



PB 59 of 2022

National Health (Continued Dispensing) Determination 2022

I, David Laffan, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 28 June 2022

David Laffan
Assistant Secretary
Pharmacy Branch
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Department of Health

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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.

1.02 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 2022.	1 July 2022

Note: This table relates only to the provisions of this instrument as originally made.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.

1.03 Authority

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

1.04 Schedule 2

Each instrument that is specified in Schedule 2 to this instrument is amended or repealed as set out in the applicable items in that Schedule, and any other item in that Schedule has effect according to its terms.

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.

patient: see subsection 3.01(1).

Section 1.06

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

requested supply: see subsection 3.01(1).

- (2) An expression that is used in this instrument and in Part VII of the Act has the same meaning in this instrument as it has in that Part.

Examples:

- (a) approved pharmacist;
- (b) listed brand;
- (c) PBS prescriber;
- (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.

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, the pharmaceutical benefits covered by an item in the table in Schedule 1 (being the listed drugs specified in the item) are determined to be pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription.

Section 3.01

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

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.

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:
 - (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.

Part 4—Application, savings and transitional provisions

4.01 Application of this instrument

Despite the repeal of the *National Health (Continued Dispensing – Emergency Measures) Determination 2020*, that instrument (the **emergency instrument**) continues to have effect, on and after 1 July 2022, for the purposes of the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* in relation to a supply of a pharmaceutical benefit made in accordance with the emergency instrument on or before 30 June 2022 as if the repeal had not happened.

Schedule 1—Pharmaceutical benefits that may be supplied without a prescription

Note: See section 3.01.

1 Pharmaceutical benefits that may be supplied without a prescription by an approved pharmacist

Item	Listed drug
1	Abacavir
2	Abacavir with lamivudine
3	Abacavir with lamivudine and zidovudine
4	Acarbose
5	Adefovir
6	Alogliptin
7	Alogliptin with metformin
8	Amiloride with hydrochlorothiazide
9	Amlodipine
10	Amlodipine with atorvastatin
11	Amlodipine with valsartan
12	Amlodipine with valsartan and hydrochlorothiazide
13	Atazanavir
14	Atazanavir with cobicistat
15	Atenolol
16	Atorvastatin
17	Beclometasone
18	Beclometasone with Formoterol (eformoterol)
19	Bictegravir with emtricitabine with tenofovir alafenamide
20	Bisoprolol
21	Budesonide
22	Budesonide with Formoterol (eformoterol)
23	Candesartan
24	Candesartan with hydrochlorothiazide
25	Captopril
26	Carvedilol
27	Chlortalidone
28	Ciclesonide
29	Cromoglycate
30	Dapagliflozin
31	Dapagliflozin with metformin
32	Darunavir
33	Darunavir with cobicistat

Schedule 1 Pharmaceutical benefits that may be supplied without a prescription

Section 1

Item	Listed drug
34	Darunavir with cobicistat, emtricitabine and tenofovir alafenamide
35	Diltiazem
36	Dolutegravir
37	Dolutegravir with abacavir and lamivudine
38	Dolutegravir with lamivudine
39	Dolutegravir with rilpivirine
40	Dulaglutide
41	Efavirenz
42	Empagliflozin
43	Empagliflozin with linagliptin
44	Empagliflozin with metformin
45	Emtricitabine with rilpivirine with tenofovir alafenamide
46	Emtricitabine with tenofovir alafenamide
47	Enalapril
48	Enalapril with hydrochlorothiazide
49	Enfuvirtide
50	Entecavir
51	Eplerenone
52	Eprosartan
53	Eprosartan with hydrochlorothiazide
54	Ertugliflozin
55	Ertugliflozin with metformin
56	Ertugliflozin with sitagliptin
57	Etacrynic acid
58	Etravirine
59	Exenatide
60	Ezetimibe with atorvastatin
61	Ezetimibe with rosuvastatin
62	Ezetimibe with simvastatin
63	Felodipine
64	Fluticasone furoate
65	Fluticasone furoate with Vilanterol
66	Fluticasone propionate
67	Fluticasone propionate with Formoterol (eformoterol)
68	Fluticasone propionate with Salmeterol
69	Fluvastatin
70	Formoterol (eformoterol)
71	Fosamprenavir
72	Fosinopril
73	Fosinopril with hydrochlorothiazide
74	Furosemide (frusemide)

Section 1

Item	Listed drug
75	Glibenclamide
76	Gliclazide
77	Glimepiride
78	Glipizide
79	Hydrochlorothiazide
80	Indacaterol
81	Indacaterol with Mometasone
82	Indapamide
83	Insulin aspart
84	Insulin aspart with insulin aspart protamine
85	Insulin degludec with insulin aspart
86	Insulin detemir
87	Insulin glargine
88	Insulin glulisine
89	Insulin isophane human
90	Insulin isophane human with insulin neutral human
91	Insulin lispro
92	Insulin lispro with insulin lispro protamine
93	Insulin neutral human
94	Irbesartan
95	Irbesartan with hydrochlorothiazide
96	Labetalol
97	Lamivudine
98	Lamivudine with zidovudine
99	Lercanidipine
100	Lercanidipine with enalapril
101	Levonorgestrel
102	Levonorgestrel with ethinylestradiol
103	Linagliptin
104	Linagliptin with metformin
105	Lisinopril
106	Lopinavir with ritonavir
107	Losartan
108	Maraviroc
109	Metformin
110	Metformin with glibenclamide
111	Metoprolol succinate
112	Metoprolol tartrate
113	Nebivolol
114	Nedocromil
115	Nevirapine

Schedule 1 Pharmaceutical benefits that may be supplied without a prescription

Section 1

Item	Listed drug
116	Nifedipine
117	Norethisterone
118	Norethisterone with ethinylestradiol
119	Norethisterone with Mestranol
120	Olmesartan
121	Olmesartan with amlodipine and hydrochlorothiazide
122	Olmesartan with hydrochlorothiazide
123	Olmesartan medoxomil with amlodipine
124	Oxprenolol
125	Perindopril
126	Perindopril with amlodipine
127	Perindopril with indapamide
128	Pindolol
129	Pioglitazone
130	Pravastatin
131	Propranolol
132	Quinapril
133	Quinapril with hydrochlorothiazide
134	Raltegravir
135	Ramipril
136	Ramipril with felodipine
137	Rilpivirine
138	Ritonavir
139	Rosuvastatin
140	Sacubitril with valsartan
141	Salbutamol
142	Salmeterol
143	Saquinavir
144	Saxagliptin
145	Saxagliptin with dapagliflozin
146	Saxagliptin with metformin
147	Semaglutide
148	Simvastatin
149	Sitagliptin
150	Sitagliptin with metformin
151	Spirolactone
152	Telmisartan
153	Telmisartan with amlodipine
154	Telmisartan with hydrochlorothiazide
155	Tenofovir with emtricitabine
156	Tenofovir with emtricitabine and efavirenz

Section 1

Item	Listed drug
157	Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat
158	Tenofovir disoproxil
159	Terbutaline
160	Tipranavir
161	Trandolapril
162	Trandolapril with verapamil
163	Valsartan
164	Valsartan with hydrochlorothiazide
165	Verapamil
166	Vildagliptin
167	Vildagliptin with metformin
168	Zidovudine

Schedule 2—Repeals

National Health (Continued Dispensing) Determination 2012

1 The whole of the instrument

Repeal the instrument.

National Health (Continued Dispensing – Emergency Measures) Determination 2020

2 The whole of the instrument

Repeal the instrument.