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.

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

Acalabrutinib

Alitretinoin

Brolucizumab

Cabotegravir

Cedazuridine

Decitabine

Enasidenib

Fosnetupitant

Fremanezumab

Gilteritinib

Indocyanine green

Isatuximab

Larotrectinib

Ozanimod

Siponimod

Tafamidis

Tucatinib

Voretigene neparvovec

Medicines for General Sale

Please note that the following medicines are now available 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;

Fexofenadine; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in tablets containing 180mg or less of fexofenadine hydrochloride with maximum daily dose of 180mg when sold in the manufacturer's original pack containing 5 dosage units or less and not more than 5 days' supply.

Dated this 17th day of February 2021.

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

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