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

Cardarine

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

Ripretinib

Faricimab

Deutetrabenazine

Eslicarbazepine

Lemborexant

Luspatercept

Trabectedin

Molnupiravir; except when specified elsewhere in this schedule

Nirmatrelvir; except when specified elsewhere in this schedule

Ritonavir; except when specified elsewhere in this schedule

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).

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 or oral health therapist registered with the Dental Council.

Benzocaine; except when specified elsewhere in this schedule; except in dermal preparations containing 2% or less of 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 or oral health therapist registered with the Dental Council.

Cariprazine

Casirivimab

Cemiplimab

Cilgavimab

Elexacaftor

Etesevimab

Filgotinib

Hyaluronidase

Imdevimab

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 schedule; except when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council.

Onasemnogene abeparvovec

Opicapone

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 schedule; except when containing 2.5% or less and used topically as a local anaesthetic in practice by a dental therapist or oral health therapist registered with the Dental Council.

Regdanvimab

Risdiplam

Sotrovimab

Tixagevimab

Trifarotene

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.

Naloxone; except when supplied as ampoules with needles and syringes, or as a prefilled syringe, by those enabled to do so under the Health (Needles and Syringes) Regulations 1998 for the treatment of opioid overdose, and when supplied with instructions for use.

Levomefolic acid; for injection.

Amivantamab

Glu-urea-Lys(ahx)-hbed-CC

Icosapent ethyl

Zanubrutinib

Faricimab

Ciltacabtagene autoleucel

Belumosudil

Estetrol monohydrate

Finerenone

Fostemsavir

Inclisiran

Pegcetacoplan

Pegvaliase

Sacituzumab govitecan

Trastuzumab deruxtecan

Vericiguat

Bufexamac

Schedule 2

Restricted Medicines

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.

Molnupiravir; for use in the treatment of COVID-19

Nirmatrelvir; for use in the treatment of COVID-19

Ritonavir; for use in the treatment of COVID-19

Schedule 3

Pharmacy-only Medicines

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.

Dated this 3rd day of November 2022.

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

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