



**Australian Government**  

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**Department of Health**  
Therapeutic Goods Administration

# **Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016**

*Therapeutic Goods Act 1989*

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I, Larry Kelly, a delegate of the Minister for Health, make this Specification under subsection 61(5D) of the *Therapeutic Goods Act 1989*.

Dated 4 May 2016

(Signed by)

**LARRY KELLY**  
Delegate of the Minister for Health

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**1 Name of Specification**

This Specification is the *Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016*.

**2 Commencement**

This Specification commences on 1 July 2016.

**3 Definitions**

In this Specification:

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

*Annual Charges Exemption Scheme* means the scheme relating to exemptions from liability to pay annual charges set out in Subdivision 2 of Division 1 of Part 7 of the Regulations.

*ARTG* means the Australian Register of Therapeutic Goods.

*Regulations* means the *Therapeutic Goods Regulations 1990*.

*Sponsor* means the person in relation to whom therapeutic goods are registered, listed or included in the ARTG.

**4 Therapeutic goods information**

The kinds of therapeutic goods information mentioned in Schedule 1 are specified under subsection 61(5D) of the Act for the purposes of subsection 61(5C) of the Act.

## Schedule 1 Specified kinds of therapeutic goods information

(section 4)

The following kinds of therapeutic goods information:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary to the public under subsection 61(5C) of the Act.

### Kinds of therapeutic goods information relating to exemptions under the Annual Charges Exemption Scheme

Item	Information	Description
(a)	Sponsor name	The name of the sponsor in relation to whom therapeutic goods were registered, listed or included in the ARTG in a particular financial year and who was exempt from paying an annual charge in relation to those goods in that financial year.
(b)	ARTG number	The ARTG number of the therapeutic goods in relation to which the exemption applied.
(c)	Name of the therapeutic goods	The name of the therapeutic goods as it appeared in the relevant ARTG entry in relation to which the sponsor was exempt from paying an annual charge in the relevant financial year.
(d)	Exemption from annual charges for a particular financial year	That the sponsor was, for a particular financial year, exempt under the Annual Charges Exemption Scheme from liability to pay an annual registration charge, annual listing charge or annual charge for inclusion in the ARTG, in respect of therapeutic goods as identified by name and ARTG number.

### Kinds of therapeutic goods information relating to exemptions found not to apply under the Annual Charges Exemption Scheme

Item	Information	Description
(a)	Sponsor name	The name of the sponsor in relation to whom therapeutic goods were registered, listed or included in the ARTG in relation to a particular financial year, and who: <ul style="list-style-type: none"> <li>declared, under regulation 43AAC or 43AAD of the Regulations that the turnover of those goods for that financial year was of low value;</li> <li>did not pay the annual charge for that financial year in relation to those goods; and</li> <li>the Secretary has given a notice under subregulation 43AAG(2) or (4) of the Regulations, stating that the sponsor was not exempt from liability to pay the annual charge in relation to the goods for that financial year.</li> </ul>
(b)	ARTG number	The ARTG number of the therapeutic goods mentioned in (a).
(c)	Name of the therapeutic goods	The name of the therapeutic goods mentioned in (a), as it appeared on the relevant ARTG entry in relation to which the sponsor was not exempt from paying the annual charge in that financial year.
(d)	No exemption from annual charges for a particular financial year	That, notwithstanding that the sponsor had declared under regulation 43AAC or 43AAD of the Regulations that the turnover of the goods mentioned in (a) for that financial year was of low value, the Secretary has given the sponsor a notice under subregulation 43AAG(2) or (4) of the Regulations, stating that the sponsor was not exempt under the Annual Charges Exemption Scheme from liability to pay the annual charge in relation to the goods for that financial year.

#### Note

- All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov.au>