

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023

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 19 June 2023

David Hurley

Governor‑General

By His Excellency’s Command

Mark Butler

Minister for Health and Aged Care

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1 Name

 This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023*.

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 2023. | 1 July 2023 |

Note: This table relates only to the provisions of this instrument as originally made.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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2022

1 Subsection 7(2)

Omit “177,830”, substitute “212,790”.

2 Subsection 7(2)

Omit “420”, substitute “430”.

3 Subsection 8(4)

Omit “101,520”, substitute “117,390”.

4 Subsection 8(4)

Omit “420”, substitute “430”.

5 Subsection 12(4)

Omit “420”, substitute “430”.

6 Section 14 (table item 1)

Omit “14,980”, substitute “15,440”.

7 Section 14 (table item 2)

Omit “20,360”, substitute “20,980”.

8 Subsection 22(2) (table)

Repeal the table, substitute:

| Fees and deposits for providing submission services |
| --- |
| Item | Column 1Evaluation categories of submissions | Column 2Fee ($) | Column 3Deposit ($) |
| 1 | Category 1 | 252,540 | 430 |
| 2 | Category 2 | 197,930 | 430 |
| 3 | Category 3 | 42,890 | 430 |
| 4 | Category 4 | 33,370 | 430 |
| 5 | Committee Secretariat category | 11,990 | 430 |
| 6 | New brand or new oral form of existing pharmaceutical item category | 6,410 | 0 |
| 7 | Standard re‑entry pathway category | 195,820 | 430 |
| 8 | Early re‑entry pathway category | 41,470 | 430 |
| 9 | Early resolution pathway category | 41,620 | 430 |
| 10 | Facilitated resolution pathway category | 269,450 | 72,440 |

9 Subsection 22(2) (note 4)

Omit “420”, substitute “430”.

10 Subsection 35(6)

Omit “420”, substitute “430”.

11 Subsection 41(1) (table item 1)

Omit “135,690”, substitute “140,280”.

12 Subsection 41(1) (table item 2)

Omit “107,480”, substitute “111,200”.

13 Subsection 41(1) (table item 3)

Omit “71,110”, substitute “73,780”.

14 Subsection 41(1) (table item 4)

Omit “19,070”, substitute “20,050”.

15 Subsection 41(1) (table item 5)

Omit “11,650”, substitute “12,430”.

16 Subsection 41(2)

Omit “420”, substitute “430”.

17 Paragraph 41(3)(a)

Omit “127,895”, substitute “131,640”.

18 Paragraph 41(3)(b)

Omit “99,685”, substitute “102,560”.

19 Paragraph 41(3)(c)

Omit “63,315”, substitute “65,140”.

20 Subsection 51(5)

Omit “420”, substitute “430”.

21 Subsection 56(1) (table)

Repeal the table, substitute:

| Fees for providing list management services |
| --- |
| Item | Column 1Powers of Minister under the Act | Column 2Fee ($) |
| 1 | Power under:(a) subsection 85AD(1) (about price agreements) of the Act; or(b) section 85B (about price determinations) of the Act;relating to a listed brand of a pharmaceutical item if subsection (2) of this section applies | 4,980 |
| 2 | Power under subsection 85E(1) of the Act (as affected by subsection 33(3) of the *Acts Interpretation Act 1901*) to vary a deed entered into under subsection 85E(1) of the Act | 1,990 |
| 3 | Power under subsection 85E(1) of the Act to enter into a deed with a person replacing an expired deed entered into with the person under that subsection | 10,820 |
| 4 | Power under any of the following provisions of the Act (relating to pricing):(a) subsection 99ACB(6A);(b) subsection 99ACBA(1);(c) subsection 99ACC(5C);(d) subsection 99ACD(7A);(e) subsection 99ACEA(1);(f) subsection 99ACF(3);(g) subsection 99ACR(6);(h) subsection 99ADHB(6) | 6,910 |
| 5 | Power under subsection 99AEKC(2) of the Act to determine an applicable quantity of a brand of a pharmaceutical item | 4,880 |

22 Subsection 60(2)

Omit “8,215”, substitute “8,640”.

23 At the end of Part 9

Add:

Division 3—Amendments made by the National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023

86 Application provision for the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023*

 (1) The amendments of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023* apply in relation to the following:

 (a) if a notice of intent in relation to an application or a submission for the provision of services is not required—an application or a submission (including a remade application or submission) that is received by the Department on or after 1 July 2023;

 (b) in any other case—an application or a submission (including a remade application or submission) for the provision of services, for which a notice of intent is given on or after 1 July 2023.

 (2) In this section:

***services*** means any of the following:

 (a) ATAGI advice;

 (b) the service of the Department holding a pre‑submission meeting with a person;

 (c) submission services;

 (d) pricing services;

 (e) list management services.