



**PB 119 of 2022**

**National Health (Pharmaceutical Benefits)  
(Pharmacist Substitution of Medicines without  
Prescription during Shortages) Amendment  
(No. 4) Determination 2022**

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

Dated 5 December 2022

Nikolai Tsyganov  
Acting Assistant Secretary  
Pricing and PBS Policy Branch  
Technology Assessment and Access Division  
Department of Health and Aged Care

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## 1 Name

- (1) This instrument is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022*.
- (2) This instrument may also be cited as PB 119 of 2022.

## 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.

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<b><u>Commencement information</u></b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
1. The whole of this instrument	6 December 2022	6 December 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Note: This table relates only to the provisions of this instrument as originally made.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.

## 3 Authority

This instrument is made under subsection 89A(3) of 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*

#### 1 Subsection 5(8)

Omit:

#### Prescribed and substitute pharmaceutical benefits

Item	Column 1 Prescribed pharmaceutical benefit	Column 2 Substitute pharmaceutical benefit
5	<p>Listed drug: Isosorbide mononitrate</p> <p>Form: Tablet 120 mg (sustained release)</p> <p>Manner of administration: Oral</p> <p>Brand: either of the following:</p> <p>(a) Imdur 120 mg;</p> <p>(b) Monodur 120 mg</p>	<p>Listed drug: Isosorbide mononitrate</p> <p>Form: Tablet 60 mg (sustained release)</p> <p>Manner of administration: Oral</p> <p>Brand: any of the following:</p> <p>(a) APO-Isosorbide Mononitrate;</p> <p>(b) Duride;</p> <p>(c) GenRx Isosorbide Mononitrate;</p> <p>(d) Imdur Durule;</p> <p>(e) ISOBIDE MR;</p> <p>(f) Isomonit;</p> <p>(g) Isosorbide AN;</p> <p>(h) Monodur 60 mg</p>

Insert:

#### Prescribed and substitute pharmaceutical benefits

Item	Column 1 Prescribed pharmaceutical benefit	Column 2 Substitute pharmaceutical benefit
1	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <p>(a) Amoxil</p>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <p>(a) APO-Amoxycillin</p> <p>(b) Amoxil</p> <p>(c) NOUMED AMOXICILLIN</p>
2	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <p>(a) Amoxil</p>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <p>(a) APO-Amoxycillin</p> <p>(b) Amoxil Forte</p> <p>(c) Amoxycillin Sandoz</p> <p>(d) Cilamox</p> <p>(e) NOUMED AMOXICILLIN</p>
3	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p>

	(a) Amoxil	(a) Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)
4	Listed drug: Amoxicillin Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL Manner of administration: Oral Brand: (a) Amoxil	Listed drug: Amoxicillin Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: (a) Maxamox
5	Listed drug: Amoxicillin Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil (c) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL Manner of administration: Oral Brand: (a) Amoxil
6	Listed drug: Amoxicillin Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil (c) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil Forte (c) Amoxycillin Sandoz (d) Cilamox (e) NOUMED AMOXICILLIN
7	Listed drug: Amoxicillin Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil (c) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A) Manner of administration: Oral Brands: any of the following: (a) Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)
8	Listed drug: Amoxicillin Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil (c) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: (a) Maxamox
9	Listed drug: Amoxicillin Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil Forte (c) Amoxycillin Sandoz (d) Cilamox (e) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL Manner of administration: Oral Brand: (a) Amoxil
10	Listed drug: Amoxicillin Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL	Listed drug: Amoxicillin Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL

	<p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> <li>(a) APO-Amoxicillin</li> <li>(b) Amoxil Forte</li> <li>(c) Amoxicillin Sandoz</li> <li>(d) Cilamox</li> <li>(e) NOUMED AMOXICILLIN</li> </ul>	<p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> <li>(a) APO-Amoxicillin</li> <li>(b) Amoxil</li> <li>(c) NOUMED AMOXICILLIN</li> </ul>
11	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 250 mg (as trihydrate) 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"> <li>(a) APO-Amoxicillin</li> <li>(b) Amoxil Forte</li> <li>(c) Amoxicillin Sandoz</li> <li>(d) Cilamox</li> <li>(e) NOUMED AMOXICILLIN</li> </ul>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <ul style="list-style-type: none"> <li>(a) Maxamox</li> </ul>
12	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> <li>(a) Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)</li> </ul>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <ul style="list-style-type: none"> <li>(a) Amoxil</li> </ul>
13	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> <li>(a) Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)</li> </ul>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 125 mg (as trihydrate) 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"> <li>(a) APO-Amoxicillin</li> <li>(b) Amoxil</li> <li>(c) NOUMED AMOXICILLIN</li> </ul>
14	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>Manner of administration: Oral</p> <p>Brands: any of the following:</p> <ul style="list-style-type: none"> <li>(a) Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)</li> </ul>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <ul style="list-style-type: none"> <li>(a) Maxamox</li> </ul>
15	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <ul style="list-style-type: none"> <li>(a) Maxamox</li> </ul>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for paediatric oral drops 100 mg (as trihydrate) per mL, 20 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <ul style="list-style-type: none"> <li>(a) Amoxil</li> </ul>
16	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p> <p>Manner of administration: Oral</p> <p>Brand:</p> <ul style="list-style-type: none"> <li>(a) Maxamox</li> </ul>	<p>Listed drug: Amoxicillin</p> <p>Form: Powder for oral suspension 125 mg (as trihydrate) 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"> <li>(a) APO-Amoxicillin</li> <li>(b) Amoxil</li> </ul>

		(c) NOUMED AMOXICILLIN
17	Listed drug: Amoxicillin Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: (a) Maxamox	Listed drug: Amoxicillin Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brands: any of the following: (a) APO-Amoxycillin (b) Amoxil Forte (c) Amoxycillin Sandoz (d) Cilamox (e) NOUMED AMOXICILLIN
18	Listed drug: Amoxicillin Form: Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL Manner of administration: Oral Brand: (a) Maxamox	Listed drug: Amoxicillin Form: Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A) Manner of administration: Oral Brands: any of the following: (a) Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)
19	Listed drug: Amoxicillin Form: Capsule 500 mg (as trihydrate) Manner of administration: Oral Brands: any of the following: (a) AMILOXYN (b) APO-Amoxycillin (c) Alphamox 500 (d) Amoxil (e) Amoxycillin Sandoz (f) Amoxycillin generichealth 500 (g) Cilamox (h) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Capsule 250 mg (as trihydrate) Manner of administration: Oral Brands: any of the following: (a) AMILOXYN (b) APO-Amoxycillin (c) Alphamox 250 (d) Amoxil (e) Cilamox
20	Listed drug: Amoxicillin Form: Capsule 500 mg (as trihydrate) Manner of administration: Oral Brands: any of the following: (a) AMILOXYN (b) APO-Amoxycillin (c) Alphamox 500 (d) Amoxil (e) Amoxycillin Sandoz (f) Amoxycillin generichealth 500 (g) Cilamox (h) NOUMED AMOXICILLIN	Listed drug: Amoxicillin Form: Tablet 1 g (as trihydrate) Manner of administration: Oral Brands: any of the following: (a) Amoxycillin Sandoz (b) Maxamox
21	Listed drug: Amoxicillin Form: Tablet 1 g (as trihydrate) Manner of administration: Oral Brands: any of the following: (a) Amoxycillin Sandoz (b) Maxamox	Listed drug: Amoxicillin Form: Capsule 250 mg (as trihydrate) Manner of administration: Oral Brands: any of the following: (a) AMILOXYN (b) APO-Amoxycillin (c) Alphamox 250 (d) Amoxil (e) Cilamox
22	Listed drug: Amoxicillin Form: Tablet 1 g (as trihydrate) Manner of administration: Oral	Listed drug: Amoxicillin Form: Capsule 500 mg (as trihydrate) Manner of administration: Oral

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Brands: any of the following:

- (a) Amoxicillin Sandoz
- (b) Maxamox

Brands: any of the following:

- (a) AMILOXYN
  - (b) APO-Amoxicillin
  - (c) Alphamox 500
  - (d) Amoxil
  - (e) Amoxicillin Sandoz
  - (f) Amoxicillin generichealth 500
  - (g) Cilamox
  - (h) NOUMED AMOXICILLIN
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23 Listed drug: Isosorbide mononitrate  
Form: Tablet 120 mg (sustained release)  
Manner of administration: Oral  
Brand: either of the following:  
(a) Imdur 120 mg;  
(b) Monodur 120 mg

Listed drug: Isosorbide mononitrate  
Form: Tablet 60 mg (sustained release)  
Manner of administration: Oral  
Brand: any of the following:  
(a) APO-Isosorbide Mononitrate;  
(b) Duride;  
(c) GenRx Isosorbide Mononitrate;  
(d) Imdur Durule;  
(e) ISOBIDE MR;  
(f) Isomonit;  
(g) Isosorbide AN;  
(h) Monodur 60 mg

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