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.

In accordance with section 106(2) of the Act, to the extent that any part of this notice is inconsistent with any provisions of any regulations made under section 105(1)(j) of the Act, the provisions in those regulations cease to have effect while this notice remains in force.

Schedule 1

Prescription Medicines

Alanylglutamine

Amethocaine; for internal use; for external use in medicines containing more than 10%; for ophthalmic use except when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except when containing 2% or less and used topically as a local anaesthetic in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council

Amivantamab

Andexanet alfa

AOH1996

Arbutin; in oral preparations except herbal preparations containing 500 milligrams or less beta-arbutin per recommended daily dose

Articaine; except when used as a local anaesthetic in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council

Asciminib

Atogepant

Avacopan

Avalglucosidase alfa

Avatrombopag

Belumosudil

Belzutifan

Benzocaine; except when specified elsewhere in this schedule; except in dermal preparations containing 2% or less total anaesthetic substances; except in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit; except when containing 20% or less and used topically as a local anaesthetic in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice)

registered with the Dental Council

Bilastine; except when specified elsewhere in this schedule

Body Protective Compound –157

Bufexamac

Cannabidiol; except when elsewhere in the schedule

Cardarine

Cariprazine

Casirivimab

Cemiplimab

Cilgavimab

Ciltacabtagene autoleucel

Clascoterone

Deucravacitinib

Deutetrabenazine

Difelikefalin

Diroximel fumarate

Dostarlimab

Edaravone

Elexacaftor

Enfortumab vedotin

Eslicarbazepine

Estetrol monohydrate

Etesevimab

Faricimab

Felypressin; except when combined with a local anaesthetic and used in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council

Fenbendazole

Fexofenadine; except for oral use

Filgotinib

Finerenone

Fostemsavir

Fruquintinib

Ganaxolone

Glecaprevir; except when supplied in combination with pibrentasvir in a manufacturer’s original pack that has received consent from the Minister of Health or Director General for treatment of chronic hepatitis C virus infection to people who meet the clinical and eligibility criteria of an approved training programme, when provided by nurses who meet the requirements of the Nursing Council or pharmacists who meet the requirements of the Pharmacy Council

Glofitamab

Hyaluronidase

Icosapent ethyl

Imdevimab

Inclisiran

Infigratinib

Ivosidenib

Lemborexant

Lenacapavir

Levomefolic acid; for injection.

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, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council; except when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) 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 schedule

Lurbinectedin

Luspatercept

Mavacamten

Mobocertinib

Molnupiravir; except when specified elsewhere in this schedule

Naloxone; except when provided as part of an approved emergency kit for the treatment of opioid overdose; except when supplied as ampoules with needles and syringes, or as a prefilled syringe, by those authorised by regulation 3, 4 or 5 of the Health (Needles and Syringes) Regulations 1998 for the treatment of opioid overdose, and when supplied with instructions for use

Nirmatrelvir; except when specified elsewhere in this schedule

Nitrofurantoin; except when supplied for oral use containing 100mg per dose unit when sold in a pack of 10 solid dosage units to a woman aged 16–65 years for the first-line empiric treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the Pharmaceutical Society of New Zealand training in the treatment of urinary tract infections

Onasemnogene abeparvovec

Opicapone

Osilodrostat

Patisiran

Pegcetacoplan

Pegvaliase

Pemigatinib

Phenol; for injection; except when specified elsewhere in this schedule; except when supplied in a manufacturer’s original pack that has received consent from the Minister or Director-General to a podiatrist registered with the Podiatrists Board of New Zealand for matrixectomy

Pibrentasvir; except when supplied in combination with glecaprevir in a manufacturer’s original pack that has received consent from the Minister of Health or Director General for treatment of chronic hepatitis C virus infection to people who meet the clinical and eligibility criteria of an approved training programme, when provided by nurses who meet the requirements of the Nursing Council or pharmacists who meet the requirements of the Pharmacy Council

Ponesimod

Pralsetinib

Prilocaine; for injection except when used as a local anaesthetic in practice by a dental therapist, or oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council; except when specified elsewhere in this schedule except when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist, oral health therapist or dental hygienist (without local anaesthetic exclusion on their scope of practice) registered with the Dental Council

Recombinant varicella zoster virus glycoprotein E antigen; 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 the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course)

Regdanvimab

Relugolix

Ripretinib

Risdiplam

Ritonavir; except when specified elsewhere in this schedule

Sacituzumab govitecan

Selinexor

Selumetinib

Somapacitan

Sotorasib

Sotrovimab

Teneligliptin

Tepotinib

Tezepelumab

Tirzepatide

Tislelizumab

Tixagevimab

Trabectedin

Trastuzumab deruxtecan

Trifarotene

Vericiguat

Vosoritide

Zanubrutinib

Zinc; except for internal use in medicines containing 25 milligrams or less per recommended daily dose; except for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose in packs that have received the consent of the Minister or the Director-General to their distribution as general sale medicines, when sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except for external use except when specified elsewhere in this schedule; except in parenteral nutrition replacement preparations

Schedule 2

Restricted Medicines

Adrenaline; in medicines containing 1% or less except in medicines for injection containing 0.02% or less; except in medicines for injection containing 0.1% for use in practice in an emergency by a dental therapist, an oral health therapist or a dental hygienist registered with the Dental Council

Cannabidiol; when supplied, in medicines with dosing instructions for 150 milligrams or less per day and containing not more than 4.5 grams, when sold in the manufacturer's original pack that has received consent from the Minister or Director-General, for adults aged 18 years and over, by a registered pharmacist

Choline Salicylate; in medicines containing 10% or less and in packs sizes of 15 grams or less when indicated for use in children under 18 months of age

Ibuprofen 300 milligrams in powder form; for oral use in powder form containing 300 milligrams per dose with a recommended daily dose of not more than 1.2 grams and sold in the manufacturers original packs containing not more than 12 dose units, and labelled for use in adults and children over 12 years of age

Melatonin; in immediate release preparations containing 5mg or less of melatonin for the treatment of jet lag in adults aged 18 or over, in a manufacturers original pack that has received consent from the Minister or Director-General containing no more than 10 dosage units

Methenamine hippurate

Molnupiravir; for use in the treatment of COVID-19

Nirmatrelvir; for use in the treatment of COVID-19

Pholcodine; in medicines for oral use containing not more than 15 milligrams of pholcodine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of pholcodine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a restricted medicine

Ritonavir; for use in the treatment of COVID-19

Schedule 3

Pharmacy-only Medicines

Bilastine; for oral use

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 20 dosage units or less and not more than 10 days' supply; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 180 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 10 days' supply

Folic acid; For oral use in medicines containing more than 500 micrograms per recommended daily dose. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose

Folinic acid; For oral use in medicines containing more than 500 micrograms per recommended daily dose. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose

Levomefolic acid; for oral use in medicines containing more than 500 micrograms per recommended daily dose. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose

Phenol; in medicines other than for injection containing more than 3% other than for matrixectomy.

Medicines for General Sale

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 20 dosage units or less and not more than 10 days' supply; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180 milligrams or less of fexofenadine hydrochloride with maximum daily dose of 180 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 10 days' supply.

Dated this 23rd day of September 2024.

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

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