Therapeutic Goods (Restricted Representations—Low Dose Aspirin) Permission 2020

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 25 November 2020

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Low Dose Aspirin) Permission 2020.*

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is made.	26 November 2020

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42DK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

(a) advertise;
(b) indication;
(c) label;
(d) medicine;
(e) Register;
(f) therapeutic goods; and
(g) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the *Therapeutic Goods Regulations 1990*.

capsule has the same meaning as in TGO 101.

low dose aspirin means a registered medicine, other than a prescription medicine, that:

(a) is manufactured in the dosage form of a capsule or tablet; and
(b) has a stated content of not less than 75 mg and not more than 150 mg of aspirin; and
(c) contains aspirin as the only active ingredient; and
(d) has an indication accepted in relation to its inclusion that relates to the reduction of risk of heart attack or stroke in patients with known cardiovascular disease or cerebrovascular disease.

prominently displayed or communicated has the same meaning as in the Therapeutic Goods Advertising Code.

registered medicine means a medicine that is included in the part of the Register for goods known as registered goods.

restricted representation means a representation referred to in section 42DD of the Act.

stated content has the same meaning as in TGO 101.

tablet has the same meaning as in TGO 101.

TGO 101 means the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019.*

Note: TGO 101 is a legislative instrument published on the Federal Register of Legislation at https://www.legislation.gov.au.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the restricted representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: restricted representation

Note: See section 5.

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Condition**
1	a representation that is to the effect that the therapeutic goods reduce the risk of heart attack and stroke in patients with known cardiovascular disease or cerebrovascular disease by helping to reduce blood clotting	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	low dose aspirin	advertisements about the therapeutic goods that are not: (a) on the label of the therapeutic goods, or (b) on the package in which the therapeutic goods are contained; or (c) on any material included with the package in which the therapeutic goods are contained; must be accompanied by statements, which are prominently displayed or communicated, to the effect of the following: (d) "Consult a medical practitioner prior to commencing use of low dose aspirin"; and (e) "Do not substitute other medicines containing aspirin for this medicine, without first consulting your pharmacist or medical practitioner"; and (f) "The use of low dose aspirin may be only one component of your medical practitioner's management plan to prevent you having a further heart attack

Permitted use of restricted representation				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Restricted representation**	**Advertisement**	**Therapeutic goods**	**Condition**
				or stroke. You should discuss this plan with your medical practitioner”