



National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) DETERMINATION 2025

I, Rebecca Richardson, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, as delegate of the Minister for Health and Ageing, make the following determination.

Dated 26 May 2025

Rebecca Richardson
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health, Disability and Ageing

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

1 Name

- (1) This instrument is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2025*.
- (2) This instrument may also be cited as PB 52 of 2025.

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.

<u>Commencement information</u>		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	28 May 2025	28 May 2025

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Repeal the table, substitute:

Prescribed and substitute pharmaceutical benefits		
Item	Column 1 Prescribed pharmaceutical benefit	Column 2 Substitute pharmaceutical benefit
1.	Listed drug: Estradiol Form: Transdermal patches 390 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 25	Listed drug: Estradiol Form: Transdermal patches 750 micrograms (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 25
2.	Listed drug: Estradiol Form: Transdermal patches 750 micrograms (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 25	Listed drug: Estradiol Form: Transdermal patches 390 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 25
3.	Listed drug: Estradiol Form: Transdermal patches 780 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 50	Listed drug: Estradiol Form: Transdermal patches 1.5 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 50
4.	Listed drug: Estradiol Form: Transdermal patches 780 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 50	Listed drug: Estradiol Form: Transdermal patches 390 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 25
5.	Listed drug: Estradiol Form: Transdermal patches 780 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 50	Listed drug: Estradiol Form: Transdermal patches 750 micrograms (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 25

6.	Listed drug: Estradiol Form: Transdermal patches 1.5 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 50	Listed drug: Estradiol Form: Transdermal patches 780 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 50
7.	Listed drug: Estradiol Form: Transdermal patches 1.5 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 50	Listed drug: Estradiol Form: Transdermal patches 390 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 25
8.	Listed drug: Estradiol Form: Transdermal patches 1.5 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 50	Listed drug: Estradiol Form: Transdermal patches 750 micrograms (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 25
9.	Listed drug: Estradiol Form: Transdermal patches 1.17 mg, 8 Manner of administration: Transdermal Brand: Estradot 75	Listed drug: Estradiol Form: Transdermal patches 585 micrograms, 8 Manner of administration: Transdermal Brand: any of the following: (a) Estradot 37.5 (b) Estradiol Transdermal System (Sandoz, USA)
10.	Listed drug: Estradiol Form: Transdermal patches 1.56 mg, 8 Manner of administration: Transdermal Brand: Estradot 100	Listed drug: Estradiol Form: Transdermal patches 3 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 100
11.	Listed drug: Estradiol Form: Transdermal patches 1.56 mg, 8 Manner of administration: Transdermal Brand: Estradot 100	Listed drug: Estradiol Form: Transdermal patches 780 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 50
12.	Listed drug: Estradiol Form: Transdermal patches 1.56 mg, 8 Manner of administration: Transdermal Brand: Estradot 100	Listed drug: Estradiol Form: Transdermal patches 1.5 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 50

13.	Listed drug: Estradiol Form: Transdermal patches 3 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 100	Listed drug: Estradiol Form: Transdermal patches 1.56 mg, 8 Manner of administration: Transdermal Brand: any of the following: (a) Estradot 100 (b) Estradiol Transdermal System (Sandoz, USA)
14.	Listed drug: Estradiol Form: Transdermal patches 3 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 100	Listed drug: Estradiol Form: Transdermal patches 780 micrograms, 8 Manner of administration: Transdermal Brand: Estradot 50
15.	Listed drug: Estradiol Form: Transdermal patches 3 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 100	Listed drug: Estradiol Form: Transdermal patches 1.5 mg (as hemihydrate), 8 Manner of administration: Transdermal Brand: Estraderm MX 50
16.	Listed drug: Insulin isophane Form: Injections (human), cartridges, 100 units per mL, 3 mL, 5 Manner of administration: Injection Brand: Protaphane InnoLet	Listed drug: Insulin isophane Form: Injections (human), cartridges, 100 units per mL, 3 mL, 5 Manner of administration: Injection Brand: Protaphane Penfill 3 mL
17.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: FORMET 1000	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 1000 mg c) Diabex 1000 d) Diaformin 1000 e) Diaformin Viatris f) Glucobete 1000 g) METFORMIN-WGR h) Metformin GH i) Metformin Sandoz
18.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: FORMET 1000	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 1000

		b) Diabex XR 1000 c) Diaformin Alphapharm XR d) Diaformin XR 1000 e) METEX XR f) METFORMIN-WGR XR g) Metformin Sandoz XR h) Pharmacor Metformin XR
19.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin Viatris	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 1000 mg c) Diabex 1000 d) Diaformin 1000 e) Formet 1000 f) Glucobete 1000 g) METFORMIN-WGR h) Metformin GH i) Metformin Sandoz
20.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin Viatris	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 1000 b) Diabex XR 1000 c) Diaformin Alphapharm XR d) Diaformin XR 1000 e) METEX XR f) METFORMIN-WGR XR g) Metformin Sandoz XR h) Pharmacor Metformin XR
21.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin GH	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 1000 mg c) Diabex 1000 d) Diaformin 1000 e) Formet 1000

		f) Glucobete 1000 g) METFORMIN-WGR h) Diaformin Viatris i) Metformin Sandoz
22.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin GH	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 1000 b) Diabex XR 1000 c) Diaformin Alphapharm XR d) Diaformin XR 1000 e) METEX XR f) METFORMIN-WGR XR g) Metformin Sandoz XR h) Pharmacor Metformin XR
23.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin Sandoz	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 1000 mg c) Diabex 1000 d) Diaformin 1000 e) Formet 1000 f) Glucobete 1000 g) METFORMIN-WGR h) Diaformin Viatris i) Metformin GH
24.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin Sandoz	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 1000 b) Diabex XR 1000 c) Diaformin Alphapharm XR d) Diaformin XR 1000 e) METEX XR f) METFORMIN-WGR XR g) Metformin Sandoz XR

h) Pharmacor Metformin XR

25.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin 1000	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 1000 mg c) Diabex 1000 d) Metformin Sandoz e) Formet 1000 f) Glucobete 1000 g) METFORMIN-WGR h) Diaformin Viatris i) Metformin GH
26.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin 1000	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 1 g Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 1000 b) Diabex XR 1000 c) Diaformin Alphapharm XR d) Diaformin XR 1000 e) METEX XR f) METFORMIN-WGR XR g) Metformin Sandoz XR h) Pharmacor Metformin XR
27.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: FORMET 1000	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 500 mg c) Diabex d) Diaformin e) Diaformin Viatris f) FORMET 500 g) Glucobete 500 h) METFORMIN-WGR i) Metformin GH

j) Metformin Sandoz

28.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: FORMET 1000	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 500 b) Diabex XR 500 c) Diaformin Alphapharm XR d) METFORMIN-WGR XR e) Metex XR f) Metformin Sandoz XR g) Pharmacor Metformin XR
29.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin Viatris	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 500 mg c) Diabex d) Diaformin e) Diaformin Viatris f) FORMET 500 g) Glucobete 500 h) METFORMIN-WGR i) Metformin GH j) Metformin Sandoz
30.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin Viatris	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 500 b) Diabex XR 500 c) Diaformin Alphapharm XR d) METFORMIN-WGR XR e) Metex XR f) Metformin Sandoz XR g) Pharmacor Metformin XR

31.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin GH	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 500 mg c) Diabex d) Diaformin e) Diaformin Viatriis f) FORMET 500 g) Glucobete 500 h) METFORMIN-WGR i) Metformin GH j) Metformin Sandoz
32.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin GH	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 500 b) Diabex XR 500 c) Diaformin Alphapharm XR d) METFORMIN-WGR XR e) Metex XR f) Metformin Sandoz XR g) Pharmacor Metformin XR
33.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin Sandoz	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 500 mg c) Diabex d) Diaformin e) Diaformin Viatriis f) FORMET 500 g) Glucobete 500 h) METFORMIN-WGR i) Metformin GH j) Metformin Sandoz

34.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Metformin Sandoz	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 500 b) Diabex XR 500 c) Diaformin Alphapharm XR d) METFORMIN-WGR XR e) Metex XR f) Metformin Sandoz XR g) Pharmacor Metformin XR
35.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin 1000	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APX-METFORMIN b) Blooms The Chemist Metformin 500 mg c) Diabex d) Diaformin e) Diaformin Viatris f) FORMET 500 g) Glucobete 500 h) METFORMIN-WGR i) Metformin GH j) Metformin Sandoz
36.	Listed drug: Metformin Form: Tablet containing metformin hydrochloride 1 g Manner of administration: Oral Brand: Diaformin 1000	Listed drug: Metformin Form: Tablet (extended release) containing metformin hydrochloride 500 mg Manner of administration: Oral Brand: any of the following: a) APO-Metformin XR 500 b) Diabex XR 500 c) Diaformin Alphapharm XR d) METFORMIN-WGR XR e) Metex XR f) Metformin Sandoz XR g) Pharmacor Metformin XR