



Therapeutic Goods (Restricted Representations— Posterior Chamber Intraocular Lenses) Permission 2021

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

Dated 24 June 2021

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

Contents

| | |
|---|----------|
| 1 Name..... | 1 |
| 2 Commencement | 1 |
| 3 Authority..... | 1 |
| 4 Definitions | 1 |
| 5 Permission..... | 2 |
| Schedule 1—Permission: restricted representation | 3 |

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Posterior Chamber Intraocular Lenses) 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. | 25 June 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

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

In this instrument:

Act means *Therapeutic Goods Act 1989*.

posterior chamber intraocular lens means a medical device that is:

- (a) an intraocular lens intended by the manufacturer to be inserted behind the iris of a human eye; 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 | <p>a representation that:</p> <p>(a) refers, expressly or by implication, to cataracts; and</p> <p>(b) is to the effect that intraocular lenses may be used in cataract surgery to replace the natural lenses of the eye; and</p> <p>(c) may include one or more of the following:</p> <p>(i) a simple, accurate and balanced description of the available intraocular lens categories (for example, monofocal, toric, presbyopia-correcting);</p> <p>(ii) a simple, accurate and balanced description of cataract surgery;</p> <p>(iii) a simple, accurate and balanced description of a typical patient experience up to, and including, surgery</p> | <p>advertisements about the therapeutic goods including, but not limited to, an advertisement that is:</p> <p>(a) on the label of the therapeutic goods;</p> <p>(b) on the package in which the therapeutic goods are contained;</p> <p>(c) on any material included with the package in which the therapeutic goods are contained</p> | <p>posterior chamber intraocular lenses</p> | <p>all of the following:</p> <p>(a) the primary and most prominent claim in the advertisement must be to the effect that the therapeutic goods are replacement lenses that may be used in cataract surgery;</p> <p>(b) any references to achieving spectacle independence through correction of refractive error must be clearly presented as a potential secondary benefit of the use of the lenses;</p> <p>(c) the representation must be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following:</p> <p>(i) extraction of a cataract and replacement with an intraocular lens will require surgery; and</p> <p>(ii) cataract surgery carries risks</p> |

Permitted use of restricted representation

| Column 1 | Column 2 | Column 3 | Column 4 | Column 5 |
|-----------------|--|---|--------------------------------------|---|
| Item | Restricted representation | Advertisement | Therapeutic goods | Conditions |
| 2 | a representation that refers, expressly or by implication, to cataracts and includes both of the following: (a) a short, simple, accurate and balanced definition of cataracts; and (b) the common symptoms of cataracts | advertisements about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained | posterior chamber intraocular lenses | references to the common symptoms of cataracts must be accompanied by a statement, which is prominently displayed or communicated and to the effect of the following: (a) if you have any symptoms, consult your eye care professional as the symptoms may be a sign of other eye problems |
