



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

Contents

1 Name.....	1
2 Commencement.....	1
3 Authority.....	1
4 Schedules.....	1
Schedule 1—Amendments	2
Part 1—Medicines	2
<i>Therapeutic Goods (Medicines—Authorised Supply) Rules 2020</i>	2
Part 2—Medical devices	3
<i>Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020</i>	3

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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	colecalfiferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
16B	colecalfiferol	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; or treatment 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	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
-----	---	----------------------	---------------------