

Therapeutic Goods (Authorised Supply) Amendment (Medicines and Medical Devices) Rules 2022

I, Jane Cook, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 9 February 2022

Dr Jane Cook

Chief Medical Adviser
Health Products Regulation Group
Department of Health

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1 Name

 This instrument is the *Therapeutic Goods (Authorised Supply) Amendment (Medicines and Medical Devices) Rules 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.

| Commencement information |
| --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | The day after this instrument is registered. |  |

Note: This table relates only to the provisions of this instrument as originally made.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 subsections 19(7A) and 41HC(6) of the *Therapeutic Goods Act 1989*.

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 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Part 1—Medicines

Therapeutic Goods (Medicines—Authorised Supply) Rules 2020

1 Schedule 1 (table item 1)

Repeal the item.

2 Schedule 1 (table items 10 and 11)

Repeal the items.

3 Schedule 1 (before table item 12)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 11A | ciclosporin, 0.05% | eye drops, emulsion | ophthalmic | treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye syndrome) |

4 Schedule 1 (after table item 16)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 16A | colecalciferol | capsule | oral | treatment of severe vitamin D deficiency and prevention of osteoporosis |
| 16B | colecalciferol | injection | intramuscular | treatment of severe vitamin D deficiency and prevention of osteoporosis |

5 Schedule 1 (table item 18)

Repeal the item.

6 Schedule 1 (after table item 26)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 26A | disulfiram | tablet | oral | deterrent to alcohol consumption |

7 Schedule 1 (after table item 40)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 40A | iloprost | injection | intravenous infusion | treatment of patients with severe disabling Raynaud’s phenomenon; ortreatment of peripheral ischaemia |

8 Schedule 1 (after table item 42)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 42A | interferon alpha-2b | eye drops | ophthalmic | treatment of ocular surface squamous neoplasia |

9 Schedule 1 (after table item 46)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 46A | lifitegrast | eye drops | ophthalmic | treatment of dry eye disease |

10 Schedule 1 (after table item 62)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 62A | progesterone | injection | subcutaneous | treatment of progesterone deficiency |
| 62B | progesterone in oil | injection | intramuscular | treatment of progesterone deficiency |

11 Schedule 1 (after table item 71)

Insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 71A | Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S | injection | intravenous | prostate cancer imaging study |

Part 2—Medical devices

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020

12 Schedule 1 (table item 4)

Repeal the item.

13 Schedule 1 (before table item 5)

Insert:

|  |  |  |  |
| --- | --- | --- | --- |
| 4A | AltiVate Reverse Shoulder system – DJO Global | for arthroplasty of the shoulder | orthopaedic surgeon |

14 Schedule 1 (table item 5, column 4)

Omit “medical practitioner”, substitute “general surgeon”.

15 Schedule 1 (table item 6, column 4)

Omit “medical practitioner”, substitute “obstetrics and gynaecology specialist”.

16 Schedule 1 (after table item 10)

Insert:

|  |  |  |  |
| --- | --- | --- | --- |
| 10A | Duraloc Acetabular Cup System – Hip Insert/Liner – Johnson & Johnson t/a DePuy Synthes | revision hip arthroplasty | orthopaedic surgeon |

17 Schedule 1 (table item 11, column 4)

Omit “medical practitioner”, substitute “obstetrics and gynaecology specialist”.

18 Schedule 1 (table item 12, column 4)

Omit “medical practitioner”, substitute “obstetrics and gynaecology specialist”.

19 Schedule 1 (table item 13, column 4)

Omit “medical practitioner”, substitute “obstetrics and gynaecology specialist”.

20 Schedule 1 (table item 14, column 4)

Omit “medical practitioner”, substitute “plastic surgeon”.

21 Schedule 1 (table item 15, column 4)

Omit “medical practitioner”, substitute “plastic surgeon”.

22 Schedule 1 (table item 17, column 4)

Omit “medical practitioner”, substitute “obstetrics and gynaecology specialist”.

23 Schedule 1 (table item 21, column 4)

Omit “medical practitioner”, substitute “cardiothoracic surgeon”.

24 Schedule 1 (table item 22)

Repeal the item.

25 Schedule 1 (table item 23)

Repeal the item.

26 Schedule 1 (table item 26, column 2)

Omit “Durasel”, substitute “Durasul PE”.

27 Schedule 1 (after table item 31)

Insert:

|  |  |  |  |
| --- | --- | --- | --- |
| 31A | Primetech Piezo Micro Manipulator and microinjection pipettes | in vitro fertilisation | obstetrics and gynaecology specialist |

28 Schedule 1 (after table item 35)

Insert:

|  |  |  |  |
| --- | --- | --- | --- |
| 35A | Regeneten Bioinductive Implant – Bone Anchors with Anthroscopic Delivery System | rotator cuff surgery | orthopaedic surgeon |