Therapeutic Goods (Restricted Representations—Andrographis) Permission 2020

I, Leanne McCauley, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 24 January 2020

Leanne McCauley
Director, Advertising Education and Assurance Section
Regulatory Education and Compliance Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Andrographis) 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.	25 January 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Note: This table relates only to the provisions of this instrument as originally made.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) label; and
(c) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient, for a medicine, has the same meaning as in the Regulations.

homoeopathic preparation has the same meaning as in the Regulations.

homoeopathic preparation ingredient means an ingredient that is a constituent of a homoeopathic preparation.

Regulations means the *Therapeutic Goods Regulations 1990*.

restricted representation has the same meaning as in section 42DD of the Act.

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 representaiton

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**	**Conditions**
1	a representation that refers to a serious form of disease, condition, ailment or defect, and is to the effect of both of the following: (a) andrographis may cause allergic reactions in some people; and (b) if you have a severe reaction (such as anaphylaxis) stop use and seek immediate medical attention	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	medicines that contain *Andrographis paniculata* as*:* (a) an active ingredient; or (b) a homoeopathic preparation ingredient	