Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination 2022

I, Nicholas Henderson, as delegate of the Secretary of the Department of Health and Aged Care, make the following determination.

Dated 8 December 2022

Nicholas Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination 2022*.

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 registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 subsections 23B(9) and (10) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) medicine.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

complementary medicine has the same meaning as in the Regulations.

Regulations means the *Therapeutic Goods Regulations 1990*.

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

5 Application

This instrument applies to medicines of the class specified in paragraph 4(1)(b) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*, as in force or existing at the commencement of this instrument.

Note: The *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018* is a notifiable instrument and is published on the Federal Register of Legislation at www.legislation.gov.au.

6 Kind of information

For the purposes of subparagraph 23B(2)(d)(i) of the Act, an application for the registration of a complementary medicine must be accompanied by information of the following kind:

(a) the information specified for the medicine in the document titled *CTD Module 1: Administrative information for registered complementary medicines, Australian regulatory guidance* (version 1.0, May 2020) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument; and

(b) the information specified for the medicine in the document titled *Mandatory requirements for an effective registered complementary medicine application, for applications lodged from March 2018* (version 1.1, July 2021) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The documents mentioned in paragraphs (a) and (b) are published at www.tga.gov.au.

7 Form of information

For the purposes of subparagraph 23B(2)(d)(ii) of the Act, the information that accompanies an application for the registration of a complementary medicine must be:

(a) contained in an application dossier; and

(b) in a form consistent with the document titled *General dossier requirements* (version 1.4, July 2018) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The document mentioned in paragraph (b) is published at www.tga.gov.au.

8 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Note: See section 8.

Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Registration) Determination August 2018

1 The whole of the instrument

Repeal the instrument.