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

Tezepelumab

Clascoterone

AOH1996

Andexanet alfa

Avatrombopag

Difelikefalin

Ivosidenib

Pralsetinib

Fexofenadine; except for oral use

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.

Schedule 2

Restricted Medicines

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.

Schedule 3

Pharmacy-only Medicines

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

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 8th day of May 2024.

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

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