



Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 23 July 2020

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*.

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. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	24 July 2020
2. Schedule 1	At the same time as Part 1 of Schedule 1 to the <i>Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020</i> commences.	25 August 2020
3. Schedules 2 to 4	The day after this instrument is registered.	24 July 2020
4. Schedule 5	At the same time as Schedule 2 to the <i>Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020</i> commences.	23 July 2020
5. Schedule 6	At the same time as Schedule 4 to the <i>Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020</i> commences.	23 July 2020
6. Schedule 7	The day after this instrument is registered.	24 July 2020
7. Schedule 8, Part 1	The day after this instrument is registered.	24 July 2020
8. Schedule 8, Part 2	25 November 2021.	25 November 2021
9. Schedules 9 and 10	The day after this instrument is registered.	24 July 2020

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Part 1—Medical device definitions

Therapeutic Goods (Medical Devices) Regulations 2002

1 Dictionary

Insert:

instructions for use, in relation to a medical device, includes information provided by the manufacturer of the device to inform a user of the device of the intended purpose of the device, of the proper use of the device and of any precautions to be taken in relation to the use of the device.

Note: These Regulations contain requirements relating to instructions for use of a medical device. For example, clauses 13.1 to 13.4 of Schedule 1 (about essential principles) deal with information that must be included in instructions for the use of a medical device.

2 Dictionary (paragraph (b) of the definition of *reusable surgical instrument*)

After “appropriate procedures”, insert “(such as cleaning, disinfection and sterilisation)”.

3 Dictionary

Insert:

user of a medical device means any person (including a health professional) who uses the device.

Part 2—System or procedure packs

Therapeutic Goods (Medical Devices) Regulations 2002

4 Paragraphs 3.10(1)(d) and (e)

Repeal the paragraphs, substitute:

- (d) a system or procedure pack to which subregulation (3) applies.

5 Subregulation 3.10(1) (notes)

Repeal the notes, substitute:

- Note 1: An *exempt device* is a medical device of a kind that is exempted from the operation of Division 3 of Part 4-11 of the Act by the regulations (see subsection 3(1) of the Act). Division 7.1 and Schedule 4 to these Regulations deal with exempt devices.
- Note 2: For a system or procedure pack to which paragraph (1)(d) applies and that contains an IVD medical device and a medical device that is not an IVD medical device:
 - (a) the system or procedure pack is classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A; and
 - (b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures for medical devices used for a special purpose in clause 7.5 of Schedule 3.
- Note 3: For a system or procedure pack to which paragraph (1)(d) does not apply:
 - (a) the system or procedure pack is classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A; and
 - (b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures that apply to the relevant classification.

6 Subregulation 3.10(1A)

Repeal the subregulation, substitute:

Exception

- (1A) However, paragraphs (1)(a), (b) and (c) do not apply to a Class 1 in-house IVD medical device, a Class 2 in-house IVD medical device or a Class 3 in-house IVD medical device.

Note: The conformity assessment procedures that must be applied to Class 1 in-house IVD medical devices, Class 2 in-house IVD medical devices or Class 3 in-house IVD medical devices are the procedures mentioned in Part 6A of Schedule 3.

7 Paragraph 3.10(3)(a)

Repeal the paragraph, substitute:

- (a) where each medical device included in the system or procedure pack is a medical device to which the relevant conformity assessment procedures have been applied; and
- (aa) if one or more medicines, biologicals or other therapeutic goods are included in the system or procedure pack—where each such medicine, biological or other therapeutic goods are entered on the Register; and

8 Subregulation 3.10(4) (note)

Omit “the package contains a medicine”, substitute “a medicine is included in the system or procedure pack”.

9 Paragraph 7.5(2)(c) of Schedule 3

Omit “or, if relevant, the contents of packaging”, substitute “or the contents of the system or procedure pack”.

10 Paragraph 7.5(2)(d) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

11 Subparagraphs 7.5(2)(e)(i) and (ii) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

12 Paragraph 7.5(2)(f) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

13 Paragraph 7.5(2)(g) of Schedule 3

Omit “package” (wherever occurring), substitute “system or procedure pack”.

14 Subparagraph 7.5(2)(h)(i) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

15 Paragraph 7.5(2)(i) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

16 Paragraph 7.5(2)(j) of Schedule 3

After “packaging”, insert “(if any)”.

17 Paragraph 7.5(2)(j) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

18 Paragraph 7.5(2)(k) of Schedule 3

Omit “package”, substitute “system or procedure pack”.

Schedule 2—Exemption of hyperbaric oxygen therapy hoods

Therapeutic Goods (Medical Devices) Regulations 2002

1 Part 1 of Schedule 4 (after table item 1.3)

Insert:

- 1.3A Medical device that is an oxygen administration hood for use in a hyperbaric chamber for hyperbaric oxygen therapy

Schedule 3—Period for notifying adverse events

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subregulation 5.7(1)

After “subsection 41MP(2)”, insert “or 41MPA(2)”.

2 At the end of subregulation 5.7(1)

Add:

; and (d) in any other case—60 days after the person becomes aware of the information.

3 After regulation 10.4

Insert:

10.4AA Civil penalty—period for notifying adverse events

For the purposes of paragraph 41MPA(1)(c) of the Act, the period for giving information of a kind mentioned in subsection 41MPA(2) of the Act is the relevant period specified in regulation 5.7.

4 Subclause 1.4(3) of Schedule 3 (note)

Omit “section 41MP”, substitute “sections 41MP and 41MPA”.

5 Subclause 3.4(2) of Schedule 3 (note)

Omit “section 41MP”, substitute “sections 41MP and 41MPA”.

6 Subclause 4.4(3) of Schedule 3 (note)

Omit “section 41MP”, substitute “sections 41MP and 41MPA”.

7 Subclause 5.4(3) of Schedule 3 (note)

Omit “section 41MP”, substitute “sections 41MP and 41MPA”.

8 Subclause 6.5(2) of Schedule 3 (note)

Omit “section 41MP”, substitute “sections 41MP and 41MPA”.

9 Subclause 7.5(4) of Schedule 3 (note)

Omit “section 41MP”, substitute “sections 41MP and 41MPA”.

Schedule 4—Approving supply of therapeutic goods under authorised prescriber scheme

Therapeutic Goods Regulations 1990

1 After subregulation 12B(1A)

Insert:

- (1B) For the purposes of subsection 19(6) of the Act, paragraph 19(6)(aa) of the Act does not apply if the supply is of a medicine by the medical practitioner to a patient of that practitioner, where:
- (a) the medicine contains an active ingredient specified in column 2 of an item in the following table and does not contain any other active ingredient; and
 - (b) the medicine only contains the active ingredient in the strength and concentration (if any) specified in column 2 of that item; and
 - (c) the medicine is in the dosage form specified in column 3 of that item; and
 - (d) the medicine is to be administered by the route specified in column 4 of that item; and
 - (e) the supply is for the indication specified in column 5 of that item.

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
1	aciclovir	eye ointment	ophthalmic	treatment of herpes simplex keratitis
2	allergens—multiple, various (including control solutions)	drops	intradermal	confirmation of suspected allergic reactions
3	allergens – multiple, various (including control solutions)	drops	skin prick	confirmation of suspected allergic reactions
4	amifampridine (3,4-diaminopyridine)	tablet	oral	treatment of Lambert-Eaton Myasthenic Syndrome
5	betaxolol 0.25% (preservative free)	eye drops	ophthalmic	treatment of elevated intraocular pressure where other treatments are inappropriate
6	bismuth subcitrate	tablet	oral	treatment of resistant <i>Helicobacter Pylori</i> infection
7	buspirone	tablet	oral	treatment of generalised anxiety disorders
8	calcitriol	liquid	oral	prevention of hypophosphatemic rickets in children; or treatment of hypoparathyroidism (with severe hypocalcaemia)

Schedule 4 Approving supply of therapeutic goods under authorised prescriber scheme

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
9	carbidopa	tablet	oral	premedication for F-18 DOPA imaging
10	cholecalciferol	capsule	oral	treatment of severe vitamin D deficiency and prevention of osteoporosis
11	cholecalciferol	injection	intramuscular	treatment of severe vitamin D deficiency and prevention of osteoporosis
12	cinnarizine	tablet	oral	treatment of vestibular disorders such as vertigo, tinnitus, nausea and vomiting (including Meniere's disease).
13	clobetasol propionate 0.05%	cream	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
14	clobetasol propionate 0.05%	lotion	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
15	clobetasol propionate 0.05%	ointment	topical	treatment, or prolongation of flare-free intervals, of dermatitis/eczema where other treatments have failed
16	clofazimine	capsule	oral	treatment of Leprosy, granulomatous cheilitis, Melkersson Rosenthal Syndrome, confirmed <i>mycobacterium avium</i> paratuberculosis in immunocompromised patients recommended by an infectious disease specialist, erythema nodosum leprosum, drug resistant tuberculosis, non-tuberculosis mycobacterial infections or other infections as recommended by an infectious diseases specialist
17	cyclopentolate, 0.2%, and phenylephrine, 1%	eye drops	ophthalmic	production of mydriasis
18	cyclosporin, 0.05%	eye drops, emulsion	ophthalmic	treatment of suppressed tear production due to ocular inflammation associated with keratoconjunctivitis

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
				sicca (dry eye syndrome)
19	deflazacort	tablet	oral	treatment of Duchenne muscular dystrophy
20	dehydrated ethanol (alcohol) 96% - 100%	ampoule	topical	treatment of progressive keratoconus and intra-operative use in superficial keratectomy (single use per procedure)
21	dexamethasone (preservative free)	eye drops	ophthalmic	treatment of inflammatory conditions of the eye that are non-infected and steroid responsive in patients sensitive to preservative-containing formulations
22	diazoxide	tablet	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
23	diazoxide	capsule	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
24	diazoxide	suspension	oral	treatment of hypoglycaemia, hyperinsulinaemia, Beckwith-Weiderman Syndrome or insulinoma
25	diflunisal	tablet	oral	treatment of amyloidosis
26	dimethyl sulfoxide (DMSO)	solution	intravesical	symptomatic relief of interstitial cystitis
27	doxycycline	injection	intralesional	sclerotherapy of lymphatic malformations
28	F-18 DCFPyl (PSMA)	injection	intravenous	prostate cancer imaging study
29	F-18 myocardial perfusion tracer (18F flurpiridaz)	injection	intravenous	myocardial perfusion study
30	F-18 NaF (sodium fluoride)	injection	intravenous	bone study
31	flunarizine	tablet	oral	treatment of vestibular disorders or prophylactic treatment of migraine
32	flunarizine	capsule	oral	treatment of vestibular disorders or prophylactic treatment of migraine

Schedule 4 Approving supply of therapeutic goods under authorised prescriber scheme

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
33	furazolidone	tablet	oral	treatment of resistant <i>Helicobacter Pylori</i> infection
34	Gallium-68 (Ga-68) Galligas	aerosol	inhalation	lung ventilation study
35	Gallium-68 (Ga-68) - MAA	injection	intravenous	lung perfusion study
36	Gallium-68 prostate specific membrane antigen (PSMA)	injection	intravenous	prostate cancer imaging study
37	glycopyrronium bromide	tablet	oral	treatment of excessive salivation in patients with neurological conditions
38	hyoscine hydrobromide	patch	transdermal	treatment of excessive salivation
39	hypertonic sodium chloride, 5 %	eye ointment	ophthalmic	temporary relief of corneal oedema (hypertonicity)
40	hypertonic sodium chloride, 5%	eye drops	ophthalmic	temporary relief of corneal oedema (hypertonicity)
41	indigo carmine	injection	intravenous	intraoperative detection of suspected urethral injuries during abdominal and pelvic surgical procedures
42	indocyanine green dye	injection	intravenous	intra-operative diagnostic use
43	levofloxacin	tablet	oral	treatment of resistant <i>Helicobacter Pylori</i> infection or drug resistant tuberculosis
44	levomepromazine	tablet	oral	treatment of nausea and vomiting or agitation
45	levomepromazine	injection	subcutaneous	treatment of nausea and vomiting or agitation
46	lorazepam	injection	parenteral	treatment of acute severe behavioural episodes in the hospital setting
47	ketotifen	tablet	oral	treatment of allergic conditions
48	melatonin	syrup	oral	treatment of sleep disorders
49	melatonin	capsule	oral	treatment of sleep disorders
50	melatonin	immediate release tablet	oral	treatment of sleep disorders
51	melatonin	lozenge	oral	treatment of sleep disorders
52	mexiletine	tablet	oral	treatment of ventricular arrhythmia or myotonic disorders

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
53	mexiletine	capsule	oral	treatment of ventricular arrhythmia or myotonic disorders
54	moxifloxacin 0.5%	eye drops	ophthalmic	treatment of refractory bacterial conjunctivitis
55	nadolol	tablet	oral	treatment of ventricular tachycardia or long QT Syndrome
56	natamycin 5%	eye drops	ophthalmic	treatment of refractory fungal blepharitis, conjunctivitis or keratitis
57	neomycin	tablet	oral	sepsis prevention for colorectal operation
58	nicotine in solution, salt or base form	liquid or solid	inhalation	smoking cessation
59	nitazoxanide	tablet	oral	treatment of giardiasis, cryptosporidiosis or blastocystis
60	nitazoxanide	suspension	oral	treatment of giardiasis, cryptosporidiosis or blastocystis
61	paromomycin	capsule	oral	antiprotozoal treatment of any of the following amoebic infections: (a) <i>blastocystis hominis</i> ; (b) <i>dientamoeba fragilis</i> ; (c) <i>entamoeba histolytica</i> ; (d) parasite infection
62	pimozide	tablet	oral	treatment of schizophrenia, chronic psychosis or Tourette syndrome
63	pristinamycin	tablet	oral	treatment of confirmed methicillin-resistant <i>Staphylococcus aureus</i> or vancomycin-resistant <i>enterococci</i> infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone/joint/prosthesis; or treatment of refractory or resistant <i>mycoplasma genitalium</i> infections; or treatment of other infections as prescribed by an infectious disease

Schedule 4 Approving supply of therapeutic goods under authorised prescriber scheme

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
				specialist
64	pyrazinamide	tablet	oral	treatment of tuberculosis
65	riboflavin, 0.1% in 20% dextran	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
66	riboflavin, 0.1% in 1.1% hydroxypropyl methylcellulose (HPMC)	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
67	riboflavin, 0.1% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
68	riboflavin, 0.22% in sodium chloride	eye drops	ophthalmic	intraoperative use in corneal collagen crosslinking (CXL) procedures for the treatment of progressive keratoconus
69	ripasudil 0.4%	eye drops	ophthalmic	treatment of refractory corneal oedema or refractory glaucoma
70	sodium benzoate	tablet	oral	treatment of urea cycle disorders
71	tacrolimus 0.03%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in children
72	tacrolimus 0.1%	ointment	topical	treatment, or prolongation of flare-free intervals, of moderate to severe atopic dermatitis/eczema in adults
73	tizanidine	capsule	oral	treatment of spasticity where other treatments have failed
74	tizanidine	tablet	oral	treatment of spasticity where other treatments have failed
75	tetracycline	capsule	oral	treatment of resistant <i>Helicobacter Pylori</i>

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active ingredient	Dosage form	Route of administration	Indication
				infection
76	tetracycline	tablet	oral	treatment of resistant <i>Helicobacter Pylori</i> infection
77	tick-borne encephalitis vaccine	injection	intramuscular	prevention of tick-borne encephalitis
78	tinidazole	tablet	oral	treatment of <i>trichomonas vaginalis</i> infections of the genito-urinary tract in female and male patients, giardiasis, amoebic dysentery or amoebic liver abscess; or treatment of acute giardiasis, acute amoebic dysentery or amoebic liver disease in children; or prevention of infection of the surgical site
79	triamcinolone acetonide	suspension for injection	ophthalmic	treatment of non-infectious uveitis, visualisation during vitrectomy, diabetic macular oedema, cystoid macular oedema secondary to retinal vein occlusion, uveitic macular oedema or post-operative macular oedema (cataract surgery)
80	verteporfin	powder for injection	intravenous infusion	photosensitisation for photodynamic therapy
81	yttrium-90 (Y-90) Citrate	injection	intraarticular	radiosynovectomy treatment

Schedule 5—Scientific advice about quality of medicine

Therapeutic Goods Regulations 1990

1 After Part 2D

Insert:

Part 2E—Scientific advice about aspects of quality, safety or efficacy of medicine

10M Scientific advice about aspects of quality, safety or efficacy of medicine

For the purposes of subsection 22G(1) of the Act, a prescribed aspect of the quality of a medicine for oral ingestion is in vitro bioequivalence.

2 Clause 3 of Schedule 9 (after table item 1AB)

Insert:

1ABA	Fee for the purposes of paragraph 22G(8)(b) of the Act for a request under section 22G of the Act	8,570
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Schedule 6—Preliminary assessment of applications for variation of permissible ingredients determination

Therapeutic Goods Regulations 1990

1 Regulation 2 (definition of IN1 application)

Omit “subsection 26BE(1)”, substitute “subsection 26BD(1)”.

2 Regulation 2 (definition of IN2 application)

Omit “subsection 26BE(1)”, substitute “subsection 26BD(1)”.

3 Regulation 2 (definition of IN3 application)

Omit “subsection 26BE(1)”, substitute “subsection 26BD(1)”.

4 Regulation 2 (definition of IN4 application)

Omit “subsection 26BE(1)”, substitute “subsection 26BD(1)”.

5 Regulation 16GI (heading)

Repeal the heading, substitute:

16GI Registration and listing of certain medicines—notification of preliminary assessment of applications and period within which decisions on recommendations must be made

6 Paragraph 16GI(1)(a)

Omit “been accepted or rejected”, substitute “passed preliminary assessment”.

7 Paragraph 16GI(1)(b)

Omit “if the application is accepted—”, substitute “if the application passes preliminary assessment—subject to subregulation (1A),”.

8 Subregulation 16GI(1) (table)

Repeal the table, substitute:

Notification of preliminary assessment of applications and period within which decisions on recommendations must be made

Item	Column 1 Kind of application	Column 2 Notification of preliminary assessment	Column 3 Decision on recommendation
1	IN1 application	Within 40 working days after the Secretary receives the application	The period of 70 working days beginning on the later of the following days: (a) the day the Secretary notifies the applicant that the application has passed preliminary assessment; (b) the day the evaluation fee is paid for the

Schedule 6 Preliminary assessment of applications for variation of permissible ingredients determination

Notification of preliminary assessment of applications and period within which decisions on recommendations must be made

Item	Column 1 Kind of application	Column 2 Notification of preliminary assessment	Column 3 Decision on recommendation application
2	IN2 application	Within 40 working days after the Secretary receives the application	The period of 120 working days beginning on the later of the following days: (a) the day the Secretary notifies the applicant that the application has passed preliminary assessment; (b) the day the evaluation fee is paid for the application
3	IN3 application	Within 40 working days after the Secretary receives the application	The period of 150 working days beginning on the later of the following days: (a) the day the Secretary notifies the applicant that the application has passed preliminary assessment; (b) the day the evaluation fee is paid for the application
4	IN4 application	Within 40 working days after the Secretary receives the application	The period of 180 working days beginning on the later of the following days: (a) the day the Secretary notifies the applicant that the application has passed preliminary assessment; (b) the day the evaluation fee is paid for the application

9 After subregulation 16GI(1)

Insert:

(1A) If:

- (a) an application (the **current application**) is made under subsection 26BD(1) of the Act in relation to an ingredient; and
- (b) the Secretary gives a notice under subsection 26BD(5) of the Act to the applicant stating that the current application has passed preliminary assessment; and
- (c) at the time the Secretary gives the notice, there is no determination in force under subsection 26BB(1) of the Act in relation to that ingredient; and
- (d) at the time the Secretary gives the notice, there are one or more other applications (each of which is a **related application**) that:
 - (i) have already been made under subsection 26BD(1) of the Act in relation to that ingredient; and
 - (ii) have already been the subject of notices given under subsection 26BD(5) of the Act; and
 - (iii) have not been finally determined;

then a decision on whether to make a recommendation on the current application must be made within the period of:

- (e) if the current application is an IN1 application—70 working days beginning on the later of the start day and the day the evaluation fee is paid for the current application; or
- (f) if the current application is an IN2 application—120 working days beginning on the later of the start day and the day the evaluation fee is paid for the current application; or
- (g) if the current application is an IN3 application—150 working days beginning on the later of the start day and the day the evaluation fee is paid for the current application; or
- (h) if the current application is an IN4 application—180 working days beginning on the later of the start day and the day the evaluation fee is paid for the current application.

(1B) For the purposes of this regulation, the *start day* is:

- (a) the day after all the related applications have been finally determined, unless paragraph (b) applies; or
- (b) if a determination is made under subsection 26BB(1) of the Act in relation to the ingredient—the day on which that determination commences.

(1C) For the purposes of this regulation, an application is *finally determined* when the application, and any applications for review or appeals arising out of it, have been finally determined or otherwise disposed of.

10 Subregulation 16GI(2)

Omit “A failure to decide an application mentioned in column 1 of an item of the table in subregulation (1) within the period mentioned in column 3 of the item”, substitute “A failure to make a decision on whether to make a recommendation on an application within the period applicable under this regulation”.

11 Clause 5 of Schedule 9 (table items 28, 30, 32 and 34)

Omit “paragraph 26BE(2)(d)”, substitute “paragraph 26BD(3)(c)”.

Schedule 7—In-house IVD medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

1 At the end of clause 6B.1 of Schedule 3

Add:

- ; (f) notify the Secretary of the manufacture of certain Class 4 in-house IVD medical devices.

2 At the end of Part 6B of Schedule 3

Add:

6B.8 Notification of certain Class 4 in-house IVD medical devices being manufactured

- (1) The manufacturer of a kind of Class 4 in-house IVD medical device that the manufacturer intends to be used to detect the presence of, or exposure to, transmissible agents in blood, stool or other specimens from a person's body in order to assess the suitability of the person to be a donor of human stool for use in the manufacture of a faecal microbiota transplant product must notify the Secretary, in accordance with subclauses (2) and (3), about that kind.
- (2) A notification under subclause (1) must:
 - (a) be in a form approved in writing by the Secretary; and
 - (b) contain the information required by the form.
- (3) A notification under subclause (1) must be given to the Secretary:
 - (a) if the manufacturer manufactures such a kind of Class 4 in-house IVD medical device on or after the commencement of this clause and before 1 July 2021—no later than 20 working days after 1 July 2021; and
 - (b) if, on or after 1 July 2021, the manufacturer manufactures such a kind of Class 4 in-house IVD medical device—no later than 20 working days after the manufacture.
- (4) Only one notification is required under this clause in relation to each kind of Class 4 in-house IVD medical device manufactured by a manufacturer.

3 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, paragraph (c))

Repeal the paragraph.

4 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, subparagraph (e)(ii))

Omit “, the product range,”.

5 Part 2 of Schedule 4 (table item 2.10, column headed “Conditions”, subparagraph (f)(ii))

Omit “, require tests to be conducted on or take samples of”, substitute “or require tests to be conducted on”.

6 Part 2 of Schedule 4 (after table item 2.10)

Insert:

- 2.10A Medical device that is a Class 4 in-house IVD medical device and that is intended by its manufacturer to be used to detect the presence of, or exposure to, transmissible agents in blood, stool or other specimens from a person's body in order to assess the suitability of the person to be a donor of human stool for use in the manufacture of a faecal microbiota transplant product
- (a) The device must comply with the essential principles.
 - (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times.
 - (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request:
 - (i) whether the device complies with the essential principles;
 - (ii) whether the conformity assessment procedures have been applied to the device;
 - (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.
 - (d) The manufacturer of the device must, at all times, have available:
 - (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or
 - (ii) information relating to changes to the device and quality management system.
 - (e) The manufacturer of the device must allow an authorised person to do any of the following:
 - (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device;
 - (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device;
 - (iii) make any still or moving image or any recording of those premises or anything on those premises.
 - (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents.
 - (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.

7 Dictionary

Insert:

faecal microbiota transplant product means a thing that:

- (a) comprises, contains or is derived from human stool; and

(b) is for introduction into a person for a therapeutic use.

Schedule 8—Changed commencement for reforms in the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

Part 1—Main changes

Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

1 Subsection 2(1) (table item 2)

Repeal the item, substitute:

2. Schedule 1	25 November 2021.	25 November 2021
2A. Schedules 2 and 3	25 February 2021.	25 February 2021

Therapeutic Goods (Medical Devices) Regulations 2002

2 Regulation 11.39 (definition of *pre-commencement entry*)

Omit “25 August 2020” (wherever occurring), substitute “25 November 2021”.

3 Regulation 11.39 (paragraphs (a) and (b) of the definition of *transitional medical device*)

Omit “25 August 2020”, substitute “25 November 2021”.

4 Subregulation 11.40(1)

Omit “25 August 2020” (wherever occurring), substitute “25 November 2021”.

5 Subparagraph 11.40(3)(a)(ii)

Omit “25 August 2020”, substitute “25 November 2021”.

6 Subparagraph 11.40(5)(b)(i)

Omit “25 February 2021”, substitute “25 May 2022”.

7 Subparagraph 11.41(2)(c)(i)

Omit “25 February 2021”, substitute “25 May 2022”.

8 Subregulation 11.43(3)

Omit “24 August 2021”, substitute “24 November 2022”.

9 Regulation 11.44 (definition of *transitional kind of medical device*)

Omit “25 August 2020”, substitute “25 February 2021”.

10 Subregulation 11.45(1)

Omit “25 August 2020” (wherever occurring), substitute “25 February 2021”.

11 Subparagraph 11.45(3)(a)(ii)

Omit “25 August 2020”, substitute “25 February 2021”.

12 Subparagraph 11.45(5)(b)(i)

Omit “25 February 2021”, substitute “25 August 2021”.

13 Subparagraph 11.46(2)(c)(i)

Omit “25 February 2021”, substitute “25 August 2021”.

14 Subregulation 11.47(1)

Omit “25 August 2020” (wherever occurring), substitute “25 February 2021”.

15 Regulation 11.48 (definition of *transitional kind of medical device*)

Omit “25 August 2020”, substitute “25 February 2021”.

16 Subregulations 11.49(1) and (2)

Omit “25 August 2020”, substitute “25 February 2021”.

17 Subregulations 11.50(1) and (2)

Omit “25 August 2020”, substitute “25 February 2021”.

18 Subregulations 11.51(1) and (2)

Omit “25 August 2020”, substitute “25 February 2021”.

19 Paragraphs 11.51(3)(a) and (b)

Omit “25 August 2020”, substitute “25 February 2021”.

20 Subregulation 11.52(1)

Omit “25 August 2020” (wherever occurring), substitute “25 February 2021”.

21 Subparagraph 11.52(3)(a)(ii)

Omit “25 August 2020”, substitute “25 February 2021”.

22 Subparagraph 11.52(5)(b)(i)

Omit “25 February 2021”, substitute “25 August 2021”.

23 Subparagraph 11.53(5)(c)(i)

Omit “25 February 2021”, substitute “25 August 2021”.

Therapeutic Goods Regulations 1990

24 Subregulation 70(3)

Omit “1 January 2021”, substitute “1 July 2021”.

25 Subregulation 70(4)

Omit “31 December 2020”, substitute “30 June 2021”.

26 Subregulation 70(4)

Omit “1 January 2021”, substitute “1 July 2021”.

27 Subregulation 70(5)

Omit “31 December 2020”, substitute “30 June 2021”.

28 Subregulation 70(5)

Omit “1 January 2021”, substitute “1 July 2021”.

29 Subregulation 71(3)

Omit “1 January 2021”, substitute “1 July 2021”.

30 Subregulation 71(4)

Omit “31 December 2020”, substitute “30 June 2021”.

31 Subregulation 71(4)

Omit “1 January 2021”, substitute “1 July 2021”.

Part 2—Other changes

Therapeutic Goods (Medical Devices) Regulations 2002

32 At the end of regulation 5.11

Add:

(5) If:

- (a) on a day on or after 25 November 2021 medical devices of a kind (the ***current kind of medical device***) referred to in a particular paragraph of subregulation (1) are included in the Register because of the amendments made by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*; and
- (b) immediately before that day, those devices were of a kind (the ***previous kind of medical device***) referred to in a different paragraph of subregulation (1) and were included in the Register;

then subparagraph (4)(a)(i) applies in relation to the current kind of medical device as if the day when the current kind of medical device is included in the Register were the day when the previous kind of medical device was included in the Register.

Schedule 9—Other amendments

Therapeutic Goods Regulations 1990

1 Regulation 2 (paragraph (a) of the definition of *designated therapeutic goods*)

Repeal the paragraph.

2 Subregulation 10C(4)

Repeal the subregulation.

3 Regulation 12B (heading)

Omit “and therapeutic devices”.

4 Subregulation 12B(4)

Repeal the subregulation.

5 Paragraph 15(1)(a)

Repeal the paragraph.

6 Regulation 16

Repeal the regulation.

7 Subregulation 48(1) (paragraph (ca) of the definition of *initial decision*)

Omit “(4),”.

8 Part 1 of Schedule 3 (heading)

Repeal the heading, substitute:

Part 1—Medicines

9 Part 1 of Schedule 3 (table item 3)

Repeal the item.

10 Schedule 4 (table items 2 and 11)

Repeal the items.

11 Schedule 5A (table item 1A, column 3, subparagraph (b)(i))

Omit “therapeutic devices and”.

12 Schedule 5A (table item 1A, column 3, subparagraph (b)(ii))

Repeal the subparagraph, substitute:

(ii) in the case of biologicals—the biologicals must be destroyed or returned to the consignor of the biologicals within 1 month of the decision not to include the biologicals

13 Schedule 5A (table item 4, column 3, subparagraph (g)(ii))

Omit “therapeutic device or”.

14 Schedule 5A (table item 8, column 3, subparagraph (f)(ii))

Omit “therapeutic device or”.

15 Schedule 5A (table item 10, column 3, subparagraph (h)(ii))

Omit “therapeutic device or”.

16 Schedule 5A (table item 11, column 3, subparagraph (g)(ii))

Omit “therapeutic device or”.

17 Schedule 5A (table item 12, column 3, subparagraph (g)(ii))

Omit “therapeutic device or”.

18 Schedule 6

Repeal the Schedule.

19 Schedule 7 (table item 2, column 2, paragraph (b))

Omit “licensed manufacturers”, substitute “a licensed manufacturer”.

20 Schedule 7 (table item 3)

Repeal the item.

21 Schedule 7 (table item 22, column 2)

Omit “radiopharmaceuticals if”, substitute “radiopharmaceuticals that are”.

22 Schedule 7 (table item 22, column 2, paragraphs (a) and (b))

Omit “the radiopharmaceuticals are”.

23 Schedule 7 (table item 23, column 2)

Omit “radiopharmaceutical active ingredients if”, substitute “radiopharmaceutical active ingredients that are”.

24 Schedule 7 (table item 23, column 2, paragraphs (a) and (b))

Omit “the ingredients are”.

25 Schedule 8 (cell at table item 1, column 3)

Repeal the cell, substitute:

the manufacture of a medicine by a
medical practitioner or a dentist
specifically for a patient under the medical
practitioner’s or dentist’s care

26 Clause 3 of Schedule 9 (table item 2A)

After:

(b) a listed medicine 440

insert:

(ba) a disinfectant 470

27 Clause 3 of Schedule 9 (table item 3, column 2, paragraph (a))

Omit “device”, substitute “disinfectant”.

28 Clause 3 of Schedule 9 (table item 6B, column 2)

Omit “and diagnostic goods for in vitro use”.

29 Part 1 of Schedule 10 (table item 13)

Omit “, unless coated on a therapeutic device”.

30 Part 3 of Schedule 10 (table item 3)

Omit “, except a therapeutic device,”.

Schedule 10—Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

1 In the appropriate position in Part 11

Insert:

Division 11.11—Application provisions relating to the Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020

11.55 System or procedure packs

The amendments made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* apply in relation to a system or procedure pack that is manufactured on or after the commencement of that Part.

11.56 Period for notifying adverse events

Paragraph 5.7(1)(d), as inserted by Schedule 3 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*, applies in relation to information that a person becomes aware of on or after the commencement of that Schedule.

11.57 Class 4 in-house IVD medical devices

Item 2.10A of the table in Part 2 of Schedule 4, as inserted by Schedule 7 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*, applies in relation to the following:

- (a) a Class 4 in-house IVD medical device that is manufactured on or after the commencement of this regulation;
- (b) a Class 4 in-house IVD medical device that is manufactured before that commencement and is intended by its manufacturer to be used on or after that commencement.

Therapeutic Goods Regulations 1990

2 In the appropriate position in Part 9

Insert:

Division 13—Application and saving provisions relating to the Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020

76 Approving supply of therapeutic goods under authorised prescriber scheme

Subregulation 12B(1B), as inserted by Schedule 4 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*, applies in

relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Schedule.

77 Preliminary assessment of applications for variation of permissible ingredients determination

- (1) The amendments of regulation 16GI and of items 28, 30, 32 and 34 of the table in clause 5 of Schedule 9 made by Schedule 6 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* apply in relation to an application made under subsection 26BD(1) of the Act on or after the commencement of those amendments.
- (2) Regulation 16GI and items 28, 30, 32 and 34 of the table in clause 5 of Schedule 9, as in force immediately before the commencement of Schedule 6 to the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*, continue to apply on and after that commencement in relation to an application made under subsection 26BE(1) of the Act before that commencement.