



## **Therapeutic Goods (TGA Assessed Claim) Authorisation 2020**

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I, John Skerritt, Deputy Secretary, make the following authorisation.

Dated 20 August 2020

Adjunct Professor John Skerritt  
Deputy Secretary  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (TGA Assessed Claim) Authorisation 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.	21 August 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Note: This table relates only to the provisions of this instrument as originally made.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 Purpose

This instrument is made for the purposes of paragraphs 42DL(9)(b) and 42DLB(6)(b) 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;
- (c) medicine;
- (d) Register; and
- (e) Secretary.

In this instrument:

*Act* means the *Therapeutic Goods Act 1989*.

*complementary medicine* has the same meaning as in the Regulations.

*Guidelines* means the *Guidelines for using the TGA assessed claim on medicine labels* (Version 1.1, August 2020) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The Guidelines are published on the internet at [www.tga.gov.au](http://www.tga.gov.au).

*Regulations* means the *Therapeutic Goods Regulations 1990*.

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***TGA assessed claim*** means the TGA assessed statement with or without the TGA assessed symbol.

***TGA assessed statement*** means the statement set out in Part 2 of Schedule 1.

***TGA assessed symbol*** means the symbol set out in Part 1 of Schedule 1.

***Therapeutic Goods Administration*** has the same meaning as in the Regulations.

## **5 Authorisation**

- (1) Subject to subsection (2), the TGA assessed claim is authorised for use in an advertisement in relation to a medicine where:
  - (a) the medicine is:
    - (i) listed in the Register under section 26AE of the Act; or
    - (ii) a complementary medicine registered under section 25 of the Act; and
  - (b) the label of the medicine displaying the TGA assessed claim was considered and agreed to by the Secretary in the course of:
    - (i) evaluating the medicine under section 25 or 26AE of the Act; or
    - (ii) deciding a request for a variation of the entry in the Register in relation to the medicine under section 9D of the Act.
- (2) The use of the TGA assessed claim must be in accordance with the requirements set out in the Guidelines.

## **6 Repeals**

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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## **Schedule 1—TGA assessed claim**

Note: See section 4, definitions of *TGA assessed symbol* and *TGA assessed statement*.

### **Part 1—TGA assessed symbol**



### **Part 2—TGA assessed statement**

Evidence for the approved indications has been assessed by the TGA.

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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods (TGA Assessed Claim) Authorisation 2019***

#### **1 The whole of the instrument**

Repeal the instrument.