



National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 11 June 2020

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020*.

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 2020.	1 July 2020

Note: This table relates only to the provisions of this instrument as originally made.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 *National Health Act 1953*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009

1 Subregulation 1A.1(1)

Omit “On or after 1 July 2020, a”, substitute “A”.

2 Subregulation 1A.1(2)

Omit “\$300,440”, substitute “\$180,960”.

3 Subregulation 1A.2(3)

Omit “\$178,550”, substitute “\$103,270”.

4 Subregulation 1A.2(6)

Omit “21-day period”, substitute “period of 15 business days”.

5 Subregulation 1A.4(1)

Omit “21 days”, substitute “15 business days”.

6 Subregulations 1A.5(2) and 1A.10(1)

Omit “14 days”, substitute “10 business days”.

7 Paragraph 1A.11(2)(a)

Omit “15th day”, substitute “11th business day”.

8 Regulation 2.1A (paragraph beginning “If the person’s application”)

Omit “and is in the major or minor evaluation category, the person will need to have given the Department prior notice at least 28 days”, substitute “the person will need to have given the Department prior notice at least 20 business days”.

9 Subregulation 2.2(1) (table item 4)

Omit “\$10,880”, substitute “\$11,280”.

10 Regulation 2.15 (heading)

Omit “major or minor applications to the Committee”, substitute “most applications”.

11 Subregulation 2.15(1)

Omit “or 2”, substitute “, 2 or 4”.

12 Paragraph 2.15(1)(b)

Omit “28 days”, substitute “20 business days”.

13 Paragraph 2.15(5)(c)

Repeal the paragraph, substitute:
(c) be sent to:

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- (i) the office of the Department administering the Committee; or
 - (ii) if the prior notice is of an application for the Minister to exercise a power mentioned in item 3.1 of Schedule 1—the office of the Department administering applications about that item.

14 Subregulation 2.17(1) (heading)

Omit “*proposed major or minor applications for the Committee*”, substitute “*prior notices of applications*”.

15 Subregulation 2.17(1)

Omit “14 days”, substitute “10 business days”.

16 Subregulation 2.17(2)

Omit “21 days”, substitute “15 business days”.

17 Subregulation 2.18(2)

Omit “14 days”, substitute “10 business days”.

18 Paragraph 2.18(3)(c)

Omit “14 days”, substitute “10 business days”.

19 Regulation 3.1 (paragraph beginning “The person”)

Omit “7 days”, substitute “5 business days”.

20 Subregulation 3.2(1)

After “under”, insert “subsection 85(2), (2A) or (3), paragraph 85(7)(b) or”.

21 Paragraph 3.10(1)(b)

Omit “7 days”, substitute “5 business days”.

22 Subregulation 3.10(1) (note 2)

Omit “42 days”, substitute “30 business days”.

23 Subregulation 3.10(4)

Omit “7 days”, substitute “5 business days”.

24 Paragraph 3.11(1)(d)

Omit “42 days”, substitute “30 business days”.

25 Subregulation 3.12(1)

Omit “14 days”, substitute “10 business days”.

26 Subregulation 3.12(2)

Omit “21 days”, substitute “15 business days”.

27 Subregulation 3.13(2)

Omit “14 days”, substitute “10 business days”.

28 Paragraph 3.13(3)(c)

Omit “14 days”, substitute “10 business days”.

29 Subregulations 3A.3(1) and 3A.4(2)

Omit “14 days”, substitute “10 business days”.

30 Subregulation 4.1(4)

Omit “28 days”, substitute “20 business days”.

31 Subregulation 6.1(1)

Omit “14 days”, substitute “10 business days”.

32 Subparagraph 6.2(2)(a)(i)

Omit “14 days”, substitute “10 business days”.

33 Subregulations 6.2(3), (4) and (5)

Omit “14 days”, substitute “10 business days”.

34 Regulation 6.4

Omit “28 days”, substitute “20 business days”.

35 Before regulation 7.1

Insert:

Division 1—Application of these Regulations as originally made

36 Before regulation 7.2

Insert:

Division 2—Application and transitional provisions relating to 2019 amendments

37 In the appropriate position in Part 7

Insert:

Division 3—Application and transitional provisions relating to amendments commencing on 1 July 2020

7.3 Application of amendments of regulation 2.15

The amendments of regulation 2.15 made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020* apply in relation to proposed applications whose submission due day is after 28 July 2020.