Therapeutic Goods (Excluded Goods) Determination 2018

made under section 7AA of the

Therapeutic Goods Act 1989

Compilation No. 8

Compilation date: 1 October 2022

Includes amendments up to: C2022A00026

Prepared by the Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Excluded Goods) Determination 2018* that shows the text of the law as amended and in force on 1 October 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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 (Excluded Goods) Determination 2018*.

3 Authority

This instrument is made under section 7AA 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:

(a) advertise;
(b) label;
(c) medical device;
(d) medicine;
(e) Register;
(f) supply;
(g) therapeutic use.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

AS 2896–2011 means the document, *Australian Standard: Medical gas systems – Installation and testing of non-flammable medical gas pipeline systems (AS 2896–2011)*, prepared by Committee HE-017 (Medical Gas Systems), approved on behalf of the Council of Standards Australia on 13 January 2011, and published by SAI Global Limited under licence from Standards Australia on 8 May 2011, as in force or existing immediately before the commencement of this instrument.

AS/NZS 2604:1998 means the document, *Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:1998)*, prepared by the Joint Technical Committee CS/42 (Sunscreen Agents), approved on behalf of the Council of Standards Australia on 31 July 1998 and the Council of Standards New Zealand on 24 August 1998, and published jointly by Standards Australia and Standards New Zealand on 5 October 1998, as in force or existing immediately before the commencement of this instrument.

AS/NZS 2604:2012 means the document, *Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2012)*, prepared by the Joint Technical Committee CS-042 (Sunscreen Agents), approved on behalf of the Council of Standards Australia on 9 May 2012 and the Council of Standards New Zealand on 9 May 2012, and published by SAI Global Limited under licence from Standards Australia on 30 May 2012, as in force or existing immediately before the commencement of this instrument.

Note: Section 2B of the *Acts Interpretation Act 1901* defines Standards Australia.

haematopoietic progenitor cells has the meaning given by clause 1 of Part 1 of Schedule 9 to the Regulations.

health professional has the same meaning as in the Medical Devices Regulations.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Poisons Standard means the legislative instrument made under section 52D of the Act, as in force immediately before the commencement of this instrument.

Regulations means the *Therapeutic Goods Regulations 1990*.

serious, for a condition, ailment or defect, has the same meaning as in the Medical Devices Regulations.

serious disease has the same meaning as in the Medical Devices Regulations.

5 Excluded goods

For subsection 7AA(1) of the Act, the goods specified in Schedule 1 are excluded goods for the purposes of the Act.

6 Excluded goods when used, advertised or presented for supply in a particular way

For subsection 7AA(2) of the Act, the goods specified in Schedule 2, when used, advertised, or presented for supply in a way specified in that Schedule are excluded goods for the purposes of the Act.

Schedule 1 Specified goods

(section 5)

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
1	adhesive removers and non-medicated skin cleansers relating to colostomy and ileostomy
1A	anatomical models that are intended by the manufacturer to be used for educational or record-keeping purposes
2	antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only
2A	articles that are non-sterile personal protective equipment or safety apparel other than articles specified in item 1 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*
2B	cosmetic finishing components for orthoses and prostheses
2C	craniofacial prostheses that are: (a) spectacle-retained; or (b) adhesive-retained
3	dental bleaches and dental whiteners
3AA	dental impression trays
3A	detergents and soaps for laundering or general cleaning use, other than detergents and soaps that are disinfectants within the meaning of the Regulations
4	devices for measuring alcohol content in body fluids or exhaled air
5	disinfectant and sterilant gases
6	drinking water purification and treatment equipment
7	ear candles
7AA	ear moulds that are intended by the manufacturer to anchor hearing aids
7A	fluoridated reticulated drinking water
8	hair bleaches, hair dyes, hair-colorants and hair-perming preparations
9	household and personal aids, or furniture and utensils, for people with disabilities
10	incontinence pads, mattress overlays and mattress protectors
10A	medicament trays that are intended by the manufacturer to hold medicaments
11	menstrual pads other than tampons and menstrual cups
11A	mouthguards intended by the manufacturer to be used to protect teeth from external forces including, but not limited to, mouthguards used in contact sports
11B	ocular prostheses intended by the manufacturer to be used for cosmetic purposes
11C	physical impressions of anatomy, and models cast from such impressions
12	sanitation, environmental control and environmental detoxification equipment (including films and coatings), other than articles specified in item 3 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* Note: Sanitation, environmental control and environmental detoxification equipment

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
	does not include disinfectants within the meaning of the Regulations.
12A	spectacle frames
13	topical preparations applied to the nails to harden, or deter the biting of, nails
14	products intended for application to the lips, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012
14A	software that is: (a) intended by its manufacturer to be used by a consumer for the self-management of an existing disease, condition, ailment or defect that is not a serious disease or serious condition, ailment or defect; and (b) not intended by its manufacturer to be used: (i) in clinical practice; or (ii) in relation to a serious disease or serious condition, ailment or defect; or (iii) for the purpose of diagnosis, treatment, or making a specific recommendation or decision about the treatment, of a disease, condition, ailment or defect that is not a serious disease or serious condition, ailment or defect
14B	software, or a combination of software and non-invasive hardware, that is: (a) intended by its manufacturer to be used by a consumer to promote or facilitate general health or wellness by measuring or monitoring (through non-invasive means) a physical parameter, such as movement, sleep, heart rate, heart rhythm, temperature, blood pressure or oxygen saturation; and (b) not intended by its manufacturer to be used:

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
	(i) in clinical practice; or (ii) for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a serious disease or a serious condition, ailment or defect
14C	software that is: (a) intended by its manufacturer to be used by a consumer to improve general health or wellness by coaching, or encouraging behavioural change, in relation to personal or environmental factors, such as weight, exercise, sun exposure or dietary intake; and (b) not intended by its manufacturer to be used: (i) in clinical practice or to provide information to the consumer that would generally be accepted to require the interpretation of a health professional; or (ii) for the purpose of diagnosis, prognosis, or making a decision about the treatment, of a disease, condition, ailment or defect
14D	software that is: (a) intended by its manufacturer to be used as a patient reported outcome measures (PROMs) questionnaire or patient survey; and (b) not intended by its manufacturer to diagnose, screen for, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14E	software that is a digital mental health tool (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user
14F	software that is: (a) intended by its manufacturer to enable communications, including the transmission of patient information, for the purposes of supporting the delivery of health services; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14G	software that is: (a) intended by its manufacturer to be used for the administration or management of health processes or facilities (including financial records, claims, billing, appointments, operating theatre management, hospital bed management, schedules, business analytics, admissions, inventory and workflow); and (b) not intended by its manufacturer to be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a disease, condition, ailment or defect
14H	software that is intended by its manufacturer to be used for the sole purpose of storing or transmitting patient images

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
14I	software that is: (a) intended by its manufacturer to be used for the sole purpose of providing alerts to health professionals in relation to patient care; and (b) not intended by its manufacturer to: (i) replace the clinical judgement of a health professional; or (ii) diagnose, screen for, prevent, alleviate, treat, or make a decision about the treatment of, a disease, condition, ailment or defect
14J	software that is: (a) intended by its manufacturer to be used for clinical workflow management; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14K	software that is middleware and is: (a) intended by its manufacturer to connect or interface applications to an underlying operating system or another application, including by communicating or transmitting information; and (b) not intended by its manufacturer to: (i) control medical devices; or (ii) perform analysis, computation or logic that relates to the intended purpose of a medical device; or (iii) be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a disease, condition, ailment or defect
14L	software that is a calculator and: (a) either: (i) uses relevant published clinical standards or authoritative sources to make calculations; or (ii) displays calculations and outputs in a manner that may be validated by the user; and (b) is not intended by its manufacturer to control the administration of a calculated dosage
14M	software, or a combination of software and hardware, that is an electronic health record (however named or described) and is: (a) intended by its manufacturer to be used in clinical practice by healthcare providers to collect, use, disclose and otherwise manage patient clinical data within or between healthcare facilities; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14N	software that is data analytics and is: (a) intended by its manufacturer to be used for the collection and analysis of class, group or population data; and

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
	(b) not intended by its manufacturer to be used for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation, of a disease, condition, ailment or defect in relation to individuals
14O	software that is a laboratory information management system (however named or described) and is not intended by its manufacturer to: (a) manipulate information or data to change, or generate new, diagnostic outputs (other than automating simple calculations or generating report comments); or (b) prevent, monitor, predict, make a prognosis of, treat or alleviate a disease, condition, ailment or defect
15	tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012
16	vaping devices, other than the following: (a) vaping devices that are intended, by the person under whose name the device is or is to be supplied, to be used exclusively for the vaporisation and administration of a medicine, including vaporiser nicotine Note 1: Examples of vaping devices include e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens. Note 2: Vaporiser nicotine is a medicine that contains nicotine in salt or base form and may also be described as nicotine vape liquid, nicotine e-liquid or simply e-liquid.

Schedule 2 Specified goods used, advertised or presented for supply in a particular way

(section 6)

Specified goods		
Column 1	**Column 2**	**Column 3**
Item	**Specified goods**	**When used, advertised or presented for supply in a particular way**
1	anti-acne skin care products, including spot treatments, cleansers, face scrubs and masks, that do not contain any substance included in Schedules 2, 3, 4 or 8 to Poisons Standard	when advertised or presented for supply as controlling or preventing acne only through cleansing, moisturising, exfoliating or drying the skin
2	antibacterial skin care products that do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard	when advertised or presented for supply as being active against bacteria and not advertised or presented for supply as being: (a) active against viruses, fungi or other microbial organisms (other than bacteria); or (b) for use in connection with disease, disorders or medical conditions; or (c) active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or (d) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or (e) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or (f) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or (g) for use in connection with a procedure involving venepuncture or delivery of an injection

3	anti-dandruff hair care products	when advertised or presented for supply as controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp
4	compressed gases	when used as a power source for medical devices
4A	goods in relation to which the following paragraphs apply: (a) the goods comprise, contain or are derived from, human cells or human tissues collected from a patient (the ***relevant patient***) who is under the clinical care of a medical or dental practitioner (the ***relevant practitioner***); (b) the relevant practitioner is registered in a State or internal Territory; (c) subject to paragraph (d), all steps in the manufacture of the goods are carried out by, or under the professional supervision of, the relevant practitioner in a hospital in a State or internal Territory (the ***relevant hospital***); (d) if a step in the manufacture of the goods relating to the storage or testing of the goods is not carried out in the relevant hospital, it is carried out by a person under contract with the relevant hospital	when the goods are: (a) used for the relevant patient, who is a patient of the relevant hospital; and (b) not advertised directly to consumers
4B	goods that are fresh viable human haematopoietic progenitor cells	when used for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution
4C	goods that are fresh viable human organs or parts of human organs	when used for direct donor-to-host transplantation
4D	goods that are human reproductive tissue	when used in assisted reproductive therapy
4E	goods that are: (a) human eggs; or (b) human sperm	when used in carrying out an activity as authorised or purportedly authorised by a mitochondrial donation licence under the *Research Involving Human Embryos Act 2002*
5	moisturising skin care products, that	when the product:

contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, for dermal application, including anti-wrinkle, anti-ageing and skin whitening products, in relation to which one of the following two paragraphs applies:

(a) for a product imported into, or manufactured in, Australia before 1 August 2018, both:
  (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and
  (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or

(b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following:
  (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and
  (ii) the product meets the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and
  (iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5

(a) is not advertised or presented for supply as having a sun protection factor of more than 15; and
(b) is not advertised or presented for supply as being water-resistant; and
(c) if the product is not stable for at least 36 months – includes an expiry date on its label; and
(d) has a pack size not larger than 300mL or 300g; and
(e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and

therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for ***broad-spectrum product*** set out in:

(a) clause 7.2 of AS/NZS 2604:1998; or
(b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012

	and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	
6	oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 to Poisons Standard	when advertised or presented for supply, the following two paragraphs apply: (a) the only benefits claimed to result from the use of the product is consequential on improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and (b) benefits in relation to such other diseases or aliments, such as gum or other oral disease or periodontal condition, are not claimed to result from use of the product
7	packs and kits containing medical devices for the prevention of blood borne and sexually transmissible diseases where each individual therapeutic good contained within the packs or kits is already included on the Register	when advertised or presented for supply as a part of a Government endorsed health promotion program, having been expressly authorised by that Government as part of that program
8	piped medical gas systems	when installed and used in compliance with AS 2896–2011
9	preparations containing a sunscreening substance, if the primary purpose of the preparation is neither protection from solar radiation nor another therapeutic purpose	when the preparation is not advertised or presented for supply with: (a) a statement of claimed sun protection factor; or (b) a description of a claimed sun protection factor; or (c) a reference to another therapeutic use in respect of the preparation
10	sunbathing skin care products, such as oils, creams, gels, tanning products without sun and after-sun care products, that contain sunscreen with a sun protection factor of at least 4 and not more than 15, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an

paragraphs applies:

(a) for a product imported into, or manufactured in, Australia before 1 August 2018, both:
  (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and
  (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or

(b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following:
  (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and
  (ii) the product meets the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and
  (iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and
  (iv) if the product's label states a protection factor, the label meets the requirements of clauses

expiry date on its label;

(d) has a pack size not larger than 300mL or 300g; and

(e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and

therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for ***broad-spectrum product*** set out in:

(a) clause 7.2 of AS/NZS 2604:1998; or

(b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012

	7.1 and 7.3 of AS/NZS 2604: 2012	
11	therapeutic goods for retaining, cushioning or repairing dentures	when advertised or presented for supply to the ultimate consumer

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 (Excluded Goods) Determination 2018	27 Sep 2018 (F2018L01350)	1 Oct 2018	—
Therapeutic Goods Amendment (Excluded Goods) Determination 2019	21 June 2019 (F2019L00853)	22 June 2019	—
Therapeutic Goods Amendment (Excluded Goods) Determination (No. 2) 2019	15 July 2019 (F2019L00985)	16 July 2019	—
Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020	23 Apr 2020 (F2020L00464)	24 Apr 2020	—
Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021	15 Jan 2021 (F2021L00047)	25 Feb 2021	—
Therapeutic Goods (Excluded Goods) Amendment (Vaping Devices) Determination 2021	11 Feb 2021 (F2021L00112)	12 Feb 2021	—
Therapeutic Goods (Excluded Goods) Amendment (Borderline Products—COVID-19) Determination 2021	30 Jul 2021 (F2021L01049)	31 Jul 2021	—
Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021	20 Aug 2021 (F2021L01161)	21 Aug 2021	—
Mitochondrial Donation Law Reform (Maeve's Law) Act 2022	5 Apr 2022 (C2022A00026)	Sch 1 (item 116); 1 Oct 2022 (s 2(1) item 2)	—

Endnote 4—Amendment history

Provision affected	How affected
s 2	rep LA s 48D
s 3	am F2019L00853
s 4	am F2019L00853; F2021L00047; F2021L00112; F2021L01161
Schedule 1	am F2019L00985; F2020L00464; F2021L00047; F2021L00112; F2021L01049; F2021L01161
Schedule 2	am F2019L00853; am C2022A00026
Note	rep F2019L00853