



## **Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Section 26AE Listing) Determination August 2018**

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I, Jane Cook, Acting First Assistant Secretary, Medicines Regulation Division, Health Products Regulation Group, a delegate of the Secretary of the Department of Health for the purposes of section 23B of the *Therapeutic Goods Act 1989*, revoke the Therapeutic Goods (Complementary Medicines – Information that Must Accompany Application for Section 26AE Listing) Determination 2018, registered on 21 May 2018, and make the following Determination under subsections 23B(9) and (10) of that Act.

Dated 20<sup>th</sup> August 2018

(Signed by)

JANE COOK

Delegate of the Secretary of the Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Complementary Medicines—Information that Must Accompany Application for Section 26AE Listing) Determination August 2018*.

## 2 Commencement

This instrument commences on the day after it is registered.

## 3 Definitions

In this instrument:

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

*complementary medicine* means a medicine of the kind specified in paragraph 4(1)(b) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*.

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

## 4 Applications to which this instrument applies

This instrument applies to an application to list a complementary medicine under section 26AE of the Act.

## 5 Kind of information

For the purposes of subsection 23B(9) of the Act, the application must be accompanied by:

- (a) the information required by the document titled *CTD Module 1: Administrative information for assessed listed medicines*, version 1, published by the TGA in March 2018; and
- (b) the information required by the document titled *Mandatory requirements for an assessed listed medicine application to pass preliminary assessment*, version 1, published by the TGA in March 2018.

Note: The documents mentioned in section 5 are available on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)).

## 6 Form of information

For the purposes of subsection 23B(10) of the Act, the information must be :

- (a) contained in an application dossier; and
- (b) in a form consistent with the document titled *General dossier requirements*, version 1.4, published by the TGA in July 2018.

Note: The document mentioned in paragraph 6(b) is available on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)).