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

Abemaciclib

Alkyl nitrites

Alpelisib

Artemisia annua extract

Avelumab

Avibactam

Baricitinib

Baloxavir marboxil

Benralizumab

Blinatumomab

Brigatinib

Budesonide; **except** when specified elsewhere in this notice

Cenegermin

Cerliponase alfa

Cilnidipine

Codeine

Crisaborole

Daratumumab

Darolutamide

Dextromethorphan; **except** when specified elsewhere in this notice

DMHA including the isomers 2-amino-6-methylhelptane (also known as 1,5-dimethylhexylamine, and octodrine) and 2-amino-5-methylheptane (also known as 1,4-dimethylhexamine)

Doravirine

Durvalumab

Entrectinib

Esketamine

Galcanezumab

Fluticasone; **except** when specified elsewhere in this notice

Human papillomavirus vaccine; **except** when administered by a registered pharmacist or registered intern 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.

Ibutamoren

Inotuzumab ozogamicin

Isavuconazole

Lanadelumab

Lifitegrast

Linaclotide

Lorlatinib

Melatonin; **except** when supplied in medicines for oral use containing 3mg or less per immediate release dose unit, or 2mg or less per modified release dose unit, when sold in the manufacturers original pack that has received consent from the Minister of Health or the Director General for the treatment of primary insomnia for adults aged 55 years or older for up to 13 weeks by a registered pharmacist.

Meldonium

Metamizole

Methylphenylpiracetam

Midostaurin

NeratinibNiraparib

Obeticholic acid

Olaratumab

Omberacetam

Opium

Phenylpiracetam

Plitidepsin

Polatuzumab vedotin

Racetams; except when specified elsewhere in this notice

Risankizumab

Romosozumab

Safinamide

Squill

Stenabolic (SR9009) and other synthetic REV-ERB agonists

Talazoparib

Tezacaftor

Tilmanocept

Tivozanib

Unifiram

UpadacitinibVoglibose

Voxilaprevir

Schedule 2

Restricted Medicines

Dextromethorphan; in liquid form when in packs containing not more than 600 milligrams and with a recommended daily dose of not more than 120 milligrams; in medicines for the treatment of symptoms of cough and cold in adults and children aged 6 years and over

Paracetamol; in modified-release forms containing 665 milligrams or less

Schedule 3

Pharmacy-only Medicines

Bilastine; in divided solid dosage forms for oral use containing 20 milligrams or less for the treatment of the symptoms of allergic rhinoconjuctivitis (seasonal and perennial) and urticaria.

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 64 micrograms per actuation and when the maximum recommended daily dose is no greater than 400 micrograms (200 micrograms per nostril)

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)

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 powder form containing not more than 1 gram per sachet and more than 10 grams per pack; except in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; except in powder form in sachets containing 1 gram or less and in packs of not more than 10 grams

Dated this 3rd day of December 2020.

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

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