Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020

made under subsection 41HC(6) of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 11 February 2022

Includes amendments up to: F2022L00123

Prepared by the Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020* that shows the text of the law as amended and in force on 11 February 2022 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020*.

3 Authority

This instrument is made under subsection 41HC(6) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) health practitioner;
(b) included in the Register;
(c) medical device;
(d) Register;
(e) sponsor; and
(f) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

SAS Guidance means the document titled *Special Access Scheme Guidance for health practitioners and sponsors* (Version 1.1, September 2017) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods Administration has the same meaning as in the *Therapeutic Goods Regulations 1990*.

5 Authorisation

Supply by a specified health practitioner

(1) A health practitioner specified in column 4 of an item in the table in Schedule 1 is authorised to supply a kind of medical device to a patient of that practitioner where:

(a) the kind of medical device is specified in column 2 of that item; and
(b) the supply is for the purpose specified in column 3 of that item; and
(c) the conditions specified in subsection (2) are satisfied.

(2) The health practitioner must:

(a) inform the patient, or a parent or guardian of the patient, that the kind of medical device is not included in the Register; and
(b) obtain informed consent from the patient, or a parent or guardian of the patient, in relation to, and before, the supply of the kind of medical device; and

(c) supply the kind of medical device in accordance with good medical practice; and

(d) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the kind of medical device about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(e) if the health practitioner becomes aware of a defect in the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the kind of medical device in accordance with the reporting guidelines set out in the SAS Guidance.

Supply to a patient of a specified health practitioner

(3) A health practitioner is authorised to supply a kind of medical device to a patient of a health practitioner specified in column 4 of an item in the table in Schedule 1 (the ***treating practitioner***) where:

(a) the kind of medical device is specified in column 2 of that item; and

(b) the supply is requested by the treating practitioner; and

(c) the supply is for the purpose specified in column 3 of that item; and

(d) the conditions specified in subsection (4) are satisfied.

(4) The health practitioner supplying the medical device must:

(a) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the kind of medical device about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(b) if the health practitioner becomes aware of a defect in the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the medical device in accordance with the reporting guidelines set out in the SAS Guidance.

Schedule 1—Medical devices authorised for supply

Note: See section 5.

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
1	14/16 Taper Femoral Heads – Oxinium – Smith & Nephew (71342280 – 71342368)	revision hip arthroplasty	orthopaedic surgeon
2	Aequalis PerForm Plus Reversed Glenoid – Wright Medical	for arthroplasty of the shoulder	orthopaedic surgeon
3	Aequalis PerForm Reversed Glenoid – Wright Medical	for arthroplasty of the shoulder	orthopaedic surgeon
4A	AltiVate Reverse Shoulder system – DJO Global	for arthroplasty of the shoulder	orthopaedic surgeon
5	Biodesign Enterocutaneous Fistula Plug	for repair of enterocutaneous fistulae	general surgeon
6	BlastGen (Product No. 1205)	culture of embryos from the 4-8 cell stage through to the blastocyst stage; or embryo transfer	obstetrics and gynaecology specialist
7	CelGro Type I/III collagen scaffold – Orthocell	articular cartilage repair: collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint; or augmentation of rotator cuff tendon repair	orthopaedic surgeon
8	CollaCote Dressing	for haemostasis or to protect the wound surface during dental procedures	dental practitioner
9	CollaPlug Absorbable Collagen Wound Dressing	for haemostasis or to protect the wound surface during dental procedures	dental practitioner
10	CollaTape Absorbable Collagen	for haemostasis or to protect the wound surface during dental procedures	dental practitioner
10A	Duraloc Acetabular Cup System – Hip Insert/Liner – Johnson & Johnson t/a DePuy Synthes	revision hip arthroplasty	orthopaedic surgeon
11	EmbryoGen (Product No. 1203)	fertilisation and culture until the 2-8 cell stage; or embryo transfer at day 2 or 3	obstetrics and gynaecology specialist

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
12	EmbryoGen & BlastGen (Product No. 1206)	culture of embryos until the 2-8 cell stage (Embryogen) and culture of embryos from the 4-8 cell stage through to the blastocyst stage (Blastgen); or embryo transfer	obstetrics and gynaecology specialist
13	EmbryoGen V2 (Product No. 1204)	culture of human embryos until the 2-8 cell stage; or embryo transfer at day 2 or 3	obstetrics and gynaecology specialist
14	Endotine Forehead	for use in subperiosteal browplasty surgery	plastic surgeon
15	Endotine Midface	for use in subperiosteal midface suspension surgery	plastic surgeon
16	Geistlich Fibro-Gide – Geistlich Pharma	dental filling material	dental practitioner
17	GM508 CultActive	for investigation of fertilization failure after previous ICSI-cycles	obstetrics and gynaecology specialist
18	Ilex Skin Protectant	for use on a variety of dermal wounds and stomal irritations as a topical skin barrier	medical practitioner; nurse practitioner
19	Insall/Burstein II Modular Knee System - Posterior Stabilised Tibial Articular Surface – Zimmer Biomet (00522003101 – 00522003506)	revision knee arthroplasty	orthopaedic surgeon
20	Journey II Bi-Cruciate Stabilized (BCS) Total Knee System - Articular Insert – Smith & Nephew (74027211 – 74027288)	revision knee arthroplasty	orthopaedic surgeon
21	Jupiter Sternal Protection Device	for use following median sternotomy incisions to add a protective layer over the entire cut surfaces of the sternal bone	cardiothoracic surgeon
24	MG II Total Knee System - Tibial Articular Surface – Zimmer Biomet (00511002309 – 00511005323)	revision knee arthroplasty	orthopaedic surgeon
25	M/G Unicompartmental Knee System - Tibial Articulating Surface – Zimmer Biomet	revision knee arthroplasty	orthopaedic surgeon

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
	(00578804008 – 00578808014)		
26	Natural Knee II System – Durasul PE Congruent Tibial Insert – Zimmer Biomet (620108809 – 620110916)	revision knee arthroplasty	orthopaedic surgeon
27	NexGen Complete Knee Solution – Cruciate Retaining (CR) Articular Surface – Zimmer Biomet (00597002009 – 00597005020)	revision knee arthroplasty	orthopaedic surgeon
28	NexGen Complete Knee Solution Legacy PS - Articular Surface – Zimmer Biomet (5996-020-09 to 00-5996-022-23 AND 00-5996-030-09 to 00-5996-051-20)	revision knee arthroplasty	orthopaedic surgeon
29	NexGen Complete Knee Solution Mobile Bearing Knee System - Articular Surface – Zimmer Biomet (00594203109 – 00594207217)	revision knee arthroplasty	orthopaedic surgeon
30	NexGen Complete Knee Solution – Posterior Stabilized (PS) Articular Surface – Zimmer Biomet (00598202010 – 00598205123)	revision knee arthroplasty	orthopaedic surgeon
31	Omnifit Crossfire Series II Cup Insert – Stryker Orthopaedics (2041C2240 - 2041C3274)	revision hip arthroplasty	orthopaedic surgeon
31A	Primetech Piezo Micro Manipulator and microinjection pipettes	in vitro fertilisation	obstetrics and gynaecology specialist
32	Pro Osteon® Bone Graft Substitute 200R	for use as a bone graft substitute only for bony voids or gaps that are not intrinsic to the stability of the bony structure	medical practitioner; dental practitioner
33	Pro Osteon® Bone Graft Substitute 500R	for use as a bone graft substitute only for voids or gaps that are not intrinsic to the stability of the	medical practitioner

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
		bony structure	
34	Quintip Individual Skin Test System	for allergy skin testing using puncture to apply the test extract	medical practitioner
35	Reflection Ceramic Acetabular System - Reflection Biolox Forte Ceramic Acetabular Liner – Smith & Nephew (71338146 – 71338456)	revision hip arthroplasty	orthopaedic surgeon
35A	Regeneten Bioinductive Implant – Bone Anchors with Anthroscopic Delivery System	rotator cuff surgery	orthopaedic surgeon
36	SeleXys Hip System – Inlay Bionit2 – Mathys Orthopaedics (55462803 – 55463612)	revision hip arthroplasty	orthopaedic surgeon
37	Trilogy AB Alternate Bearing Shell Insert – Zimmer Biomet (00640502601 – 00640503206 AND 00641502802 – 00641503206)	revision hip arthroplasty	orthopaedic surgeon

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

<u>underlining</u> = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020	17 Sep 2020 (F2020L01174)	18 Sep 2020	—
Therapeutic Goods (Authorised Supply) Amendment (Medicines and Medical Devices) Rules 2022	10 Feb 2022 (F2022L00123)	11 Feb 2022	—

Endnote 4—Amendment history

Provision affected	How affected
s 2	rep LA s 48D
s 6	rep LA s 48C
Sch 1	am F2022L00123
Sch 2	rep LA s 48C