

Therapeutic Goods (Change of Sponsorship— Notification Form) Approval 2024

I, Chris Bedford, as delegate of the Secretary of the Department of Health and Aged Care, make the following approval.

Dated 14 June 2024

Chris Bedford Acting First Assistant Secretary Regulatory Practice and Support Division Health Products Regulation Group Department of Health and Aged Care

Contents

| 1 | Name | 1 |
|---|--|---|
| 2 | Commencement | 1 |
| 3 | Authority | 1 |
| 4 | Definitions | 1 |
| 5 | Approved form-change of sponsorship following death, bankruptcy or winding up | 2 |
| 6 | Approved form-change of sponsorship following transfer or assignment of business | 2 |
| 7 | Repeals | 2 |
| | | |

i

1 Name

This instrument is the *Therapeutic Goods* (*Change of Sponsorship—Notification Form*) Approval 2024.

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| Note: | This table relates only to the provisions of this instrume | ent as originally made. It will | | |

te: This table relates only to the provisions of this instrument as originally made.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 regulations 10AB, 10F and 10H of the *Therapeutic Goods Regulations 1990*.

4 Definitions

Note:

- A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:
 - (a) biological;
 - (b) included in the Register
 - (c) kind, in relation to a medical device;
 - (d) medical device;
 - (e) Register
 - (f) Secretary;
 - (g) therapeutic goods.

In this instrument:

Act means the Therapeutic Goods Act 1989.

Regulations means the Therapeutic Goods Regulations 1990.

relevant person means a person in relation to whom:

- (a) therapeutic goods are registered or listed; or
- (b) a kind of medical device is included in the Register under Chapter 4 of the Act; or

1

(c) a biological is included in the Register under Part 3-2A of the Act.

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

5 Approved form—change of sponsorship following death, bankruptcy or winding up

For the purposes of notifying the Secretary of:

- (a) the death of a relevant person under subregulations 10AB(2), 10F(2) and 10H(2) of the Regulations; and
- (b) the bankruptcy of a relevant person under subregulations 10AB(3), 10F(3) and 10H(3) of the Regulations; and
- (c) the winding up of a body corporate that is a relevant person under subregulations 10AB(4), 10F(4) and 10H(4) of the Regulations;

the approved form is the form titled *Notification: Transfer of sponsorship following death, bankruptcy or winding up*, published on the Therapeutic Goods Administration website, as in force or existing at the commencement of this instrument.

Note: The Therapeutic Goods Administration website can be accessed at www.tga.gov.au.

6 Approved form—change of sponsorship following transfer or assignment of business

For the purposes of notifying the Secretary of a transfer or assignment under subregulations 10AB(5), 10F(5) and 10H(5) of the Regulations, the approved form is the form titled *Notification: Transfer of sponsorship*, published on the Therapeutic Goods Administration website, as in force or existing at the commencement of this instrument.

Note: The Therapeutic Goods Administration website can be accessed at www.tga.gov.au.

7 Repeals

This instrument repeals all instruments to approve a form made under regulations 10AB, 10F or 10H of the Regulations that commenced before the commencement of this instrument.