



## **Therapeutic Goods (Prohibited Representations—Condoms and Sunscreens) Permission 2018**

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I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 21 December 2018



Nicole McLay  
Assistant Secretary  
Regulatory Education and Compliance Branch  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Prohibited Representations—Condoms and Sunscreens) Permission 2018*.

## 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.	

Note: This table relates only to the provisions of this instrument as originally made.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 42DK(2) and 42DK(3) 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) included in the Register;
- (b) label;
- (c) listed goods;
- (d) registered goods; and
- (e) therapeutic goods.

In this instrument:

*Act* means *Therapeutic Goods Act 1989*.

*AS/NZS 2604:2012* means the document, Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2012), prepared by the Joint Technical Committee CS-042 (Sunscreen Agents), approved on behalf of the Council of Standards Australia on 9 May 2012 and the Council of Standards New Zealand on 9 May 2012, and published by SAI Global

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Limited under licence from Standards Australia on 30 May 2012, as in force or existing immediately before the commencement of this instrument.

Note: Section 2B of the *Acts Interpretation Act 1901* defines Standards Australia.

***prohibited representation*** has the same meaning as in subsection 42DJ(1) of the Act.

***sun protection factor*** has the same meaning as in AS/NZS 2604:2012.

## 5 Repeals

Each instrument that is specified in Schedule 1 to this instrument is repealed as set out in the applicable items in that Schedule, and any other item in Schedule 1 to this instrument has effect according to its terms

## 6 Permission

For subsections 42DK(2) and 42DK(3) of the Act, in relation to each item, the prohibited representations specified in column 2 of the table in Schedule 2 to this instrument are permitted to be used in an advertisement specified in column 3 of the table, about the therapeutic goods specified in column 4 of the table, subject to the conditions (if any) specified in column 5 of the table.

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## Schedule 1—Repeals

Note: See section 5.

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<b>Repeal of instruments</b>		
<b>Item</b>	<b>Name of instrument and delegate</b>	<b>Date of making</b>
1	Notice of permission to use restricted representations under section 42DK of the <i>Therapeutic Goods Act 1989</i> by Dr Jane Cook, Head, Office of Product Review	31 October 2014
2	Notice of permission to use restricted representations under section 42DK of the <i>Therapeutic Goods Act 1989</i> by Pio Cesarin, Assistant Secretary, Regulatory Practice, Education and Compliance Branch	4 August 2017

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## Schedule 2—Permission

Note: See section 6.

Column 1 Item	Column 2 Prohibited representation	Column 3 Advertisement	Column 4 Therapeutic goods	Column 5 Condition
1	<p>a representation that the therapeutic goods may:</p> <p>(a) assist in preventing some skin cancer, or words to that effect; or</p> <p>(b) reduce the risk of some skin cancers, or words to that effect</p>	<p>an advertisement about the therapeutic goods specified in column 4, including, but not limited to, an advertisement that is:</p> <p>(a) on the label of the specified therapeutic goods;</p> <p>(b) on the package in which the specified therapeutic goods are contained; or</p> <p>(c) on any material included with the package in which the specified therapeutic goods are contained</p>	<p>broad spectrum sunscreens with a sun protection factor of 30 or more that are registered goods or listed goods</p>	
2	<p>a representation that the therapeutic goods may help reduce the risk of transmission of HIV/AIDS and other sexually transmitted infections, or words to that effect</p>	<p>an advertisement about the therapeutic goods specified in column 4, including, but not limited to, an advertisement that is:</p> <p>(a) on the label of the specified therapeutic goods;</p> <p>(b) on the package in which the specified therapeutic goods are contained; or</p>	<p>natural latex rubber condoms included in the Register</p>	

Column 1 Item	Column 2 Prohibited representation	Column 3 Advertisement	Column 4 Therapeutic goods	Column 5 Condition
		(c) on any material included with the package in which the specified therapeutic goods are contained		