueous nasal sprays delivering up to 50 micrograms per actuation when the maximum recommended daily dose is no greater than 200 micrograms (as a single dose) in a pack containing 200 actuations or less

Nizatidine; in medicines for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in the manufacturer's original pack containing not more than 14 days' supply

Nystatin; for dermal use except when sold in practice by a podiatrist registered with the Podiatrists Board

Omeprazole; in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 28 dosage units

Oxymetazoline; except for nasal use when sold at an airport; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less

Pantoprazole; in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 28 dosage units

Ranitidine; in medicines for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in the manufacturer's original pack containing not more than 14 days' supply; except in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

Terbinafine; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Tioconazole; for dermal use except in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Medicines for General Sale

Please note that the following medicines are now available for general sale.

Adrenaline; in medicines for injection containing 0.02% or less

Amorolfine; in preparations for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

C1 esterase inhibitors

Cetirizine; in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply

Ciclopirox; for external use in medicines containing 2% or less when for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Clotrimazole; for external use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Diclofenac; in preparations for external use other than for the treatment of solar keratosis

Econazole; for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Factor VIII inhibitor bypassing fraction

Fexofenadine; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply

Guaiphenesin; for oral use in medicines containing 2% or less or 200 milligrams or less per dose form; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing not more than 10 days' supply

Human protein C

Ibuprofen; for external use; in divided solid dosage forms for oral use containing 200 milligrams or less per dose

form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack

Isoconazole; for dermal use when sold in practice by a podiatrist registered with the Podiatrists Board

Ketoconazole; for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board; in medicines for treatment of the scalp containing 1% or less

Loratadine; in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply

Mepyramine; for external use in medicines containing 2% or less in packs not exceeding 25 grams.

Miconazole; for external use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Nystatin; for dermal use when sold in practice by a podiatrist registered with the Podiatrists Board

Oxymetazoline; for nasal use when sold at an airport; for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less

Ranitidine; in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

Terbinafine; for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Tioconazole; for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board

Dated this 12th day of December 2014.

Dr DON MACKIE, Chief Medical Officer, Clinical Leadership, Protection and Regulation Business Unit, Ministry of Health.

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