# Therapeutic Goods (Restricted Representations—Automated External Defibrillators) Permission 2021

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

Dated 12 March 2021

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

## Contents

## 1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Automated External Defibrillators) Permission 2021*.

## 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. | 13 March 2021 |

Note: This table relates only to the provisions of this instrument as originally made.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 section 42DK of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

(a) advertise;
(b) included in the Register;
(c) medical device;
(d) Register;
(e) therapeutic goods; and
(f) Therapeutic Goods Advertising Code.

In this instrument:

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

***AED*** means a medical device that is:

(a) an automated external defibrillator; and
(b) included in the Register; and
(c) classified under the *Therapeutic Goods (Medical Devices) Regulations 2002* as Class IIb or higher.

***prominently displayed or communicated*** has the same meaning as in the Therapeutic Goods Advertising Code.

***restricted representation*** means a representation referred to in section 42DD of the Act.

## 5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the restricted representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

# Schedule 1—Permission: restricted representation

Note: See section 5.

| Permitted use of restricted representation | | | | |
|---|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** | **Column 5** |
| **Item** | **Restricted representation** | **Advertisement** | **Therapeutic goods** | **Conditions** |
| 1 | a representation that is to the effect that the therapeutic goods may increase survival when someone has had a sudden cardiac arrest | an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:<br>(a) on the label of the therapeutic goods;<br>(b) on the package in which the therapeutic goods are contained;<br>(c) on any material included with the package in which the therapeutic goods are contained | an AED | the representation must:<br>(a) be consistent with the instructions for use of the therapeutic goods; and<br>(b) be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following:<br>(i) call 000 immediately and ask for an ambulance if you suspect someone has had a sudden cardiac arrest; and<br>(ii) an AED will only deliver a shock to a person with a shockable rhythm; and<br>(iii) follow any verbal or visual prompts displayed on the AED until medical treatment arrives; and<br>(iv) additional emergency treatment such as CPR and rescue breaths may be required until medical treatment arrives; and<br>(c) not be accompanied with claims or representations in |

| Permitted use of restricted representation | | | | |
|---|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** | **Column 5** |
| **Item** | **Restricted representation** | **Advertisement** | **Therapeutic goods** | **Conditions** |
| | | | | relation to the effectiveness of the AED that are based on statistics about the prevalence of, or survival rates of, cardiac arrest |
| 2 | a representation that refers, expressly or by implication, to one or more heart conditions (including, but not limited to, sudden cardiac arrest); and<br>(a) relates to the proper use of the therapeutic goods; or<br>(b) is made in the context of providing accurate, balanced and contemporary information about the therapeutic goods and heart conditions | an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:<br>(a) on the label of the therapeutic goods;<br>(b) on the package in which the therapeutic goods are contained;<br>(c) on any material included with the package in which the therapeutic goods are contained | an AED | the representation must:<br>(a) be consistent with the instructions for use of the therapeutic goods; and<br>(b) be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following:<br>(i) call 000 immediately and ask for an ambulance if you suspect someone has had a sudden cardiac arrest; and<br>(ii) an AED will only deliver a shock to a person with a shockable rhythm; and<br>(iii) follow any verbal or visual prompts displayed on the AED until medical treatment arrives; and<br>(iv) additional emergency treatment such as CPR and rescue breaths may be required until medical treatment arrives; and |

| Permitted use of restricted representation | | | | |
|---|---|---|---|---|
| **Column 1** | **Column 2** | **Column 3** | **Column 4** | **Column 5** |
| **Item** | **Restricted representation** | **Advertisement** | **Therapeutic goods** | **Conditions** |
| | | | | (c) not be accompanied with claims or representations in relation to the effectiveness of the AED that are based on statistics about the prevalence of, or survival rates of, cardiac arrest |