Commonwealth Coat of Arms

Therapeutic Goods (Charges) Regulations 1990

Statutory Rules No. 395, 1990 as amended

made under the

Therapeutic Goods (Charges) Act 1989

**Compilation start date:** 1 July 2014

**Includes amendments up to:** SLI No. 61, 2014

**About this compilation**

**This compilation**

This is a compilation of the *Therapeutic Goods (Charges) Regulations 1990* as in force on 1 July 2014. It includes any commenced amendment affecting the legislation to that date.

This compilation was prepared on 3 July 2014.

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of each amended provision.

**Uncommenced amendments**

The effect of uncommenced amendments is not reflected in the text of the compiled law but the text of the amendments is included in the endnotes.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Modifications**

If a provision of the compiled law is affected by a modification that is in force, details are included in the endnotes.

**Provisions ceasing to have effect**

If a provision of the compiled law has expired or otherwise ceased to have effect in accordance with a provision of the law, details are included in the endnotes.

Contents

1 Name of regulations 1

2 Interpretation 1

3 Annual charges 2

Endnotes 6

Endnote 1—About the endnotes 6

Endnote 2—Abbreviation key 8

Endnote 3—Legislation history 9

Endnote 4—Amendment history 11

Endnote 5—Uncommenced amendments [none] 13

Endnote 6—Modifications [none] 13

Endnote 7—Misdescribed amendments [none] 13

Endnote 8—Miscellaneous [none] 13

1 Name of regulations

These Regulations are the *Therapeutic Goods (Charges) Regulations 1990*.

2 Interpretation

(1) In these Regulations, unless the contrary intention appears:

***biologic***, in relation to therapeutic goods, means goods in which the active ingredient is a biological substance.

***biological substance*** means a substance of biological origin that:

(a) in many cases, is chemically complex and with a molecular weight of more than 1 000; and

(b) is not defined by a chemical name because its purity, strength and exact composition cannot be readily determined by chemical analysis.

Example: Hormones, enzymes and related substances are biological substances. Herbal substances and antibiotics are not biological substances.

***Class 1 biological*** has the same meaning as in the *Therapeutic Goods Regulations 1990*.

***Class 2 biological*** has the same meaning as in the *Therapeutic Goods Regulations 1990*.

***Class 3 biological*** has the same meaning as in the *Therapeutic Goods Regulations 1990*.

***Class 4 biological*** has the same meaning as in the *Therapeutic Goods Regulations 1990*.

***Poisons Standard*** has the same meaning as ***current Poisons Standard*** in Part 5B of the *Therapeutic Goods Act 1989*.

***the Act*** means the *Therapeutic Goods (Charges) Act 1989*.

(2) In these Regulations, a reference to a medical device of a particular class is a reference to a medical device classified as that class under Division 3.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

3 Annual charges

(1) For the purposes of subsection 4(1) of the Act, the annual charges for the registration or listing of therapeutic goods are:

(a) for goods of a kind whose registration is in force at any time during the financial year to which the charge relates and that is not mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*:

(i) if the goods are a medicine—$1 350; and

(ii) if the goods are a medical device—$2 650; and

(iii) in any other case—$1 515; and

(b) for goods of a kind whose registration is in force at any time during the financial year to which the charge relates and that is mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*:

(i) if the goods are a biologic—$6 585; and

(ii) if the goods are not a biologic—$3 955; and

(c) for goods (other than goods produced for export) the listing of which is in force at any time during the financial year to which the charge relates:

(i) if the goods are a medicine—$965; and

(ii) if the goods are a medical device—$1 350; and

(iii) in any other case—$770.

(1A) For the purposes of subsection 4(1A) of the Act, the annual charge for the registration or listing of grouped therapeutic goods is:

(a) for grouped goods whose registration is in force at any time during the financial year to which the charge relates and that are not mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*:

(i) if the goods are medicines—$1 350; and

(ii) if the goods are medical devices—$2 650; and

(iii) in any other case—$1 515; and

(b) for grouped goods whose registration is in force at any time during the financial year to which the charge relates and that are mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*:

(i) if the goods are biologics—$6 585; and

(ii) if the goods are not biologics—$3 955; and

(c) for grouped goods (other than goods all of which are produced for export) the listing of which is in force at any time during the financial year to which the charge relates:

(i) if the goods are medicines—$965; and

(ii) if the goods are medical devices—$1 350; and

(iii) in any other case—$770.

(1AA) For subsection 4(1AA) of the Act, the annual charges for inclusion of a biological in the Register under Part 3‑2A of the Act are:

(a) for a class 1 biological whose inclusion in the Register is in force at any time during the financial year to which the charge relates—$615; and

(b) for a Class 2, Class 3 or Class 4 biological whose inclusion in the Register is in force at any time during the financial year to which the charge relates—$6 125.

(1B) For the purposes of subsection 4(1B) of the Act, the annual charges in respect of the inclusion of kinds of medical devices (other than medical devices produced for export) in the Register under Chapter 4 of the *Therapeutic Goods Act 1989* that has effect at any time during a financial year are as follows:

(a) for a Class I medical device (other than a Class I medical device to which paragraph (b) applies)—$80;

(b) for a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function—$615;

(c) for a Class IIa medical device or Class IIb medical device—$940;

(d) for a Class AIMD medical device or Class III medical device—$1 210;

(e) for an IVD medical device—nil.

(2) For the purposes of subsection 4(2) of the Act, the annual charge for a licence that is in force at any time during a financial year is as follows:

(a) for a licence for the manufacture of sterile or non‑sterile therapeutic goods—$11 500;

(b) for a licence for the manufacture of containers in which therapeutic goods are to be packed—$11 500;

(c) for a licence for the manufacture of ingredients or components for use in the manufacture of therapeutic goods—$5 900;

(d) for a licence for a single step in the manufacture of therapeutic goods—$5 900;

(e) for a licence for the manufacture of a sterile or non‑sterile single medicine—$5 900;

(f) for a licence for the manufacture of a sterile or non‑sterile single type of therapeutic device—$5 900;

(g) for a licence for the manufacture of sterile or non‑sterile diagnostic goods for in vitro use—$5 900;

(h) for a licence for the manufacture of herbal or homoeopathic preparations that are not included in a Schedule to the Poisons Standard (other than Schedule 5 or 6)—$5 900;

(j) for a licence for the manufacture of human blood and blood components (other than haematopoietic progenitor cells) at manufacturing premises covered by the licence:

(i) for a primary site—$148 200; and

(ii) for a fixed (non‑mobile) manufacturing site—$7 290;

(ja) for a licence for the manufacture of haematopoietic progenitor cells at manufacturing premises covered by the licence—$6 380;

(k) for a licence for a single step in the manufacture of a single human tissue at manufacturing premises covered by the licence—$6 380;

(l) for a licence for 2 or more steps in the manufacture of human tissues at manufacturing premises covered by the licence—$12 400;

(m) despite paragraphs (a) to (l)—for a licence for the manufacture of a biological only—Nil.

(3) If, but for this subregulation, more than one charge referred to in subregulation (1) or any of paragraphs (2)(a) to (l) would otherwise apply in respect of a financial year in relation to:

(a) the registration or listing of particular goods; or

(b) a particular licence;

the charge that is the greatest applicable charge (other than a charge payable under any of paragraphs (2)(a) to (l) only because biologicals are manufactured) is the only charge that applies in respect of the registration or listing of those goods or in relation to that licence in that year.

Note: Under regulation 43AAJ of the *Therapeutic Goods Regulations 1990*, the annual charge for a licence under Part 3‑3 of the *Therapeutic Goods Act 1989* payable by a person whose wholesale turnover of therapeutic goods in a financial year is not more than $90 500 is half the amount mentioned in subregulation (2) for the person. The reduction in the annual charge does not apply to a licence for the manufacture of human blood and blood components.

(4) For subregulation (2):

***haematopoietic progenitor cells*** means primitive pluripotent haematopoietic cells capable of self‑renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage‑restricted progenitor cells.

***primary site*** means the principal premises in the capital city of each State and Territory where human blood and blood components are manufactured.

Endnotes

Endnote 1—About the endnotes

The endnotes provide details of the history of this legislation and its provisions. The following endnotes are included in each compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Endnote 5—Uncommenced amendments

Endnote 6—Modifications

Endnote 7—Misdescribed amendments

Endnote 8—Miscellaneous

If there is no information under a particular endnote, the word “none” will appear in square brackets after the endnote heading.

**Abbreviation key—Endnote 2**

The abbreviation key in this endnote sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended the compiled law. The information includes commencement information for amending laws and details of application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision level. It also includes information about any provisions that have expired or otherwise ceased to have effect in accordance with a provision of the compiled law.

**Uncommenced amendments—Endnote 5**

The effect of uncommenced amendments is not reflected in the text of the compiled law but the text of the amendments is included in endnote 5.

**Modifications—Endnote 6**

If the compiled law is affected by a modification that is in force, details of the modification are included in endnote 6.

**Misdescribed amendments—Endnote 7**

An amendment is a misdescribed amendment if the effect of the amendment cannot be incorporated into the text of the compilation. Any misdescribed amendment is included in endnote 7.

**Miscellaneous—Endnote 8**

Endnote 8 includes any additional information that may be helpful for a reader of the compilation.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| ad = added or inserted | pres = present |
| am = amended | prev = previous |
| c = clause(s) | (prev) = previously |
| Ch = Chapter(s) | Pt = Part(s) |
| def = definition(s) | r = regulation(s)/rule(s) |
| Dict = Dictionary | Reg = Regulation/Regulations |
| disallowed = disallowed by Parliament | reloc = relocated |
| Div = Division(s) | renum = renumbered |
| exp = expired or ceased to have effect | rep = repealed |
| hdg = heading(s) | rs = repealed and substituted |
| LI = Legislative Instrument | s = section(s) |
| LIA = *Legislative Instruments Act 2003* | Sch = Schedule(s) |
| mod = modified/modification | Sdiv = Subdivision(s) |
| No = Number(s) | SLI = Select Legislative Instrument |
| o = order(s) | SR = Statutory Rules |
| Ord = Ordinance | Sub‑Ch = Sub‑Chapter(s) |
| orig = original | SubPt = Subpart(s) |
| par = paragraph(s)/subparagraph(s) /sub‑subparagraph(s) |  |

Endnote 3—Legislation history

| Number and year | FRLI registration or gazettal | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| 1990 No. 395 | 6 Dec 1990 | 1 July 1990 |  |
| 1991 No. 85 | 30 Apr 1991 | 30 Apr 1991 | — |
| 1992 No. 88 | 14 Apr 1992 | 14 Apr 1992 | — |
| 1993 No. 140 | 25 June 1993 | 1 July 1993 | — |
| 1994 No. 149 | 2 June 1994 | 2 June 1994 | — |
| 1994 No. 223 | 30 June 1994 | 1 July 1994 | — |
| 1995 No. 193 | 30 June 1995 | 1 July 1995 | — |
| 1996 No. 132 | 28 June 1996 | 1 July 1996 | — |
| 1997 No. 161 | 30 June 1997 | 1 July 1997 | — |
| 1998 No. 246 | 31 July 1998 | 1 Aug 1998 | — |
| 1998 No. 260 | 12 Aug 1998 | 12 Aug 1998 | — |
| 2000 No. 71 | 12 May 2000 | 1 July 2000 | — |
| 2000 No. 125 | 22 June 2000 | 1 July 2000 | — |
| 2000 No. 266 | 28 Sept 2000 | 28 Sept 2000 | — |
| 2001 No. 161 | 29 June 2001 | 1 July 2001 | — |
| 2002 No. 144 | 27 June 2002 | 1 July 2002 | — |
| 2002 No. 235 | 4 Oct 2002 | 4 Oct 2002 (*see* r. 2) | — |
| 2003 No. 152 | 26 June 2003 | 1 July 2003 | — |
| 2004 No. 160 | 25 June 2004 | 1 July 2004 | — |
| 2005 No. 194 | 19 Aug 2005 (*see* F2005L02314) | 20 Aug 2005 | — |
| 2006 No. 213 | 10 Aug 2006 (*see* F2006L02570) | 11 Aug 2006 | — |
| 2007 No. 162 | 25 June 2007 (*see* F2007L01523) | 1 July 2007 | — |
| 2008 No. 118 | 20 June 2008 (*see* F2008L01351) | 1 July 2008 | — |
| 2009 No. 142 | 25 June 2009 (*see* F2009L02018) | 1 July 2009 | r. 4 |
| 2009 No. 180 | 9 July 2009 (*see* F2009L02091) | 10 July 2009 | — |
| 2010 No. 131 | 18 June 2010 (*see* F2010L01283) | 1 July 2010 | — |
| 2011 No. 31 | 16 Mar 2011 (*see* F2011L00431) | 31 May 2011 (*see* r. 2) | — |
| 2011 No. 103 | 21 June 2011 (*see* F2011L01097) | 1 July 2011 | — |
| 2012 No. 144 | 29 June 2012 (*see* F2012L01457) | 31 May 2011 | — |
| 2012 No. 145 | 29 June 2012 (*see* F2012L01462) | 1 July 2012 | — |
| 94, 2013 | 3 June 2013 (*see* F2013L00896) | 1 July 2013 | — |
| 61, 2014 | 30 May 2014 (*see* F2014L00631) | 1 July 2014 | — |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| r. 1 | rs. 1998 No. 260 | |
| r. 2 | am. 2000 No. 71; 2002 No. 235; 2003 No. 152; 2011 No. 31 |
| r. 3 | am. 1991 No. 85; 1992 No. 88; 1993 No. 140; 1994 Nos. 149 and 223; 1995 No. 193; 1996 No. 132; 1997 No. 161; 1998 No. 246; 2000 Nos. 71, 125 and 266; 2001 No. 161; 2002 Nos. 144 and 235; 2003 No. 152; 2004 No. 160; 2005 No. 194; 2006 No. 213; 2007 No. 162; 2008 No. 118; 2009 No. 180; 2010 No. 131; 2011 Nos. 31 and 103; 2012 Nos. 144 and 145; No. 94, 2013; No 61, 2014 |
| Note to r. 3(3) | rs. 2000 No. 266 |
|  | am. 2001 No. 161; 2002 No. 235; 2003 No. 152; 2004 No. 160; 2005 No. 194; 2006 No. 213; 2007 No. 162; 2008 No. 118; 2009 No. 180; No. 94, 2013 |
|  | rs. 2010 No. 131 |
|  | am. 2011 No. 103; 2012 No. 145; 61, 2014 |
| r. 4 | am. 1992 No. 88; 1993 No. 140; 1998 No. 246 |
|  | rep. 1998 No. 260 |
| r. 4A | ad. 1994 No. 149 |
|  | rep. 2011 No. 31 |
| r. 4B | ad. 1998 No. 260 |
|  | am. 2002 No. 235 |
|  | rep. 2009 No. 142 |
| r. 4C | ad. 1998 No. 260 |
|  | am. 2001 No. 161; 2002 Nos. 144 and 235; 2003 No. 152 |
|  | rep. 2009 No. 142 |
| r. 4D | ad. 1998 No. 260 |
|  | rep. 2009 No. 142 |
| r. 4E | ad. 1998 No. 260 |
|  | am. 2002 Nos. 144 and 235; 2003 No. 152; 2004 No. 160; 2005 No. 194; 2006 No. 213; 2007 No. 162; 2008 No. 118 |
|  | rep. 2009 No. 142 |
| r. 4F | ad. 1998 No. 260 |
|  | | am. 2002 No. 235 |
|  | | rep. 2009 No. 142 |
| r. 5 | | am. 1991 No. 85; 1998 No. 260; 2002 No. 235 |
|  | | rep. 2009 No. 142 |

Endnote 5—Uncommenced amendments [none]

Endnote 6—Modifications [none]

Endnote 7—Misdescribed amendments [none]

Endnote 8—Miscellaneous [none]