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

Asciminib

Atogepant

Avacopan

Avalglucosidase alfa

Bilastine; except when specified elsewhere in this Schedule.

Body Protective Compound –157

Deucravacitinib

Edaravone

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

Lenacapvir

Mobocertinib

Osilodrostat

Patisiran

Pemigatinib

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.

Relugolix

Teneligliptin

Tirzepatide

Tislelizumab

Vosoritide

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 3

Pharmacy-only Medicines

Bilastine; for oral use.

Medicines for General Sale

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

Zinc; for external use **except** zinc chloride in medicines containing more than 5%;

for internal use in medicines containing 25 milligrams or less per recommended daily dose;

for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose and in packs which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are 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** in parenteral nutrition replacement preparations.

Dated this 31st day of August 2023.

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

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