# Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023

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

Dated 24 January 2023

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 (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023*.

## 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 | 1 February 2023. | 1 February 2023 |

Note: This table relates only to the provisions of this instrument as originally made.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 26BD(8) and (9) 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) Secretary.

In this instrument:

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

***Therapeutic Goods Administration*** means the part of the Department known as the Therapeutic Goods Administration.

## 5 Kind of information

For the purposes of subparagraph 26BD(3)(e)(i) of the Act, an application for a recommendation by the Secretary that the Minister vary a section 26BB determination must be accompanied by information of the following kind:

(a) the information specified in the document titled *Mandatory requirements for an effective application to vary the Permissible Ingredients*

*Determination* (Version 1.0, February 2023), published by the Therapeutic Goods Administration, as in force or existing on 1 February 2023.

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

## 6 Form of information

For the purposes of subparagraph 26BD(3)(e)(ii) of the Act, the information that must accompany an application for a recommendation by the Secretary that the Minister vary a section 26BB determination must be:

(a) contained in an application dossier; and

(b) in a form consistent with the document titled *Mandatory requirements for an effective application to vary the Permissible Ingredients Determination* (Version 1.0, February 2023), published by the Therapeutic Goods Administration, as in force or existing on 1 February 2023; and

(c) 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 on 1 February 2023.

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