

Therapeutic Goods (Charges) Amendment (2015 Measures No. 1) Regulation 2015

Select Legislative Instrument No. 86, 2015

I, General the Honourable Sir Peter Cosgrove AK MC (Ret’d), Governor‑General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation.

Dated 17 June 2015

Peter Cosgrove

Governor‑General

By His Excellency’s Command

Fiona Nash

Assistant Minister for Health

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1 Name

This is the *Therapeutic Goods (Charges) Amendment (2015 Measures No. 1) Regulation 2015*.

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 | 1 July 2015. | 1 July 2015 |

Note: This table relates only to the provisions of this instrument as originally made.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 the *Therapeutic Goods (Charges) Act 1989.*

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Annual charges for 2015‑16

Therapeutic Goods (Charges) Regulations 1990

1 Amendments of listed provisions

| Amendments of charges | | | |
| --- | --- | --- | --- |
| Item | Provision | Omit | Substitute |
| 1 | Subparagraph 3(1)(a)(i) | 1 350 | 1 380 |
| 2 | Subparagraph 3(1)(a)(ii) | 2 650 | 2 705 |
| 3 | Subparagraph 3(1)(a)(iii) | 1 515 | 1 545 |
| 4 | Subparagraph 3(1)(c)(i) | 965 | 985 |
| 5 | Subparagraph 3(1)(c)(ii) | 1 350 | 1 380 |
| 6 | Subparagraph 3(1)(c)(iii) | 770 | 785 |
| 7 | Subparagraph 3(1A)(a)(i) | 1 350 | 1 380 |
| 8 | Subparagraph 3(1A)(a)(ii) | 2 650 | 2 705 |
| 9 | Subparagraph 3(1A)(a)(iii) | 1 515 | 1 545 |
| 10 | Subparagraph 3(1A)(c)(i) | 965 | 985 |
| 11 | Subparagraph 3(1A)(c)(ii) | 1 350 | 1 380 |
| 12 | Subparagraph 3(1A)(c)(iii) | 770 | 785 |
| 13 | Paragraph 3(1AA)(a) | 615 | 630 |
| 14 | Paragraph 3(1AA)(b) | 6 125 | 6 255 |
| 15 | Paragraph 3(1B)(b) | 615 | 630 |
| 16 | Paragraph 3(1B)(c) | 940 | 910 |
| 17 | Paragraph 3(1B)(d) | 1 210 | 1 175 |
| 18 | Paragraphs 3(2)(a) and (b) | 11 500 | 11 700 |
| 19 | Paragraphs 3(2)(c) to (h) | 5 900 | 6 025 |
| 20 | Subparagraph 3(2)(j)(i) | 148 200 | 151 300 |
| 21 | Subparagraph 3(2)(j)(ii) | 7 290 | 7 445 |
| 22 | Paragraphs 3(2)(ja) and (k) | 6 380 | 6 515 |
| 23 | Paragraph 3(2)(l) | 12 400 | 12 700 |
| 24 | Subregulation 3(3) (note) | 90 500 | 92 400 |

Schedule 2—Annual charges for goods that are not biologics

Therapeutic Goods (Charges) Regulations 1990

1 Paragraph 3(1)(a)

Omit “of a kind”.

2 Paragraph 3(1)(a)

Omit “that is not”, substitute “that are of a kind not”.

3 Paragraph 3(1)(b)

Repeal the paragraph, substitute:

(b) for goods:

(i) whose registration is in force at any time during the financial year to which the charge relates; 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;

$6 725; and

4 At the end of subregulation 3(1)

Add:

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 regulation 4.

5 Paragraph 3(1A)(a)

Omit “that are not”, substitute “that are of a kind not”.

6 Paragraph 3(1A)(b)

Repeal the paragraph, substitute:

(b) for grouped therapeutic goods:

(i) whose registration is in force at any time during the financial year to which the charge relates; 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;

$6 725; and

7 At the end of subregulation 3(1A)

Add:

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 regulation 4.

8 At the end of the Regulations

Add:

4 Annual charges for goods that are not biologics

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

(a) the registration of the goods is in force at any time during the financial year (the ***charge year***) to which the charge relates; 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 the higher and lower amounts are payable

(2) The annual charge for the goods for the charge year is the higher amount if any one or more of subregulations (3) to (8) apply to the goods. Otherwise, the annual charge is the lower amount.

Note: ***Higher amount*** and ***lower amount*** are defined in subregulation (9).

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 less than 8 years.

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

(5) 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) subregulation (4) applies for the charge year to the parent goods of those goods.

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

(6) 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) the charge year is the year beginning 1 July 2016 or a later charge year;

(e) at the beginning of the charge year, the relevant goods have been included in the grouped goods for less than 8 years.

Entries before 1 July 2015—goods that are not grouped therapeutic goods

(7) 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 less than 8 years.

Entries before 1 July 2015—goods that are grouped therapeutic goods

(8) 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 less than 8 years.

Definitions

(9) In this regulation:

***extension of indications*** has the same meaning as in item 4 of the table in Part 2 of Schedule 9 to the *Therapeutic Goods Regulations 1990*.

***higher amount*** means $3 835.

***lower amount*** means $3 110.

***new chemical entity*** has the meaning given by subclause 1(1) of Schedule 9 to the *Therapeutic Goods Regulations 1990*.

***parent goods***: 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.

***relevant goods*** means goods that, at the time the registration of the goods commenced, were:

(a) a new chemical entity; or

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

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

(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).