Therapeutic Goods (Charges) Regulations 2018

made under the

Therapeutic Goods (Charges) Act 1989

Compilation No. 2

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Charges) Regulations 2018* that shows the text of the law as amended and in force on 1 July 2020 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

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

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Part 1—Preliminary

1 Name

This instrument is the *Therapeutic Goods (Charges) Regulations 2018*.

3 Authority

This instrument is made under the *Therapeutic Goods (Charges) Act 1989*.

5 Definitions

Note: Subsection 3(1) of the Act incorporates the *Therapeutic Goods Act 1989*. A number of expressions used in this instrument are defined in the *Therapeutic Goods Act 1989*, including the following:

(a) biological (see also section 6 for classes of biological, but see the note to the definition of ***biologic***);
(b) current Poisons Standard;
(c) grouped therapeutic goods;
(d) medical device (see also section 6 for classes of medical device);
(e) medicine;
(f) Register;
(g) registered goods;
(h) therapeutic goods.

In this instrument:

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

biologic means therapeutic goods in which the active ingredient is a substance of biological origin (within the ordinary meaning of the term "biological") 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 substances of biological origin of the type described. Herbal substances and antibiotics are not.

Note: The term "biological" is not used in this definition as defined in the *Therapeutic Goods Act 1989*.

charge year, in relation to an annual charge, means the financial year to which the charge relates.

haematopoietic progenitor cells has the same meaning as in Schedule 9 of the *Therapeutic Goods Regulations 1990*.

parent goods: see subsection 8(7).

relevant goods: see subsection 8(5).

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6 Classes of medical devices and biologicals

In this instrument:

(a) 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*; and

(b) a reference to a biological of a particular class is a reference to a biological of that class within the meaning of the *Therapeutic Goods Regulations 1990*.

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Part 2—Charges

7 Annual charges for biologics and some other goods

Registration or listing of non-grouped therapeutic goods

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

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

(i) if the goods are a medicine—$1,520; and

(iii) in any other case—$1,700; and

(b) for goods:

(i) whose registration is in force at any time during the charge year; and

(ii) that are of a kind mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*; and

(iii) that are a biologic;

$7,410; and

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

(i) if the goods are a medicine—$1,160; and

(iii) in any other case—$880.

Note: For goods of a kind mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* that are not a biologic, see section 8.

Registration or listing of grouped therapeutic goods

(2) 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 charge year and that are of a kind not mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*:

(i) if the goods are medicines—$1,520; and

(iii) in any other case—$1,700; and

(b) for grouped therapeutic goods:

(i) whose registration is in force at any time during the charge year; and

(ii) that are of a kind mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*; and

(iii) that are biologics;

$7,410; 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 charge year:

(i) if the goods are medicines—$1,160; and

(iii) in any other case—$880.

Note: For grouped therapeutic goods of a kind mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* that are not biologics, see section 8.

Biologicals

(3) For the purposes of subsection 4(1AA) of the Act, the annual charges for inclusion of a biological in the Register under Part 3-2A of the *Therapeutic Goods Act 1989* are:

(a) for a Class 1 biological whose inclusion in the Register is in force at any time during the charge year—$690; 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 charge year—$6,890.

Medical devices

(4) 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 the charge year are as follows:

(a) for a Class I medical device (other than a Class I medical device to which paragraph (b) applies)—$90;

(b) for a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function—$640;

(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—$1,200;

(e) for an IVD medical device (of a class other than a Class 4 in-house IVD medical device)—$690;

(f) for a Class 4 in-house IVD medical device—nil.

(4A) However, for the purposes of subsection 4(1B) of the Act, the annual charges in respect of the inclusion of the following 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 the charge year that starts on 1 July 2020 are as follows:

(a) for a Class IIa medical device, or Class IIb medical device, that is a listed prosthesis within the meaning of the *Private Health Insurance (Prostheses) Rules (No. 1) 2020* as in force on 8 April 2020—$470;

(b) for a Class AIMD medical device, or Class III medical device, that is a listed prosthesis within the meaning of the *Private Health Insurance (Prostheses) Rules (No. 1) 2020* as in force on 8 April 2020—$600.

Licences

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

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(a) for a licence for one or more steps in the manufacture of sterile or non-sterile therapeutic goods—$4,770;

(b) for a licence for the manufacture of containers in which therapeutic goods are to be packed—$4,770;

(c) for a licence for the manufacture of ingredients or components for use in the manufacture of therapeutic goods—$4,770;

(e) for a licence for the manufacture of herbal or homoeopathic preparations that are not included in a Schedule to the current Poisons Standard (other than Schedule 5 or 6)—$4,770;

(f) 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 the principal premises in the capital city of a State or Territory where human blood and blood components are manufactured—$166,800; and

(ii) for a fixed (non-mobile) manufacturing site—$8,210;

(g) for a licence for the manufacture of haematopoietic progenitor cells at manufacturing premises covered by the licence—$7,180;

(h) for a licence for a single step in the manufacture of a single human tissue at manufacturing premises covered by the licence—$7,180;

(i) for a licence for 2 or more steps in the manufacture of human tissues at manufacturing premises covered by the licence—$14,100;

(j) despite paragraphs (a) to (i)—for a licence for the manufacture of a biological only—nil.

Only highest applicable charge is payable

(6) If, but for this subsection, more than one charge referred to in subsection (1) or any of paragraphs (5)(a) to (i) would otherwise apply in respect of a charge year in relation to:

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

(b) a particular licence;

only the highest applicable charge (other than a charge payable under any of paragraphs (5)(a) to (i) only because biologicals are manufactured) applies in respect of the registration or listing of those goods or in relation to that licence in that year.

Note 1: 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 charge year is not more than $101,800 is half the amount mentioned in subsection (5) for the person. The reduction in the annual charge does not apply to a licence for the manufacture of human blood and blood components.

Note 2: For provisional registration of a medicine, see section 9.

8 Annual charges for goods that are not biologics

(1) For the purposes of subsections 4(1) and (1A) of the Act, this section sets out the annual charge for the registration of therapeutic goods if:

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(a) the registration of the goods is in force at any time during the charge year; and

(b) the goods are of a kind mentioned in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*; and

(c) either:

(i) if the goods are not grouped therapeutic goods—the goods are not a biologic; or

(ii) if the goods are grouped therapeutic goods—the goods are not biologics.

When higher and lower amounts are payable

(2) The annual charge for the goods for the charge year is:

(a) if one or more of the conditions in subsections (3) to (10) apply to the goods—$4,220; or

(b) otherwise—$3,430.

Goods containing certain active ingredients

(3) The goods contain any of the following active ingredients:

(a) thalidomide;

(b) leflunomide;

(c) lenalidomide;

(d) mifepristone;

(e) clozapine;

(f) isotretinoin.

New chemical entities, extensions of indications and changes to intended patient groups

(4) The following conditions are met:

(a) the registration of the goods commenced on or after 1 July 2015;

(b) the goods are relevant goods;

(c) for goods whose registration commenced before the beginning of the charge year—at the beginning of the charge year, the goods have been registered for fewer than 8 years.

(5) ***Relevant goods*** are goods that, at the time the registration of the goods commenced, were:

(a) a new chemical entity, within the meaning of subclause 1(1) of Schedule 9 to the *Therapeutic Goods Regulations 1990*; or

(b) separate and distinct from other goods that are registered:

(i) because of an extension of indications, within the meaning of item 4 of the table in Part 2 of Schedule 9 to the *Therapeutic Goods Regulations 1990*, other than an extension of indications mentioned in paragraph (bc) of that item; or

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(ii) because of a change to the intended patient group (within the meaning of paragraph (e) of the definition of ***major variation*** in subclause 1(1) of Schedule 9 to those Regulations).

Goods whose parent goods have been registered for fewer than 8 years

(6) The following conditions are met:
   (a) the registration of the goods commenced on or after 1 July 2015;
   (b) the goods are not relevant goods;
   (c) subsection (4) applies for the charge year to the parent goods of those goods.

(7) Goods (the ***initial goods***) are ***parent goods*** of other goods if:
   (a) the initial goods were registered before the other goods; and
   (b) the initial goods are relevant goods; and
   (c) the initial goods and the other goods have:
      (i) the same active ingredient; or
      (ii) the same active ingredients in the same quantitative amounts; and
   (d) at the time the registration of the other goods commenced, the other goods were registered in relation to:
      (i) the person in relation to whom the initial goods were registered at that time; or
      (ii) a person authorised by the person in relation to whom the initial goods were registered at that time.

Grouped therapeutic goods as a result of extension of indications or changes to intended patient group

(8) The following conditions are met:
   (a) the goods are grouped therapeutic goods;
   (b) relevant goods that are included in those grouped goods were grouped on or after 1 July 2015 (whether or not other goods that are included in those grouped goods were registered before that time);
   (c) the grouping occurred in a financial year before the charge year;
   (d) at the beginning of the charge year, the relevant goods have been included in the grouped goods for fewer than 8 years.

Entries before 1 July 2015—goods other than grouped therapeutic goods

(9) The following conditions are met:
   (a) the goods are not grouped therapeutic goods;
   (b) the goods (the ***chargeable goods***) were registered before 1 July 2015;
   (c) immediately before 1 July 2015:
      (i) if there is only one active ingredient contained in the chargeable goods—any other goods containing that active ingredient (and no other active ingredients) are registered in relation to the person in relation to whom the chargeable goods are registered; or

(ii) otherwise—any other goods containing the same active ingredients in the same quantitative amounts as the chargeable goods (and no other active ingredients) are registered in relation to the person in relation to whom the chargeable goods are registered;

(d) at the beginning of the charge year, the goods have been registered for fewer than 8 years.

Entries before 1 July 2015—grouped therapeutic goods

(10) The following conditions are met:

(a) the goods were grouped therapeutic goods immediately before 1 July 2015;

(b) immediately before 1 July 2015:

(i) if there is only one active ingredient contained in the grouped goods—any other goods containing that active ingredient (and no other active ingredients) are registered in relation to the same person in relation to whom the grouped goods are registered; or

(ii) otherwise—any other goods containing the same active ingredients in the same quantitative amounts as the grouped goods (and no other active ingredients) are registered in relation to the same person in relation to whom the grouped goods are registered;

(c) at the beginning of the charge year, the first of the goods to be registered have been registered for fewer than 8 years.

Note: For provisional registration of a medicine, see section 9.

9 Annual charges for provisionally registered medicines

(1) For the purposes of subsection 4(1) of the Act, the annual charges for the provisional registration of a medicine, if the provisional registration is in force at any time during the charge year, are:

(a) for goods that are a biologic—$16,700; and

(b) for goods that are not a biologic—$13,700.

(2) If a provisional registration for a medicine is in force at any time in a charge year, and the medicine is otherwise registered later in the same charge year, sections 7 and 8 do not apply in relation to its registration in respect of that charge year.

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Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key 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 (or will amend) the compiled law. The information includes commencement details for amending laws and details of any 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 (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

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Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Charges) Regulations 2018	14 June 2018 (F2018L00774)	s 5–9 and Sch 1: 1 July 2018 (s 2(1) item 2) Remainder: 15 June 2018 (s 2(1) item 1)	
Therapeutic Goods (Charges) Amendment Regulations 2019	25 Mar 2019 (F2019L00395)	1 July 2019 (s 2(1) item 1)	—
Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019	18 Dec 2019 (F2019L01660)	Sch 1 (items 44, 45): 25 Aug 2020 (s 2(1) item 2)	—
Therapeutic Goods (Charges) Amendment (2020 Measures No. 1) Regulations 2020	16 June 2020 (F2020L00727)	1 July 2020 (s 2(1) item 1)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 2	rep LA s 48D
s 4	rep LA s 48C
Part 2	
s 7	am F2019L00395; F2019L01660; F2020L00727
s 8	am F2019L00395; F2020L00727
s 9	am F2019L00395; F2020L00727
Part 3	
Part 3	ad F2019L01660
Division 1	
s 10	ad F2019L01660
Schedule 1	rep LA s 48C