Classification of Medicines

Pursuant to section 106(1) of the Medicines Act 1981, I, Chris James, Group Manager, Medsafe, 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

Adapalene; except in medicines containing 1 milligram or less per millilitre or gram and when supplied by a pharmacist in a pack containing not more than 30 grams for the treatment of comedo, papular and pustular acne (acne vulgaris) of the face, chest or back

Alectinib

Alirocumab

Aloracetam

Amifampridine

Aniracetam

AOD-9604

Apremilast

Armodafinil

Artesunate

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

Asfotase alfa

Asunaprevir

Atezolizumab

Azelastine; except when specified elsewhere in this notice

Bedaquiline

Benzbromarone

Benzodiazepine derivatives; except when specified elsewhere in this notice

Benzodiazepines; except when specified elsewhere in this notice

Benzydamine; except for oromucosal or topical use

Betaine; for the treatment of homocystinuria

Bifonazole; except when specified elsewhere in this notice

Bilastine; except when specified elsewhere in this notice

Bosutinib

Brentuximab vedotin

Brivaracetam (and its stereoisomers)

Carfilzomib

Carglumic acid

Cebaracetam (and its stereoisomers)

Cholic acid

CJC-1295

Cobimetinib

Coluracetam

Daclatasvir

Daratumumab

Defibrotide

Deoxycholic acid; for injection

Dermatophagoides farinae

Dermatophagoides pteronyssinus

Desogestrel; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme

Di-iodohydroxy quinoline; except when specified elsewhere in this notice

Dimiracetam (and its stereoisomers)

Diphtheria, tetanus and pertussis (acellular, component) vaccine; except when administered in a single dose to a person 18 years of age or over or to a pregnant woman aged 13 years and 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

Doliracetam (and its stereoisomers)

Dupracetam

Elbasvir

Elosulfase alfa

Elotuzumab

Eluxadoline

Esomeprazole; except when specified elsewhere in this notice

Ethinyloestradiol; except when supplied at a strength of 35 micrograms or less in combination with either levonorgestrel or norethisterone for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme

Etiracetam

Fasoracetam (and its stereoisomers)

Felbamate

Felypressin; except when combined with a local anaesthetic and used in practice by a dental therapist or oral health therapist registered with the Dental Council

Fibroblast growth factors

Flubromazolam

Flunarizine

Follitropin delta

Fomepizole

Fonturacetam (and its stereoisomers)

Glecaprevir

Grazoprevir

Growth Hormone Releasing Hormones

Growth Hormone Releasing Peptide-6

Growth Hormone Releasing Peptides

Hexyl aminolevulinate

Idarucizumab

Idebenone

Idelalisib

Imuracetam

Influenza vaccine; except when administered to a person 13 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

Ixazomib

Ixekizumab

Ketoprofen; except when specified elsewhere in this notice

Lenvatinib

Lesinurad

Levomilnacipran

Levonorgestrel; except when specified elsewhere in this notice; except in medicines for use as emergency post-coital contraception when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme

Lignocaine; for injection except when used as a local anaesthetic in practice by a nurse whose scope of practice permits the performance of general nursing functions or by a podiatrist registered with the Podiatry Board or by a dental therapist or oral health therapist registered with the Dental Council; for ophthalmic use except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use except in throat lozenges in medicines containing 30 milligrams or less per dose form; for external use in medicines containing more than 10%; except in throat sprays in medicines containing 2% or less; except when specified elsewhere in this notice

Lipegfilgrastim

Lisdexamfetamine

Loratadine; except when specified elsewhere in this schedule; 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 10 days' supply

Lumacaftor

Mepolizumab

Methylhexanamine (1,3-dimethylamylamine (DMAA)); except when present as an unmodified, naturally occurring substance

Milnacipran

Molracetam

Naloxegol

Naloxone; except when provided as part of an approved emergency kit for the treatment of opioid overdose

Nebracetam (and its stereoisomers)

Nefiracetam

Nepidermin

Netupitant

Nicoracetam

Nitazoxanide

Nivolumab

Noopept (and its stereoisomers)

Norethisterone; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme

Ocrelizumab

Olaparib

Osimertinib

Otilonium bromide

Oxiracetam (and its stereoisomers)

Palbociclib

Paritaprevir

Pegaspargase

Peginterferon beta-1a

Pembrolizumab

Pentostatin

Phleum pratense extract

Pibrentasvir

Picibanil

Piperacetam

Pirfenidone

Ponatinib

Pralmorelin

Pramiracetam

Prilocaine; for injection except when used as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council; except when specified elsewhere in this notice

Ranitidine; except when specified elsewhere in this notice; except in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

Ramucirumab

Ranolazine

Recombinant human Epidermal Growth Factor

Rolipram (and its stereoisomers)

Rolziracetam

Rufinamide

Sacubitril

Sargramostim

Sarilumab

Secukinumab

Seletracetam (and its stereoisomers)

Sodium phenylbutyrate

Sodium zirconium cyclosilicate

Sonidegib

Stiripentol

Streptozocin

Sunifiram

Suvorexant

Talimogene laherparepvec

TB-500

Thymosin beta-4

Tizanidine

Tofacitinib

Trientine

Ulipristal

Velpatasvir

Venetoclax

Vorapaxar

Schedule 2

Restricted Medicines

Cyclizine; for oral use other than in medicines used for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 6 dosage units; for oral use in medicines used for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

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

Levonorgestrel; in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health

Schedule 3

Pharmacy-only Medicines

Azelastine; in preparations for nasal use containing 0.15% azelastine hydrochloride or less; in topical eye preparations containing 0.05% or less

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

Bilastine; in divided solid dosage forms for oral use containing 20 milligrams or less for the treatment of the symptoms of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria when sold in a pack containing not more than 30 dosage units

Esomeprazole; 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 gastro-oesophageal reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 7 dosage units

Lignocaine; for urethral use; for external use in medicines containing 10% or less and more than 2%

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 10 days' supply

Macrogols; in preparations for oral use as a liquid concentrate for laxative use

Paracetamol; in liquid form; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams and not more than 50 grams; in slow-release forms containing 665 milligrams or less and more than 500 milligrams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack

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

Medicines for General Sale

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

Albutrepenonacog alfa

Benzydamine; for oromucosal or topical use

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

Deoxycholic acid; for oral use

Efmoroctocog alfa

Lignocaine; in throat lozenges in medicines containing 30 milligrams or less per dose form; for external use in medicines containing 2% or less; in throat sprays in medicines containing 2% 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 10 days' supply

Rurioctocog alfa pegol

Simoctocog alfa

Ranitidine; in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

Dated this 27th day of July 2017.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health.

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