

# **National Health (Continued Dispensing) Determination 2022**

PB 59 of 2022

made under subsection 89A(3) of the

National Health Act 1953

# Compilation No. 9

**Compilation date:** 1 March 2025

**Includes amendments:** F2025L00218

Prepared by the Office of Parliamentary Counsel, Canberra

# About this compilation

#### This compilation

This is a compilation of the *National Health (Continued Dispensing) Determination 2022* that shows the text of the law as amended and in force on 1 March 2025 (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 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 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 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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

#### 1.01 Name

- (1) This instrument is the *National Health (Continued Dispensing) Determination 2022.*
- (2) This instrument may also be cited as PB 59 of 2022.

#### 1.03 Authority

This instrument is made under subsection 89A(3) of the *National Health Act* 1953.

#### 1.05 Definitions

(1) In this instrument:

Act means the National Health Act 1953.

*electronic prescription* has the meaning given by subsection 5(1) of the Regulations.

*increased maximum quantity*, for a pharmaceutical item, means a quantity or number of units that has been determined under paragraph 85A(2)(a) of the Act as the maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit that may, for a relevant purpose, be directed in a prescription to be supplied on any one occasion.

*patient*: see subsection 3.01(1).

purposes code has the meaning given by the National Health (Listing of Pharmaceutical Benefits) Instrument 2024.

**Regulations** means the *National Health (Pharmaceutical Benefits)* Regulations 2017.

relevant purpose, for a pharmaceutical benefit, means a purpose, mentioned in Part 1 of Schedule 4 of the National Health (Listing of Pharmaceutical Benefits) Instrument 2024 for a purposes code specified in Schedule 1 of that instrument for the pharmaceutical benefit, that includes the phrase "The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient".

requested supply: see subsection 3.01(1).

(2) Where an expression that is used in this instrument is defined for the purposes of Part VII of the Act, it has the same meaning in this instrument as it has in that Part. Expressions used in this instrument that are defined in Part VII include the following:

#### Section 1.06

- (a) approved pharmacist;
- (b) pbs prescriber;
- (c) pharmaceutical benefit has a drug;
- (d) pharmaceutical benefit;
- (e) pharmaceutical item;
- (f) schedule equivalent.

### 1.06 Purpose

The purpose of this instrument is to determine:

- (a) the pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription; and
- (b) the conditions that must be satisfied when making a supply of those pharmaceutical benefits.

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# Part 2—Pharmaceutical benefits that may be supplied without a prescription

#### 2.01 Pharmaceutical benefits covered by this instrument

For the purposes of paragraph 89A(3)(a) of the Act, each pharmaceutical benefit that has a drug mentioned in an item in Schedule 1 is determined to be a pharmaceutical benefit that may be supplied by an approved pharmacist without a prescription.

Note:

A pharmaceutical benefit has the drug or medicinal preparation referred to in paragraph (a) of the definition pharmaceutical benefit in relation to that benefit – see subsection 84ABA(3).

# Part 3—Specified conditions for supplying pharmaceutical benefits without a prescription

#### 3.01 General

(1) For the purposes of paragraph 89A(3)(b) of the Act, the conditions specified in this Part are determined to be the conditions that must be satisfied when making a supply (the *requested supply*) of a pharmaceutical benefit to a person (the *patient*) requesting the supply without a prescription in accordance with subsection 89A(1) of the Act.

#### (2) In this Part:

- (a) a reference to the PBS prescriber is a reference to the PBS prescriber who most recently prescribed the supply of the pharmaceutical benefit to the patient; and
- (b) a reference to "the pharmaceutical benefit" in sections 3.03, 3.05, 3.06 and 3.07 includes a reference to a pharmaceutical benefit that is a Schedule equivalent.

#### 3.02 Condition—unable to obtain prescription

The approved pharmacist must be satisfied of either or both of the following:

- (a) the PBS prescriber is unable to be contacted;
- (b) the PBS prescriber is unable to provide an electronic prescription.

#### 3.03 Condition—previous supply of pharmaceutical benefit

The approved pharmacist must be satisfied that:

- (a) the patient has previously been supplied the pharmaceutical benefit on the basis of a prescription from a PBS prescriber; and
- (b) the PBS prescriber prescribed the supply of the pharmaceutical benefit for the patient in at least one of the circumstances determined for that pharmaceutical benefit under paragraph 85(7)(b) of the Act.

Note: The circumstances determined under paragraph 85(7)(b) of the Act relate to pharmaceutical benefits that are relevant pharmaceutical benefits under section 88A of the Act.

#### 3.04 Condition—stability of therapy

The approved pharmacist must be satisfied that the patient's therapy is stable.

#### 3.05 Condition—prior clinical review by PBS prescriber

The approved pharmacist must be satisfied that:

(a) the patient has been taking the pharmaceutical benefit regularly for an uninterrupted period; and

(b) since the start of that period, the PBS prescriber has assessed the patient's condition and decided that there is a need for ongoing treatment with the pharmaceutical benefit.

Note: See paragraph 3.01(2)(a) for references to the PBS prescriber.

#### 3.06 Condition—prescription for last supply of pharmaceutical benefit

The approved pharmacist must be satisfied that the patient had a valid prescription under Part VII of the Act for the last supply of the pharmaceutical benefit to the patient before the requested supply.

#### 3.07 Condition—no continued dispensing in previous 12 months

The approved pharmacist must be satisfied that the patient was not supplied with the pharmaceutical benefit under subsection 89A(1) of the Act in the 12 months before the requested supply.

#### 3.08 Condition—declaration for supply of pharmaceutical benefit

The approved pharmacist must ensure that the patient, or an agent of the patient (other than the approved pharmacist), signs a declaration acknowledging that the patient is being supplied with the pharmaceutical benefit without the presentation of a valid prescription under Part VII of the Act.

#### 3.09 Condition—maximum quantity of supply

- (1) The approved pharmacist must supply a maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit determined under paragraph 85A(2)(a) of the Act.
- (2) However, where an increased maximum quantity has been determined for the pharmaceutical item in the pharmaceutical benefit, the approved pharmacist may only supply that increased maximum quantity if the last supply to the patient of the pharmaceutical benefit, or a pharmaceutical benefit that is Schedule equivalent, was on the basis of a prescription written for:
  - (a) a relevant purpose for the pharmaceutical benefit; or
  - (b) a relevant purpose for a pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit.

#### 3.10 Condition—preparing and recording information

- (1) The approved pharmacist must, when the pharmaceutical benefit is supplied:
  - (a) record the information that the pharmacist used to support the pharmacist's decision to supply the pharmaceutical benefit; and
  - (b) prepare information about the supply to the patient that the pharmacist will send to the PBS prescriber.
- (2) The information that must be recorded and prepared under subsection (1) must include the following:

#### Section 3.10

- (a) a statement that the pharmaceutical benefit supplied is a pharmaceutical benefit covered by Schedule 1;
- (b) a statement that the conditions mentioned in sections 3.02 to 3.05 are satisfied;
- (c) a statement that the approved pharmacist is satisfied that the pharmaceutical benefit needs to be supplied to the patient to facilitate continuity of treatment.

# Schedule 1—Pharmaceutical benefits that may be supplied without a prescription - pharmaceutical benefits that have certain listed drugs

Note: See section 2.01.

# 1 Pharmaceutical benefits that may be supplied without a prescription by an approved pharmacist – pharmaceutical benefits that have certain listed drugs

Item	Listed drug	
1	Abacavir	
2	Abacavir with lamivudine	
3	Acarbose	
4	Alogliptin	
5	Alogliptin with metformin	
6	Amlodipine	
7	Amlodipine with atorvastatin	
8	Amlodipine with valsartan	
9	Amlodipine with valsartan and hydrochlorothiazide	
10	Atazanavir	
11	Atazanavir with cobicistat	
12	Atenolol	
13	Atorvastatin	
14	Beclometasone	
15	Beclometasone with formoterol	
16	Bictegravir with emtricitabine with tenofovir alafenamide	
17	Bisoprolol	
18	Budesonide	
19	Budesonide with formoterol	
20	Candesartan	
21	Candesartan with hydrochlorothiazide	

- Section 1		
Item	Listed drug	
22	Captopril	
23	Carvedilol	
24	Chlortalidone	
25	Ciclesonide	
26	Dapagliflozin	
27	Dapagliflozin with metformin	
28	Dapagliflozin with sitagliptin	
29	Darunavir	
30	Darunavir with cobicistat	
31	Darunavir with cobicistat, emtricitabine and tenofovir alafenamide	
32	Diltiazem	
33	Dolutegravir with abacavir and lamivudine	
34	Dolutegravir with lamivudine	
35	Dolutegravir with rilpivirine	
36	Drospirenone with ethinylestradiol	
37	Dulaglutide	
38	Empagliflozin	
39	Empagliflozin with linagliptin	
40	Empagliflozin with metformin	
41	Emtricitabine with rilpivirine with tenofovir alafenamide	
42	Emtricitabine with tenofovir alafenamide	
43	Enalapril	
44	Enalapril with hydrochlorothiazide	
45	Eplerenone	
46	Eprosartan	
47	Eprosartan with hydrochlorothiazide	
48	Etravirine	
49	Ezetimibe and rosuvastatin	
50	Ezetimibe with atorvastatin	
51	Ezetimibe with simvastatin	

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Item	Listed drug	
52	Felodipine	
53	Fluticasone furoate	
54	Fluticasone furoate with vilanterol	
55	Fluticasone propionate	
56	Fluticasone propionate with formoterol	
57	Fluticasone propionate with salmeterol	
58	Fluvastatin	
59	Formoterol	
60	Fosinopril	
61	Furosemide	
62	Glibenclamide	
63	Gliclazide	
64	Glimepiride	
65	Glipizide	
66	Hydrochlorothiazide	
67	Hydrochlorothiazide with amiloride	
68	Indacaterol	
69	Indacaterol with mometasone	
70	Indapamide	
71	Insulin aspart	
72	Insulin aspart with insulin aspart protamine suspension	
73	Insulin degludec with insulin aspart	
74	Insulin detemir	
75	Insulin glargine	
76	Insulin glulisine	
77	Insulin isophane	
78	Insulin lispro	
79	Insulin lispro with insulin lispro protamine suspension	
80	Insulin neutral	
81	Insulin neutral with insulin isophane	

Item	Listed drug	
82	Irbesartan	
83	Irbesartan with hydrochlorothiazide	
84	Labetalol	
85	Lamivudine	
86	Lamivudine with zidovudine	
87	Lercanidipine	
88	Lercanidipine with enalapril	
89	Levonorgestrel	
90	Levonorgestrel with ethinylestradiol	
91	Linagliptin	
92	Linagliptin with metformin	
93	Lisinopril	
94	Lopinavir with ritonavir	
95	Maraviroc	
96	Metformin	
97	Metoprolol	
98	Metoprolol succinate	
99	Nebivolol	
100	Nevirapine	
101	Nifedipine	
102	Norethisterone	
103	Norethisterone with ethinylestradiol	
104	Olmesartan	
105	Olmesartan with amlodipine	
106	Olmesartan with amlodipine and hydrochlorothiazide	
107	Olmesartan with hydrochlorothiazide	
108	Perindopril	
109	Perindopril with amlodipine	
110	Perindopril with indapamide	
111	Pioglitazone	

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Item	Listed drug	
112	Pravastatin	
113	Propranolol	
114	Quinapril	
115	Quinapril with hydrochlorothiazide	
116	Ramipril	
117	Ramipril with felodipine	
118	Rilpivirine	
119	Ritonavir	
120	Rosuvastatin	
121	Sacubitril with valsartan	
122	Salbutamol	
123	Salmeterol	
124	Saxagliptin	
125	Saxagliptin with dapagliflozin	
126	Saxagliptin with metformin	
127	Semaglutide	
128	Simvastatin	
129	Sitagliptin	
130	Sitagliptin with metformin	
131	Sotalol	
132	Spironolactone	
133	Telmisartan	
134	Telmisartan with amlodipine	
135	Telmisartan with hydrochlorothiazide	
136	Tenofovir	
137	Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat	
138	Tenofovir with emtricitabine	
139	Tenofovir with emtricitabine and efavirenz	
140	Terbutaline	
141	Trandolapril	

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 $\textbf{Schedule 1} \ \ \text{Pharmaceutical benefits that may be supplied without a prescription - pharmaceutical benefits that have certain listed drugs$ 

# Section 1

Item	Listed drug	
142	Trandolapril with verapamil	
143	Valsartan	
144	Valsartan with hydrochlorothiazide	
145	Verapamil	
146	Vildagliptin	
147	Vildagliptin with metformin	
148	Zidovudine	

#### **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 how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

#### Endnote 2—Abbreviation key

#### **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)

 $\underline{underlining} = whole or part not$ 

commenced or to be commenced

# **Endnote 3—Legislation history**

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Continued Dispensing) Determination 2022 (PB 59 of 2022)	30 June 2022 (F2022L00884)	1 July 2022 (s 1.02(1) item 1)	
National Health (Continued Dispensing) Amendment Determination 2022 (No. 1) (PB 88 of 2022)	30 Sept 2022 (F2022L01306)	1 Oct 2022 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2023 (No. 1) (PB 70 of 2023)	31 July 2023 (F2023L01045)	1 Aug 2023 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2023 (No. 2) (PB 83 of 2023)	31 Aug 2023 (F2023L01156)	1 Sept 2023 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2023 (No. 3) (PB 115 of 2023)	30 Nov 2023 (F2023L01576)	1 Dec 2023 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 1) (PB 50 of 2024)	30 Apr 2024 (F2024L00507)	1 May 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 2) (PB 98 of 2024)	30 Sept 2024 (F2024L01242)	1 Oct 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 3) (PB 114 of 2024)	31 Oct 2024 (F2024L01393)	1 Nov 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2024 (No. 4) (PB 134 of 2024)	29 Nov 2024 (F2024L01544)	1 Dec 2024 (s 2(1) item 1)	_
National Health (Continued Dispensing) Amendment Determination 2025 (No. 1) (PB 16 of 2025)	28 Feb 2025 (F2025L00218)	1 Mar 2025 (s 2(1) item 1)	_

#### **Endnotes**

# Endnote 4—Amendment history

# **Endnote 4—Amendment history**

Provision affected	How affected
Part 1	
s 1.02	rep LA s 48D
s 1.04	rep LA s 48C
s 1.05	am F2023L01576; F2024L01393
Part 2	
s 2.01	rs F2024L01393
Part 3	
s 3.09	rs F2023L01576
Part 4	rep F2024L01393
Schedule 1	
Schedule 1 heading	am F2024L01393
Schedule 1	am F2024L01393
s 1	am F2022L01306; F2023L01045; F2023L01156; F2024L00507; F2024L01242; F2024L01393; F2024L01544; F2025L00218
Schedule 2	rep LA s 48C