



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

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 (OTC Medicines – Information that Must Accompany Application for Registration) Determination 2018 that was registered on 27 April 2018, and make the following Determination under subsections 23B(9) and (10) of that Act.

Dated 20th of August 2018

(Signed by)

JANE COOK

Delegate of the Secretary of the Department of Health

1 Name

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

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

4 Therapeutic goods to which this instrument applies

This instrument applies to medicines of the kind specified in paragraph 4(1)(c) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*.

5 Kind of information

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

- (a) the information specified in the document titled *Common Technical Document Module 1: OTC Medicines*, version 1.2, published by the TGA in June 2017; and
- (b) the information required by the document titled *Mandatory requirements for an effective over-the-counter medicines application*, version 1.1, published by the TGA in March 2016.

Note: The documents mentioned in section 5 are available on the TGA website (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).