



National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021

PB 84 of 2021

made under subsection 89A(3) of the

National Health Act 1953

Compilation No. 13

Compilation date: 15 September 2023

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Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* that shows the text of the law as amended and in force on 15 September 2023 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name

- (1) This instrument is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*.
- (2) This instrument may also be cited as PB 84 of 2021.

3 Authority

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

4 Definitions

Note: The expression premises that is used in this instrument is defined in the Act.

In this instrument:

Act means the *National Health Act 1953*.

approved pharmacist has the same meaning as in Part VII of the Act.

listed drug has the same meaning as in Part VII of the Act.

PBS prescriber has the same meaning as in Part VII of the Act.

pharmaceutical benefit has the same meaning as in Part VII of the Act.

5 Supply of pharmaceutical benefits by approved pharmacist without prescription

- (1) A pharmaceutical benefit (the *substitute benefit*) described in column 2 of an item of the table in subsection (8) may be supplied without a prescription to a person by an approved pharmacist, at or from premises in respect of which the pharmacist is approved, if:
 - (a) a prescription for a pharmaceutical benefit (the *prescribed benefit*) described in column 1 of the item is presented to the approved pharmacist; and
 - (b) subsections (2), (3), (4), (5), (6) and (7) apply.

Approved pharmacist cannot supply prescribed benefit

- (2) This subsection applies if the approved pharmacist cannot supply the prescribed benefit.

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Person cannot obtain prescription for substitute benefit in time

- (3) This subsection applies if the approved pharmacist is satisfied that it is not practicable for the person to obtain a prescription for the substitute benefit from a PBS prescriber before the person needs the supply of the prescribed benefit.

Substitution permitted under Therapeutic Goods Act

- (4) This subsection applies if the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*.

Person presenting prescription has been informed of cost implications

- (5) This subsection applies if the approved pharmacist has informed the person presenting the prescription of:
- (a) each substitute benefit that the approved pharmacist can supply instead of the prescribed benefit; and
 - (b) for each substitute benefit that the approved pharmacist can supply:
 - (i) the amount (which may be a nil amount) that the approved pharmacist would, if the approved pharmacist supplied the substitute benefit to the person for whom the prescribed benefit was prescribed, be permitted by Part VII of the Act to charge that person for that supply; and
 - (ii) the amount that the approved pharmacist would, if the approved pharmacist supplied the substitute benefit otherwise than under Part VII of the Act to the person for whom the prescribed benefit was prescribed, charge that person for that supply; and
 - (c) the amount (which may be a nil amount) that the approved pharmacist would, if the approved pharmacist supplied the prescribed benefit to the person for whom it was prescribed, be permitted by Part VII of the Act to charge that person for that supply.

Record of information justifying supply of substitute benefit

- (6) This subsection applies if the approved pharmacist records the information that the approved pharmacist used to support the decision to supply the substitute benefit, including the following statements:
- (a) a statement that the substitute benefit supplied is a pharmaceutical benefit determined under paragraph 89A(3)(a) of the Act;
 - (b) a statement that the conditions in this section are satisfied;
 - (c) a statement that the approved pharmacist is satisfied that the substitute benefit needs to be supplied because:
 - (i) the approved pharmacist cannot supply the prescribed benefit; and
 - (ii) it is not practicable for the person to obtain a prescription for the substitute benefit from a PBS prescriber before the person needs the supply of the prescribed benefit.

Arrangements to inform PBS prescriber of substitution

- (7) This subsection applies if the approved pharmacist has in place arrangements for giving, to the PBS prescriber who wrote the prescription for the prescribed benefit, written notice of the supply of the substitute benefit, within 72 hours after that supply.

Table of prescribed and substitute pharmaceutical benefits

- (8) For the purposes of subsection (1), the table is as follows.

| Prescribed and substitute pharmaceutical benefits | | |
|--|---|---|
| Item | Column 1 Prescribed pharmaceutical benefit | Column 2 Substitute pharmaceutical benefit |
| 1 | Listed drug: Warfarin Form: Tablet containing warfarin sodium 5 mg Manner of administration: Oral Brand: Coumadin | Listed drug: Warfarin Form: Tablet containing warfarin sodium 1 mg Manner of administration: Oral Brand: Coumadin |
| 2 | Listed drug: Warfarin Form: Tablet containing warfarin sodium 5 mg Manner of administration: Oral Brand: Coumadin | Listed drug: Warfarin Form: Tablet containing warfarin sodium 2 mg Manner of administration: Oral Brand: Coumadin |
| 3 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL Manner of administration: Oral Brand: Cilicaine V |
| 4 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT |

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| 5 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Capsule 250 mg phenoxymethylpenicillin (as potassium) Manner of administration: Oral Brand: Any of the following: a) Cilicaine VK b) LPV |
| 6 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Tablet 250 mg phenoxymethylpenicillin (as potassium) Manner of administration: Oral Brand: Aspecillin VK |
| 7 | Listed drug: Phenoxymethylpenicillin Form: Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL Manner of administration: Oral Brand: Cilicaine V | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT |
| 8 | Listed drug: Phenoxymethylpenicillin Form: Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL Manner of administration: Oral Brand: Cilicaine V | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT |
| 9 | Listed drug: Phenoxymethylpenicillin Form: Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL Manner of administration: Oral Brand: Cilicaine V | Listed drug: Phenoxymethylpenicillin Form: Capsule 250 mg phenoxymethylpenicillin (as potassium) Manner of administration: Oral Brand: Any of the following: a) Cilicaine VK b) LPV |
| 10 | Listed drug: Phenoxymethylpenicillin Form: Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL Manner of administration: Oral Brand: Cilicaine V | Listed drug: Phenoxymethylpenicillin Form: Tablet 250 mg phenoxymethylpenicillin (as potassium) Manner of administration: Oral Brand: Aspecillin VK |

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| 11 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT |
| 12 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL Manner of administration: Oral Brand: Cilicaine V |
| 13 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Capsule 250 mg phenoxymethylpenicillin (as potassium) Manner of administration: Oral Brand: Any of the following: a) Cilicaine VK b) LPV |
| 14 | Listed drug: Phenoxymethylpenicillin Form: Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL Manner of administration: Oral Brand: Phenoxymethylpenicillin-AFT | Listed drug: Phenoxymethylpenicillin Form: Tablet 250 mg phenoxymethylpenicillin (as potassium) Manner of administration: Oral Brand: Aspecillin VK |
| 15 | Listed drug: Cefaclor Form: Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: Ceclor | Listed drug: Cefaclor Form: Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL Manner of administration: Oral Brand: Any of the following a) Ceclor b) Keflor c) APO-Cefaclor d) Aclor 250 |

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| 16 | Listed drug: Cefaclor Form: Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: Keflor | Listed drug: Cefaclor Form: Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL Manner of administration: Oral Brand: Any of the following a) Ceclor b) Keflor c) APO-Cefaclor d) Aclor 250 |
| 17 | Listed drug: Cefaclor Form: Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL Manner of administration: Oral Brand: Ceclor | Listed drug: Cefaclor Form: Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL Brand: Any of the following: a) Ceclor b) Keflor c) Aclor 125 |
| 18 | Listed drug: Cefaclor Form: Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL Manner of administration: Oral Brand: Keflor | Listed drug: Cefaclor Form: Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: Any of the following: a) Ceclor b) Keflor c) Aclor 125 |
| 19 | Listed drug: Insulin degludec with insulin aspart Form: Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5 Manner of administration: Injection Brand: Ryzodeg Flextouch | Listed drug: Insulin degludec with insulin aspart Form: Injections, cartridges, 70 units-30 units per mL, 3 mL, 5 Manner of administration: Injection Brand: Ryzodeg Penfill |
| 20 | Listed drug: Cefalexin Form: Granules for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: any of the following: (a) Cefalexin Sandoz (b) Ibilex 125 (c) Keflex | Listed drug: Cefalexin Form: Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) Cefalexin Sandoz (b) Ibilex 250 (c) Keflex |

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| 21 | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <ul style="list-style-type: none"> (a) Cefalexin Sandoz (b) Ibilex 125 (c) Keflex | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)</p> <p>Manner of administration: Oral</p> <p>Brand: Keforal (s19A)</p> |
| 22 | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <ul style="list-style-type: none"> (a) Cefalexin Sandoz (b) Ibilex 125 (c) Keflex | <p>Listed drug: Cefalexin</p> <p>Form: Capsule 250 mg (as monohydrate)</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> (a) APO-Cephalexin (b) Ibilex 250 (c) Keflex |
| 23 | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <ul style="list-style-type: none"> (a) Cefalexin Sandoz (b) Ibilex 250 (c) Keflex | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> (a) Cefalexin Sandoz (b) Ibilex 125 (c) Keflex |
| 24 | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <ul style="list-style-type: none"> (a) Cefalexin Sandoz (b) Ibilex 250 (c) Keflex | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)</p> <p>Manner of administration: Oral</p> <p>(a) Brand: Keforal (s19A)</p> |
| 25 | <p>Listed drug: Cefalexin</p> <p>Form: Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <ul style="list-style-type: none"> (a) Cefalexin Sandoz (b) Ibilex 250 (c) Keflex | <p>Listed drug: Cefalexin</p> <p>Form: Capsule 250 mg (as monohydrate)</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <ul style="list-style-type: none"> (a) APO-Cephalexin (b) Ibilex 250 (c) Keflex |

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| 26 | Listed drug: Vigabatrin | Listed drug: Vigabatrin |
| | Form: Tablet 500 mg | Form: Oral powder, sachet 500 mg |
| | Manner of administration: Oral | Manner of administration: Oral |
| | Brand: Sabril | Brand: Sabril |

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.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

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| ad = added or inserted | o = order(s) |
| am = amended | Ord = Ordinance |
| amdt = amendment | orig = original |
| c = clause(s) | par = paragraph(s)/subparagraph(s) /sub-subparagraph(s) |
| C[x] = Compilation No. x | pres = present |
| Ch = Chapter(s) | prev = previous |
| def = definition(s) | (prev...) = previously |
| Dict = Dictionary | Pt = Part(s) |
| disallowed = disallowed by Parliament | r = regulation(s)/rule(s) |
| Div = Division(s) | reloc = relocated |
| ed = editorial change | renum = renumbered |
| exp = expires/expired or ceases/ceased to have effect | rep = repealed |
| F = Federal Register of Legislation | rs = repealed and substituted |
| gaz = gazette | s = section(s)/subsection(s) |
| LA = <i>Legislation Act 2003</i> | Sch = Schedule(s) |
| LIA = <i>Legislative Instruments Act 2003</i> | Sdiv = Subdivision(s) |
| (md) = misdescribed amendment can be given effect | SLI = Select Legislative Instrument |
| (md not incorp) = misdescribed amendment cannot be given effect | SR = Statutory Rules |
| mod = modified/modification | Sub-Ch = Sub-Chapter(s) |
| No. = Number(s) | SubPt = Subpart(s) |
| | <u>underlining</u> = whole or part not commenced or to be commenced |

Endnote 3—Legislation history

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
|--|----------------------------|------------------------------|---|
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021 (PB 84 of 2021) | 15 Aug 2021 (F2021L01118) | 16 Aug 2021 (s 2(1) item 1) | |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2021 (PB 95 of 2021) | 19 Aug 2021 (F2021L01138) | 20 Aug 2021 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021 (PB 108 of 2021) | 17 Sept 2021 (F2021L01296) | 18 Sept 2021 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2022 (PB 10 of 2022) | 7 Feb 2022 (F2022L00117) | 8 Feb 2022 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2022 (PB 42 of 2022) | 19 May 2022 (F2022L00711) | 20 May 2022 (s 2(1) item 1) | — |

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Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
|--|----------------------------|-----------------------------|---|
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 3) Determination 2022 (PB 73 of 2022) | 29 July 2022 (F2022L01030) | 1 Aug 2022 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022 (PB 119 of 2022) | 5 Dec 2022 (F2022L01581) | 6 Dec 2022 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 5) Determination 2022 (PB 131 of 2022) | 20 Dec 2022 (F2022L01715) | 21 Dec 2022 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2023 (PB 20 of 2023) | 16 Mar 2023 (F2023L00235) | 17 Mar 2023 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2023 (PB 32 of 2023) | 14 Apr 2023 (F2023L00441) | 17 Apr 2023 (s 2(1) item 1) | — |

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
|---|----------------------------|------------------------------|---|
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 3) Determination 2023 (PB 41 of 2023) | 1 May 2023 (F2023L00516) | 1 May 2023 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2023 (PB 66 of 2023) | 5 July 2023 (F2023L00974) | 6 July 2023 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 5) Determination 2023 (PB 78 of 2023) | 31 July 2023 (F2023L01047) | 1 Aug 2023 (s 2(1) item 1) | — |
| National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 6) Determination 2023 (PB 90 of 2023) | 14 Sept 2023 (F2023L01236) | 15 Sept 2023 (s 2(1) item 1) | — |

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

| Provision affected | How affected |
|--------------------|--|
| s 2 | rep LA s 48D |
| s 5 | am F2021L01138; F2021L01296; F2022L00117; F2022L00711; F2022L01030; F2022L01581; F2022L01715; F2023L00235 |
| | ed C8 |
| | am F2023L00441; F2023L00516; F2023L00974; F2023L01047; F2023L01236 |
