

Therapeutic Goods Amendment (2018 Measures No. 1) Regulations 2018

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 regulations.

Dated 21 November 2018

Peter Cosgrove

Governor‑General

By His Excellency’s Command

Greg Hunt

Minister for Health

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1 Name

 This instrument is the *Therapeutic Goods Amendment (2018 Measures No. 1) Regulations 2018*.

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 registered. | 27 November 2018 |

Note: This table relates only to the provisions of this instrument as originally made.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 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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Amendments

Therapeutic Goods Regulations 1990

1 Subregulation 43A(1)

Repeal the subregulation.

2 Before subregulation 43A(2)

Insert:

Certain applications to transfer entries of kinds of medical devices

3 Before subregulation 43A(4)

Insert:

Certain applications for the listing of medicines

4 Paragraph 43A(4)(d)

Omit “the day Schedule 2 to the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* commences”, substitute “6 March 2018”.

5 Before subregulation 45(1)

Insert:

Reduction of evaluation fee for certain goods—supply in the interest of public health that would otherwise not be commercially viable

6 Before subregulation 45(2)

Insert:

Waiver or reduction of evaluation fee for certain goods—goods with same active ingredient and common information

7 Paragraph 45(2)(a)

Repeal the paragraph, substitute:

 (a) the goods to which each application relates contain the same active ingredient;

8 Subregulation 45(3)

Repeal the subregulation.

9 Before subregulation 45(3A)

Insert:

Waiver or reduction of application and evaluation fees for certain medicines—additional applications for goods with same active ingredient and common information

10 Before subregulation 45(4)

Insert:

Waiver or reduction of evaluation fees for certain goods—abridged evaluation procedure

11 Before subregulation 45(4AA)

Insert:

Waiver or reduction of evaluation fees for supply of certain medicines in public health emergency—abridged evaluation procedure

12 Subregulations 45(4A), (8), (9), (10) and (11)

Repeal the subregulations, substitute:

Reduction of application and evaluation fees for certain medicines—abridged preliminary assessment and evaluation procedure

 (5) Subregulation (6) applies in relation to an application made under section 23 of the Act for the registration of a medicine if:

 (a) the medicine is a product of a kind specified in Part 1 of Schedule 10; and

 (b) apart from the directions for use or the dosage model, the medicine is the same as another medicine that is included in the Register; and

 (c) the Secretary is satisfied that:

 (i) the differences in the directions for use or the dosage model are necessary to ensure the safe use of the medicine; and

 (ii) neither non‑clinical nor quality data needs to be evaluated in the evaluation of the medicine for registration; and

 (d) the Secretary has information relating to the medicine that enables the preliminary assessment of the application and the evaluation of the medicine for registration to be abridged.

 (6) The Secretary may:

 (a) reduce the application fees specified in Schedule 9 that are payable in relation to the application to $1,100; and

 (b) reduce the evaluation fees specified in Schedule 9 that are payable in relation to the application to $4,360.

Waiver of application and registration fees for designated orphan drugs

13 Schedule 5 (table item 8, column 2, paragraph (b))

Repeal the paragraph.

14 Clause 3 of Schedule 9 (table item 8A)

Repeal the item, substitute:

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| 8A | Application fee for the purposes of paragraph 40B(2)(g) of the Act, for an application under subsection 40B(1) of the Act (addition of manufacturing sites) for the variation of a licence to which paragraph (a) of item 8 applies | 770 |
| 8B | Application fee for the purposes of paragraph 40B(7)(d) of the Act, for an application under subsection 40B(6) of the Act for the variation of the manufacturing site authorisation in relation to a licence to which paragraph (a) of item 8 applies | 770 |
| 8C | Application fee for the purposes of paragraph 40B(9B)(c) of the Act, for an application under subsection 40B(9A) of the Act (removal of manufacturing sites) for the variation of a licence to which paragraph (a) of item 8 applies | 770 |