

National Health (Pharmaceutical Benefits)

(Pharmacist Substitution of Medicines without

Prescription during Shortages) Amendment (No. 2) Determination 2024

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

Dated 28 February 2024

Nikolai Tsyganov

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Department of Health and Aged Care

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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. 2) Determination 2024*.
2. This instrument may also be cited as PB 13 of 2024.

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.

|  |  |  |
| --- | --- | --- |
| **Commencement information** | |  |
| **Column 1** | **Column 2** | **Column 3** |
| **Provisions** | **Commencement** | **Date/Details** |
| 1. The whole of this instrument | 29 February 2024 | 29 February 2024 |

Note: This table relates only to the provisions of this instrument as originally made.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

1. 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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:  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 |
| 2 | 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 |
| 3 | 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 (s19A)  Manner of administration: Oral  Brand: Keforal (s19A) |
| 4 | 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: Capsule 250 mg (as monohydrate)  Manner of administration: Oral  Brands: any of the following:  (a) APO‑Cephalexin  (b) Ibilex 250  (c) Keflex |
| 5 | Listed drug: Cefalexin  Form:  Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL  Manner of administration: Oral  Brand:  any of the following:  (a) Cefalexin Sandoz  (b) Ibilex 250  (c) Keflex | Listed drug: Cefalexin  Form:  Granules for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL  Manner of administration: Oral  Brands: any of the following:  (a) Cefalexin Sandoz  (b) Ibilex 125  (c) Keflex |
| 6 | Listed drug: Cefalexin  Form:  Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL  Manner of administration: Oral  Brand: any of the following:  (a) Cefalexin Sandoz  (b) Ibilex 250  (c) Keflex | Listed drug: Cefalexin  Form:  Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)  Manner of administration: Oral  (a) Brand: Keforal (s19A) |
| 7 | Listed drug: Cefalexin  Form:  Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL  Manner of administration: Oral  Brand: any of the following:  (a) Cefalexin Sandoz  (b) Ibilex 250  (c) Keflex | Listed drug: Cefalexin  Form:  Capsule 250 mg (as monohydrate)  Manner of administration: Oral  Brand: any of the following:  (a) APO‑Cephalexin  (b) Ibilex 250  (c) Keflex |
| 8 | Listed drug:  Fluoxetine  Form:   Tablet, dispersible, 20 mg (as hydrochloride)  Manner of administration: Oral  Brand:  Zactin Tablet | Listed drug:  Fluoxetine  Form:    Capsule 20 mg (as hydrochloride)  Manner of administration: Oral  Brand:   any of the following:  (a) APO‑Fluoxetine  (b) BTC Fluoxetine  (c) Blooms the Chemist Fluoxetine  (d) FLUOTEX  (e) Fluoxetine APOTEX  (f) Fluoxetine Sandoz  (g) Fluoxetine generichealth  (h) NOUMED FLUOXETINE  (i) Prozac 20  (j) Zactin |
| 9 | Listed drug:  Fluoxetine  Form:   Tablet, dispersible, 20 mg (as hydrochloride)  Manner of administration: Oral  Brand:  Zactin Tablet | Listed drug:  Fluoxetine  Form:    Capsule 10 mg (Medreich) (S19A)  Manner of administration: Oral  Brand: Fluoxetine Capsules 10 mg (Medreich, UK) |
| 10 | Listed drug: Gliclazide  Form: Tablet 30 mg (modified release)  Manner of administration: Oral  Brand: any of the following:   1. APO-Gliclazide MR 2. Gliclazide MR Viatris 3. Pharmacor Gliclazide MR | Listed drug: Gliclazide  Form: Tablet 60 mg (modified release)  Manner of administration: Oral  Brand: any of the following:   1. ARDIX GLICLAZIDE 60mg MR 2. Diamicron 60mg MR 3. Gliclazide Lupin MR 4. Pharmacor Gliclazide MR |